Drug Pricing Investigation

Selected Investigation Documents

Committee on Oversight and Reform
U.S. House of Representatives
December 2021
oversight.house.gov

Document #	Citation	Short Description
AbbVie 1	ABV-HOR-00031271	January 19, 2011 Memorandum
AbbVie 2	ABV-HOR-00032198	February 2014 Presentation
AbbVie 3	ABV-HOR-00033966	August 2014 Presentation
AbbVie 4	ABV-HOR-00034201	August 2010 Presentation
AbbVie 5	ABV-HOR-00034291	June 2011 Presentation Excerpt
AbbVie 6	ABV-HOR-00039036	November 28, 2017 Email
AbbVie 7	ABV-HOR-00042146	April 2008 Strategy Document
AbbVie 8	ABV-HOR-00042168	October 16, 2008 Strategy Document Titled: "Humira and Hidradenitis Suppurativa"
AbbVie 9	ABV-HOR-00048274	September 2016 Presentation Excerpt
AbbVie 10	ABV-HOR-00136539	January 2012 Emails
AbbVie 11	ABV-HOR-00138392	February 2015 Presentation Excerpt
AbbVie 12	ABV-HOR-RR-00000739	November 5, 2018 Letter to Vermont Attorney General
AbbVie 13	ABV-HOR-RR-00001539	October 29, 2017 Email
AbbVie 14	ABV-HOR-RR-00012724	October 2016 Presentation Excerpt
Amgen 1	AMGN-HCOR-RR-00029310	December 2017 Emails
Amgen 2	AMGN-HCOR-RR-00039834	2017 Table
Amgen 3	AMGN-HCOR-RR-00040017	April 2016 Emails
Amgen 4	AMGN-HCOR-RR-00040614	June 2016 Emails
Amgen 5	AMGN-HCOR-RR-00041867, at Slide 4	September 2018 Presentation Excerpt
Amgen 6	AMGN-HCOR-RR-000434916, at Slides 5 and 6	May 2016 Presentation Excerpt

Amgen 7	AMGN-HCOR-RR-00126493, at Slide 10	December 2018 Presentation Excerpt
BMS-Celgene 1	CELG_HCOR_000023827, at Slide 13	April 2017 Presentation Excerpt
BMS-Celgene 2	CELG_HCOR_000027347, at Slide 3	October 2018 Presentation Excerpt
BMS-Celgene 3	CELG_HCOR_000042225, Slide 22	2016 Presentation Excerpt
BMS-Celgene 4	CELG_HCOR_000047526, at Slide 8	February 2014 Presentation Excerpt
BMS-Celgene 5	CELG_HCOR_000047564, at Slide 5	March 2014 Presentation Excerpt
BMS-Celgene 6	CELG_HCOR_000049208	March 1, 2014 Emails
BMS-Celgene 7	CELG_HCOR_000051076 and Attachment	May 2016 Email, and Attached Memorandum
Eli Lilly 1	COR-BOX-00013359, at Slide 26	December 2011 Presentation Excerpt
Eli Lilly 2	COR-BOX-00016555	June 2014 Emails
MNK 1	MNK_InCamera-000000128172, at Slide 9	March 2014 Presentation Excerpt
MNK 2	MNK_InCamera-000000131863, at Slide 22	March 2014 Presentation Excerpt
NNI 1	NNI-ERR_0002505, at Page 1	August 2016 Briefing Materials
NNI 2	NNI-ERR_0010319, at Slide 3	March 2015 Presentation Excerpt
NNI 3	NNI-ERR_0011316, at Slide 2	2013 Presentation Excerpt
NNI 4	NNI-ERR_0016771	December 2015 Emails
NNI 6	NNI-ERR_0044087, at Slides 1 and 2	January 2018 Presentation Excerpt
NNI 7	NNI-ERR_0045711, at Page 2	October 2013 Presentation Excerpt

NNI 8	NNI-ERR_0046393, at Pages 1 and 2	August 2014 Emails
NNI 9	NNI-ERR_0052538, at Page 5	2018 Presentation Excerpt
NNI 10	NNI-ERR_0072582, at Slide 26	March 2015 Presentation Excerpt
NNI 11	NNI-ERR_0080488, at Slide 3	Presentation Excerpt
NNI 12	NNI-ERR_0082875, at Pages 1 and 2	May 2017 Emails
NNI 13	NNI-ERR_0083044, at Slide 10	June 2015 Presentation Excerpt
Novartis 1	CTRL-0025801, at Slide 12	January 2015 Presentation Excerpt
Novartis 2	CTRL-0029114, at Slide 1	June 2013 Presentation Excerpt
Novartis 3	CTRL-0088408, at Page 1	2014 Draft Messaging Document
Novartis 4	CTRL-0092356, at Slide 1	Presentation Excerpt (Undated)
Novartis 5	CTRL-0095459, at Slide 19	July 2013 Presentation Excerpt
Pfizer 1	SRR_PFIZHCOR_00000001	April 2016 Risk Assessment
Pfizer 2	SRR_PFIZHCOR_00000002	April 2017 Risk Assessment
Pfizer 3	SRR_PFIZHCOR_00000176.00001, at Slides 2, 10, and 11	May 2017 Presentation Excerpt
Pfizer 4	SRR_PFIZHCOR_00002156, at Page 1	July 2016 Emails
Pfizer 5	SRR_PFIZHCOR_00002163	August 2016 Emails
Pfizer 6	SRR_PFIZHCOR_00002176, at Page 2	Presentation Excerpt (Undated)
Pfizer 7	SRR_PFIZHCOR_00004032.0001, at Slides 7 and 8	August 2018 Presentation Excerpt
Pfizer 8	SRR_PFIZHCOR_00005033.00001, at Slides 8 and 12	May 2018 Presentation Excerpt

Pfizer 9	SRR_PFIZHCOR_00005325, at Slide 14	May 2016 Presentation Excerpt
Pfizer 10	SRR_PFIZHCOR_00007540.00001, at Slide 32	September 2016 Presentation Excerpt
Pfizer 11	SRR_PFIZHCOR_00009966.00001, at Slides 3 and 6	February 2017 Presentation Excerpt
Pfizer 12	SRR_PFIZHCOR_00011875, at Slide 19	August 2017 Presentation Excerpt
Pfizer 13	SRR_PFIZHCOR_00020320.00001, at Slide 6	May 2016 Presentation Excerpt
Pfizer 14	SRR_PFIZHCOR_00026816, at Slide 10	Presentation Excerpt (Undated)
Pfizer 15	SRR_PFIZHCOR_00026835, at Slides 12-13	August 2017 Presentation Excerpt
Sanofi 1	SANOFI_COR_00013187, at Slides 2 and 3	November 2013 Presentation Excerpt
Sanofi 2	SANOFI_COR_00045089	November 2014 Emails
Sanofi 3	SANOFI_COR_00049967, at Pages 1 and 3	2014 Sales Team Document
Sanofi 4	SANOFI_COR_00057517, at Pages 4 and 12	2018 Presentation Excerpt
Sanofi 5	SANOFI_COR_00067805, at Pages 1 and 2	February 2018 Emails
Sanofi 6	SANOFI_COR_00134729, at Page 2	2017 Presentation Excerpt
Sanofi 7	SANOFI_COR_00234570, at Page 10	September 2014 Presentation Excerpt
Teva 1	TEVA_HCO_IC_005000887	October 2016 Talking Points
Teva 2	TEVA_HCO_IC_005001347, at Slide 1	2018 Presentation Excerpt
Teva 3	TEVA_HCO_IC_005002063	January 2018 Emails

Teva 4	TEVA_HCO_IC_005007009	April 2017 Emails
Teva 5	TEVA_HCO_IC_005008955	February 2017 Emails
Teva 6	TEVA_HCO_IC_005021634, at Slide 4	October 2017 Presentation Excerpt
Teva 7	TEVA_HCO_IC_005035591, at Slide 11	January 2017 Presentation Excerpt
Teva 8	TEVA_HCO_IC_005036573, at Slide 28	October 2016 Presentation Excerpt
Teva 9	TEVA_HCO_IC_005040409, at Slide 32	September 2016 Presentation Excerpt
Teva 10	TEVA_HCO_IC_005132452	August 2008 Emails
Teva 11	TEVA_HCO_IC_005141157, at Slide 41	November 2014 Presentation Excerpt
Teva 12	TEVA_HCO_IC_005141925, at Slide 50	August 2008 Presentation Excerpt
Teva 13	TEVA_HCO_IC_005142081, at Slide 27	August 2011 Presentation Excerpt
Teva 14	TEVA_HCO_IC_005159378, at Slides 2 and 5	June 2009 Presentation Excerpt
Teva 16	TEVA_HCO_IC_005199492, at Slide 12	February 2017 Presentation Excerpt
Teva 17	TEVA_HCO_IC_005233185	December 2008 Emails
Teva 18	TEVA_HCO_IC_005234121, at Slide 4	July 2008 Presentation Excerpt

	Pharmaceutical Products Group		
	INTEROFFICE CORRESPONDENCE		Richard A. Gonzalez Executive Vice President

Date:	January 19, 2011
RE:	Humira

TO: [redacted]

As we continue to look for ways to grow and protect Humira, I would like the team to explore as many possible options as we can come up with. We are currently working on a number of enhancements such as:

- High concentration / less pain formulation
- Smaller needle
- Room temperature
- New pen
- Monthly dosing
- Etc.

I'm not sure which forum (TEC, PEC, etc.) is the best to evaluate additional options, but I would like the appropriate group to evaluate the technical feasibility and market benefit of these ideas:

- Next generation product that would significantly improve ACR scores (≈ 20 pts)
- Improve safety profile with similar efficiency through dosing changes - - - instead two week bolus dosing, disposable patch pump or similar delivery method that provides lower continuous dosing with minimal pain.
- Transdermal, disposable patch pump or other more convenient, less painful dosing.
- Dx marker to identify Humira responders.

AbbVie 1

- Additional indications where anti-TNF might be effective - - Dry Eye, Transplant, etc?
- Dx marker for early detection of RA.
- Dx marker to monitor deep sustained remission in Crohn's.
- Humira University - - State of the art physician immunology training facility to provide education and training to physicians on the latest treatment techniques, similar to the concept AV (the Institute)

    - Risk/benefit of biologic treatment
    - Early RA treatment
    - TX after one DMARD failure
    - Patient compliance
    - Deep sustained remission in Crohn's
    - Treat to target
    - State of the art plant tour

- Head to head trial against Enbrel or Stelara in Ps to demonstrate superiority.
- DX marker to identify Mtx/oral DMARD failure patients, so they move directly to Biologics.
- Head to head trial of Remicade vs Humira in Crohn's.

These are just a few concepts that I would like evaluated, but let's also try to get as many ideas as possible vetted, once the team has evaluated these I would like to meet to discuss their thoughts.

Best regards,

Rick

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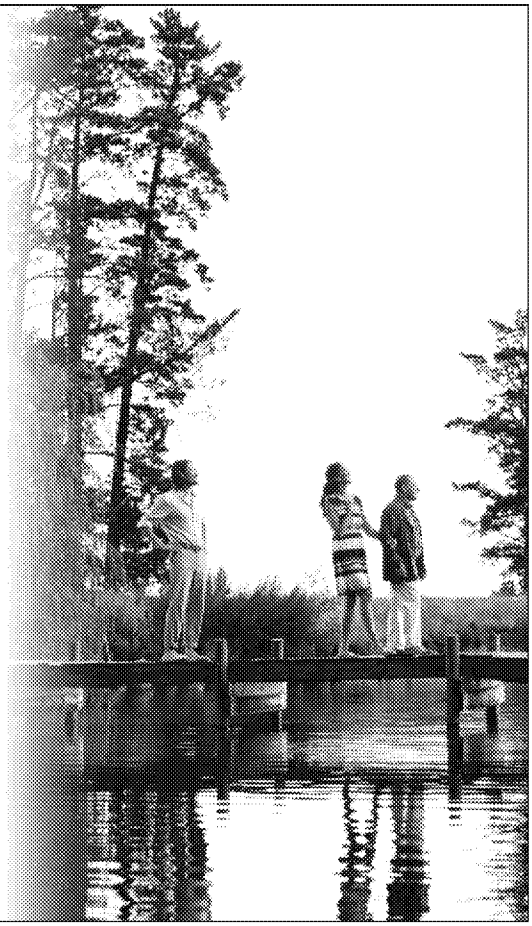
2014 LRP
US HUMIRA Biosimilar Erosion

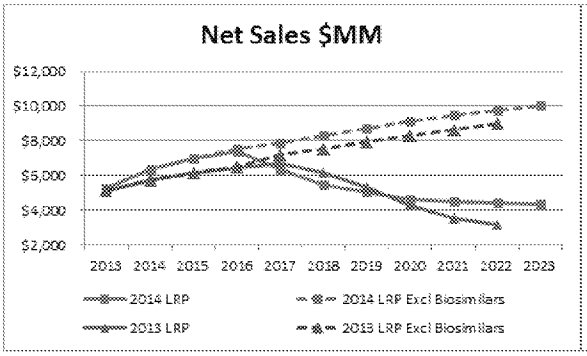
JRS Review

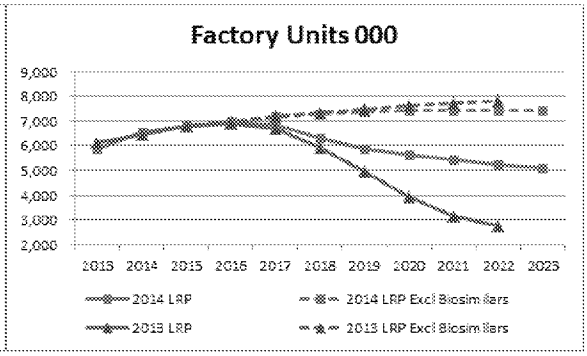
February 14th, 2014



2014 LRP vs. 2013 LRP

Total US HUMIRA





2014 LRP vs 2013 LRP (including Biosimilar erosion)

	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Total HUMIRA Var $MM	$113	$652	$850	$966	($351)	($643)	($259)	$286	$962	$1,243
% Var	2%	11%	14%	15%	-5%	-10%	-5%	7%	27%	39%
Price Var	$340	$596	$840	$919	($485)	($966)	($1,029)	($1,086)	($925)	($855)
Vol Var	($227)	$56	$9	$47	$134	$322	$770	$1,372	$1,887	$2,098

2014 LRP Biosimilar Erosion

	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Total HUMIRA Var	$0	$0	$0	($77)	($1,562)	($2,808)	($3,695)	($4,535)	($4,966)	($5,365)	($5,744)
% Var	0%	0%	0%	-1%	-20%	-34%	-42%	-50%	-52%	-55%	-57%
Price Var	$0	$0	$0	($8)	($1,259)	($1,968)	($2,399)	($3,044)	($3,289)	($3,537)	($3,797)
Vol Var	$0	$0	$0	($69)	($303)	($840)	($1,296)	($1,490)	($1,676)	($1,828)	($1,947)

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2014 LRP - Revised Financial Summary

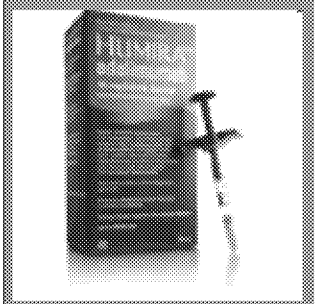
August, 2014

HUMIRA Biosimilars delayed by 6 months

	Net Sales $MM				
	2014	2015	2016	2017	2018
Base Case (2014 LRP)					
Sales excluding Biosimilar Erosion	$6,367	$7,141	$7,736	$8,195	$8,618
Price Erosion				($861)	($1,514)
Volume Erosion			($80)	($229)	($640)
Total Biosimilar Erosion	$0	$0	($80)	($1,089)	($2,155)
Sales including Biosimilar Erosion	$6,367	$7,141	$7,656	$7,106	$6,463
6 month BS delay (to July 2017)					
Sales excluding Biosimilar Erosion	$6,367	$7,141	$7,736	$8,195	$8,618
Price Erosion				($315)	($1,091)
Volume Erosion			($80)	($136)	($442)
Total Biosimilar Erosion	$0	$0	($80)	($450)	($1,533)
Sales including Biosimilar Erosion	$6,367	$7,141	$7,656	$7,745	$7,085
Impact of 6-month delay					
Sales excluding Biosimilar Erosion	$0	$0	$0	$0	$0
Price Erosion	$0	$0	$0	$546	$424
Volume Erosion	$0	$0	$0	$93	$199
Total Biosimilar Erosion	$0	$0	$0	$639	$622
Sales including Biosimilar Erosion	$0	$0	$0	$639	$622

	$MM's		
Scenario #2: 6mo Bios delay	**2016**	**2017**	**2018**
Net Sales	-	639	622
Dist Margin		590	582
% Net Sls	92.6%	92.3%	93.5%
SG&A	-	-	-
% Net Sls		0.0%	0.0%
Div Margin	-	590	582
% Net Sls		92.3%	93.5%

Note: Assumes no incremental SG&A. Utilized Distribution Margin profile for simplicity. Potential small incremental upside as no additional COGS (approx 2%) on price portion of favorability.



PRELIMINARY

CONFIDENTIAL

Assessing the Risk to Humira from Biosimilars and JAK-3

Abbott
A Promise for Life

Proposed Project Approach

August 24, 2010

McKinsey&Company

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CONTENTS FOR TODAY'S DISCUSSION

- **Our understanding of project context and objectives**
- Proposed approach / deliverables and working model
- Why McKinsey?
- Summary of McKinsey perspectives on biosimilars

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CONTEXT FOR THIS EFFORT

PRELIMINARY

- Humira continues to be the major revenue driver for Abbott with expected 2010 revenues of ~$6.5B (~25% of total revenues)
- However, the potential entry of both biosimilars and oral DMARDs (in particular Pfizer's JAK-3 inhibitor) puts Humira at risk across its key markets
- Abbott has established a working team that has been assessing the nature and timing of the threat to Humira and modeling the impact on the LRP of both biosimilars and the JAK-3 compound. This internal team has identified a projected decline in revenue of ~$8.5B in 2019 off baseline projected LRP revenues of ~$12B
- Given the extent of the projected decline, it raises a number of tough decisions that you will face for the brand and company. As a result, you have asked us to work with your team to reassess the threat and timing of both biosimilars and JAK-3 on the Humira LRP (US and ex-US) and what could be done to minimize that risk
- In addition, based on our assessment of the biosimilars markets in the US and other key markets, you are seeking a perspective on whether biosimilars could be an attractive market for Abbott to enter and, if yes, the best approach to do so

PROJECT OBJECTIVES

PRELIMINARY

1. Develop country-by-country assessment of the likely **impact of biosimilars on Humira in key markets** based on detailed evaluation of key factors, including
   - Regulatory environment / IP landscape (e.g., assess level of regulatory risk, current / projected pathway and how it might change, likely development requirements, implications on innovators and entrants, etc.)
   - Market access issues (including listing / reimbursement, likely payor reactions, etc.)
   - Evolution of MD treatment patterns (including conversion drivers by segment, impact of persistency)
   - Pricing
   - Competitive landscape, including likely number of entrants, impact of other biosimilar products and implications on pricing
2. Identify **potential actions** that could be taken by Abbott **to sustain Humira usage** post- biosimilar entry, including policy / government affairs, development (e.g., new formulation), commercial levers (e.g., pricing / contracting, counter-detailing, switching, etc.)
3. Determine **likely impact of Pfizer's JAK-3 compound**, including assessment of likelihood of approval in US and key EMEA markets, likely positioning and strategy and projected impact on Humira in key markets
4. Develop **integrated financial model** quantifying risk to Humira from biosimilars and JAK-3 compound through 2019 (and relative to current LRP), as well as potential impact of Abbott "defense" strategies (where possible)
5. Conduct **assessment of attractiveness to Abbott of entering the biosimilars** market as well as potential entry options

OVERVIEW OF KEY MARKETS FOR HUMIRA

PRELIMINARY

	Market	FY10 Update $M
Markets included in ABT initial deep-dive assessment	US	2,742
	Germany	497
	UK	341
	Spain	293
	France	289
	Canada	242
	Netherlands	232
	Italy	221
	Japan	104
	Sweden	94
	Rest of WE*	688
	Lat AM**	444
	AAAME***	223
	CEE****	102
	RIC	10
	Total	**6,520**

* Biggest remaining market Belgium at $109M
** Biggest market Brazil at $213M
***Biggest market Australia at $118M
**** Biggest market Czech Republic at $29M

- Ten markets covered by ABT working team represent 77% of Humira revenue
- Recommend our assessment covers US, EU5 and other select important markets in Scandinavia and Benelux that are aggressively pushing biosimilars (e.g., Sweden or Norway, Netherlands)
- Also recommend including one "low cost" biosimilar market to serve as "testing grounds" for whether biosimilars at a lower price point could drive volume uptake, assuming market access could be improved, e.g.,
  - Brazil (top 10 market)
  - China or Columbia (biosimilar TNFs on market today)
- Recommend not including
  - Japan—tough biosimilars market due to very strict regulatory pathway and negative MD perceptions
  - Canada—recently finalized biosimilars guidance; similar dynamics expected as other developed markets

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CONTENTS FOR TODAY'S DISCUSSION

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- Why McKinsey?
- Summary of McKinsey perspectives on biosimilars

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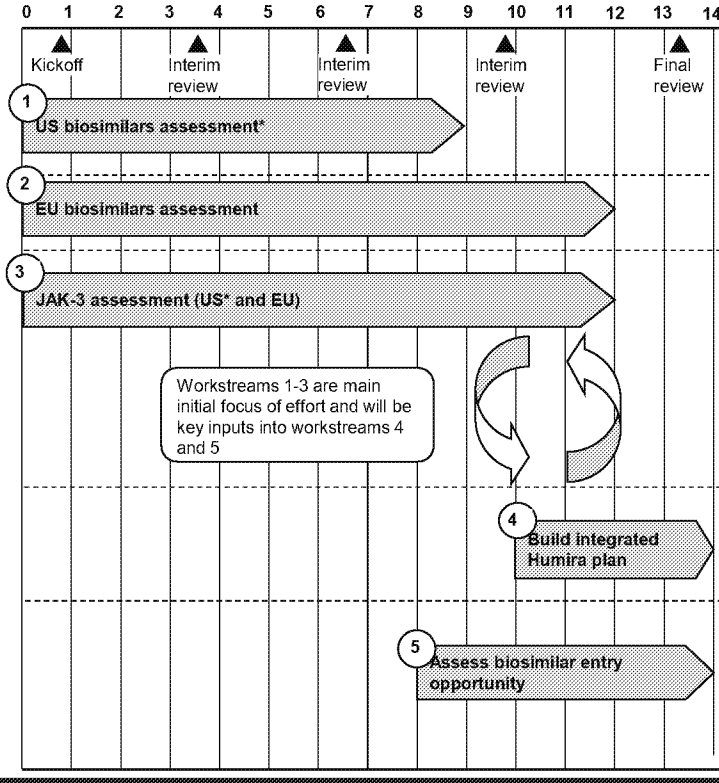
OVERALL PROJECT APPROACH AND DELIVERABLES

PRELIMINARY



Detailed deliverables

- Detailed assessment of impact of biosimilars on Humira (both penetration and pace) based on assessment of
  - Regulatory environment
  - Market access—payor receptivity, reimbursement / listing, etc.
  - Physician treatment patterns
  - Patient perceptions
  - Competitive environment
- Country-specific modeling of volume and price impact
- Country –specific ideas to sustain Humira usage

- Detailed assessment of impact of Pfizer's JAK-3 compound on Humira (both penetration and pace) by market based on assessment of
  - Scenarios on likelihood and timing of regulatory approval
  - Likely clinical profile and positioning
  - Market access—payor receptivity, reimbursement / listing
  - Physician treatment patterns
  - Patient perceptions
  - Competitive environment for RA therapies
- Country-specific modeling of volume and price impact
- Country –specific ideas to blunt impact of JAK-3 entry

- Develop integrated financial model across all markets to assess impact on Humira and define key swing factors
- Develop integrated plan to sustain Humira usage following biosimilar and JAK-3 entry, including potential impact on Humira volume / price (where possible)

- Detailed assessment of biosimilar entry opportunity, including business case covering
  - Potential markets / molecules to pursue
  - Projected revenue for targeted molecules based on expected competitive landscape
  - Costs / capabilities required to enter
  - Market entry options and feasibility / risks based on current position relative to others

*US team also to address Brazil

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PROPOSED DETAILED PROJECT APPROACH AND ACTIVITIES (1/3)

PRELIMINARY

	Timing*	Key activities
1/2 **Biosimilars assessments – US and ex-US**	9-12 weeks total	• Define current status of regulatory pathway, potential evolution and implications for biosimilar development requirements, substitutability / interchangeability, market entry, penetration and pricing through assessment of existing and pending legislation, guidance, etc., interviews with country-specific market experts and, for US, interviews with McKinsey and external regulatory experts • Define projected market scenarios for timing of product entry, potential number of competitive entrants and model likely impact on pricing for key markets (based on market scenarios, case studies, expert interviews) • Conduct interviews with relevant payor(s) and / or payor experts in each market to determine stance on biosimilars (in general and for RA) and likely impact on listing, pricing, reimbursement, etc. • Conduct interviews with physicians in each market to determine likely impact of biosimilars on treatment approach—develop preliminary physician segmentation and patient flow, including assessment of persistency risk • Conduct quantitative survey of physicians across key markets to determine impact of biosimilars on treatment patterns in RA (depending on different profiles for potential biosimilar entrants—e.g., data, etc.) • Model degree of impact by market on Humira volume and price, including pace of change based on market specific incidence / prevalence (assuming MDs unlikely to switch existing patients)

* Overall project 14 weeks; workstreams 1-3 overlap with workstreams 4 and 5

PROPOSED DETAILED PROJECT APPROACH/ACTIVITIES (2/3)

PRELIMINARY

	Timing*	Key activities
3 JAK-3 assessment – US and EU	12 weeks	• Develop scenarios on likelihood and timing of approval for Pfizer's JAK-3 compound based on expert interviews • Conduct interviews with physicians in each market to determine views on existing and future treatment patterns for RA and expected clinical profile and positioning of key products (with particular focus on perceptions and impact of Pfizer's JAK 3 compound) and assess likely impact on Humira—develop preliminary physician segmentation and patient flow • Conduct interviews with payor(s) and / or payor experts to determine perspectives and likely management related to current and future RA treatments (with particular focus on perceptions and impact of Pfizer's JAK 3 compound) and assess likely impact on Humira • Review analyst expectations of Pfizer's JAK-3 (as well as other potential JAK-3 entrants) where available • Develop perspective on expected strategy / positioning for Pfizer's JAK-3 based on likely clinical data in light of other likely RA products on market and key stakeholder perceptions • Conduct quantitative survey of physicians across key markets to determine impact of Pfizer's JAK-3 on treatment patterns in RA (depending on different profiles for potential biosimilar entrants—e.g., data, etc.) • Model degree of impact by market of Pfizer's JAK-3 on Humira volume and price based on projected market-specific adoption curves

* Overall project 14 weeks; workstreams 1-3 overlap with workstreams 4 and 5

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PROPOSED DETAILED PROJECT APPROACH AND ACTIVITIES (3/3)

PRELIMINARY

	Timing*	Key activities
4 Build integrated Humira plan	4 weeks	• Build integrated financial model across all markets to assess impact on Humira of both biosimilars and JAK-3 and determine key swing factors in model—identify key assumptions / swing factors / scenarios for forecast (both globally and for specific markets) • Synthesize and assess market specific ideas to sustain Humira usage following biosimilars and JAK-3 entry • Determine applicability of global programs, actions against either threat • Where possible, model impact of potential actions to blunt impact of biosimilar and JAK-3 entry • Develop integrated plan to sustain Humira usage
5 Assess biosimilar entry opportunity	6 weeks	• Conduct detailed assessment of biosimilar market entry opportunity, including – Project size of overall biologics opportunity by market and molecule – Determine likely market share based on likely timing of entry and number of competitors – Determine likely pricing / margin based on industry / expert interviews – Develop full P&L, including estimates for development costs, COGS, SG&A, partnership terms, any depreciation / amortization on capital outlays, etc. – Assess key risks, including • Market / competitive risk • Patent / regulatory risk • Execution risk • Partnership risk • Assess potential market entry options, including potential partners as appropriate

* Overall project 14 weeks; workstreams 1-3 overlap with workstreams 4 and 5

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KEY QUESTIONS TO ADDRESS AS WE GET STARTED

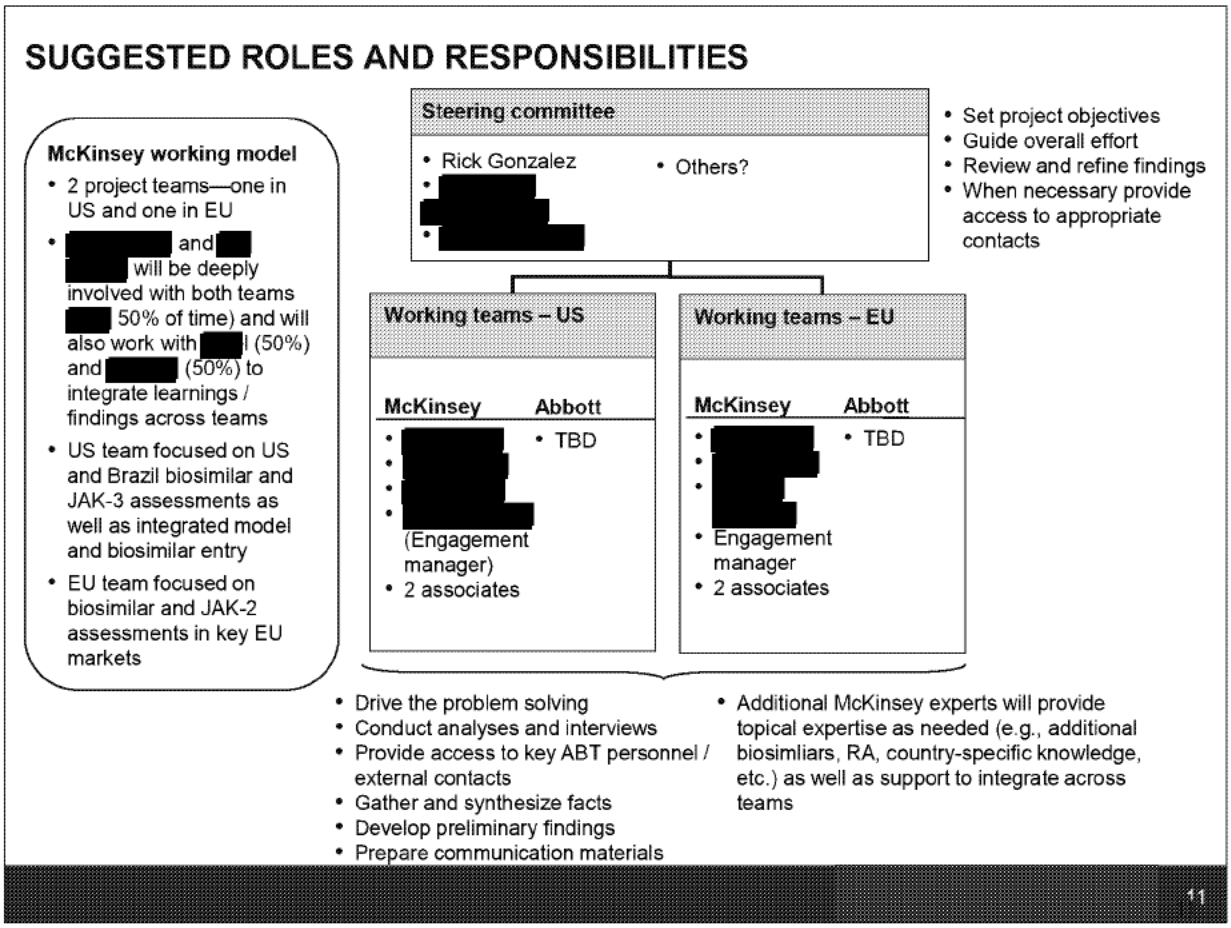
FOR DISCUSSION

Project sponsorship and governance

- Interactions with Rick / [redacted]—weekly / bi-weekly updates?
- Who should be on Steering Committee? How often should it meet?
- Should we involve any other key PPG functional leaders or business heads and if so when / how (e.g., ~2 individual discussions with key other senior staff to get input and discuss findings)?
- Who should be on working team? Should we involve key individuals from countries?

Project timeline and working model

- When should we get started? 14 week project will be completed on either 12/10 or 12/17 based on early to mid Sept. start date (e.g., 9/7 or 9/13)?
- Where should we locate our 2 project teams in US (assumption onsite at Abbott Park) and EU?
- How should we interact with ABT working team?
- Should we have a project kick-off? Who would we involved and what would goal of meeting be?


SUGGESTED ROLES AND RESPONSIBILITIES
McKinsey working model
• 2 project teams—one in US and one in EU
• [redacted] and [redacted] will be deeply involved with both teams [redacted] 50% of time) and will also work with [redacted] (50%) and [redacted] (50%) to integrate learnings / findings across teams
• US team focused on US and Brazil biosimilar and JAK-3 assessments as well as integrated model and biosimilar entry
• EU team focused on biosimilar and JAK-2 assessments in key EU markets
Steering committee
• Rick Gonzalez
• Others?
• [redacted]
• [redacted]
• [redacted]
• Set project objectives
• Guide overall effort
• Review and refine findings
• When necessary provide access to appropriate contacts
Working teams – US
McKinsey
Abbott
• [redacted]
• [redacted]
• [redacted]
• [redacted]
(Engagement manager)
• 2 associates
• TBD
Working teams – EU
McKinsey
Abbott
• [redacted]
• [redacted]
• [redacted]
• [redacted]
• Engagement manager
• 2 associates
• TBD
• Drive the problem solving
• Conduct analyses and interviews
• Provide access to key ABT personnel / external contacts
• Gather and synthesize facts
• Develop preliminary findings
• Prepare communication materials
• Additional McKinsey experts will provide topical expertise as needed (e.g., additional biosimliars, RA, country-specific knowledge, etc.) as well as support to integrate across teams
11

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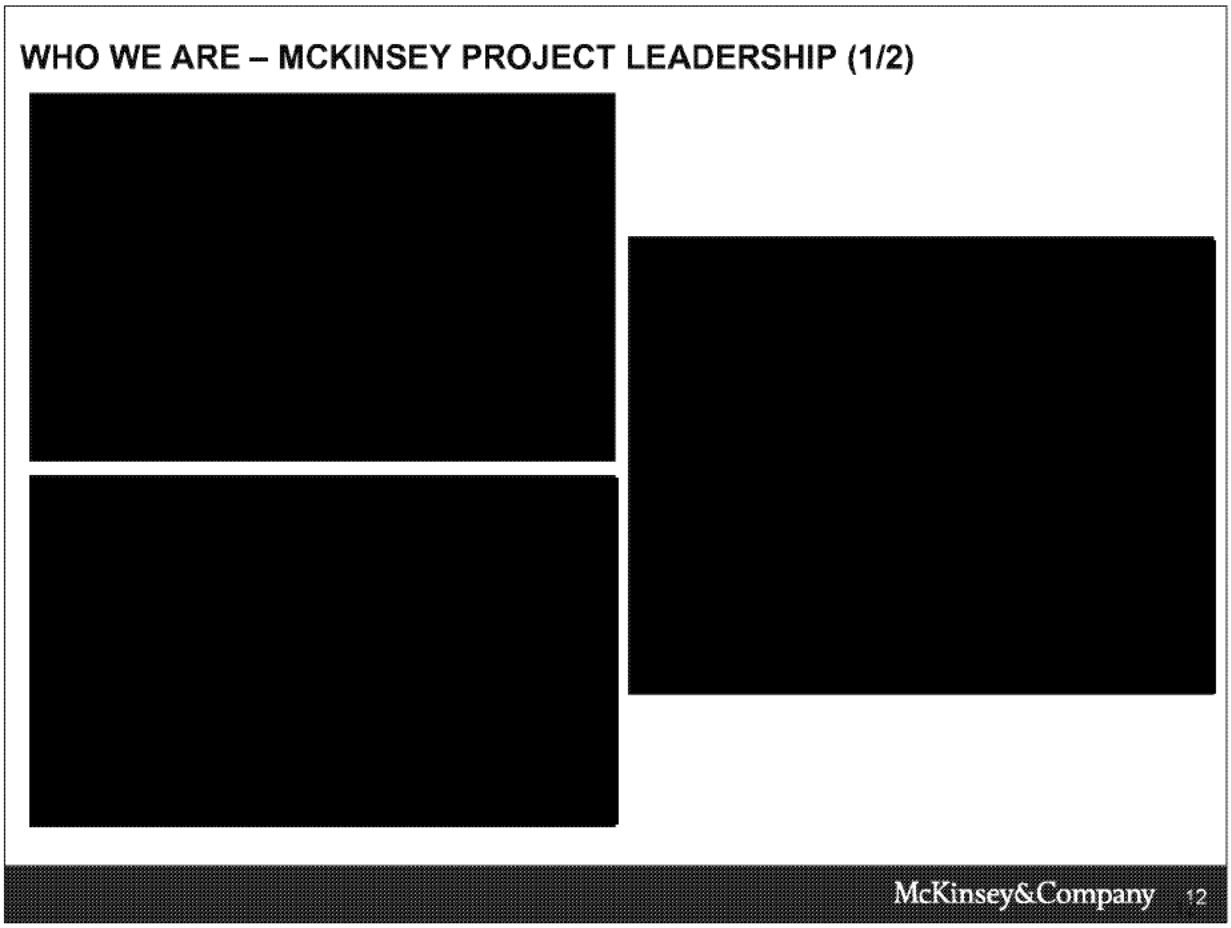
WHO WE ARE – MCKINSEY PROJECT LEADERSHIP (1/2)
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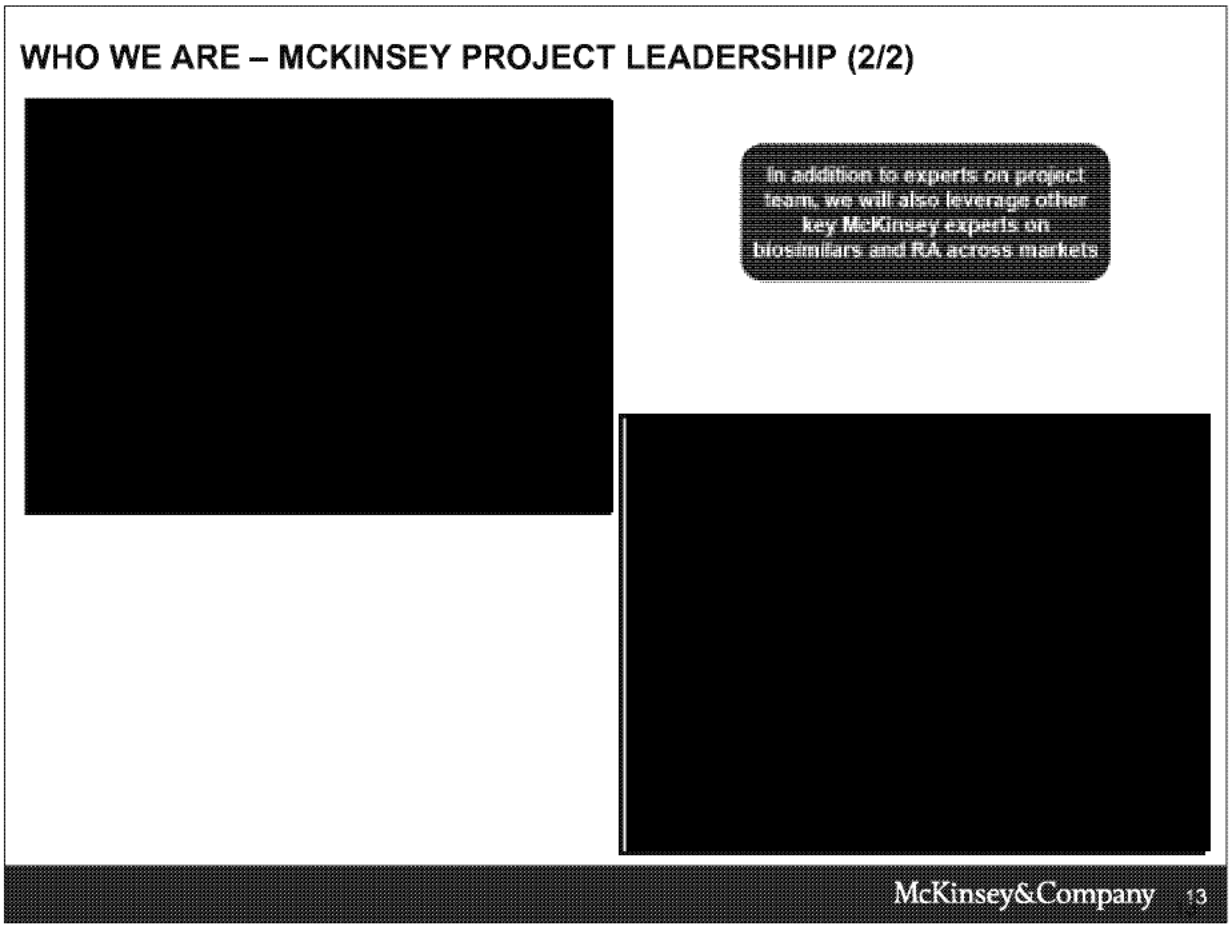
WHO WE ARE – MCKINSEY PROJECT LEADERSHIP (2/2)
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In addition to experts on project team, we will also leverage other key McKinsey experts on biosimilars and RA across markets
[redacted]
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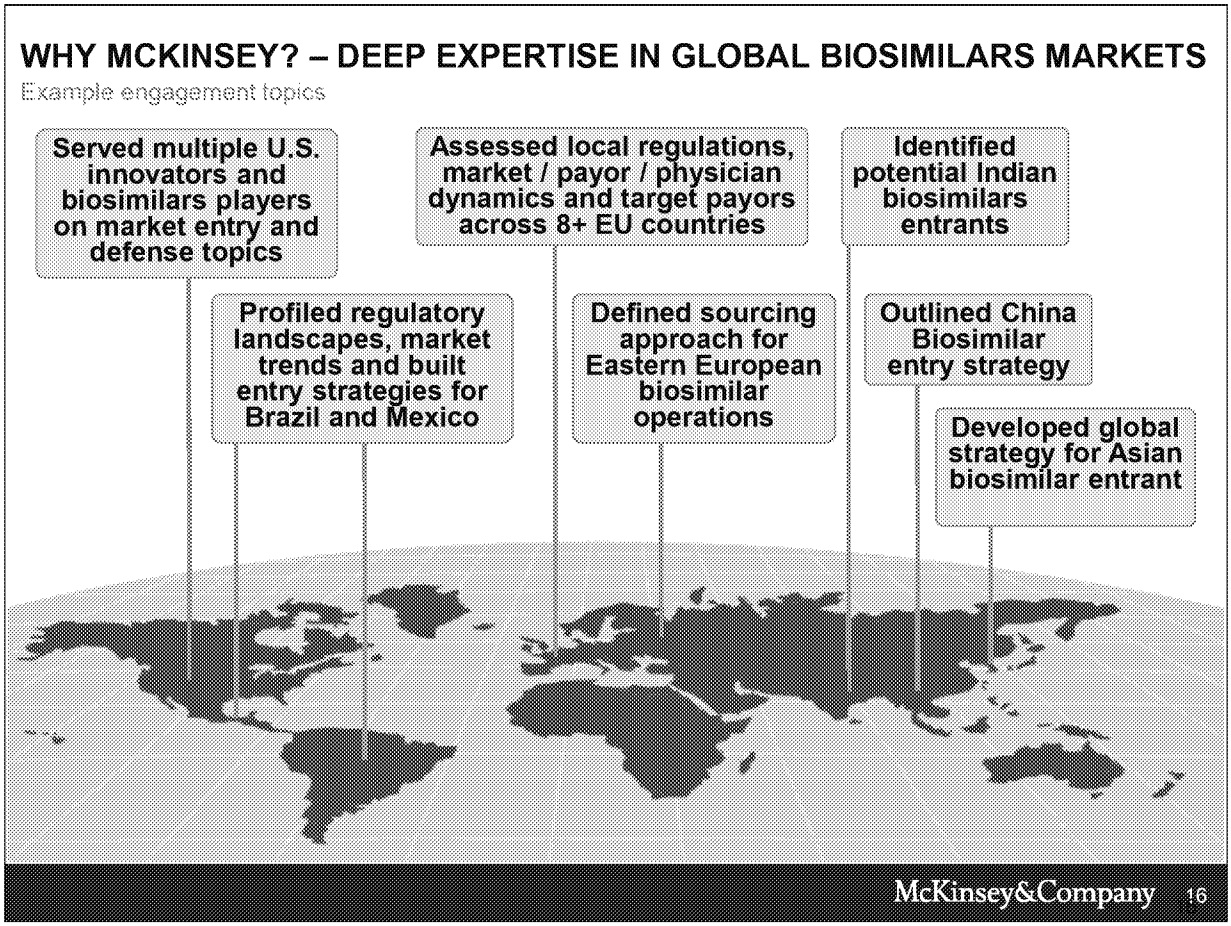
CONTENTS FOR TODAY'S DISCUSSION

- Our understanding of project context and objectives
- Proposed approach / deliverables and working model
- **Why McKinsey?**
- Summary of McKinsey perspectives on biosimilars

WHY MCKINSEY?

Deep expertise in biosimilars across markets	• McKinsey has been at the forefront of developing industry-leading perspectives on biosimilars, publishing several topical white-papers on key issues • We have deep expertise working across all major biosimilars markets on both innovator and market entry strategies • We have extensive biologics expertise in each key functional area, e.g., clinical, operations, commercial, regulatory, etc. • We have proprietary methodologies for evaluating biosimilars market opportunities as well as existing knowledge on regulatory landscapes, market sizing, etc. that we can leverage to jump-start effort
Broad expertise across healthcare spectrum	• We have deep expertise working with leading payors, national health systems and key regulatory agencies across global markets • McKinsey has established a Center for US Healthcare Reform in Washington, D.C. as well as a Health Systems Institute in London to ensure that we are at the forefront of understanding health care reform and impact on our clients • We also supplement our own knowledge and experts with panels of relevant leading outside experts that are aligned with McKinsey only, e.g., regulatory, health policy, etc.
Deep knowledge of Abbott	• History of service to Abbott corporate leadership and key businesses • Client service team leadership brings expertise in managing complex cross-country international growth strategies for Abbott



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CONTENTS FOR TODAY'S DISCUSSION

- Our understanding of project context and objectives
- Proposed approach / deliverables and working model
- Why McKinsey?
- **Summary of McKinsey perspectives on biosimilars**

SUMMARY OF CURRENT MCKINSEY PERSPECTIVES ON BIOSIMILARS

- Biosimilars market is growing rapidly and is expected to reach ~$30B in size by 2020. As a result, it is drawing attention from a large number of players and that is reflected in level of deal activity
- Recent US healthcare legislation opens pathway for biosimilars in U.S. but U.S. environment likely to be innovator friendly, and details still to be worked out. From biosimilar entrant perspective, EU regulatory landscape is most attractive, followed by US regulatory landscape while Japan regulations are least attractive
- However, several business and execution risks are inherent in the biosimilar market. In addition, high investment levels are required for clinical trials and manufacturing to target major markets
- Biosimilars space is likely to be very competitive with only 4-6 players being profitable (compared to 10-15 players attacking innovator products)
  - High investment level in trials (irrespective of product sales potential). As a result most players will need to focus on major products with branded sales of >$2-3B to be profitable
  - Small number of products with branded sales >$2-3B will result in high competition
- Significant competition expected for biosimilars for major products and innovators should have diligent competitive intelligence efforts to understand development stage and efforts of various competitors pursuing key products
- Innovators should consider a range of defense strategies including but not limited to legal challenge, formulation/delivery change, pricing action etc.
  - Formulation changes is one potential defense strategy.
  - Further, several new entrants – especially smaller players - will lack IP capabilities, and thus adopting and aggressive IP/legal stance can benefit innovators

GLOBAL BIOSIMILAR MARKET EXPECTED TO GROW RAPIDLY TO REACH ~$30 BILLION BY 2020…

ROUGH ESTIMATE

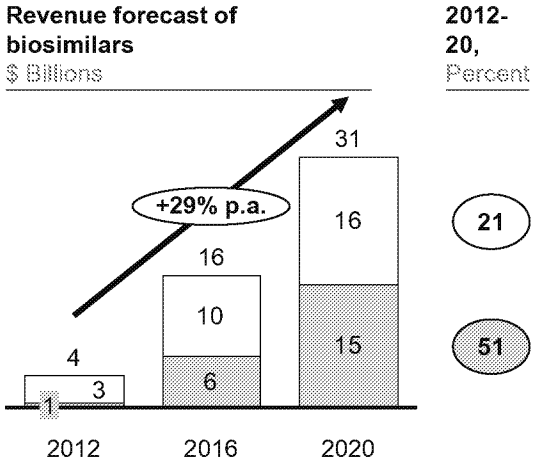
Other biologics | Monoclonal antibodies

Key driving forces for growth

- Multiple blockbuster biologics with combined annual revenues over $75 billion will go off patent during 2010-20
- Opening of biosimilar regulatory pathway in US
- Significant payor pressure to control healthcare expenditure in US & EU
- Relatively lower price erosion of biosimilars expected compared to small molecule generics

However, there are high entry barriers due to clinical trial costs for U.S./E.U. trials and manufacturing requirements

Global biosimilar market is expected to reach ~$30 billion by 2020, driven by growth of monoclonal antibodies



Source: VisionGain (2009); Nature biotechnology; industry interviews; Team analysis

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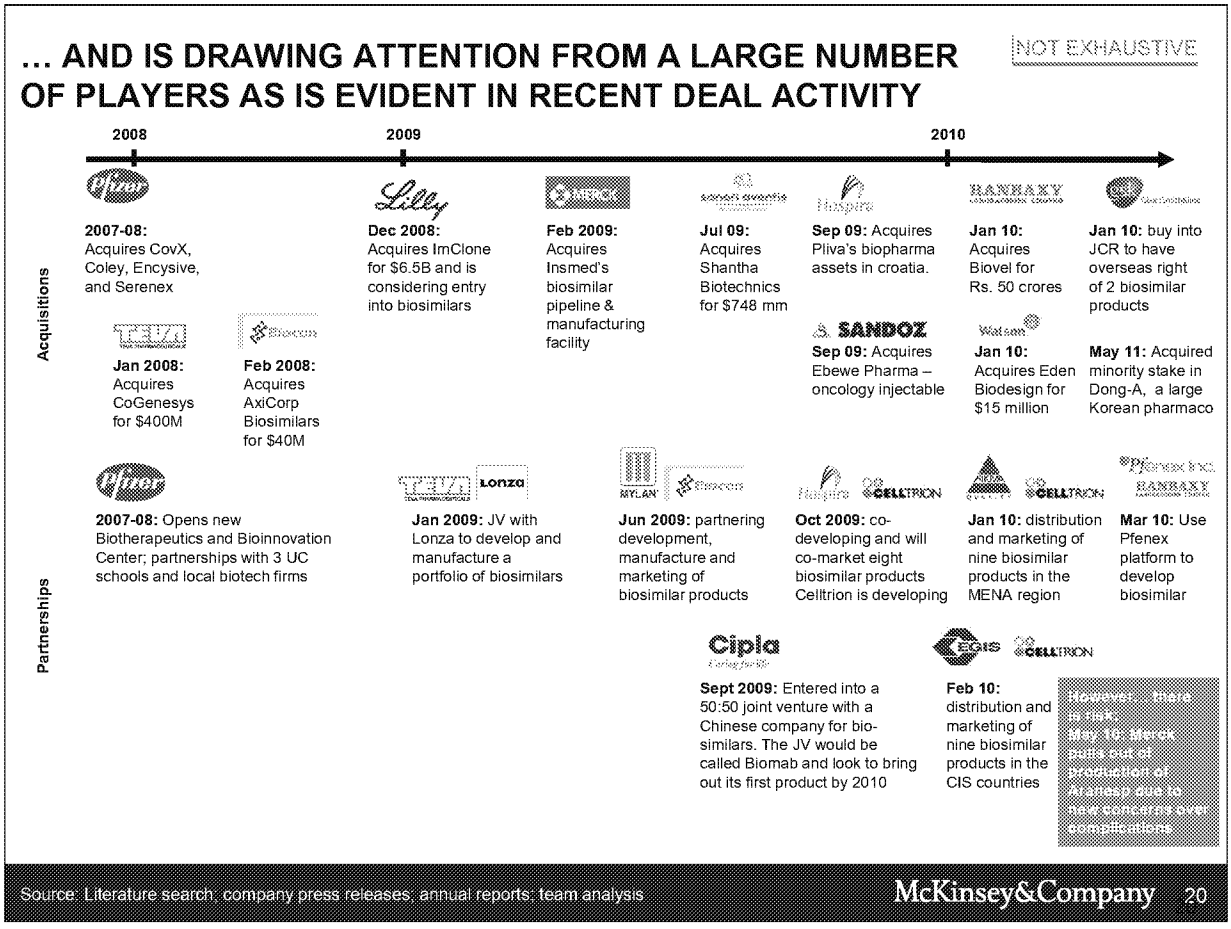

RECENT US LEGISLATION OPENS PATHWAY FOR BIOSIMILARS BUT REGULATORY SITUATION REMAINS INNOVATOR FRIENDLY

Low
High

Current status

- No FDA pathway currently established for biosimilars
- Biosimilar bill approved by House and Senate in Mar 2010
- Biotechnology lobby (BIO) continuing to influence policy in favor of innovators

Key uncertainties/risks:

- Lack of a dedicated FDA Biogenerics office will likely favor innovators
- FDA expected to create a clear pathway for biosimilars by Oct 2010

	Description of guidelines	Biosimilar "friendliness"
Interchange-ability	• FDA likely to require rigorous switching studies to show same expected clinical effect as reference drug	
Nomenclature	• Unique nomenclature required for biosimilars	
Exclusivity	• 12 years of data exclusivity for innovators after mkt authorization, plus 6 mo. pediatric extension • 1-year market exclusivity for first biosimilar, but may require comparable immunogenicity	
Clinical data requirements	• Immunogenicity, PK/PD trials for safety, purity and efficacy likely required for all indications • US may be open to EU-based clinical trials • Reference product must be authorized in US	
Post-market surveillance	• Risk management plan likely required, though FDA has not determined detailed clinical requirements	
Manufacturing requirements	• US cGMP certification required • Comparability study likely required after mfg site transfer, though exact requirements not defined	
Pricing and reimbursement	• Interchangeable FOBs receive same Medicare part B billing code as reference drug • Pricing for non-interchangeable FOBs set at ASP+6%	

Source: Regulatory expert interviews; UBS Biogenerics report; US House and Senate bills

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HIGHLIGHTS OF NEW US BIOSIMILAR LEGISLATION

Regulatory pathway	• FDA authorized to develop detailed regulatory guidelines for biosimilars • Both analytical testing and clinical studies required for approval • Biosimilars need to pay user fee similar to NDAs and are subject to same REMS requirements as innovators
Interchange-ability	• Allowance for interchangeability with reference product if biosimilar demonstrates comparable safety, efficacy and immunogenicity to reference product with switching with biosimilar during clinical trials • 1 year marketing exclusivity permitted for first interchangeable biosimilar
Innovator exclusivity period	• Innovators receive 12 year data exclusivity (i.e.. biosimilar companies cannot leverage safety and efficacy data for their application) • Biosimilar applications not permitted within 4 years of licensure of reference product • Clauses in place such that innovators cannot make incremental/non-clinically significant changes to extend exclusivity
Patent litigation	• Outlined patent certification process by which key patents for dispute are identified in advance to biosimilar companies
Medicare Part B reimburse-ment	• Reimbursement policy in place to remove financial incentives for physicians to prescribe more expensive innovator products • Biosimilar products reimbursed at ASP (of biosimilar product) + 6% of reference product

Source: Biologics Price Competition and Innovation Act (2009) enacted in March 2010

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IMPLICATIONS OF NEW US BIOSIMILARS LEGISLATION FOR KEY STAKEHOLDERS

Biosimilar companies

- Clinical and cost burden to market entry can be quite significant (upto 6 years and $100+ Million per indication, based on TA)
- Interchangeability and 1-yr market exclusivity provision can significantly drive adoption for first interchangeable biosimilar entrant
- Regulatory strategy should consider clinical risk vs. commercial upside tradeoffs for achieving interchangeability
- For non-interchangeable biosimilars, a hybrid (i.e., generic/innovator) commercial model is likely required

Innovator companies

- 12-yr data exclusivity period provision enables innovators to generate returns from their R&D investments and allows time to convert patients to their next generation therapies
- The interchangeability provision has potential to rapidly drive down revenues of their reference product; however the likelihood of a biosimilar entrant gaining interchangeability status is unknown

Payers

- Biosimilars offers significant opportunity to control cost for high growth/high cost biologics
- Payors are likely to manage utilization of biosimilars e.g., through step edits, prior authorizations, formulary tiers

EU REGULATORY LANDSCAPE IS MOST ATTRACTIVE FOR BIOSIMILARS FOLLOWED BY REGULATORY LANDSCAPE WHILE JAPAN REGULATIONS ARE LEAST ATTRACTIVE

Relative attractiveness for biosimilars

	Current status	Expected progress	Implications for Player
EU	• EMEA established biosimilars pathway in 2003	• EMEA expected to issue MAb specific guidance by 2013	• **6 biosimilar drugs have already been approved under current guidelines** • **Key hurdles for biosimilars:** – Interchangeability decision at country level – Reference product must be EU authorized – Immunogenicity studies required
US	• Biosimilar bill approved in March 2010	• More detailed FDA guidance timing expected by October 2010	• **New regulations/guidelines still being defined** • **Key hurdles for biosimilars:** – FDA guidelines still not finalized – Interchangeability has strict clinical trial requirements – 1-year exclusivity difficult to achieve – Separate nomenclature for biosimilars likely
Japan	• MHLW[1] issued biosimilar guidance in May 2009 • Pricing guidance announced in early 2010	• New manufacturing/ production guidelines expected by 2014	• **Biosimilars will be priced at 70% of original drug price; and likely to be tough market for generics** • **Lengthy clinical trials requirement** • **Key hurdles for biosimilars:** – In-market preclinical and clinical trials required – No exclusivity or interchangeability allowed – Widespread perception among physicians that biosimilars have lower quality/safety/efficacy

1 Japan's Ministry of Health, Labor, and Welfare

Source: EMEA Mab concept paper; US Library of Congress, Japan biologics paper; Press search; Regulatory expert interviews; team analysis

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HOWEVER, SEVERAL BUSINESS AND EXECUTION RISKS EXIST IN THE BIOSIMILAR BUSINESS FOR NEW ENTRANTS

NOT EXHAUSTIVE

	Description of potential risks	Actions entrants are likely to take mitigate the risk
Market risk	• Overall market is unfavorable to biosimilars, affecting adoption rate and pricing • Competition overly intensifies, diminishing likely market share, affecting order of entry, or price	• **Monitor market evolution** around biosimilars to respond in a timely manner (market intelligence) • **Develop competitive intelligence** capability and make investments in a stage-gate manner • **Form alliance with partners** with strong sales and marketing capabilities
Patent/ regulatory risk	• Key patents and regulation prevent/ slow biosimilars to gain market access • Originator challenges	• **Run IP assessment early** and leverage experienced IP/legal resources to develop effective IP strategy • **Develop working relationships** and open dialogs with local regulatory bodies early on
Execution risk	• Clinical trials execution is delayed, affecting order of entry	• **Hire key capabilities** experience with clinical trials and regulatory affairs in EU and US • **Support necessary resources** to accelerate research & development (e.g. incentive system tied to milestones) • Have **investment review process** that accommodates market challenges
Partnership risk	• Inability of smaller entrants to find strong partner to enter major markets (US/EU)	• **Improve value proposition** to potential partners (e.g. expand portfolio, accelerate clinical trials) • **Hire key BD talents** with strong existing BD network • **Approach** broad set of potential partnership candidates **aggressively and early**

In addition, investment requirements are high with clinical trial costs for U.S./E.U. trials (in many cases ~$150M per molecule, not correlated with product sales potential) and manufacturing requirements (potential upfront CAPEX or lower margins)

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MOST ENTRANTS HAVE HIGHER CHANCE OF ACHIEVING PROFITABILITY ONLY IF THEY FOCUS ON BIOLOGICS WITH PEAK SALES >$2-3B

Risk unadjusted NPV > 0

Step 1 : NPV analysis based on peak sales

Step 2 : Attractive peak sales analysis to identify screening criteria for portfolio candidates based on market size

Overview

- Analyzed NPV of a target biologic based on peak year sales (i.e. sales after partnership fee)
- Based on the NPV analysis, **peak year sales of $40M - $60M were required for positive NPV**

Assumption

- 30-40% biosimilar adoption
- 30% price discount
- 40% revenue sharing with partner

Biosimilar player sales in peak year
in million USD

Target branded biologics peak year sales	*Biosimilar player market share*[1] 5%	10%	15% (*Base case M/S*)	20%	25%
500	<5	<10	10 - 15	15 - 20	15 - 25
1,000	<10	15 - 20	15 - 25	25 - 35	30 - 40
1,500	10-15	15 - 25	30 - 40	**40 - 50**	**45 - 65**
2,000	10-20	25 - 35	**40 - 50**	**50 - 65**	**65 - 85**
2,500	15-25	30 - 40	**45 - 65**	**65 - 85**	**80 - 105**
3,000	20-25	**40 - 50**	**55 - 75**	**75 - 100**	**95 - 125**

1 Assuming simultaneous entry along with other competitors, market share scenarios translates into # of competitors in the market – 1 competitor (50% market share), 2 competitors (30-40%), 3 competitors (20-30%), 4 competitors (~20%), 5 competitors (10-20%), etc

2 Biologics with 2014 branded sales > $1B are also considered in the selection process to be more comprehensive
Note: For NPV analysis, terminal value is not considered for NPV analysis, but sales are extrapolated till 2025

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LIMITED NUMBER OF BIOLOGICS WITH SALES >$2-3 BILLION LIKELY TO CREATE AN INTENSELY COMPETITIVE SPACE

BIOLOGICS WITH LOE BEFORE 2020 WITH SALES > $1 BILLION

Revenue size

$ Billions

		2014 branded sales[1]	CAGR 2012-14 Percent
>5 billion	Avastin	8.8-9.7	4-10
	Enbrel	7.3-8.0	
	Humira	7.9-8.7	0-1
	Rituxan	7.4	6
	Herceptin	6.2-7.0	1
	Lantus	6.5	3-5
>3 billion	Remicade	4.5-5.4	5
	Prevnar	3.9	-10
	Neulasta	3.8	4
	NovoRapid/Log	3.2	2
>1.5 billion	Lucentis	2.9-3.3	11
	Erbitux	2.5-2.8	2-4
	Levemir	2.6	5-7
	Humalog	2.4	13
	Avonex	2.4	1
	Rebif	2.1	-2
	Botox	2.0	-2
>1.5 billion (continued)	Epogen	2.0	-6
	NovoMix	1.9	8
	Tysabri	1.2-1.8	-1-6
	NovoSeven	1.6	4
	Pegasys	1.6	-3
	Kogenate	1.6	4
>1B	Xolair	1.4	4-7
	Orencia	1.4	11
	Procrit/Eprex	1.4	-12
	Neupogen	1.2	-3
	Gardasil	1.1	0
	Actemra[2]	1.1-1.9	29
	Cervarix	1.1	6
	Norditropin	1.1	5
	Cerezyme	1.1	1

1 Forecasted sales can differ by research firms; 2014 branded sales are ranged if there are notable discrepancies between different sources

2 Actemra launched in early 2010; and will have data exclusivity in US that will be until 2021; and also given early stage of launch sales estimates uncertain

Source: Datamonitor; Evaluate; press search; company websites; analyst reports; team analysis

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SIGNIFICANT COMPETITION EXPECTED FOR BIOSIMILARS OF MAJOR BIOLOGICS AND DILIGENT COMPETITIVE INTELLIGENCE NECESSARY ON POTENTIAL ATTACKERS (1/2)

HERCEPTIN EXAMPLE

Current progress of competitors in Herceptin

Company	Country of origin	Current progress: Research (Varies)	Phase I (6-9 months)	Phase III (1.5-2 years)
CELLTRION[1]	Korea	———	———	———
Hanwha	Korea	———		
Yeda Axis	Korea	———		
SCI Cell	Korea	———		
JCR	Japan	———		
zenotech	India	———		
Glycenax Biotech Inc.	Taiwan	———		
biogen idec	USA	———		
DONG-A PHARMACEUTICAL	Korea	———		
Shenzen Wanle pharma[2]	China	———		
Teva / Lonza	Israel/ Swiss	———		
CURAXIS	Spain	———		
GTC Biotherapeutics[3]	USA	———		

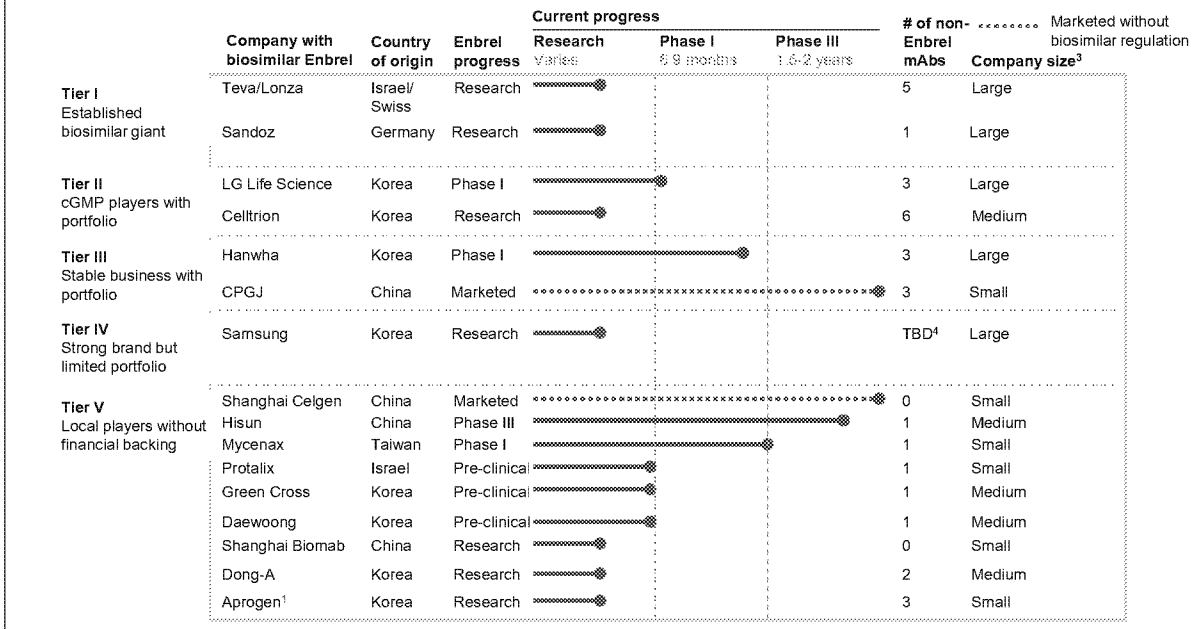
- ~13 known players competing for Herceptin biosimilar market, with likely more competitors researching or developing Herceptin due to its attractiveness
- Competitors likely to start accelerating the process in coming years given the patent expiry date of 2014 – 2015 in US/EU

1 Celltrion announced that it completed non-clinical research on Herceptin in 2Q 2009; so we assume it has completed Ph 1 already in last 12 months
2 Shenzen Wanle pharma submitted pre-IND application in Dec.3, 2009, currently under SFDA review; expect 3-4 years until market entry
3 GTC Biotherapeutics announced its plan to file IND for Herceptin in 2012

Source: Press search; Analyst reports; Industry insiders; Company websites; IMS patent focus; Team analysis

SIGNIFICANT COMPETITION EXPECTED FOR BIOSIMILARS OF MAJOR BIOLOGICS AND DILIGENT COMPETITIVE INTELLIGENCE NECESSARY ON POTENTIAL ATTACKERS (2/2)

ENBREL EXAMPLE



	Company with biosimilar Enbrel	Country of origin	Enbrel progress	# of non-Enbrel mAbs	Company size[3]
Tier I Established biosimilar giant	Teva/Lonza	Israel/ Swiss	Research	5	Large
	Sandoz	Germany	Research	1	Large
Tier II cGMP players with portfolio	LG Life Science	Korea	Phase I	3	Large
	Celltrion	Korea	Research	6	Medium
Tier III Stable business with portfolio	Hanwha	Korea	Phase I	3	Large
	CPGJ	China	Marketed	3	Small
Tier IV Strong brand but limited portfolio	Samsung	Korea	Research	TBD[4]	Large
Tier V Local players without financial backing	Shanghai Celgen	China	Marketed	0	Small
	Hisun	China	Phase III	1	Medium
	Mycenax	Taiwan	Phase I	1	Small
	Protalix	Israel	Pre-clinical	1	Small
	Green Cross	Korea	Pre-clinical	1	Medium
	Daewoong	Korea	Pre-clinical	1	Medium
	Shanghai Biomab	China	Research	0	Small
	Dong-A	Korea	Research	2	Medium
	Aprogen[1]	Korea	Research	3	Small

1 Bought by Schnell Biopharmaceuticals in 2009 2 R=Research, P=Pre-clinical, I=Phase I, III=Phase III; Based on press search
3 Revenue >$1B = large, Revenue > $100M = medium, Revenue < $100M = small 4 Announced they will add ~7 molecules mostly inorganically

Source: literature search; company websites; team analysis

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INNOVATORS CAN TAKE A RANGE OF ACTIONS TO DEFEND THEMSELVES AGAINST THE THREAT OF BIOSIMILARS

○ Low
● High

	Level of threat to biosimilar player	Example actions taken by innovators
1. Differentiate the product through extensions / next-gen products		▪ Development of pre-filled formulations or injection pens (less preparation than freeze-dried formulation) ▪ Genentech starting PIII trials of T-DM1, next gen version of Herceptin
2. Delay/block biosimilar entry through legal/ lobbying actions		▪ BIO members spent over $20M on US lobbying efforts in 2008-9 targeting healthcare reform provisions dealing with biosimilars ▪ Aggressive litigation against new entrants to prevent US market entry (e.g., against Shire's Dynepo in 2006)
3. Shape physician/ patient/ payor perceptions		▪ Advertising in medical journals or company websites to suggest need to manage safety risk of follow-on biologics
4. Lower price to capture share		▪ Innovator lowered price of Eprex (Epo) in E.U. by 15% to defend against new entrants
5. Compete in generics market		▪ In future, some innovators could decide to enter with generics competitors

Source: Literature search; Company websites; Clinicaltrials.gov; Team analysis

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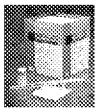
FORMULATION CHANGE IS ONE TACTIC INNOVATORS SUCCESSFULLY EMPLOY TO DIFFERENTIATE PRODUCTS

ENBREL EXAMPLE

	Freeze-dried (vial)	Pre-filled syringe	Injection pen (SureClick)
			
Year of launch	1999	2003	2006
Description	Solid powder	Stable liquid formulation	Stable liquid formulation
Patent expiry	2009-15	2023-27	2023-20
Administration	Administered by HCP	Self-administered by patient	Self-administered by patient
Cost	Low cost	Same cost as vial	~2x cost of vial/syringe
Convenience	Difficult to mix/use; Requires costly physician visit	Easy to use; Needle-associated anxiety/pain	Very easy to use; Lower anxiety

Source: USPTO, JPO, and EPO websites; IMS Patent Focus; EvaluatePharma; team analysis

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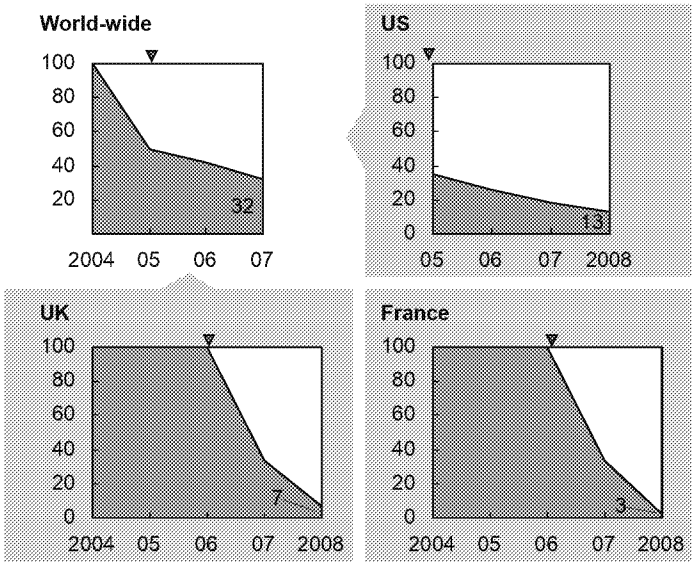
TRANSITION TO NEW FORMULATION IS RAPID GIVEN THE CONVENIENCE AND SIMILAR PRICE POINTS

ENBREL EXAMPLE

- Pre-filled + pen
- Freeze-dried
- Pre-filled introduced

Pre-filled Enbrel formulation comprises more than 75% of global sales, and likely ~90% in developed markets (e.g. US, UK, FR)

Percent of total Enbrel sales (except world wide, which is in units)



Pre-filled's cost competitiveness likely to accelerate adoption in RoW as well

Country / formulation	Price
Korea	
• 25 mg, vial	KRW 134,316
• 25mg, syringe	KRW 134,316
Russia	
• 25mg, vial	EUR 1,130
• syringe	N/A
Turkey	
• 25 mg, vial	TL 1,002
• 50mg, sureclick	TL 1,002
India	
• 25mg, vial	INR 9,065
• 25mg, syringe	INR 7,983

Transition to syringe likely to happen even in RoW given the pricing policy (e.g. same price for freeze dried and syringe)

1 Pre-filled syringe patented in US (2027), EU (2023), Japan (2023), Turkey (2023). Patents not found in Brazil, India, Mexico, Russia

Source: US Drug Delivery (Frost & Sullivan 2008); USPTO, JPO, and EPO websites; IMS patent focus; company website

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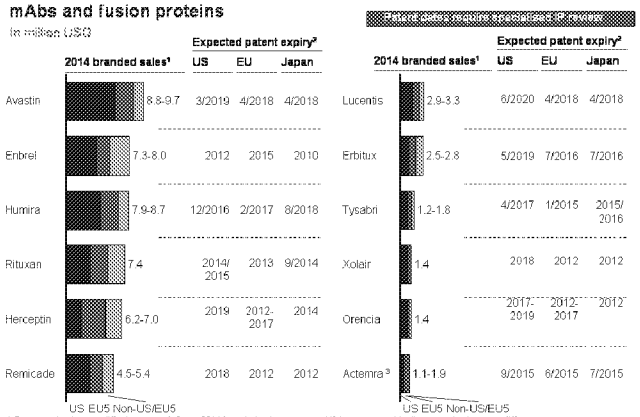
SEVERAL NEW ENTRANTS – ESPECIALLY SMALLER PLAYERS – WILL LACK IP CAPABILITIES, AND THUS ADOPTING AGGRESSIVE IP/LEGAL STANCE CAN BENEFIT INNOVATORS

Challenges in understanding IP rights

- Unclear what patents define possible entry date for biosimilars as multiple patents exist per product
- Different data sources (e.g. Vision gain, IMS) publish different IP expiry dates
- IP rights are often extended by new filings or litigation by the originator

Estimated patent expiry dates in major markets for top 12 mAbs and fusion proteins

In million USD



1 Forecasted sales can differ by research firms; 2014 branded sales are ranged if there are notable discrepancies between different sources
2 Patent expiry based on analyst view and need to be validated through IP/legal assessment 3 Longer timeframe due to 12-year data exclusivity
SOURCE: Datamonitor; IMS patent focus; press search; team analysis

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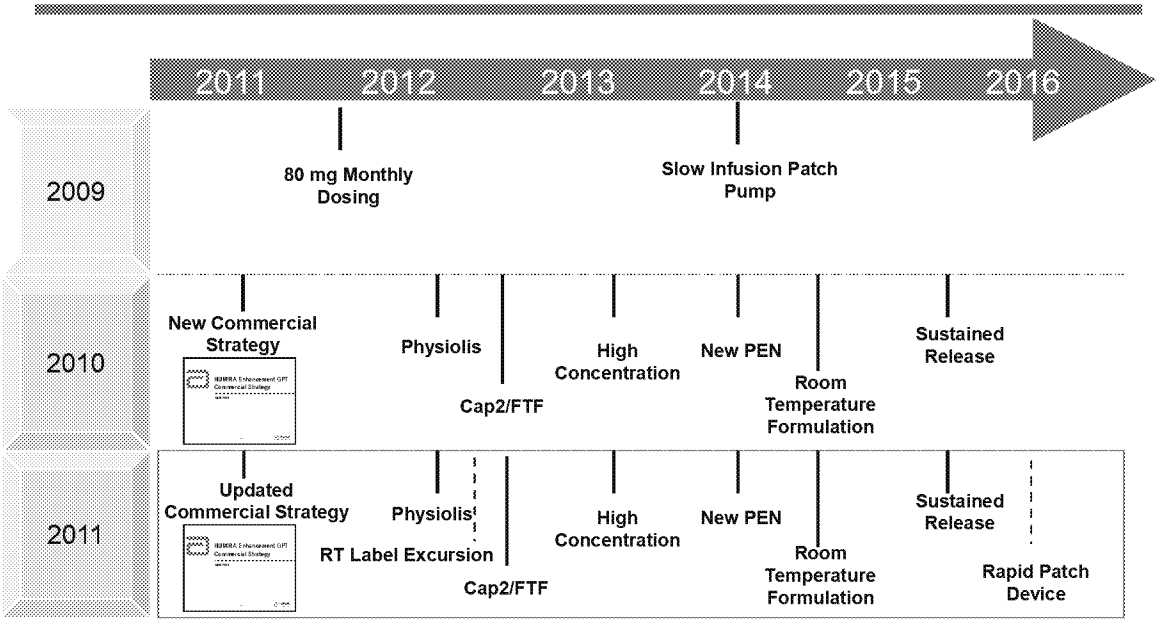
FEB 2010: Major Milestone in the Enhancement Strategy Development at the LU Meeting



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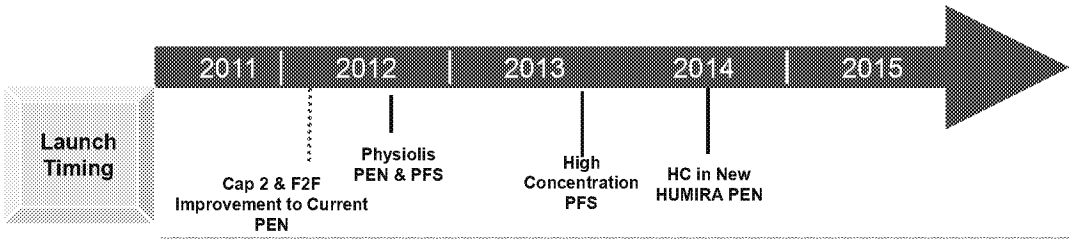
HUMIRA Enhancement Strategy and Commercial Launch Plan in 2011

HUMIRA Enhancement Vision

Through constant innovation HUMIRA will be recognized as the Best in Class biologic offering and the product most preferred by patients and HCPs

- 3 Key Strategic Objectives
  1. Enhance the patient on-boarding and continued experience with HUMIRA
  2. Drive brand preference and loyalty through clear product (formulation and device) differentiation – make HUMIRA patients "stick"
  3. Raise barriers to competitor ability to replicate

Commercial Launch Plan



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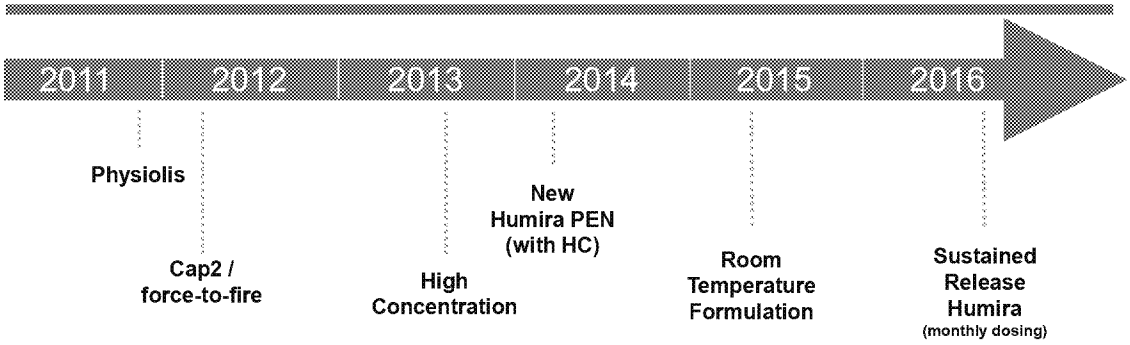
HUMIRA Enhancement Projects anticipated approval dates



	Maintain Competitiveness	Differentiation	Biosimilar defense	Oral DMARDs defense	Potential for additional IP
Cap2 / force-to-fire					
Physiolis					
High Concentration					
New Humira PEN					
Room Temperature Formulation					
Sustained Release Humira (monthly dosing)					

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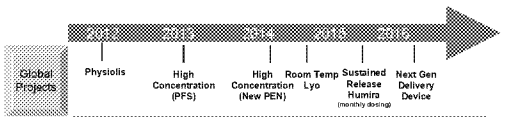
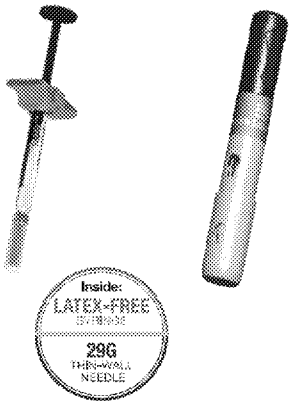
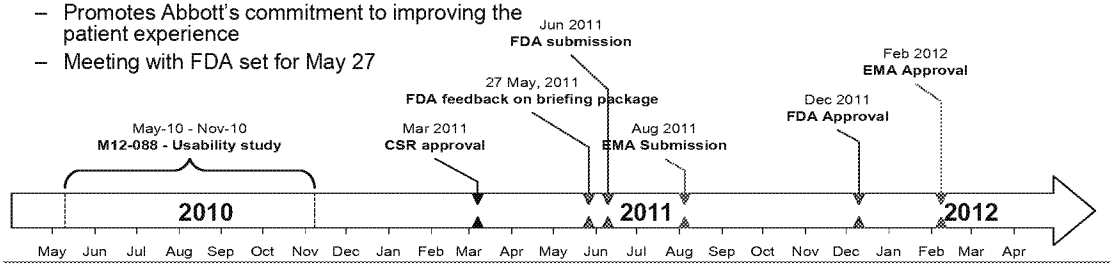
HUMIRA
Physiolis – PFS & PEN



- Project Description
  - Improvement of current PFS and PEN
  - Reduced needle size from 27 gauge to 29 gauge
  - Latex free rigid needle shield
  - PEN appearance remains the same
  - Will be a 100% replacement



- Commercial Considerations
  - HUMIRA will have the thinnest needle of any of the biologics in our space
  - Cimzia is the only other product that's latex free
  - Smaller needle size may give the perception of less needle stick pain on injection
  - Promotes Abbott's commitment to improving the patient experience
  - Meeting with FDA set for May 27



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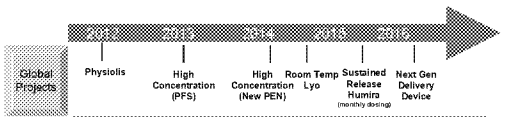
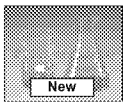
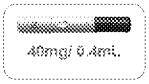
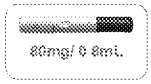
HUMIRA
High Concentration Formulation

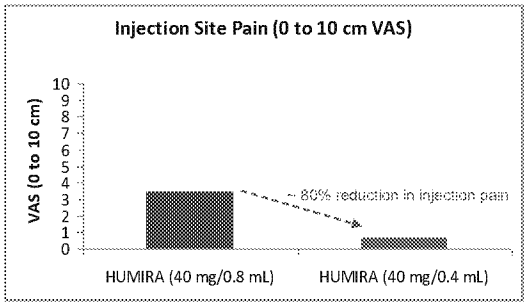


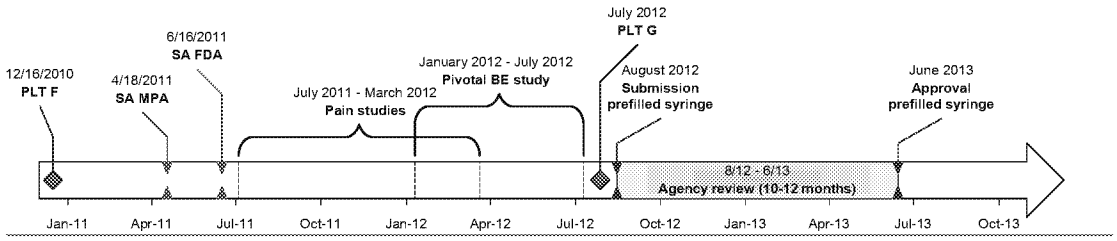






- **Project Description**
  - HUMIRA New Formulation is associated with reduced pain (e.g. stinging/burning) than current formulation
  - New Formulation has a 2-fold higher protein concentration (100mg/mL vs. 50mg/mL) to reduce the dose volume in half.
  - It is likely that the New Formulation will **first** be available in the PFS (2013) **followed by** the New Pen (2014)
  - Once approved, the New Formulation will replace the current HUMIRA formulation.





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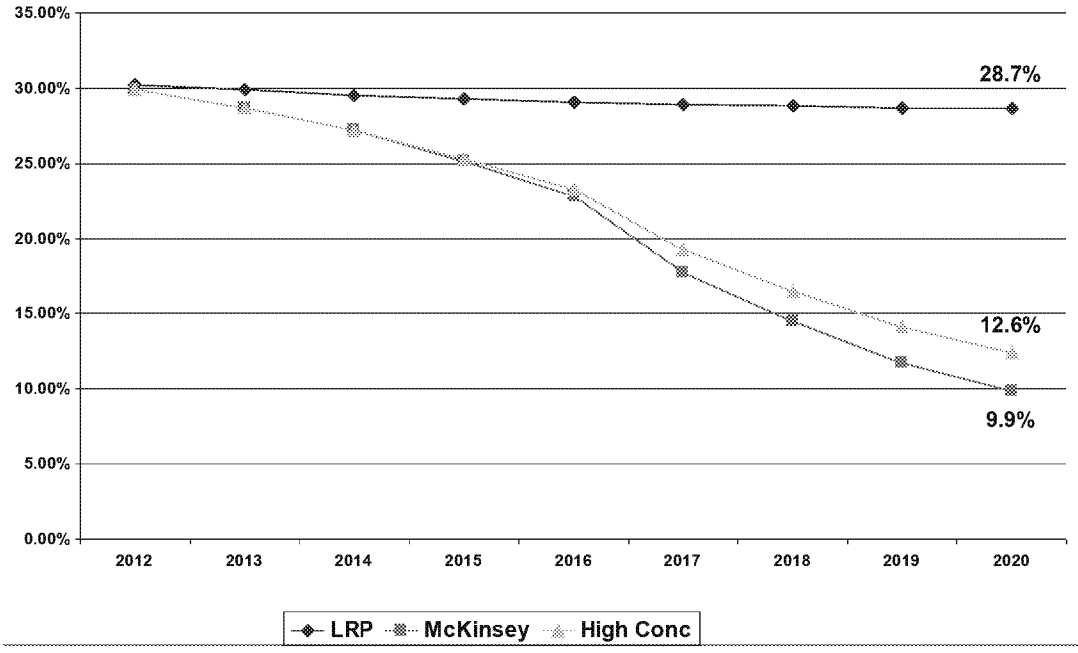
PPD
Market Share Retention with High Conc. Product



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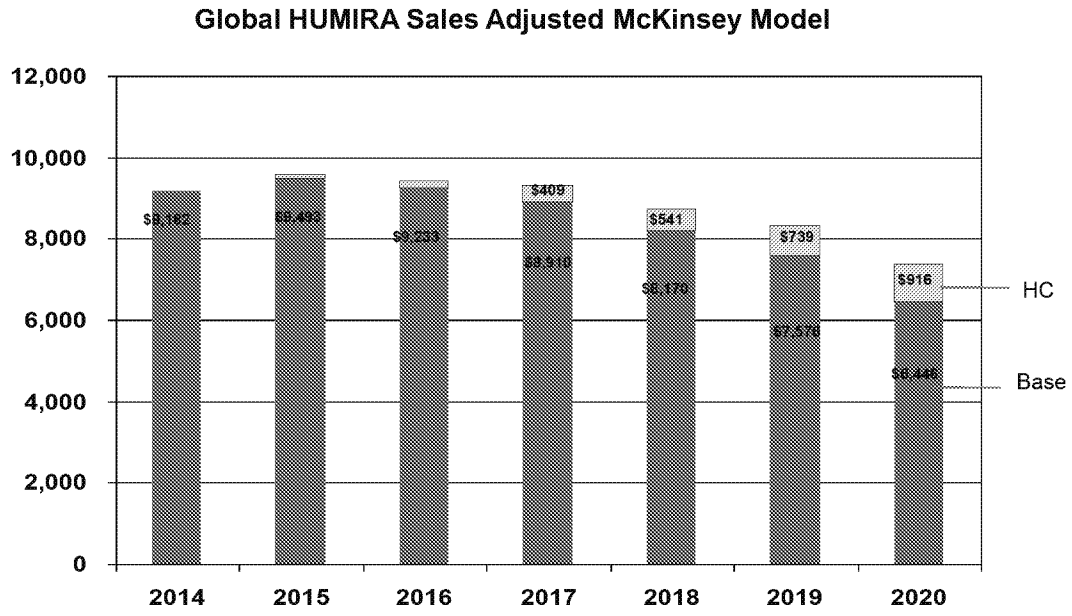
HC HUMIRA will retain $0.9B in Global Sales in 2020 (cumulative sales retention 2014-2020 of $2.9B)



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From: [redacted]@panfoundation.org>
Sent: Tuesday, November 28, 2017 9:13 AM
To: [redacted]
Cc: [redacted]
Subject: Support for Autoimmune Disease Funds

Hello [redacted]

As you know, the Patient Access Network (PAN) Foundation is one of the leading independent charitable patient assistance foundations in the U.S. PAN has been providing co-pay, travel and premium assistance programs for patients with life-threatening, chronic and rare diseases since 2004. With the generous support of drug manufacturers like Abbvie, the PAN Foundation has provided more than $2.6 billion in financial assistance to nearly one million patients who otherwise would have been unable to afford their critical medications.

PAN offers several co-pay assistance programs for autoimmune diseases, which are open to Medicare beneficiaries with incomes at or below 400% of the Federal Poverty Level. Over the years, we have provided assistance to several thousand patients through these programs. However, the need for assistance vastly outstrips available funding. Our autoimmune disease funds typically open for a few days at the beginning of each year. We are then forced to close these funds for the remainder of the year due to a lack of support.

Based upon data from CMS and the National Health and Nutrition Examination Survey we know that as many as one million people with ankylosing spondylitis, plaque psoriasis, psoriatic arthritis and rheumatoid arthritis are eligible for assistance from PAN. We also know these patients would be much more likely to start and stay on treatment if they were not stymied by high out-of-pocket costs. To that end, we are asking Abbvie and the other major manufacturers of drugs for these diseases to collectively commit to keeping these funds open for at least one month each calendar quarter. PAN can reopen these funds only if we receive sufficient pledges from two or more manufacturers. For 2018, our actuaries calculate that this would require the following levels of support:

Disease Fund	Projected 2018 Need			
	Q1	Q2	Q3	Q4
Ankylosing Spondylitis	$11,137,579	$7,118,526	$7,118,526	$8,772,947
Plaque Psoriasis	$26,072,526	$16,650,947	$16,650,947	$20,530,421
Psoriatic Arthritis	$11,310,000	$7,229,368	$7,229,368	$8,908,421
Rheumatoid Arthritis	$23,543,684	$15,037,579	$15,037,579	$18,539,368

While these numbers may seem large, they are a fraction of what Medicare beneficiaries spend on treatments for these diseases. We hope that by spreading the cost among several donors, Abbvie would be willing to pledge its support.

We appreciate your willingness to consider making a donation, contingent on others doing the same. We would welcome the opportunity to discuss this approach with you in more detail. Please let me know a time in coming weeks when you are available for a phone call.

Thank you and best regards,

[redacted]
President & CEO
Patient Access Network Foundation
1331 F Street NW, Suite 975, Washington, DC 20004
O: [redacted]
M: [redacted]
panfoundation.org

PAN Foundation

Humira Dermatology Development Strategy
April 2008

Overview of Dermatology LRP Strategic Objectives

Psoriasis is a non-contagious, chronic immune disease that speeds the growth cycle of skin cells and results in thick scaly areas of skin. The psoriasis market is attractive due to the large prevalence of the disease and relatively undeveloped nature of the biologic segment. Abbott enters this market with a portfolio of two highly attractive products, HUMIRA (approved for psoriatic arthritis in 2005 and for psoriasis in December 2007 (E.U.) and January 2008 (U.S. and Canada)) and ABT-874 (phase 3, approval expected 2011).

Global sales in dermatology are expected to contribute significantly to the overall immunology sales portfolio over the extended long-range plan. By 2011, global sales will exceed $1 billion and will increase to $2.3 billion at the end of the LRP period, with Abbott dermatology having two blockbuster products in HUMIRA and ABT-874. The U.S. is the main contributor of sales for both HUMIRA and ABT-874 throughout the LRP period with peak sales of $1.5 billion. The Ex-U.S. market contributes more significantly to sales in later years with peak sales of $771 million.

Effective functional strategies must be developed to comprehensively address the market issues above. To ensure long-term success in this market Abbott has to not only successfully establish HUMIRA and ABT-874 as first choice biologic therapies in psoriasis but also concentrate significant efforts now on developing this market to grow biologic penetration in all TNF and IL12/23 mediated dermatoses. The strategic objectives and functional strategies as outlined in the 2008 LRP are provided below with highlights to specific strategies targeted by the Humira Psoriasis Global Project Team overall development strategy.

1) Establish HUMIRA and ABT-874 as the first choice for TNF and IL-12/23 mediated dermatoses

- *Develop and launch ABT-874 with best-in-market profile**
- *Competitively position against new market entrants**
- *Establish favorable benefit / risk ratio**

2) Expand the biologic opportunity within dermatology
   - Develop increased awareness of medical seriousness of psoriasis and need for systemic treatment
   - *Identify and evaluate opportunities outside psoriatic disease**
   - *Generate patient demand for biologics**
   - Establish relationships with patient advocacy groups
   - Define disease severity to expand into moderate patient types

3) Optimize pricing and reimbursement for biologics in dermatology
   - Reduce patient and payer barriers affecting initiation and persistence

*Strategies targeted by Humira Psoriasis Development GPT

This document outlines the overall development strategy with details on the ongoing studies, 2008 new study starts, and a new study proposal for 2009 portfolio that supports meeting the overall LRP objectives.

Overall Humira Dermatology Development Portfolio

Table 1 provides an overview of all the studies put forward for the 2008 portfolio and the key areas where each study meets the LRP strategic objectives and strategies. This will be followed by a detailed description of the status, and key strategic features of each study.

Each functional strategy is further defined below:

Further establish favorable benefit/risk profile:

Studies that provide further efficacy information not already established from the registration development program and/or where significant long-term safety information will be collected to solidify the safety profile in dermatology.

Competitively position against new market entrants:

Studies that will provide new data beyond those with current or new competitors and that may also provide positive experience ahead of new market entrants in dermatology.

Develop & launch ABT-874 with best-in-market profile:

Humira studies that will enhance the ABT-874 competitive profile.

Identify opportunities outside psoriasis:

Studies intended to show efficacy and safety within dermatology but outside chronic plaque psoriasis.

Generate patient demand for biologics in dermatology:

Studies that will provide opportunities for increased patient demand of biologics due to positive experiences with Humira, or by expanding the areas of effectiveness outside the regulatory development program.

Increased awareness of medical seriousness of psoriasis:

Studies that will provide additional patient reported outcomes to characterize the seriousness of psoriatic disease in patient lives.

Table 1

Humira Dermatology Studies Aligned with LRP Strategic Objectives

Functional Strategy	Ongoing Studies				Approved 2008 Studies				New 2009 Study
	M03-658* (Long-term Extension)	M10-060 (BELIEVE)	M10-238 (Systemic Switch)	M04-702* (Japan extension)	P10-023* (Registry)	M10-405 (Psoriasis of Hands/Feet)	M04-717 & M06-872* (Pediatric)	Hidradenitis Suppurativa	Humira +/- MTX & ABT-874
Further establish favorable benefit/risk profile	√	√	√	√	√	√	√	√	√
Competitively position against new market entrants		√	√			√		√	√
Develop & launch ABT-874 with best-in-market profile									√
Identify opportunities outside psoriasis								√	
Generate patient demand for biologics in dermatology		√		√		√		√	√
Increased awareness of medical seriousness of psoriasis						√			

*Regulatory commitments

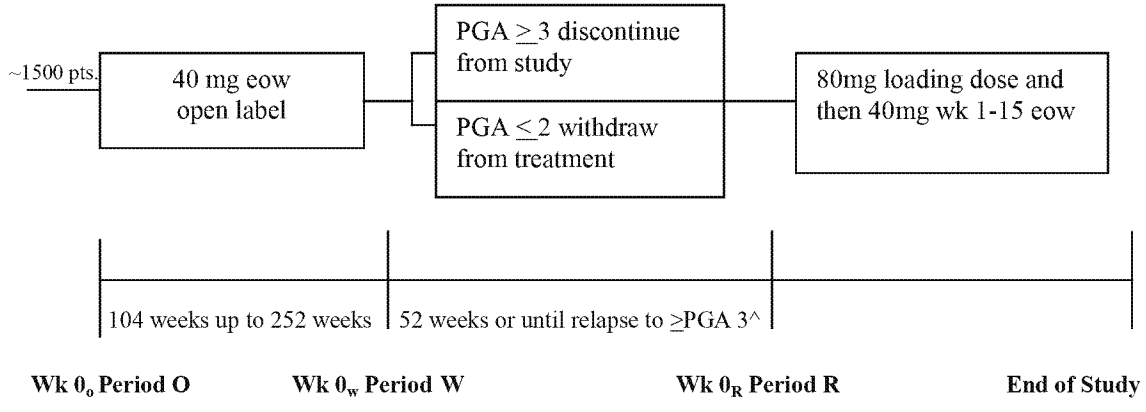
Ongoing Studies in Humira Dermatololgy

Study M03-658

Study M03-658 is the long-term open label extension study offered to subjects rolling over from the various completed phase 2 and phase 3 studies. An interim report was provided as part of the regulatory submissions for the psoriasis global applications and updated data were provided in the 120 day safety update during the review.

This study was planned to close after the regulatory approvals were achieved in all of the participating countries and subjects were to be offered to continue in the Humira psoriasis registry. However, FDA requested an additional post-marketing study to further evaluate the relapse rate and subsequent retreatment upon relapse from what was available in the Study M03-656/M03-658 dataset. Rather than initiate a de novo study, Abbott gained agreement with FDA to amend study M03-658 to fulfill this commitment. By using this study to provide the requested data, it serves as the most time and cost efficient way to meet this regulatory obligation

A major amendment to Study M03-658 is planned in May 2008 with a commitment to provide relapse and retreatment data in a minimum of an additional 120 patients by April 2010. The following schematic represents the design of the amended study:



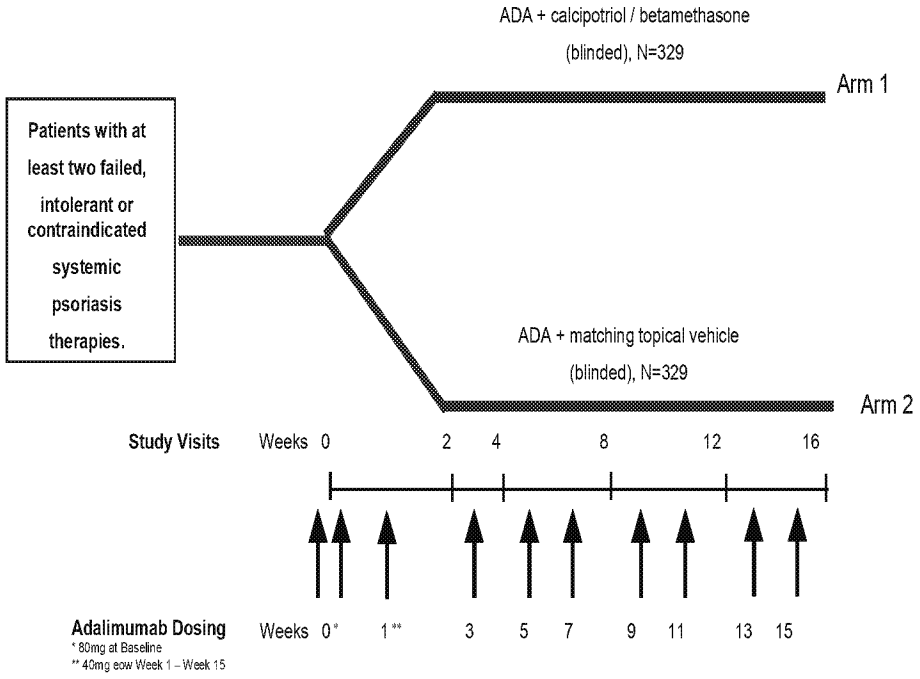
^When the 150th evaluable subject enters Period R, all subjects remaining subjects in Period W will enter Period R. Evaluable subjects include those subjects entering Period W with a PGA of 0 or 1 at the last two visits in Period O, at least 12 weeks apart,

PGA responses have been used as the criteria for relapse and response based on FDA requirements. FDA no longer accept PASI responses as an adequate primary measure of efficacy in the treatment of psoriasis. Once the 150th patient that meets the evaluation criteria has relapsed, all patients will be moved to Period R of the study where they will receive 16 weeks of adalimumab to complete the study.

Overall Study M03-658 provides significant long-term safety data in plaque psoriasis patients to further establish the positive benefit/risk profile of Humira. It will now also provide more complete information in a controlled setting on one cycle of relapse and retreatment in order to determine the ability of such patients to regain response. Anti-adalimumab (AAA) antibodies will be captured in the new portion of the study to help in understanding the contribution of AAA in the relapse/retreatment setting. These data will be important across all indications, not just in the treatment of psoriasis.

M10-060 (BELIEVE)

BELIEVE is a European based multinational, randomized controlled trial in 658 subjects comparing the safety and efficacy of adalimumab in the treatment of chronic plaque psoriasis with or without combination treatment of a commonly used topical therapy (calcipitriol/betamethasone).



Since concomitant high potency steroids were excluded from the phase 3 program, this study will provide information to prescribers on the whether there is additional benefits to continuing these therapies while a patient is on adalimumab, and to confirm there are no safety concerns with such a combination.

Since this is a European based study, the criteria for entry into the study is reflective of the approved indication in the EU, for which adalimumab is indicated after failure to prior systemic therapies. Therefore the study requires at least two prior systemic therapies, one of which must be either cyclosporine, methotrexate or oral PUVA.

The size and scope of the study will provide additional information from that obtained in the phase 3 program with sub-analyses planned around improvements in subtypes of plaque psoriasis such as scalp psoriasis and nail psoriasis that can match and possibly exceed that which is available with current and future competitor products. The study also has the additional benefit of providing positive experience to dermatologists in up to

16 different European countries which can lead to further future demand for therapy to untreated or suboptimally treated moderate to severe psoriasis patients in these countries.

The study will be completed by the end of 2008 with data becoming available in early 2009.

Study M10-238

Study M10-238 is an open-label study being conducted in 150 subjects with moderate to severe chronic plaque psoriasis who are having a suboptimal response to etanercept, methotrexate or narrow band UVB. Suboptimal response is determined at the discretion of the investigator as part of the inclusion criteria. Upon meeting these inclusion criteria, the patients are administered adalimumab therapy for 16 weeks of treatment to determine whether adalimumab can provide a satisfactory response in these patients.

In essence, the study represents three substudies in one protocol and will provide meaningful efficacy information to practioners who are using these common treatments both within and outside the anti-TNF class. It also provides supportive safety information with respect to transitioning patients from these therapies to adalimumab

M04-702

This study is the Japan extension study from the original study M04-688 that was key in supporting the psoriasis application. Currently the psoriasis application is under review and an updated interim report on M04-702 will be provided by end of June 2008 to support long-term safety and efficacy in Japanese psoriasis patients.

Adalimumab is projected to be the first anti-TNF therapy approved for the treatment of moderate to severe psoriasis in Japan thereby increasing the overall global marketplace of psoriasis. This ongoing study will provide the essential additional data to secure this approval.

Approved 2008 Studies in Humira Dermatology

Study P10-023

P10-023 is the long-term registry that is a post-marketing commitment to both the EMEA and FDA. This has been a standard commitment for all biogical therapies in the treatment of psoriasis. The registry proposal submitted with the application for moderate to severe plaque psoriasis included a 5000 patient global registry over a 5-year duration. It was proposed that patients that were currently being treated in the Abbott extension study M03-658 would be offered to convert to participating in the registry and the extension study being closed after the regulatory approvals were obtained. The original plan was to also offer the registry to patients that were participating in the BELIEVE study in Europe. By allowing patients to participate from these two studies it would (1) in the case of M03-658, offer the advantage to continue to follow patients that already have long-term exposures before initiating the registry and (2) through both studies, facilitate enrollment to meet the required timelines and objectives.

However, FDA required significant changes to the registry proposal during the review of the application that had a major impact on the overall strategy. A summary of the most significant changes are as follows:

- Due to concerns regarding the generalizability of safety data from patients outside the US compared to the US psoriasis patient population, the FDA required that all 5000 patients be located in the US. Abbott has now agreed to expand the overall sample size to 6000 patients to allow up to 1000 patients to be enrolled in countries outside the US in order to provide some EU/Canada representative safety data to ex US regulatory authorities (e.g. EMEA).
- Due to concerns regarding the unknown latency period of events of interest such as malignancies, the FDA extended the duration of the registry to 10 years.
- FDA also requested further justification on the 5000 patient sample size to detect signals in the lowest frequency events of interest. To address this as

well as to address the concerns regarding latency period to events, Abbott offered to observationally follow patients for up to the first 5 years of the registry even if the patient discontinues adalimumab during this first 5 year period.

As part of the EMEA approval negotiations, it was agreed that data on treatment interruptions (including "on demand" treatment approach) will be collected during this registry in lieu of conducting a new "on demand" post-marketing study. This was agreed before the FDA insisted on their own relapse/retreatment study as a post-marketing commitment. With the respect to the registry, the treatment interruption analyses will focus only on detecting any potential safety issues with this type of treatment approach.

The final protocol was submitted to both FDA and EMEA in March 2008. It is not yet known whether either agency will request further changes including whether FDA will insist that the observational approach for patients discontinuing drug will be extended to the full 10 years.

Due to the significant number of changes required, the initiation of the registry was postponed until September 2008. This delay impacts the ability to offer the opportunity to a number of patients in the BELIEVE study to roll over into the registry since a substantial number of these patients will complete the study before the registry is in place. In addition, the FDA relapse/retreatment post-marketing is to be satisfied through the use of patients currently enrolled in M03-658 (see discussion above on this study). Although patients in this study will still be offered to rollover into the registry, it is expected that the disruption of this study and the impact on timing will significantly increase the attrition of eligible and willing patients to rollover into the registry from M03-658. The agreed enrollment period with FDA was been extended from 3 to 4 years to accommodate all of the above changes.

The GPT will work closely with the UBC, the CRO for the registry, as well as the affiliates and CSMs to execute this registry. In addition, a Steering Committee will be

considered to also provide assistance in optimizing the execution of the registry as well as to provide guidance on the best way to release information on the registry over the coming years.

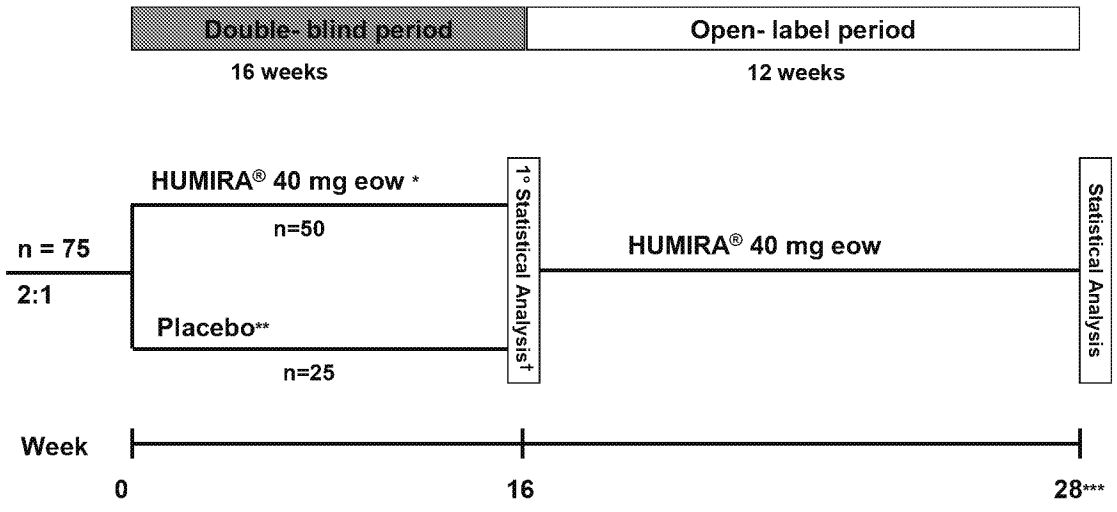
Overall the registry will provide valuable safety information on a substantial number of psoriasis patients and will offer a useful source of data that can provide continual reinforcement of the safety profile of adalimumab in this patient population.

M10-405 (psoriasis of hands/feet)

Upon receiving the approval of moderate to severe chronic plaque psoriasis in January 2008, the GPT focused on further differentiating adalimumab from not only other anti-TNF therapies, but also any new market entrants by examining other psoriasis subtypes that are particularly problematic to patients suffering from psoriasis, but have not been specifically studied. Both scalp and nail psoriasis, as mentioned previously will be examined in the European BELIEVE study where it is expected that a significant proportion of patients will have psoriatic involvement in these areas. One important subtype that warrants its own dedicated clinical study investigation is psoriasis of the hands and feet that includes predominately palmoplantar involvement. Psoriasis involving the hands and feet presents as chronically recurring lesions that are accompanied by cracking, swelling, blisters and are often painful and disabling. Although hands and feet represent only a small percentage of body surface area the impact on quality of life is significant given the chronicity, the visibility and the physical disability. Subjects may have difficulties in performing daily activities like walking, self-care, with usual activities at work or housework, with their studies and with family or leisure activities.

The GPT has agreed to the concept and design of the study and will initiate the study in the summer of 2008. Being a subtype of chronic plaque psoriasis, the study is not intended for an additional labeling claim and is being conducted within the approved labeling with the approved adalimumab dose for chronic plaque psoriasis. All patients, however, will be required to have a certain level of involvement in the hands/feet.

The study includes an initial 16-week double-blind placebo-controlled period, which will be followed by an open-label 12 week period. Randomization will be 2:1 (adaliumumab:placebo). The open-label period will allow patients on placebo to receive adalimumab treatment as well as to provide information on sustainable efficacy and safety out to a total of 28 weeks on the group of patients originally randomized to adalimumab.



* Week 0 loading dose of HUMIRA® 80 mg, followed by 40 mg eow from Week 1 until Week 27. At Week 16 will receive 2 doses of placebo to maintain the study blind).
** Placebo subjects receive a Week 16 loading dose of HUMIRA® 80 mg, followed by 40 mg eow from Week 17 through Week 27
*** All subjects will have a follow-up phone call 70 days after their last dose of study drug
† Primary endpoint: PGA of 0 or 1

The primary endpoint of this study is a 5 point physician's global assessment tool adapted specifically to evaluate psoriasis of the hands/feet. This endpoint was used in a recently completed study of efalizumab (Raptiva®) in this same subtype.

In addition the study will use an evaluation scoring tool specifically for palmoplantar involvement (ESIF) as a key secondary endpoint.
Other HEOR related outcomes (e.g. Work Productivity, Depression, DLQI) will be collected as well in this study.

The study is well placed to support the dermatology LRP strategy. To date, no other anti-TNF has studied psoriasis of the hands/feet in a well-controlled study as being initiated by Abbott. It will also provide data that is unlikely to be produced in the near future by the new market entrant, ustekinumab. It has the potential to show the significant impact psoriasis of the hands/feet can have on overall quality of life and work productivity which, thereby potentially expanding the patient populations that would be considered appropriate candidates for the use of adalimumab to treat their disease.

M04-717 and M08-672 (pediatric psoriasis)

As required by both US and EU regulations, a pediatric program to evaluate the safety and efficacy of adalimumab in the treatment of pediatric psoriasis patients will initiate in first half of 2009.

Currently, no biological therapies are approved for the treatment of pediatric psoriasis, however, the results of an etanercept study in this patient population was recently published showing the efficacy of etanercept in an initial 12-week placebo controlled, double-blind period. After 12 weeks, all patients in this study were given open label etanercept up until Week 36. After Week 36, patients were re-randomized to either continue etanercept or be given placebo until completion of the study at Week 48. The results show that patients remaining on etanercept maintained a better response than those randomized to placebo. Methodologically this study is very similar to the adalimumab adult phase 3 Study M03-656 (REVEAL). The etanercept application in pediatric psoriasis patients is currently under regulatory review.

Abbott initially approached both the EMEA Scientific Advice Working Party (SAWP) as well as the FDA in early 2007 to get input on an initial trial design proposal to study adalimumab in pediatric psoriasis patients. At the time, only the initial 12 weeks of the etanercept study were publicly released. However Abbott concluded that, with these data now available, any further placebo-controlled studies were not feasible. Therefore, Abbott proposed a study with a 16-week open label lead-in followed by a randomization

to either placebo or continued adalimumab therapy out to 52 weeks. A fixed dose was proposed similar to the approach being taken for JIA and Crohn's disease where the dose would be 40 mg eow for patients ≥ 30 kg and 20 mg for patients < 30 kg.

The FDA was unwilling to meet with Abbott until the adult psoriasis application was reviewed. The EMEA SAWP provided feedback on the design in January 2007 and had a number of issues with the proposal:

- SAWP did not believe the target population (candidates for systemic or phototherapy) was likely to be appropriate. Detailed documentation of prior therapies would also be critical. Suggested pursuing rarer forms of psoriasis with unmet need (e.g. erythrodermic psoriasis, or generalized pustular)
- SAWP did not agree to open-label lead-in, and recommended an active comparator such as MTX unless the population was to be restricted to last line.
- SAWP expressed concern on the lack of dose-finding for the pediatric population
- SAWP did not agree to the fixed dose approach and recommended a continuous body weight or BSA dosing approach.

During the SAWP advice process, Abbott proposed an alternative design that would include a randomized period for the first 16 weeks between the original dose (40 mg eow for patients ≥ 30 kg and 20 mg eow for patients < 30 kg) and a low dose (20 mg eow for patients ≥ 30 kg and 10 mg eow for patients < 30 kg). Patients achieving a clinical response would stay on their blinded treatment assignment out until Week 52.

SAWP welcomed the new randomized portion of the design, however, the fundamental issues outlined above remained.

It is also important to note that new EU Pediatric legislation was just coming into force at the time of the SAWP discussions and that a final pediatric plan was to be submitted through a new process with a dedicated pediatric committee.

Therefore, upon receiving the SAWP advice, the decision was made to suspend plans for the pediatric study until after the adult approvals were received where FDA advice could once again be pursued, while also the guidances around the new EU legislation were being finalized.

An FDA meeting has now been set for July 23, 2008 with the two-dose design adapted during the SAWP process being used as the foundation of the proposal. An extension trial (Study M08-672) will be offered to patients completing the study or to those that are non-responding. All patients will receive the high dose in the extension study.

After receiving feedback from the FDA, Abbott will submit the pediatric psoriasis trial for another round of discussions in the EU. However, in this instance the trial will be reviewed by the new PDCO (pediatric committee) in the EU and the study proposal will be included in the Pediatric Investigational Plan (PIP) that will also include discussions around Humira pediatric programs for JIA and Crohn's disease. If a global harmonized approach cannot be obtained between the FDA and EU PDCO, separate development programs for pediatric psoriasis will be needed.

Study M10-467 (Hidradenitis Suppurativa)

Hidradenitis Suppurativa (HS) is a disease marked by recurrent draining abscesses of the armpits, groins or other apocrine gland areas that can become so severe it can lead to sinus tract or fistula formation as well as scarring of the areas. Patients experience significant pain along with the malodorous discharge and it represents a dermatological disease associated with the most significant impact on quality of life. There are no approved therapies for the treatment of the disease and it is currently be treated with antimicrobials, topical clindamycin, systemic retinoids, systemic or intralesional steroids, methotrexate, hormonal therapy, or cyclosporine. However, none of these therapies are considered very effective.

HS, therefore, represents a disease with significant unmet medical need and there is small study and case study evidence that anti-TNF therapies such as adalimumab, infliximab and etanercept may be effective in this disease.

The GPT is planning to conduct the first ever well-controlled study in this disease to fully explore the effectiveness of adalimumab therapy. Conducting such a study not only re-emphasizes Abbott's intent to be a leader in dermatology, but will also provide the ability to further differentiate adalimumab from other current therapies as well as new market entrants. It may increase patient demand by creating an opportunity in patients outside psoriasis.

The current strategy is to conduct a double-blind placebo-controlled phase 2 study evaluating two doses of adalimumab over a 16 week period versus placebo. The doses will include the standard 40 mg eow dose (with loading dose) and 40 mg weekly dosing (with loading dose). After 16 weeks, patients will be given open-label adalimumab at the standard dose of 40 mg eow for up to one year.

Depending upon the outcome of this study, the results have the opportunity to be published in a top tier journal and, although not the primary strategy, may allow the incremental opportunity to pursue a phase 3 program for an indication in the treatment of HS. Because of the possible opportunity for the regulatory claim, a FDA meeting will be requested to obtain feedback on the design and approach to this disease.

An advisory board with key experts in the field is currently set for June 7 and will provide the input needed to finalize the design for the FDA meeting. The study is scheduled to start in December 2008.

New 2009 Study

Humira +/- Low Dose MTX vs. ABT-874

This study represents the one major study proposal being put forward for a 2009 start to support the overall dermatology franchise.

Although the phase 3 adalimumab program showed excellent efficacy in the treatment of moderate to severe psoriasis, some questions remain regarding the sustainable response, in particular, as it may or may not be impacted by the presence of anti-adalimumab antibodies (AAA).

During the first 6 months of therapy, adalimumab has a PASI 75 response rate in the range of 60 to 70%, which is unsurpassed by an biological therapy to date with the exception of infliximab. However infliximab's infusion method of administration is problematic with respect to gaining acceptance in a disease such as psoriasis. When attempting to determine the adalimumab response after 1 year of therapy, it would appear the response decreases to the 50 to 60% response rate, and thereafter appears to stabilize. However these data are extrapolated from various studies and no long-term controlled data exists to accurately characterize the long-term efficacy of adalimumab in this fashion. The role of AAA clearly has an impact on the efficacy of adalimumab in the short –term response rates. AAA is also suspected of having a potential impact on the sustainability of the efficacy of adalimumab in this disease.

When looking to the future, the anti-IL 12/23 mechanism will also become available in the marketplace with Centocor's ustekinumab as well as Abbott's ABT-874. Depending on the ustekinumab dose approved, the efficacy of this agent is comparable to that of Humira in the short-term and there is uncertainty whether it may have a sustainability advantage with the data publicly available to date. ABT-874 appears to have the best short-term efficacy and currently no long-term data are available.

One way that Abbott can continue to improve upon the competitiveness of adalimumab in this marketplace is to explore the abilities to decrease the impact of AAA and potentially improve both the short-term and long-term efficacy. This could possibly be addressed with the addition of concomitant MTX administration in this disease. It is already proven in RA that concomitant MTX significantly reduces AAA formation and that the combination of both agents has more efficacy than adalimumab monotherapy. Whether the incremental efficacy is due to the therapeutic incremental benefits of MTX or whether it is due to MTX ability to assist in the suppression of AAA is not entirely understood.

Therefore the GPT proposes to examine this more precisely in psoriasis by comparing adalimumab monotherapy to adalimumab plus MTX in the treatment of psoriasis. However, since the efficacy of adalimumab monotherapy in this disease is already profound, the goal is to improve the efficacy with minimal incremental risk on safety. Thus, only low dose MTX will be considered with the concomitant MTX to examine its impact on AAA in psoriasis. There is supportive evidence from the RA program to suggest that the ability of MTX to suppress AAA formation is not MTX-dose dependent, thereby supporting this potential investigation. In fact, some dermatologists already are prescribing patients on low dose MTX dosing concomitantly with adalimumab today, even with no evidence to understand its potential benefits.

By conducting a study comparing adalimumab monotherapy vs adalimumab with concomitant low dose MTX:

- A better understanding of the impact of AAA formation on adalimumab efficacy will be obtained.
- A determination on whether a small dose of MTX can inhibit AAA formation will be known.
- The potential to further enhance adalimumab efficacy with a safe and inexpensive dose of MTX may be achieved
- Depending upon the outcome, the knowledge gained may have future benefits in exploring optimal adalimumab use in other indications.

In addition to studying adalimumab +/- MTX, the GPT is proposing to also add a third comparator arm into the study. This third arm would include Abbott's own ABT-874. The strategy of adding ABT-874 to the study has many potential advantages that are specific to the study objectives, as well as to the advancement of Abbott as a clear leader in the area of biologics in dermatology.

- Supports the overall LRP strategy of offering a 'best in class' vs 'best in class' investigation with the potential for both assets to be enhanced as the first choice biologics in dermatology with the potential to establish ABT-874 as the most effective biologic for psoriasis
- Provides a more rapid establishment of the safety profile for ABT-874 by providing incremental long-term safety in a direct comparator study.
- Will make the trial a 'gold reference' trial in the field of psoriasis by directly comparing the two most effective mechanisms in the treatment of psoriasis.
- Provides Abbott a bridge from the time that ustekinumab launches to the time ABT-874 launches with the anticipation of the most important data to consider with respect to positioning of the two classes.

The study will be a 1:1:1 randomization to adalimumab/adalimumab + MTX/ABT-874 in 1200 subjects for either 52 or 76 weeks. Final discussions on the appropriate timing and length of the study are pending.

Humira and Hidradenitis Suppurativa

Executive Summary

Hidradenitis Suppurativa (HS) is a painful, chronic, skin disease characterized by recurrent inflamed nodules, abscesses, and fistulas with significant impact on quality of life. Although reported rates vary, best estimates indicate HS occurs in approximately 1% of the population based on US and Europe published literature, with nearly 20% of these patients with severe disease. Currently there are no approved or effective treatments for this disease. In the 2007 portfolio review, three psoriasis subtype and TNF-mediated dermatoses studies were approved as part of the core Humira dermatology development program. One of these studies was to evaluate the efficacy and safety of the adalimumab in the treatment of HS. This study (M10-467) was planned to start in December 2008, allowing time to engage thought leader and regulatory feedback on an appropriate disease assessment tool and design. Through the collaboration with dermatology thought leaders, the GPT has met all major milestones to initiate the study on schedule with a design acceptable to all stakeholders. Recently, Abbott Management has put funding on hold for this study with new concerns being raised on both the scientific and commercial rationale of the study. This document serves to communicate the Humira Dermatology GPT and Humira TEC basis for continuing to move forward with Study M10-467 in HS.

There is a growing body of scientific evidence supporting the use of anti-TNF therapy in the treatment of HS, from initial case reports to, more recently, prospective studies in the treatment of HS including an infliximab, double-blind, placebo-controlled study presented at EADV in September 2008. M10-467 is designed to answer key questions on the effectiveness, sustainability and optimal dosing of adalimumab in HS using a novel endpoint.

M10-467 supports the core 2008 LRP strategic objectives including expanding the opportunity for biologics within dermatology. It also supports the strategic shift for Abbott dermatology from an opportunistic strategy that complements rheumatology and GI, to that of a core Abbott franchise with two highly effective therapies (ABT-874 and

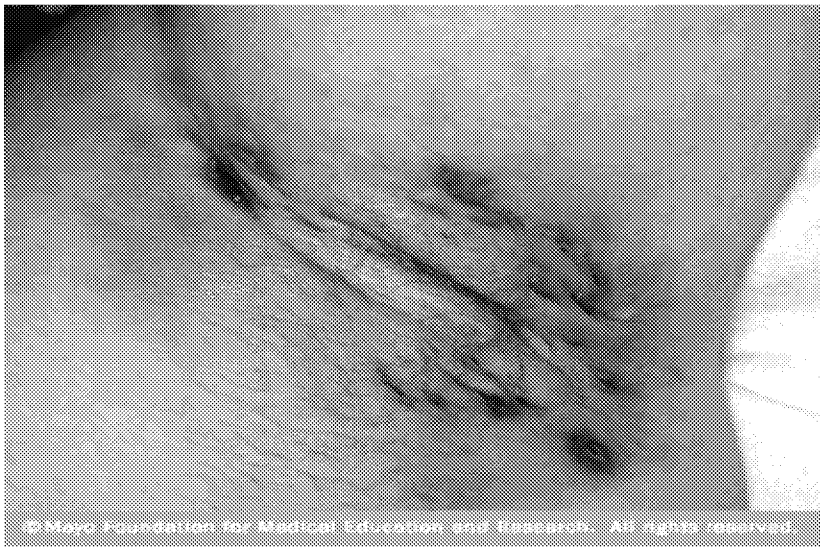
adalimumab) in two different mechanisms. To achieve the target of more than $2.0 billion sales over the LRP, Abbott must emerge as a leader in biologic dermatology research, with HS representing a key initiative in this area. This study under the current schedule and design will provide timely and important data for the use of Humira outside of plaque psoriasis but within the same specialty. With the introduction of ABT-874 in psoriasis by 2011, the timing of the HS study results for Humira is important for the successful execution of the co-positioning strategy of the two products in dermatology. Finally, encouraging results from M10-467 may lead to a development path for a HS label claim for Humira, creating further value to the overall Humira profile while also providing additional brand protection to biosimilar entries (~2014).

HS Disease Overview

HS Disease Characteristics

Hidradenitis Suppurativa (HS) is a painful, chronic, skin disease characterized by recurrent inflamed nodules, abscesses, and fistulas, which may heal with scarring. The most commonly involved anatomic locations are the inguino-crural and axillary folds, with sub-mammary folds (in women) and the perineal area less commonly involved[1]. HS has a severely negative effect on patients' quality of life[2]. Using the same quality of life scale as used in psoriasis patients (DLQI), a recent study[3] showed a greater than 50% higher DLQI score (ie. lower quality of life) compared to that studied in Abbott's phase 3 psoriasis program.

HS typically presents with painful, deep-seated nodules, which either resolve spontaneously, persist as non-tender nodules, or progress to form abscesses. Abscesses typically rupture and release purulent drainage. Nodules and abscesses may heal with scarring and the formation of fistulas or sinus tracts. Rare complications of HS include fistula formation into urethra, bladder, rectum, or peritoneum, lymphedema of the limbs or scrotal elephantiasis, or squamous cell carcinomas of the skin originating from HS lesions.



Epidemiology

The prevalence of HS is not well understood with variable reported rates. Rates have been reported in the literature anywhere from 0.07 to 2% in the US population. The best quality data occurs from a survey of a large representative population in France indicating a prevalence of 1%, with 20% of these patients having severe HS. As this is also within the US published estimates, it represents our current best estimate for the overall prevalence of this disease in western populations (refs to be added). HS affects women from 2 to 5 times more commonly than men. Several factors may predispose a person to HS, including genetics, cigarette smoking, and obesity[4]. It is widely suspected that the disease is under-reported due the potential embarrassment of the condition, as well as the lack of very effective therapies to treat HS patients that would bring patients to physician offices.

With respect to patients currently seeking treatment, an Abbott review of the Wolters Kluwer health claims database suggests that, at minimum, approximately 75,000 US patients per year are treated by a health care professional for HS. Two-thirds of these patients have moderate to severe HS representing the minimum of TNF inhibitor eligible patients currently seeking treatments. As suggested previously, the true scope of an eligible patient population would be expected to be significantly larger with the introduction of a proven effective therapy.

Current Treatments

Treatment of HS depends on the extent and activity of disease[4]. There is no approved treatment for this condition, but the standard of care for mild or limited forms of the disease consists of topical clindamycin, short courses of systemic antibiotics, or intralesional steroids. In more advanced cases, surgical therapy is required to remove scarring, fistulas, and sinus tracts, and long-term systemic antibiotic therapy is required to control inflammation. For patients whose inflammation fails to improve satisfactorily, immunosuppressive therapy, including corticosteroids, cyclosporine, and methotrexate (MTX) may be effective. More recently, anti-TNF therapy is being used to treat HS patients.

The potential for scarring is an important factor to consider in the future treatment strategies for HS, where proven effective therapies would likely be considered earlier in the disease condition.

Scientific Rationale for Adalimumab in the Treatment of HS

The histopathologic characteristics of HS include a dense inflammatory cell infiltrate of neutrophils, lymphocytes, and histiocytes.[5] Tumor necrosis factor-alpha (TNF-α), which induces pro-inflammatory cytokines and activates neutrophils and lymphocytes, may have a pathogenic role.

In fact, there has been growing clinical evidence of the utility of anti-TNF therapy. From the initial positive case reports in 2001 to the present, published literature or publicly presented studies report approximately 80 patients treated with infliximab, 20 patients treated with etanercept, and 10 treated with adalimumab. Most of these represent single case reports or small case series, and most report patients improving with these treatments.[2,6,7,8,9] Data from two prospective studies were recently released in 2008:

1. Giamarellos-Bourboulis, et al[6] reported positive data on the use of etanercept 50 mg once weekly in a prospective 10 patient open-label study. The author states that the study used reviewers unaware of the study conditions. Eight of 10 patients had a greater than 30% improvement of their disease activity and 6 of 10 had greater than 50% improvement of their disease activity. Disease activity was defined as the sum of (diameter x severity) of each lesion. Severity was determined on a scale of 0 to 4.

2. Grant, Gonzalez and Kerdel[2] reported the most robust positive data, to date, using infliximab 5 mg/kg at weeks 0, 2 and 6. This trial was a double-blind placebo-controlled study in 33 patients reported at EADV in September 2008. The primary endpoint of the study was a unique HSSI composite instrument.

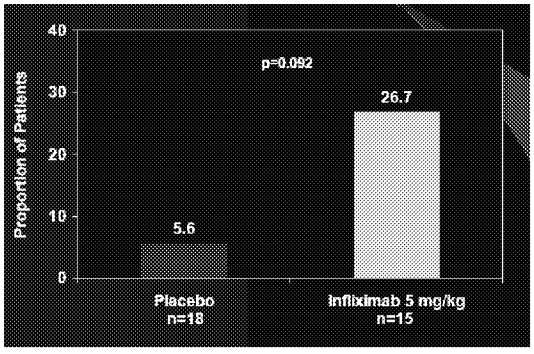
HSSI Scoring Table

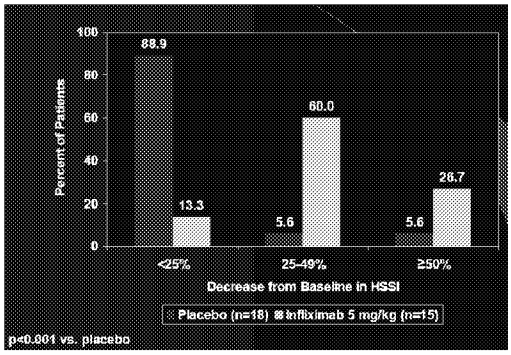
	Number of Sites	Body Surface Area (%) SAGE	# Lesions (erythematous, painful)	Drainage (# dressing changes/working hours)	Pain (VAS)
0	0	0	0	0	0-1
1	1	1	1-2		
2	2	2-3	2-3	1	2-4
3	3	4-5	3-4	>1	5-7
4	>4	>5	>5		8-10

HSSI Composite Scoring (0-19)
Mild = 0-7
Moderate = 8-12
Severe > 13

As can be seen, the HSSI is a complex scoring system that combines some static measurements (e.g. BSA and number of sites), with more dynamic measures of improvement. This study was the first to use this instrument.

The primary endpoint of the study was the proportion of patients responding at Week 8. Response was defined as a 50% reduction in HSSI score from baseline. In addition the proportion of patients with a 25 to 50% reduction from baseline were evaluated. The results as presented at EADV are given below.





Although the primary endpoint of the proportion of patients with greater than 50% reduction in HSSI from baseline did not reach statistical significance due to the small sample size (left figure), the data show that over 80% of patients achieved at least a 25% improvement in this measurement compared to only 11% of placebo patients (right figure). When evaluating the HSSI tool retrospectively, the principal investigator, Dr. Francisco Kerdel, believes an ~30% improvement in HSSI corresponds to a clinically relevant reduction in disease activity.

In addition to the HSSI, clinically and highly statistically significant differences were observed in favor of infliximab versus placebo for DLQI and VAS pain improvement.

Overall the data from this trial support the potential clinical benefit of anti-TNF therapy in HS patients. The data also confirm that placebo patients do not significantly spontaneously improve, at least within the 8 week period tested, thereby further corroborating the case report series previously cited in the literature.

Dr. Kerdel IIS Study of Adalimumab in HS

In addition to being the principle investigator of the infliximab trial, Dr. Francisco Kerdel from the University of Miami Hospital also recently completed a small IIS supported by the Humira HIS Committee. This open label study planned to enroll 10 patients using adalimumab dosing of 160 mg at Week 0, 80 mg at Week 2 and 40 mg every other week, thereafter. The study used the same HSSI tool as previously discussed. Some preliminary data have been received from the investigator on this study. Four of the 10 patients discontinued at 4 weeks or earlier (with one patient for reasons of non-compliance), making it difficult to assess efficacy beyond week 4.

For patients who did receive adalimumab for 12 weeks, the study showed modest activity, with 4 of 6 subjects improving slightly and 2 of 6 patients worsening slightly. Two of the patients that improved currently remain on Humira therapy. In discussing these data with Dr. Kerdel, it became evident that these patients were more severe than the previously discussed infliximab study with respect to baseline disease activity. In addition, the adalimumab study enrolled several patients who had prior infliximab experience, but who were either infliximab non-responders, had lost response, or were unable to tolerate infliximab therapy. Overall, Dr. Kerdel stated that patients appeared to improve but that the HSSI requires further refinement to optimally measure clinical benefit. He remains very optimistic about the potential for anti-TNF therapy in HS, but

suggest that higher doses may be required than used in other diseases. He expressed his enthusiasm to participate in the planned Abbott sponsored Humira study.

Conclusions

The overall clinical data to date, support the hypothesis that adalimumab will demonstrate clinical benefit in HS patients. However, HS is expected to be a tougher to treat disease than has been seen with psoriasis. We expect that the proportion of patients that benefit from adalimumab will be analogous to the experience in Crohn's disease rather than psoriasis. In fact, it is notable that HS and Crohn's disease have been known to co-exist (ref to be added). We also expect the dose to achieve the desired benefit will be comparable to Crohn's disease where a high induction dose may be most effective, and more patients may need to dose escalate to 40 mg every week to sustain their benefit than seen in psoriasis. All HS thought leaders that Abbott has approached are highly enthusiastic about the planned Abbott study.

Commercial Rationale for Testing Adalimumab in HS

With the progress of the ABT-874 clinical development program in psoriasis, dermatology represents the first therapy area where Abbott Immunology has to shift from individual brand management to product portfolio management. As such, it is important to recognize and identify opportunities that allow maximizing the success of each brand in the portfolio while aligning it with external market dynamics, life cycle management and time considerations.

Supports Dermatology LRP

Three strategic objectives were outlined in the 2008 Dermatology LRP.

1. Establish Humira and ABT-874 as the first and best choices for TNF and IL 12/23 mediated dermatoses.

2. Expand the opportunity for biologics within dermatology.

3. Generate patient demand for biologics.

Demonstrating the effectiveness of adalimumab in HS supports all of these objectives with particular focus on expanding the opportunity for biologics within dermatology. As stated in the LRP:

"Patients with TNF-antagonist responsive dermatoses, such as Hidradenitis suppurativa (HS) and Pyoderma gangrenosum (PG) and Psoriasis sub types (palmoplantar, nail and scalp) have few treatment options. Dermatologists continue to seek more robust clinical data to expand treatment options in these severe dermatoses. Through KOL partnerships, Abbott must design studies and validate instruments that will provide new options for patients suffering from these dermatoses with high unmet need. It is important to acknowledge that this strategy can also prove critical in HUMIRA's defense against biosimilar etanercept. By demonstrating efficacy outside of plaque psoriasis HUMIRA will build an even stronger efficacy platform and broader utilization. This will also minimize the importance of new compounds in dermatology space (whether biosimilar or new competitive options) that can demonstrate efficacy in plaque psoriasis only and will allow physicians to stay with HUMIRA.

The subtype and TNF related dermatoses studies were funded during the 2007 portfolio review as part of the core Humira psoriasis program.

Enhances Abbott's Leadership Position in Dermatology Biological Research

In the initial post-acquisition period of Humira, plaque psoriasis was considered an opportunistic market for Humira complementing the areas of RA and Crohn's disease. However, the exceptional efficacy seen with Humira in psoriasis followed by the even more impressive phase 2 efficacy with ABT-874 has elevated dermatology to be a cornerstone franchise within Abbott with sales expected to exceed $2 billion over the LRP. In order to achieve these goals with Humira and ABT-874, Abbott must strategically shift from the original opportunistic strategy to a strategy of market leadership in biologic dermatology research.

The planned HS study is an important step in establishing Abbott's leadership with dermatologists. It will be the first adequate and well-controlled study ever conducted in this disease with the opportunity to establish a new endpoint in the measurement of disease improvement. It will address the outstanding questions for dermatologists as to the magnitude of efficacy, sustainability of response and most optimal dosing strategy for adalimumab in the treatment of HS. A small substudy is also planned at European sites to evaluate tissue samples to better understand other key inflammatory mediators that may be involved in HS. This would include IL 12 and 23 to investigate whether ABT-874 may play a future therapeutic role in HS.

Lastly, with a successful outcome, this study may ultimately lead to a development path for a new labeled indication in the treatment of moderate to severe HS. Based on our current understanding of the prevalence of HS and the number of severe patients that are potentially suitable for systemic treatment with biologic therapy we would also expect an HS indication to contribute to overall sales in dermatology (potentially up to additional 30% of current psoriasis sales). Broadening the Humira profile with further indications such as HS also has the benefit of providing a level of protection for the Humira brand from future biosimilar competition expected as early as 2014 with the anticipated introduction of etanercept biosimilars.

With the introduction of ABT-874 into the marketplace by 2011, the timing of study M10-467 as well as any future HS development is important in optimally executing the co-positioning of ABT-874 and Humira. At minimum, Study M10-467 will serve to solidify Abbott's commitment to advancing important research in the most severe dermatologic diseases.

Study Design Strategy and Current Status

The GPT has approached the M10-467 study with the aim to answer the primary objective of defining the magnitude of efficacy, sustainability of response and optimal dosing strategy of adalimumab in HS. In addition, the study is designed to achieve the secondary objective of establishing an acceptable endpoint and regulatory pathway for a potential future indication.

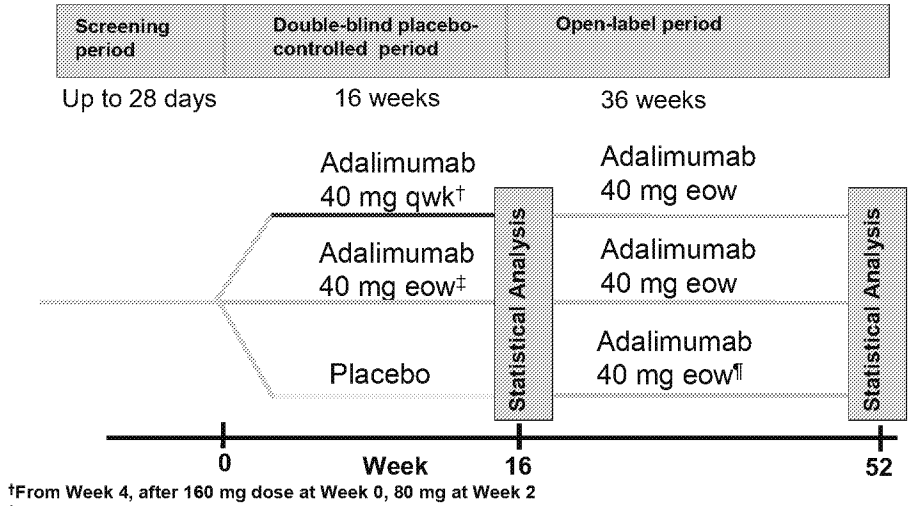
An advisory board with key opinion leaders in the field of HS in both US and Europe was assembled on June 3, 2008. Consensus was reach on the trial design along with the proposed primary endpoint definition.

Study Design

Approximately 150 subjects will be randomly assigned to one of the three treatment arms with the study divided into two treatment periods.

Period 1: A 16-week, double-blind, placebo-controlled treatment period where subjects are randomized in a 1:1:1 ratio to receive adalimumab (40 mg qwk or 40 mg eow) or matching placebo for an evaluation of efficacy and safety. Both adalimumab arms will include a loading doses of 80 mg Week 0/40 mg Week 1 and 160 mg Week 0/80 mg Week 2 as is used in psoriasis, and Crohn's disease, respectively.

Period 2: a 36-week, open-label treatment period where all subjects will receive open label adalimumab 40 mg eow for an evaluation of long-term safety and efficacy. This period will define whether response can be maintained on standard adalimumab dosing.



Study Endpoint

Abbott has proposed a new Physicians Global Assessment endpoint to the FDA. Unlike the more complex indices that have been used in prior smaller studies (i.e. HSSI, Sartorius scale), this endpoint is a simple categorical scale that focuses on improvement in the key clinical components of the disease (i.e. inflammatory nodules, abscesses and fistulas),

Score	PGA Rating	Description
0	Clear	No abscesses, no draining fistulas, no nodules
1	Minimal	No abscesses, no draining fistulas, no inflammatory nodules, presence of non-inflammatory nodules
2	Mild	• no abscesses or draining fistulas, and less than 5 inflammatory nodules, or • single abscess or draining fistula, and no inflammatory nodules
3	Moderate	• no abscesses or draining fistulas, and at least 5 inflammatory nodules, or • single abscess or draining fistula in the presence of inflammatory nodules, or • between 2 and 5 abscesses or draining fistulas with or without inflammatory nodules, up to 10
4	Severe	Between 2 and 5 abscesses and draining fistulas and at least 10 inflammatory nodules
5	Very Severe	More than 5 abscesses or draining fistulas

The primary endpoint will analyze the proportion of patients who achieve clinical response in each treatment arm through Period I. Clinical response is defined as achieving a PGA of clear, minimal, or mild, with a minimum of 2 grades improvement (reduction) from Baseline.

Current Study Status and Budget

The initial planned study costs for M10-467 was approximately $2.9 MM with study start in December 2008, Period 1 database lock in October 2009, and Period 2 database lock in July 2010. These costs have recently been reduced to approximately $2.3 MM with the agreement that all monitoring and study management would be done internally (i.e. use of USCFO and ICFO).

The GPT had originally planned a pre-IND meeting with the FDA in August 2008 to be followed with the IND filing in October 2008 in order to support the first subject to be enrolled in December. However, FDA declined the meeting request and suggested Abbott submit any questions within the new IND submission rather than have a separate meeting. Consequently, the GPT accelerated the IND filing by 2 months, with the submission occurring on August 15 with the aim to move the scheduled first subject forward to October. However, incremental money in 2008 ($200K) was not available to support the accelerated study start and the GPT reverted to the original December start date.

During the IND review, FDA requested some additional safety monitoring specific to the potential for secondary skin infections in the affected HS areas, for which Abbott has agreed and added to the protocol. The FDA has agreed that Abbott may move forward with the study as designed. Additional comments from FDA may be forthcoming at a later date on more strategic questions around HS development.

A total of 25 sites (20 in the US and 5 in Europe) are planned for the study. Fifteen of the 20 US and 5 EU sites have already been identified. Additional interest from sites in Europe could not be accommodated with the current scope and size of the study.

With the new unexpected funding freeze on the study, the GPT has immediately stopped activity in our best attempt to mitigate damage to key opinion leader and other participating investigator relationships, until further confirmation on Abbott's commitment to the study is received.

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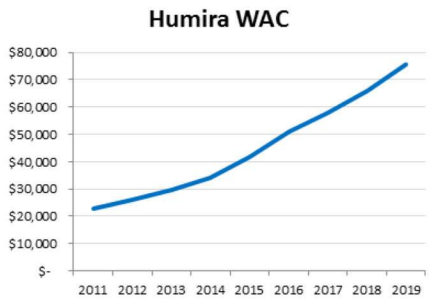
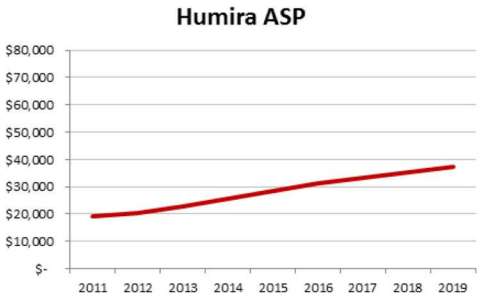
HUMIRA Pricing
Annual Price per Patient

- Average WAC price is anticipated to increase given anticipated price actions
- Price Protection (Non-Resetting and Resetting) provides value to payers insulating risk up to the level of price protection
  - Variations include 6%-10% Non-Resetting Price Protection, 9-10% Resetting Price Protection and No Price Protection
- Despite Price Protection, Payers anticipate net cost per syringe to rise, consistent with LRP assumptions





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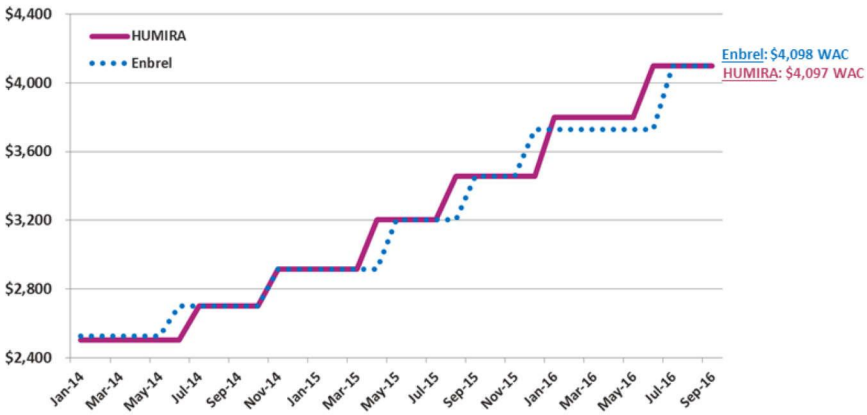
HUMIRA Pricing
WAC Price per NDC – HUMIRA and Enbrel



Brand	NDC	Quantity	Length of Therapy per NDC
HUMIRA	00074-4339-02	2x40mg Pen	28 Days of RA Therapy (EOW Dosing)
Enbrel	58406-0445-04	4x50mg Pen	28 Days of RA Therapy

Source: analysource.com referenced 9-02-2016

DRAFT
AbbVie Confidential

This document is aspirational in nature and for Management discussion only. All strategies and tactics are subject to review by Medical, Regulatory, Legal & OEC prior to execution.

abbvie 3

From: [redacted]@abbott.com
Sent: Saturday, January 28, 2012 2:52 PM
To: Richard A Gonzalez
Subject: FW: CI ALERT: Enbrel price increase

Importance: High

Rick, FYI

Great Week-end

[redacted]

Sent with Good (www.good.com)

----- Forwarded by [redacted] on 01/28/2012 02:51:34 PM-----

-------- Original Message --------

From : [redacted]
To : [redacted]@abbott.com>
Cc :
Sent on : 01/21/2012 08:47:27 AM
Subject : Fw: CI ALERT: Enbrel price increase

Please see below.

[redacted]

----- Original Message -----

From: [redacted]

Sent: 01/21/2012 08:38 AM CST

To: [redacted]

Cc: [redacted]

Subject: CI ALERT: Enbrel price increase

Enbrel's price was increased 6.9% on 1.20.12:

- New WAC for 50mg SureClick Pen and 50mg syringe: $483.66 (previous price of 7.1.11: $452.44, following 5.9% increase).
- Based on WAC pricing, the annual price for Enbrel has increased to $25,150 (for 52 weekly doses) from $23,527.
- For RA patients, HUMIRA annual cost, based on the assumption of 40mg every other week, is $24,913, following a 6.9% price increase on 1.3.12.

[redacted]

[redacted]

Abbott
200 Abbott Park Road
AP 30-3, Dept. 032N
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BOARD OF DIRECTORS DISCUSSION DOCUMENT

Rick Gonzalez
Chairman of the Board and Chief Executive Officer

February 18, 2015

Although Some New Public Events Have Emerged Around Biosimilars, Nothing Has Fundamentally Changed from Our Prior Assumptions

- Remicade biosimilar in Europe still has very low share, minimal impact
- Neither Remicade nor Enbrel biosimilars should have a significant impact on HUMIRA in Europe
- Amgen HUMIRA biosimilar Phase 3 results and timing are consistent with our biosimilar assumptions
- Our defense strategy remains the same:
  - Aggressively defend our IP position
  - Gain approval (EU/U.S.) of HUMIRA High Concentration Formulation
  - Advance Immunology pipeline assets to drive future growth (JAK1, DVD, biologics)
  - Exercise HUMIRA strong profile, safety data base, market share position, and commercial strength to maintain share (respond on price as necessary, but not to biosimilar level)

AbbVie 11

U.S. Viekira

Redacted – NR Product

Redacted – NR Product

Redacted – NR Product

Investor Meetings and Interactions with Key Sell-Side Analysts Have Helped Identify the Drivers of the Erosion of Investor Sentiments

Current Situation

- Redacted – NR Product
- Without a product in the $3-4 billion range, biosimilar threat/ HUMIRA concentration has re-emerged and we are a year closer to the potential LOE event
- Recent biosimilar news flow combined Redacted – NR Product has increased concerns about 2016-2019
- Redacted – NR Product

Future Objective

- Deliver strong 1Q performance – Redacted – NR Product HUMIRA international growth, Redacted – NR Product Redacted – NR Product
- Refocus efforts to characterize the late stage pipeline value against biosimilar risk to HUMIRA
- More aggressively tell our biosimilar strategy (IP strategy)
- Move more aggressively on the L&A front to build stronger future growth platform and reduce dependence on HUMIRA Redacted

Investor Relations Action Plan Has Been Developed to Re-Frame the Debate

1

Redacted – NR Product

2

HUMIRA Biosimilar Framing

- Provide clearer picture around IP defense strategy
- Consider disclosure of HUMIRA High Concentration filing
- Potentially provide more specifics around our planning assumptions for biosimilar impact

3

Redacted – NR Product

4

AbbVie 11

November 5, 2018

Office of the Vermont Attorney General
109 State Street
Montpelier, VT 05609
[redacted]@vermont.gov

Dear Attorney General Donovan:

Based upon notification posted on the Office of the Vermont Attorney General's website, AbbVie has been instructed to provide a report regarding the "justification for the increase in the net cost" of HUMIRA to the Department of Vermont Health Access ("DVHA"), pursuant to 18 V.S.A. § 4635(c)(1)(B). We understand that the request is based on DVHA's calculation of the net cost of HUMIRA to DVHA between 2016 and 2017.

We respectfully request the opportunity to continue to work with your office and DVHA, as we were not able to successfully replicate the specific calculations that DVHA used to determine HUMIRA's net cost for this requirement.

Accordingly, while we are providing a report as instructed, such action should not be seen as AbbVie's agreement with -- (i) DVHA's calculation of the HUMIRA net cost increase to DVHA, (ii) HUMIRA's inclusion on the list of drugs identified under 18 V.S.A. § 4635(c)(1)(A) (the "Net Cost List"), or (iii) the determination that AbbVie is required by law to provide this report -- and we reserve the right to dispute each of the foregoing.

We appreciate that the Prescription Drug Cost Transparency Law is something that has been discussed widely by the State Legislature and therefore are providing this report in good faith as we seek to clarify our open questions. Below is the information required pursuant to 18 V.S.A. § 4635(c)(1)(B)(i)(I)-(III). Factors outside AbbVie's control, such as pharmacy reimbursement methodologies set by the State, the data and methodology used by DVHA to calculate its net cost, and potentially increases in utilization of HUMIRA, are likely relevant factors that help explain DVHA's calculation of HUMIRA's net cost increase.

AbbVie's pricing decisions are determined after consideration of a number of interdependent factors, including, but not limited to, the therapeutic alternatives in a given class and the particular value of the therapy at issue to the patient and health care system. With respect to HUMIRA, it is a therapy that has significantly advanced the treatment paradigm for no less than ten different diseases, including chronic conditions such as rheumatoid arthritis (RA), Crohn's disease, and plaque psoriasis. To illustrate this impact, it is well recognized by key rheumatology experts that "[t]reatment for RA has changed profoundly over the past 25 years, evolving from a strategy of providing symptomatic relief, to implementation of therapeutic regimens that impact disease activity and ultimately have been shown to slow or arrest structural joint damage. . . . Currently therapy for RA is such that progression from symptom onset to

significant disability is now no longer inevitable, and RA patients can anticipate comfortable and productive lives on medical therapy."[1]

Factor	*% of Increase*	*Explanation*
Therapeutic Category	We do not assign percentages to individual factors but consider a multitude of factors, including as described herein.	HUMIRA competes in an extremely competitive therapeutic category which is not a single medicine market. There are at least 20 different approved treatment options in one or more of the conditions that HUMIRA is approved to treat. HUMIRA represents less than one-third of the total prescriptions written in the conditions for which HUMIRA is approved to treat (30.1% for 2017). With new medicines and new classes of therapies continuing to enter the market, aggressive negotiations occur between pharmaceutical companies and payers.
Rebates and Discounts	See above	The 2018 changes to the Prescription Drug Cost Transparency Law include references to net cost in addition to the wholesale acquisition cost (WAC) price of a medicine. We see the change as recognition that the 2016 law was not wholly reflective of the marketplace for prescription drugs. Manufacturers negotiate rebates and discounts with payers on the basis of clinical evidence, physician and patient experience, and cost. In the case of HUMIRA, there are at least 20 medicines in the anti-inflammatory category and negotiations with commercial payers, for example, have yielded discounts and rebates for HUMIRA that have increased by more than 80% in aggregate between 2013 and 2017. The average rebate across all channels for HUMIRA is approaching 45% and, for Medicaid, the rebate is greater than 80%, resulting in a significantly reduced net cost to the state for the program. Moreover, the majority of HUMIRA's business has price protections in place that limit how much the price of a medicine may increase in a single year. Health plans run by the U.S. government have government-mandated pricing, such as Medicaid, or fixed pricing, such as the U.S. Department of Veterans Affairs (VA), U.S. Department of Defense, etc. Such fixed pricing U.S. government health plans receive an average discount of approximately 85%, and VA patients pay less than $10 per month out of pocket.
Patient Access	See above	Patients have broad access to HUMIRA, regardless of financial condition. In addition to the rebates and

[1] Upchurch, Katherine S. and Jonathan Kay. 2012. Rheumatology 51 (suppl 6): vi28-vi36. doi: 10.1093/rheumatology/kes278

		discounts noted above, AbbVie provides significant financial support to help ensure patients have access to our medicines. In 2017, approximately 92% of patients in the private managed health care channel were enrolled in the HUMIRA co-pay program. Co-pay assistance varies based upon insurance benefit design and can reduce patient out of pocket costs to as low as $5 per month. In 2017, the annual patient benefit could be as high as $12,000 per year. The AbbVie Patient Assistance Foundation provides HUMIRA and other AbbVie medications at no cost to eligible patients in need but facing financial difficulty. In 2017, nearly 77,000 U.S. patients received AbbVie medicine at no cost, including nearly 47,000 HUMIRA patients.
Research and Development Costs	See above	AbbVie makes significant investments in research, discovery, and development that can lead to critical medical innovations for patients. Significant investments are necessary given the high failure rate in drug development programs throughout the industry. Since becoming an independent company in 2013, AbbVie has invested over $21.2 billion[2] collectively in research and development and has invested over $1 billion in HUMIRA alone. HUMIRA has been studied in over 100 clinical trials, and FDA has approved HUMIRA to treat patients in 10 important indications, including, in the last five years, the orphan drug indications of Pediatric Crohn's Disease, Juvenile Idiopathic Arthritis (age 2-4), Uveitis, and Hidradenitis Suppurativa (HS). HUMIRA is the first and only FDA-approved treatment for HS and the first and only FDA-approved biologic treatment for Uveitis.

Sincerely,

Matthew Williams
Vice President, State Government Affairs
AbbVie

[2] Non-GAAP; excluding specified items

Message

From: [redacted]@suntrust.com]
Sent: 10/29/2017 6:58:45 PM
To: [redacted]@abbvie.com]
Subject: ABBV @ STRH - Raising Est's on Commercial Execution & Pipeline De-Risk; PT to $105 (from $95)
Attachments: ATT00001

CHANGING TARGET
October 29, 2017

AbbVie Inc. (ABBV)

SunTrust Robinson Humphrey

CLICK HERE TO VIEW COMPLETE PDF

Raising Est's on Commercial Execution & Pipeline De-Risk; PT to $105 (from $95)

Best-in-group 15% growth, margin expansion to 50%, & OCF $80B+ over next 5 yrs.

Rating: Buy
Market Cap (M): $147,676; Price: $91.93 as of 10/29/2017
Price Target new: $105.00; Price Target prior: $95.00

Sector: US Major Pharmaceuticals

What's Incremental To Our View

We raised our '17 sales +$80M to $28.11B (+10%) vs. ABBV's/Street's $28.12B (+10%)/$27.98B on Humira/Imbruvica/Mavyret growth & maintained in-line EPS at $5.54 as ABBV invests in new Imbruvica/Venclexta uses, Mavyret global HCV rollout & pre-launch plans for pipeline [Elagolix, Rova-T, UPAD & RISA]. Our '16A-21E sales/EPS CAGRs (+9.8%/+15% are above Street's +8%/+14%, with operating margins expanding from 42.4% in '16A to 50.5% by '20E (vs. ABBV's 50% est). Reiterate Buy/raising PT to $105 (from $95) on 13.4x our '19E (rolled over from '18) EPS of $7.86 vs. Street's $7.60, supported by DCF.

Raised '17 sales but maintained EPS; PT to $105 from $95 on pipeline

We raised our '17E revenue by +$80M on higher Humira sales to $28.11B (+10.0%) vs. the Street's $27.98B & ABBV's 10% growth ($28.12B) projection. Our EPS is unchanged at $5.54 vs. the Street's $5.54 & ABBV's $5.53-$5.55 range. We maintained our gross margin at 80.7% vs. ABBV's 80.5% & the Street's 80.5%. Our R&D as a % of sales remains 17.3% vs. ABBV's 17.5% estimate & the Street's 17.4%. Our SG&A as % of sales is also unchanged at 20.6%, slightly above ABBV's 20.5% projection vs. the Street's 20.7%. Our tax rate is 19.2%, vs. ABBV's ~19% and Street's 18.2%. We recommend accumulating ABBV's shares as Humira's patent risk has lessened and its pipeline of innovative assets unfolds. ABBV's long-range plan revised its global Humira sales target upwards $21B (from >$18B) by 2020 vs. our/Street's $21.0B/$18.9B, and risk-adjusted pipeline sales of ~$35B by 2025 displays confidence in its growth platform. ABBV's CEO is delivering on his long-term strategic plan, with best-in-class growth. Over the last five years (2013-17E), ABBV is on track to throw off ~$35B of operational cash flow & is committed to its dividend after an 11% increase. We project operational cash flow of $80B+ from '18E-22E. ABBV's leadership position in Immunology (Humira & upadacitinib/risankizumab pipeline assets), Hematology leadership through Imbruvica/Venclexta (new uses), Rova-T solid tumor platform, growing HCV presence with Mavyret, the only 8-week value priced pan-genotypic regimen, & emerging Women's Health franchise with Elagolix granted FDA Priority Review position the

company for sustainable long-term growth. Relative to its peers. ABBV's execution on shareholder value creation is best in class, in our view, while still trading at a discount to peers. Reiterate Buy (click here for 4Q17 high conviction ideas note) & raised our PT to $105 (prior $95) on 13.4x our '19E EPS of $7.86 (rolled over from '18) which is a discount to the group multiple average multiple of ~14x. Key risks include clinical, regulatory, & commercial execution around Imbruvica/ Venclexta new uses & Rova-T data from TRINITY in 1H18, as well as Humira intellectual property (IP) risk.

Pipeline of $35B in risk-adj. sales by '25E to drive multiple expansion

ABBV's pipeline of differentiated assets supports our long-term growth estimates. ABBV's revised strategic plan set 2025E risk adjusted pipeline sales at $35B, which is in-line with our risk-adjusted pipeline projections supported by Immunology, Hematological Oncology (solid tumors), HCV & other (Women's Health/Neuroscience) franchises. Oncology sales represent 36% of our total sales in 2025, overtaking Humira at 29%. Growth in ABBV's Immunology franchise is supported by its next-generation assets, upadacitinib (oral JAK inhibitor) & risankizumab (IL-23 inhibitor). We model both products launching in 2020, with initial indications (rheumatoid arthritis & Psoriasis, respectively) expanding through its broad clinical development program into new uses. We model '21E sales of $1.6B combined for both assets vs. Street's $1.2B. ABBV is eyeing ~$6.5B/~$5.0B in non-risk-adjusted sales for Upadacitinib/Risankizumab by 2025. In Hematology, Imbruvica& Venclexta cement ABBV's leadership position where the market is expected to grow from ~$33B in '17 to ~$50B (+12% CAGR) by '20E. Imbruvica's "pipeline within a molecule" and Venclexta's label expansion into broader Chronic Lymphocytic Leukemia (CLL) & other indications is expected to drive further growth. ABBV's solid tumor platform (Rova-T and library of Stemcentrx assets) targets the high unmet needs in Small Cell Lung Cancer (SCLC) where Rova-T & Bristol-Myers' (BMY, $59.94, Hold) Opdivo + Yervoy combo have a first-mover advantage. We model Rova-T sales of $951M in '21E, above the Street's $840M. In HCV, Mavyret (Maviret in international markets) is priced at a significant discount to other HCV therapies and has a shorter duration of therapy and pan-genotypic efficacy that treats all HCV genotypes in as few as eight weeks. Mavyret's efficacy/dosing advantages & significant price discount have contributed to US/German share of 15%/50%. We estimate ABBV's total HCV sales at $1.6B in 2020E vs. ABBV's $3.0B projection and Street's $1.6B. In Women's Health, Elagolix is a paradigm shift in the treatment of endometriosis/uterine fibroids by reducing the level of pain & opioid use. Our patient-driven model projects Elagolix sales of $1.1B vs. the Street's $0.8B in 2021E.

Humira new less pain/burn formula has converted 75% of ex-US sales

Humira is experiencing robust growth in US/ex-US markets, with its reported sales beating our/Street estimates four quarters in a row. Despite numerous competitors in the Immunology market, Humira remains the market leader across multiple therapeutic uses. ABBV's global resolution (click here for our note) of all IP-related litigation with Amgen (AMGN, $175.28, not rated) over biosimilar adalimumab (Amjevita) launch in the US on Jan. 31, 2023 & in the EU on Oct. 16, 2018 provides Humira a clear pathway for further growth. ABBV raised its expectation for '20E Humira sales to ~$21B (prior >$18B based on October 2015 update) vs. our $21B estimate. Moreover, we assume biosimilar adalimumab erosion is slower than expected by the Street. The underperformance of biosimilars in multiple markets (Remicade/Enbrel) so far is driven by multiple factors such as physicians' low interest in using biosimilars, limited discounts to innovator drugs, a high interchangeability hurdle, etc. Further, as we have shared previously (click here for our note), ABBV has converted ~75% of ex-US Humira to its newer lower volume injection, less painful/less burning formulation. The new formulation 1) comes in a 27-gauge needle, 2) is citrate-free, reducing the "burning" sensation associated with administration; & 3) requires 50% less volume, making it less painful. We expect ABBV to replicate its ex-US strategy by switch a meaningful portion of its US Humira users to its new formulation prior to biosimilar entry in early 2023E. The switch to a less painful/low concentration Humira formulation should blunt the impact of biosimilar competition. ABBV expects to begin roll-out of the new Humira formulation in the US in 2018 as it negotiates a *"less painful/less burning"* label claim from the FDA. Based on our expectations for a slower erosion of the Humira franchise from biosimilars in ex-US markets, we raised our Humira 2020E sales from ~$20B to $21.0B (vs. Street's $18.9B, which is up +$2.0B since mid-September).

Immunology leadership in $50B global mkt extended by UPAD & RISA

As Humira matures, ABBV's next-generation assets – upadacitinib (oral JAK inhibitor) & risankizumab (IL23 inhibitor) are positioned to extend its leadership in the global Immunology market. Our global Immunology Market Model assumes the market grows from ~$49B in 2016A to ~$57B in '21E. On Upadacitinib, ABBV updated the rate of deep venous thrombosis (DVT) and pulmonary embolism (PE) in its clinical development as being within the background rate of Rheumatoid Arthritis patients (0.29–0.79 instances per 100 patient years). This helped address (but does not completely remove) the concerns raised by the citation of DVT/PE episodes in the full results of the SELECT-BEYOND trial shared in a late-breaking ACR abstract (#10L, click here for our ACR Preview note). DVT/PE events have been experienced in other oral JAK-inhibitors as well. Pfizer (PFE, $35.60, Hold) is presenting Xeljanz/XR safety data at ACR 2017 (abstract #16L), with the abstract pointing to a few DVT/PE observances. Eli Lilly (LLY, $83.86, Buy) also shared on its 3Q17 call that the rate of DVT/PE in Olumiant's clinical development & real world evidence (RWE) setting still remains within the background rate of RA patients. At the upcoming 2017 annual meeting of the American College of Rheumatology (ACR), ABBV is presenting the full results from its upadacitinib Phase 3 SELECT-NEXT & SELECT-BEYOND trials in RA that were both top-lined in 2H17. Apart from these two Ph-3 trials, ABBV is studying upadacitinib in four other Ph-3 trials (SELECT-COMPARE, SELECT-MONOTHERAPY, SELECT-EARLY, SELECT-CHOICE) and is aiming to submit NDA filing for the drug based on results from at least five of the six trials in 2H18. ABBV is also pursuing UPAD clinical development in psoriatic arthritis (Ph-3), Crohn's Disease (Ph-3 ready), ulcerative colitis (Ph-2) & atopic dermatitis (Ph-3 ready). We model UPAD '21E sales at $967M vs. the Street's $700M. ABBV recently shared impressive Phase 3 Psoriasis results (click here for our note) for Risankizumab (IL-23), which showed superiority over Humira and Johnson & Johnson's (JNJ, $141.78, not rated) & Stelara (IL-12/23) & comparable results to JNJ's newly launched Tremfya (IL-23). Biologic drugs have the lowest penetration rate in the dermatology office (10%/3% US/Intl.) compared to rheumatology (39%/18%) or gastroenterology (29%/18%), which supports our thesis that there is significant room for risankizumab growth in an underpenetrated psoriasis market. ABBV is targeting psoriasis as the first indication for risankizumab, with label expansion opportunities in PsA, CD & UC. We model risankizumab '21E sales at $636M vs. the Street's $520M.

Mavyret launch is impressive; raising '21E sales to $1.0B (from $0.5B)

ABBV launched Mavyret, an 8-week pan-genotypic HCV regimen for treatment-naïve, non-cirrhotic patients in the US in early August at a WAC price of $13K/month, a 58%/27% discount to Gilead's (GILD, $77.07, not rated) Harvoni / Merck's (MRK, $58.24, Buy) Zepatier. The TRx/NRx data for the HCV market (Exhibit 5-6) show that Mavyret has quickly grabbed share in the market. ABBV has achieved an overall US HCV market share of 15% only ten weeks into the Mavyret launch. GILD noted on its 3Q17 conference call that *"the arrival of new competition has further eroded Gilead's market share & net pricing, which is now similar across genotypes."* In Germany, 10 weeks into the launch, Mavyret has captured 40% share. ABBV recorded $100M in global sales for Mavyret in 3Q17 by focusing on the public channel. We estimate the split of HCV patients in the public vs. commercial channel is ~70%/30%. While the US commercial channel is often under and exclusive contract with the market leading drug, we believe the public channel (Medicare, Medicaid, Veteran's Affairs, etc.) provides ABBV an attractive market to jumpstart Mavyret. ABBV expects Mavyret to address the residual unmet medical need in the HCV market and believes that the drug can deliver cure rates approaching 100% across all genotypes through a convenient 8-week duration of therapy vs. 12-week for most other HCV drugs such Harvoni, Sovaldi and Epclusa. ABBV also commented that currently it is *"tracking below the $3B"* in '20E sales for the HCV franchise (Viekira Pak & Mavyret); however, it considers Mavyret a *"multi-billion-dollar"* peak year sales opportunity but plans to update its long-term projection by 2Q18. Mavyret's value-based price discount, combined with pan-genotypic efficacy & shorter 8-week duration helped to enable its significant uptake. Based on the significant advantages & strong growth trajectory of Mavyret/Maviret, we raised our '21E sales to $1.0B (from $552M) vs. Street's $561M. We estimate ABBV's total HCV sales at $1.6B in 2020 vs. ABBV's $3.0B projection and Street's $1.6B.

Imbruvica/ Venclexta are foundational assets in $50B HemOnc market

Imbruvica & Venclexta cement ABBV's leadership position in the Hematology market, which is expected to grow from ~$33B in 2017 to ~$50B (+12% CAGR) by 2020E. Imbruvica remains a market leader in Chronic lymphocytic leukemia (CLL) market, with a 35% share in first-line & 70% share in second-line+ patient population. We remain bullish on Imbruvica, modelling '21E global

sales of $5.8B vs. the Street's $5.3B in our global patient driven market models. ABBV projects 2020E Imbruvica sales of $5B, which is in-line with our estimate and $300M above the Street's $4.7B. Imbruvica's strong durable response & superior survival benefit over standard of care (SOC) is further supported by its *"pipeline within a molecule"* strategy. Imbruvica label build-out includes interim Ph-3 results in 1L Mantle Cell Lymphoma (SHINE) in 4Q17 & 2L Follicular Lymphoma (SELENE) in 2018. ABBV is on its path to expand the label for Venclexta, with multiple read-outs in CLL and other blood cancers (and combo with Imbruvica) supporting our '21E sales estimate of $1.5B vs. the Street's $1.2B. Venclexta positive PFS data was top-lined for the MURANO trial recently (click here for our note), with full data at ASH 2017 (Dec. 9-12) & filing in a broader set of relapsed/refractory CLL patients by YE17. Key clinical read-outs for Venclexta include interim/full data for Phase 3 study of Gazyva+ Venclexta in younger & more-fit first-line CLL in 2018, Phase 3 for Venclexta + Velcade + dexamethasone in 2L-4L multiple myeloma, Phase 3 for Venclexta+ Imbruvica in 2L+ Mantle Cell Lymphoma.

Rova-T data/transparency on other Stemcentrx assets expected in '18

ABBV unveiled the broad clinical development plan that it is pursuing for Rova-T and the opportunities related to other Stemcentrx assets ($5.8B acquisition paid upfront in 2016, with $4B in potential milestones, click here for our note). ABBV is aiming to establish Rova-T as a foundational asset in Small Cell Lung Cancer (SCLC), which currently has no drugs approved, an attractive patient population (US incidence: 29K/yr, US/EU5/JP: 81K), with a high unmet medical need (3% five-year survival rate). As a reminder (click here for our note), at ASCO 2016, ABBV presented impressive Rova-T data in 3L SCLC, illustrating a one-year overall survival (OS) rate of 32% in DLL3+ tumors, almost triple that of 3rd line historical standard-of-care chemotherapy at 12%. ABBV shifted the read-out for Rova-T's registrational TRINITY study in 3L+ DLL-3(+) SCLC from 4Q17 to 2Q18 (full results at ASCO 2018) as FDA requires a six-month durability assessment as a part of the regulatory package. ABBV remains confident in Rova-T's TRINITY data in 3L+ SCLC, with ABBV aiming for late 2018 or early 2019 launch (assuming Priority Review). However, we also note that Opdivo + Yervoy combination offered an OS of 48% in 2L SCLC, according to BMY's presentation at ASCO 2016 from Ph-1/2 Checkmate-032 trial. At World Lung 2017 (click here for our note), BMY also showed that patient with high-tumor mutation burden in CM-032 trial had an even more robust efficacy, with one-year OS at 62%. Based on the market dynamics, we assume Rova-T has first-mover advantage. However, we expect Rova-T to be initially focused on later lines of therapy (3L) moving into earlier lines of therapy (1L-2L) where it might face competition from the Opdivo/Yervoy combination. ABBV is aiming to seek label expansion for Rova-T in 2L SCLC (TAHOE study), 1L SCLC (MERU) and neuroendocrine tumors (BASKET). The total commercial opportunity for Rova-T across these multiple indications totals up to ~$5B peak-year sales, however we modestly model '21E sales at $951M vs. Street's $840M.

Stemcentrx pipeline visibility on additional assets should rise in 2018

As a reminder, Stemcentrx acquisition added a library of novel compounds that ABBV is progressing into the clinic. ABBV plans to advance ~3 Stemcentrx assets into human clinical trial each year. Apart from Rova-T, the other most advanced asset in this pipeline is PF-06647020, which is a PTK7-auristatin antibody drug conjugate that is being pursued for non-small cell lung cancer (NSCLC), breast cancer and ovarian cancer. PTK7 (protein tyrosine kinase-7) is overexpressed in a range of tumor types such as colon, lung, gastric, acute myeloid leukemia (AML) and intrahepatic cholangiocarcinoma, according to published literature (World Journal of Surgical Oncology). We expect results from PF-06647020 Phase 1b study becoming available in 2019, based on the primary completion date of July 2019 on clinicaltrials.gov. ABBV/PFE also initiated a small PF-06647020 Phase 1 study with 18 patients in Sept. '17, which is evaluating the drug in triple-negative breast cancer (TNBC) & metastatic breast cancer in combination with PFE's PI3K drug gedatolisib. Recall that PFE has *'some rights'* for PF-06647020, while ABBV has not fully disclosed the economics. ABBV also has a next-generation Rova-T & a number of other undisclosed assets that are being pursued in a wide variety of solid tumors.

Range of catalysts should put upward pressure on ABBV's multiple

We believe ABBV's bounty of catalysts will drive outperformance. Catalysts include Mavyret uptake in 4Q17/2018 relative to management's 2020E sales expectations, Rova-T final registrational data from its TRINITY study in 3L+ DLL-3(+) SCLC in 4Q17, with regulatory submissions in 4Q17 and launch in 2018. ABBV has initiated enrolling patients in two other Rova-

T studies [Phase 1/2 basket study & Phase 1 1L SCLC] and expects to provide interim-results in 2H17. Risankizumab full Phase 2b data in psoriatic arthritis is lined up at ACR 2017. Imbruvica label build-out includes interim Ph-3 results in 1L Mantle Cell Lymphoma (SHINE) in 4Q17 & 2L Follicular Lymphoma (SELENE) in 2018. Venclexta positive PFS data was top-lined for the MURANO trial, with full data at ASH 2017 (Dec. 9-12) & filing in a broader set of relapsed/refractory CLL patients by YE17. ABBV also expects data from ABT-414's Phase 2 trial for 2L glioblastoma multiforme (INTELLANCE-2) by YE17, which we view as having a high degree of risk. Elagolix NDA submission for endometriosis received a Priority review, setting the PDUFA date for 2Q18. The Elagolix uterine fibroids program data is expected in 1Q18. See Exhibit 5 for our ABBV catalyst calendar through 2018.

Δ Key Drivers

'21E Revenue to **$40.8B** from **$38.5B**

Higher Humira & Mavyret sales

[redacted]@suntrust.com

[redacted]CFA
[redacted]@suntrust.com

[redacted]@suntrust.com

FOR INSTITUTIONAL CLIENTS ONLY

Disclosures

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imbruvica
(ibrutinib) 140mg capsules

Janssen Recommendation 2017 FTEs and OOPs

October 26, 2016

Executive Summary- Janssen Recommendation

- Investment focused on optimal spend to maximize IMBRUVICA sales growth in existing and new indications (2+ new indications in 2017)

- JBI recommends increase YOY spend of +30% ($66M) based on forecasted increase in sales goal of 39% in 2017

- Used Competitive Benchmarking and cROI to guide appropriate investment

- Priority of Investment:
  1. Sales force expansion
  2. Commercial OOP increase/MAF OOP increase
  3. Commercial FTE increase /MAF FTE

FTEs & OOP 2016 – 2017 Comparison- JBI Reco

	Current		Proposed			
	FY 2016 (JU) Collaboration		FY 2017 Collaboration		Change Collaboration	
	OOP$	FTE$	OOP$	FTE$	OOP$	FTE$
Marketing	$29,724	$6,126	$41,446	$8,278	$11,722	$2,151
Market Access	$11,104	$10,356	$10,386	$9,724	-$718	-$632
MR / BA	$3,864	$3,701	$5,432	$6,305	$1,568	$2,604
Sales	$2,192	$42,684	$2,711	$44,236	$519	$1,552
Medical Affairs	$25,963	$27,724	$29,642	$33,734	$3,679	$6,010
PR/Communications	$0	$0	$1,360		$1,360	
Support Services	$2,624	$2,928	$2,624	$2,775	$0	-$153
Foundations	$47,000	$0	$55,000	$0	$8,000	$0
Sales Expansion	$0	$0		$28,268		$28,268
TOTAL	**$122,471**	**$93,519**	**$148,601**	**$133,319**	**$26,129**	**$39,800**
FTE & OOP Combined	**$215,990**		**$281,919**		**$65,929**	

From: Niksefat, Kave [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=80085F1047D5465AAC8EF82A5E0C30A3-KAVEN]
Sent: Thursday, December 21, 2017 11:50:58 PM
To: [redacted]
Subject: Fwd: PI Decision

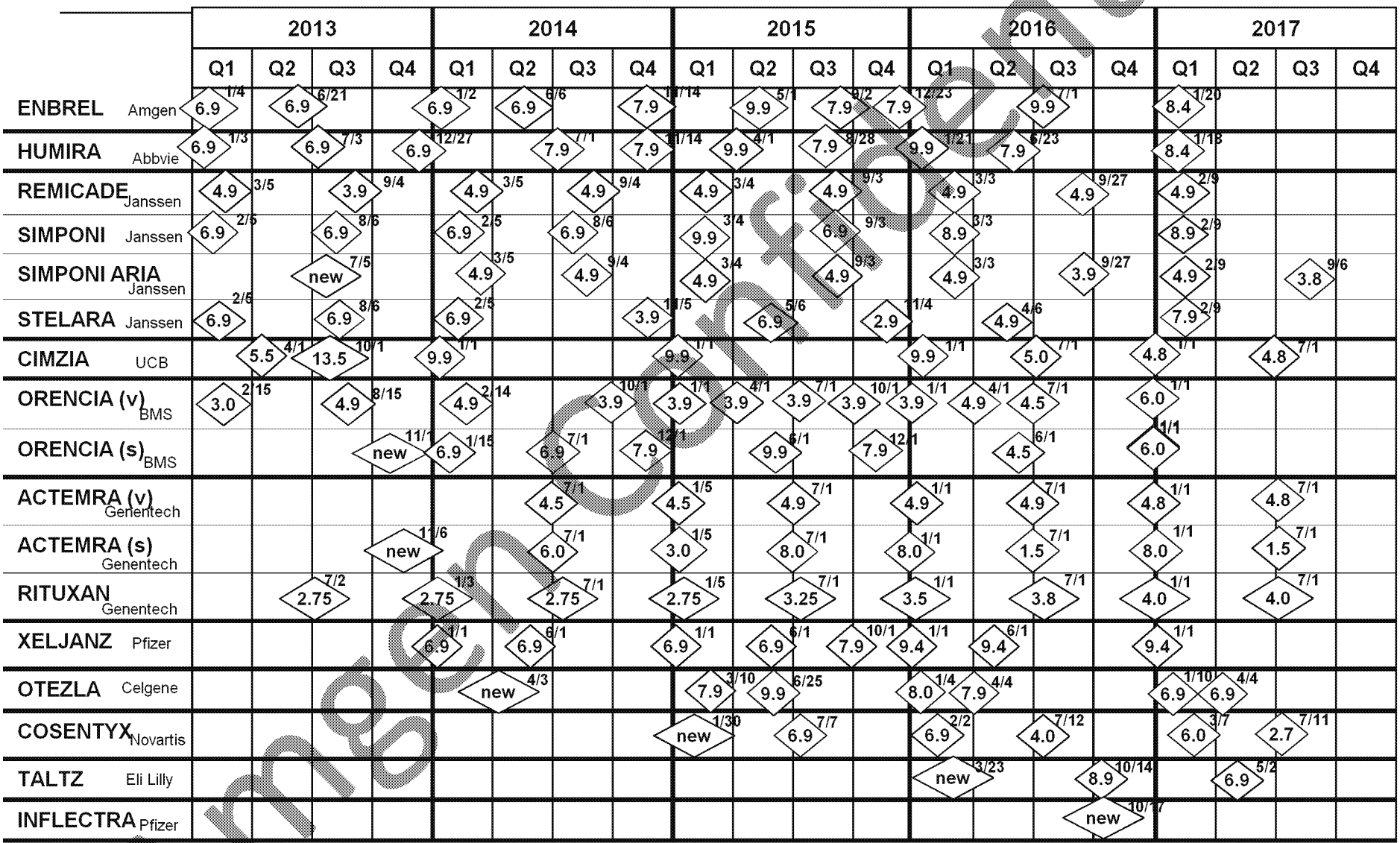
For your records.

Sent from my iPhone

Begin forwarded message:

> **From:** "Niksefat, Kave" [redacted]
> **Date:** December 21, 2017 at 3:44:00 PM PST
> **To:** [redacted]
> **Subject: Fwd: PI Decision**
>
> We're a go with current plan. Kave
>
> Sent from my iPhone
>
> Begin forwarded message:
>
> > **From:** "Hooper, Tony" [redacted]
> > **Date:** December 21, 2017 at 3:36:41 PM PST
> > **To:** "Niksefat, Kave" [redacted]
> > **Cc:** [redacted] "Hamill, Laura" [redacted]
> > **Subject: PI Decision**
> >
> > Kave,
> >
> > You have authorization from me - to proceed at 11.01pm on 12/31/17 for 4.9%. In addition, you have authorization to proceed with a competitive price increase for Enbrel - should Humira pull the trigger at any point.
> >
> > Regards,
> > Tony
> >
> > Anthony C. Hooper
> > [redacted]

Enbrel Therapeutic Class
Price Increases 2013 – Current



Grey - subQ, dark red - infused, dark blue - oral

From: [redacted]

Sent: Monday, April 25, 2016 8:26:47 PM
To: Bradway, Bob
CC: Hooper, Tony
Subject: Sensipar & Pediatric Exclusivity

Bob,

Following the Quarterly Business Review, Tony asked that I clarify for you the current status of the Pediatric Exclusivity extension for Sensipar in the US, and the Product Team's expectations of securing. The current base case LRP assumes patent expiry in March of 2018 without extension, as it is not anticipated that the formal FDA requirements will be met. However the team is proceeding with filing efforts (File: November 2016), with notification of grant of exclusivity in May 2017.

I have briefly summarized the situation below:

- Patent expiry for Sensipar in the US is March of 2018 –with opportunity for 6 month Pediatric exclusivity extension to November 2018
- A Written Request (WR) - formal requirements for pediatric exclusivity from FDA - has been in place prior to initiation of pediatric studies in 2011.
- Unique challenges in meeting the terms of the request have existed from time of request, with some additional hurdles added over time:
  - o Low prevalence in children <6 years
  - o High rate of kidney transplantation
  - o Country selection challenges
  - o Delays &challenges related to partial clinical hold &revised eligibility criteria –further limiting potential eligible subjects
- In addition, regulatory efforts to renegotiate the terms of the WR have been exhausted with the recent request for Type C meeting denied by the FDA in December 2015.
- To be eligible for the patent extension, the terms of the WR must be met –and this will not occur, as shortfalls in the clinical data package remain, despite progress in the past few months.
- The probability of regulatory success for pediatric exclusivity is LOW –and the extension is not assumed as base case in the LRP
- However, it is anticipated that the FDA Pediatric Exclusivity Board can apply some judgment with regards to meeting the terms. The consideration of exclusivity is triggered by our regulatory submission, planned for November 2016. The regulatory team believes the subsequent filing and pre-filing meetings provide an opportunity to continue to delineate our arguments related to good faith efforts to complete the pediatric studies and the strength of the data package.
- Despite low probability of regulatory success, the potential upside to the LRP is meaningful and all available options are being leveraged by the team.
- Notification of grant of exclusivity is anticipated 6 months following submission (May 2017).

Please let me know if you require further details.

Best regards,

[redacted]

Global Product General Manager (GPGM)
Parsabiv™ &Sensipar®/Mimpara®

Amgen
One Amgen Center Drive
[redacted]

From: [redacted]

Sent: Wednesday, June 29, 2016 7:14:20 AM

To: [redacted]

CC: [redacted] Hooper, Tony; [redacted]
[redacted] Hamill, Laura

Subject: Re: Pediatric LOE extension for Sensipar

[redacted]

Thank you for confirming these details. The team remains committed and engaged with urgency and best efforts in preparing for the filing. Next steps include a request for pre-filing meeting, including a final request to amend the Written Request (WR) requirements for exclusivity.

Let me know if you require further details.

[redacted]

Sent from my iPhone

On Jun 29, 2016, at 5:12 AM, [redacted] wrote:

[redacted]

During one of our Parsabiv readiness meetings, the question was asked what is a potential 6 month extension on the LOE for Sensipar worth.
The team ran the numbers ……and a six month extension of LOE for Sensipar is worth $0.25B for the 18-19 period in the US

Both [redacted] and I wanted to share this number with you……we realize you know how important maximizing our shot of obtaining this objective is…..now it also has a dollar sign attached to it.

[redacted]

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ENBREL LIST PRICE AND INVENTORY CONSIDERATIONS

September 11, 2018

DRAFT

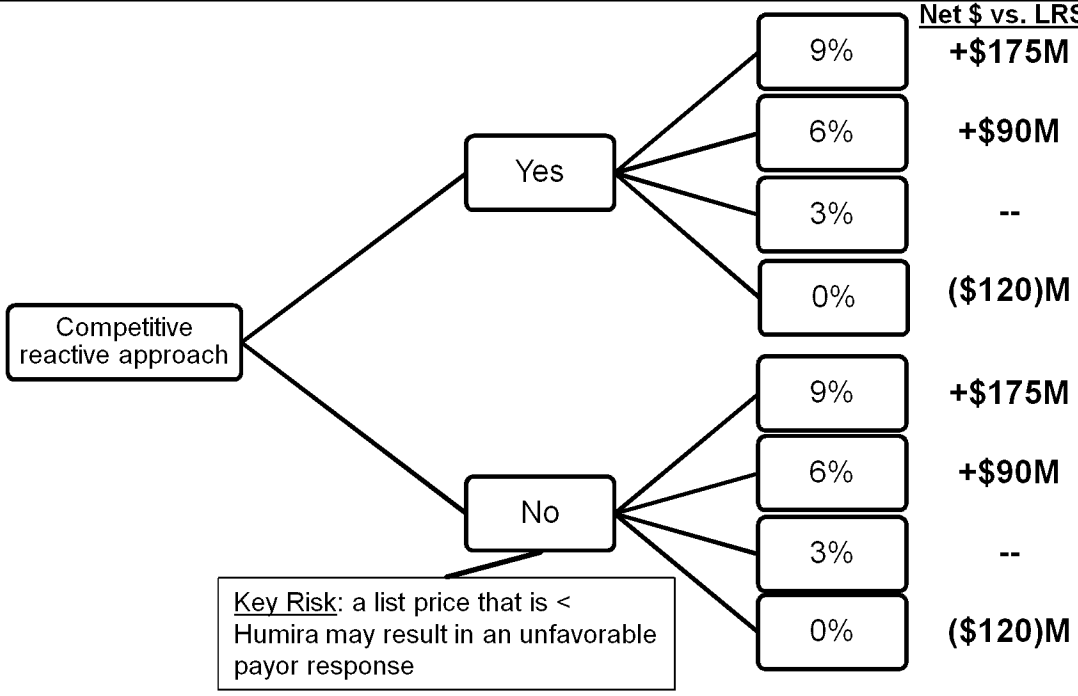
WHEN ASSESSING POTENTIAL LIST PRICE CHANGES FOR ENBREL IN 2019, NEED TO CONSIDER MAGNITUDE, AND POTENTIAL COMPETITOR AND PAYOR ACTIONS

1. What we've seen, done and planned for to date

Most recent List Price Increases
Humira: 9.7% on 12/31/17, 8.4% on 1/18/17
Enbrel: 9.7% on 12/31/17, 8.4% on 1/20/17

LRS List Price Assumption
Enbrel +3% on 1/1/19, competitively reactive to Humira

2. What some of the options are



3. Recommendation

React competitively to AbbVie's list price actions on Humira;

Impact -$120M to +$175M, depending upon Humira change

Any list price increase for Enbrel in 2019 assumes the 60-day notification to the state of CA, potentially impacting Intermediary Inventory levels at YE 2018 if notification occurs prior to YE

* Excludes potential impact of Inventory changes

U.S. PRICING COMMITTEE

MAY 12, 2016

Redacted - Non-Responsive

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Product: ENBREL®

Customer or Segment: Price Increase

EXECUTIVE SUMMARY
ENBREL® PRICE INCREASE

Background

- Enbrel® last price Increase was 7.9% on Dec 23rd 2015
- Price increase strategy is to follow AbbVie's price increases
- Feb LEDR assumed a 7.9% price increase in June of 2016
- Anticipated net sales of $6.1B in 2016

Seeking approval on:

- Approve an Enbrel® price increase up to 9.9% prior to Aug 1, 2016, as soon as operationally feasible, following AbbVie's anticipated price increase

SUMMARY – ENBREL® PI

Feb LEDR Date of PI's Jun, 1 2016 , Dec 1 2016 Jun 1 2017, Dec 1, 2017	Included in LE/LEDR	Comparison	Overall Est. Change in Net Revenue for 2016**	Overall Est. Change in Net Revenue for 2017**
Jul 1 2016 – 7.9%	N	Compared to Feb LEDR	**Commercially Sensitive Material Redacted at Amgen's Request**	
Aug 1 2016 – 7.9%	N	Compared to Feb LEDR		
Aug 1 2016 – 9.9%	N	Compared to Feb LEDR	($32M)	$60M
May LEDR PI's **Jul 1 2016 – 7.9% Dec 2016 PI – 0%** **Jan 1 2017 – 6% Dec 2017 PI – 0%**	Y	Compared to Feb LEDR	**Commercially Sensitive Material Redacted at Amgen's Request**	

**Financial Impact based on June 1, 2016 Price Increase

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USBO 2018 JUNE FORECAST SALES REVIEW

December 14, 2018

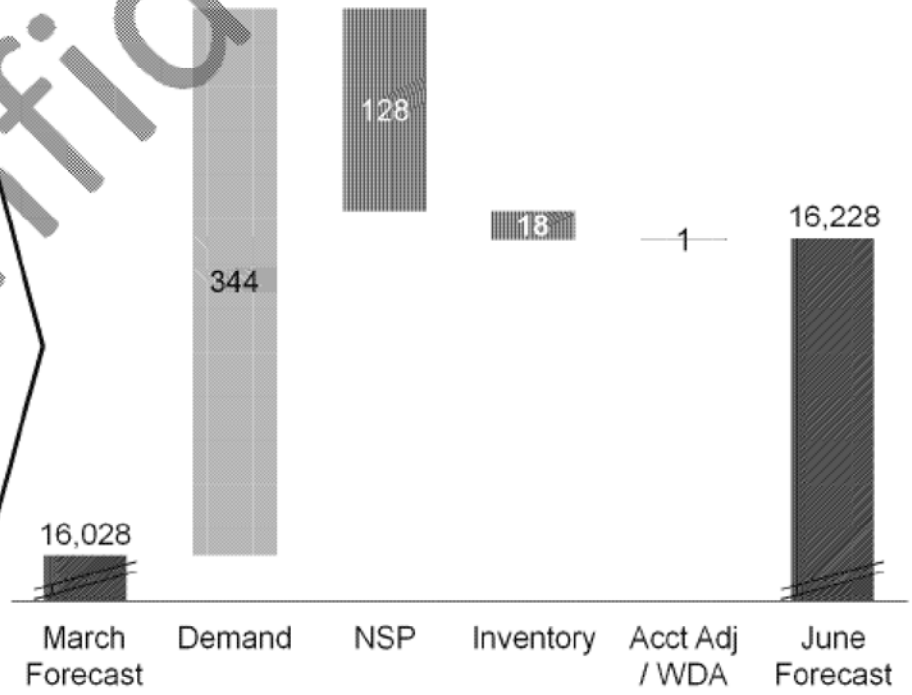
v. March Forecast

FULL YEAR JUNE FORECAST VS. PLAN +$200M DRIVEN BY SENSIPAR DEMAND AND ENBREL PERFORMANCE

Changes from March Forecast driven by:

- **Demand +$344M**
  - *Sensipar +$202M; delay of generic entry from 3/31 to 6/15*
  - **Redacted - Non-Responsive**
  - *Enbrel +$122M; demand driven by rheum market +4.9% and derm market +8.8% as compared to March Forecast*
  - **Redacted - Non-Responsive**
- **NSP -$128M**
  - **Redacted - Non-Responsive**
  - *Enbrel +$32M; favorable sales mix (lower sales through Gov-Fed)*
- **Inventory -$18M**
  - *Enbrel -$12M; Primarily 1.7 DoH wholesaler inventory depletion at end-user*
  - *Sensipar -$12M; wholesaler inventory depletion in Q3*
- **Accounting Adjustments / WDA +$1M**
  - *Enbrel +$11M; Favorable Q1 true-up vs. Mar Fcst due to AMP unit reimbursement rate*

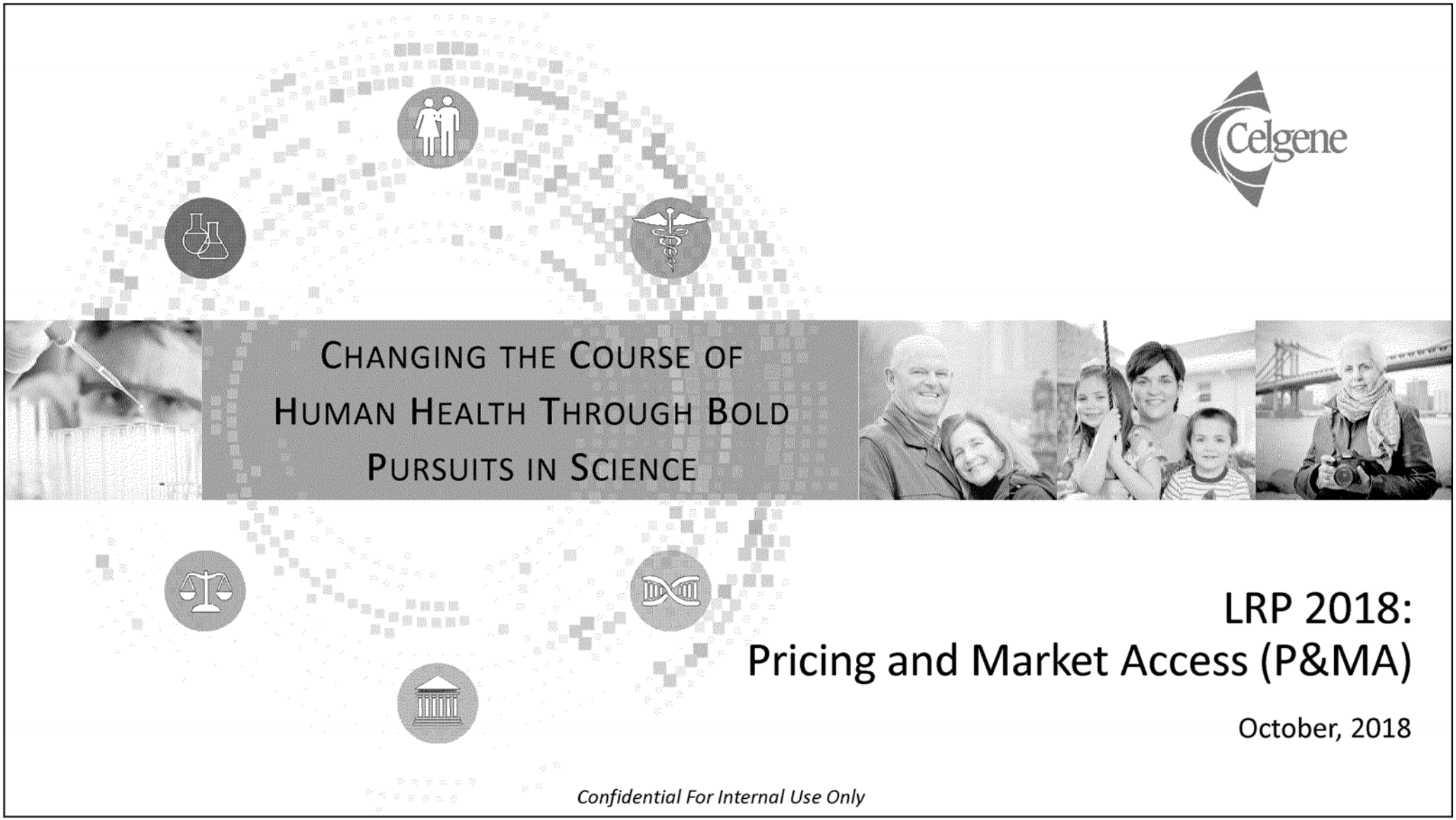
FY Sales at $16.2B; results in -5% YoY
(U: -4%, NSP* -1%, O: -1%)



Welcome!

U.S. Multiple Myeloma LRP Highlights

- Can the U.S. Multiple Myeloma franchise grow from **$4.8B** in '16 to **$8B** by '20?
  - In order to achieve **+60%** growth from **'16 to '20**:
    - Grow and protect Market Share for Rev and Pom in ndMM and rrMM segments
    - Increase Duration of Therapy in ndMM and rrMM segments
    - Ability to realize favorable net price



LRP 2018:
Pricing and Market Access (P&MA)

October, 2018

Confidential For Internal Use Only

Celgene's key markets have historically been favorable toward pricing and market access for innovative products

RECENT PAST: PMA Environment

Manageable P&MA environment for Celgene

Stagnated price growth due to growing value assessments, reference pricing, & price negotiations throughout the product lifecycle

Unique access dynamics and budget pressures by country

Highly favorable environment with free-market pricing

P&MA pressures concentrated in competitive, high budget impact areas

Generally favorable coverage in oncology

Generally favorable access environment, particularly in the private sector

Fragmented system with a focus on cost-effectiveness and drug pricing

Generally favorable product pricing informed by rigid methodologies

Broad reimbursement for approved therapies

3

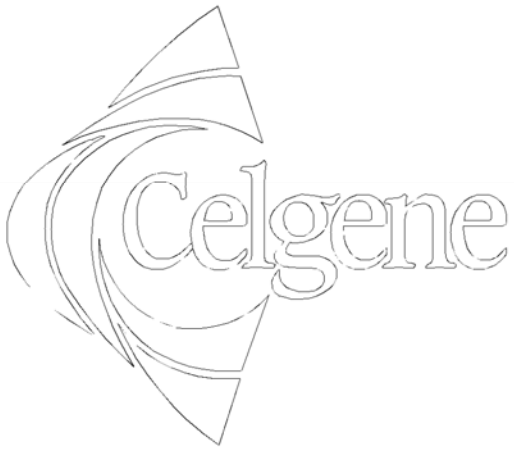
BMS-Celgene Document 2

2016 Corporate Affairs and Market Access Goals

BMS-Celgene Document 3

Shape the operating environment to support business goals through proactive and collaborative engagement (20 percent)

Goal	Franchise	Owners	Metric	Status
Achieve milestones and outcomes on priority cross portfolio U.S. public policy and access objectives as endorsed by CMAC: (cont.)				
Increase awareness and support among key US stakeholders for the REMS patient safety paradigm and prevent legislative erosion of REMS program	Hem	Alan, Greg, Francesca, Joel, Brian	Achieve exemptions on any state drug repository and takeback bills and execute effective compliance strategy for existing county ordinances Attain external awareness and positive attitudes about REMS program amongst external audiences Maintain and support active engagement of allied groups (SWHR, Aimed Alliance, Patients' Alliance for Drug Safety Protections) on Capitol Hill and KoL forums (Alan) Increase REMS education and awareness through support of content creation for DrugProtections.org (Alan) INCLUDE A METRIC ON MEDIA IMPRESSIONS	



Multiple Myeloma Strategy Day

Pre-read Summary

February 14, 2014

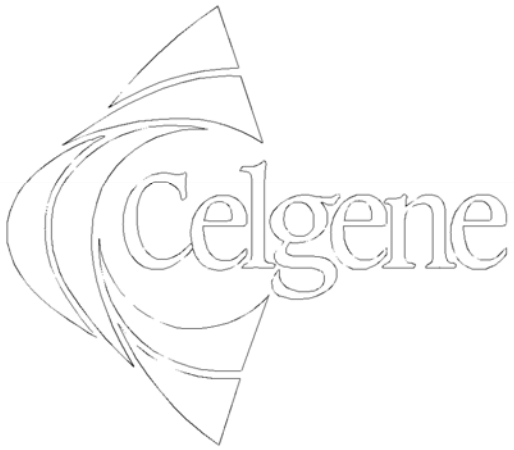
BMS-Celgene Document 4

IP/Exclusivity Assumptions

Compound	% Prob.	US	% Prob.	EU	% Prob.	JP	% Prob.	CN	% Prob	AU
Lenalidomide		Sept. 2024		June 2022		2020		2017		2022
	80%	April 2025	80%	March 2023	80%	2021	80%	2018	50%	2023
	65%	April 2026			70%	2022	70%	2019		
	50%	April 2027			60%	2023	65%	2020		
					50%	2024	60%	2021		
							55%	2022		
							50%	2023		
[redacted]										

*Up to 5 year PTE (Patent Term Extension)
** Pending inclusion of Pom/dex combination in label

BMS-Celgene Document 4



1Q and 2Q2014 U.S. Pricing Actions

Corporate Market Access Committee Meeting
March 5, 2014

BMS-Celgene Document 5

2014 US MM Pricing Strategy - Revlimid

- **Implemented semi-annual pricing actions approved by CMAC in 1Q2013**

- **Implementing a March 7 price increase of 4.0% instead of the planned 3.0% on April 1 will yield incremental net sales of $24.8M in 2014**

	1Q2014	2Q2014	3Q2014	4Q2014	2014
Incremental Net Sales	$ 4,236,732	$ 6,660,194	$ 6,805,825	$ 7,085,203	$ 24,787,954

From: Mark Alles
Sent: Saturday, March 1, 2014 10:51 AM
To: [redacted]
Subject: Q1 REVLIMID

Hi [redacted]

As you may have read from my overall Q1 update to the team, our latest Q1'14 global LE for REVLIMID is ~$1,125M vs. Q4'13 actual RECLAIMED at $1,136M (-1% Q/Q growth).

I was glad to see that your latest Q1 LE for REVLIMID was increased by $5M to $645M, but the current consolidated Q1 REVLIMID and total sales LE is forcing me to reconsider the 2014 pricing plan for REVLIMID in the US. I'd like to ask for you and I to discuss on Monday the pros and cons of taking a 4% price increase for REVLIMID not later than the end of next week and a second price increase of 3% on September 1st rather than October 1st.

We know that Q2 will be an excellent quarter for our US and global performance, but Q1 looks extremely challenged. I have to consider every legitimate opportunity available to us to improve our Q1 performance. Of course an early March and an early September price increase adds to the full-year not just to Q1.

Thanks [redacted] Hope you have a great weekend.

Mark

From: Mark Alles
Sent: Friday, May 6, 2016 7:13 AM
To: [redacted]
Subject: MM-020
Attachments: May09FIRSTMM020 (3).doc

Per our discussion. You will also note how we grossly underestimated the cumulative and annual sales potential for REVLIMID.

BMS-Celgene Document 7

Frontline **I**nvestigation of **R**evlimid vs. **S**tandard **T**halidomide

Strategic Rationale

April 2009

BMS-Celgene Document 7

Document Purpose

Global Marketing and the Global Myeloma Project Team prepared this position paper to reinforce the strategic importance of the MM-020 trial for the short and long-term commercial success of REVLIMID® in multiple myeloma. Additionally, this document seeks confirmation by Celgene Management that the FIRST TRIAL will continue to be fully resourced as planned.

Background

Multiple Myeloma (MM), the second most common hematologic malignancy, causes approximately 19,000 and 13,000 deaths per year in Europe and the US, respectively. Effective treatment became available in the early 1960s when the alkylating agent melphalan was introduced. The most commonly used standard-dose treatment in previously untreated MM patients for almost 40 years was the combination of melphalan and prednisolone/prednisone (MP). Responses to this oral regimen may be delayed and, unless disease progression develops, treatment is continued for at least one year. Prolonged melphalan-containing therapy after MP induction therapy has not been found to improve clinical outcomes and is associated with increased toxicity, including an increased risk for the development of secondary myelodysplastic syndromes and/or acute myeloid leukemia. The overall response rate to MP is 50% to 60% with a median overall survival time of 24-30 months. Most responders to MP attain a plateau phase during which the malignant myeloma clone appears to be dormant. Studies of chemotherapeutic agents including vincristine, carmustine, cyclophosphamide, doxorubicin, and high-dose dexamethasone in different combinations did not result in a survival advantage compared to MP despite the achievement of superior response rates (60%-70%).

Clinical data indicates that two new regimens, MP plus thalidomide (MPT) and REVLIMD® plus low-dose dexamethasone (Rd), results in superior outcomes compared with the standard-dose regimens of the past in patients with previously untreated MM.

An Intergroupe Francophone du Myélome (IFM) trial was conducted in which previously untreated MM patients aged 65-75 years were randomized to receive MP, MPT, or high-dose melphalan (MEL100). An improvement in median PFS time and median OS time were achieved in patients treated with MPT for 12 six-week cycles compared to those who received MP or MEL100. Similar results were observed in a multicenter, randomized trial of previously untreated MM patients older than 65 years (or younger, but unable to undergo stem cell transplantation [SCT]) performed by the Italian Multiple Myeloma Network (GIMEMA). Due to these findings, the MPT regimen has become a standard treatment for newly diagnosed MM patients who are at least 65 years old.

In May 2006, FDA approved the sNDA for THALIDOMIDE in combination with dexamethasone for patients with previously untreated MM. In April 2008, EMEA approved the marketing authorization for THALIDOMIDE in combination with melphalan and prednisone for elderly patients with previously untreated MM. THALIDOMIDE is approved in Japan and Australia for use in patients with previously untreated MM. Additional approvals are pending in important global markets.

Currently (Sep '08 market data), the market share of MPT in elderly patients with previously untreated MM is approximately 64% in France, 16% in Germany, 6% in Spain, 18% in Italy, and 13% in the UK. Estimated share of MPT in previously untreated MM across all EU member states is 23%. Celgene is currently launching MPT across major EU markets. A current (Dec '08 market data) estimate of the MPT market share in the US is approximately 10%. The overall US and EU

market share for any THALIDOMIDE containing regimen used for the 1st line treatment of Multiple Myeloma is approximately 45%.

Studies investigating the use of REVLIMID plus dexamethasone in patients with previously untreated MM have also been recently reported. Thirty-four patients with newly diagnosed MM were treated with REVLIMID plus high-dose dexamethasone (40 mg once daily orally on days 1-4, 9-12, and 17-20 of each 28-day cycle) for at least 4 cycles in a phase II study conducted by the Mayo Clinic (Rochester, MN). The overall response rate was 91% and the 2-year PFS rate was 74%. Because of these encouraging results, the Eastern Cooperative Oncology Group (ECOG) performed a large phase III study in which previously untreated MM patients were randomized to receive either REVLIMID plus standard high-dose dexamethasone (RD) or REVLIMID plus low-dose dexamethasone (40 mg once daily orally on days 1, 8, 15, and 22 of each 28-day cycle) (Rd) to investigate the effects of REVLIMID combined with dexamethasone administered at a lower dose intensity. Preliminary results demonstrate that Rd therapy was associated with an improved safety profile and a significantly greater survival rate at one year compared to RD (96% vs. 87%; p = 0.0001). Furthermore, the 1-year and 2-year survival rates achieved in Rd-treated patients compares favorably to that attained by patients treated with MPT (Rd- 96%, MPT-88%) and (Rd-87%, MPT-78%), respectively. These findings warrant studies investigating the use of Rd versus the standard of care for previously untreated MM patients who are at least 65 years old or who are not candidates for SCT.

Description of the FIRST TRIAL

The FIRST TRIAL (MM-020/IFM 07-01) is a Celgene sponsored phase III, randomized, open-label, 3-arm study developed and launched in direct collaboration with the IFM to determine the efficacy and safety of REVLIMID in combination with low dose dexamethasone (Rd) when given until progression of disease or for 18 four-week cycles (72 weeks) versus the combination of melphalan, prednisone, and thalidomide given for 12 six-week cycles (72 weeks). It is important to recognize that this trial was originally conceived by the IFM and was intended to be a phase 3 trial conducted exclusively through this group. In May 2007, Celgene proactively approached the leadership of the IFM to initiate the collaboration which led to the development and full sponsorship of MM-020. The FIRST TRIAL study schema and clinical rationale has been featured in multiple international congresses (ASH, ASCO, and IMW) and is actively accruing patients. International patient advocacy organizations have created awareness campaigns to drive patient accrual.

The targeted population for this study is patients diagnosed with previously untreated multiple myeloma who are 65 years of age or older and who are not eligible for or decline autologous stem cell transplantation (NSCT). The primary endpoint of the trial is progression free survival (PFS) and secondary endpoints include overall survival, response rate, duration of response, time to response, safety, time to treatment failure, time to 2nd line anti-myeloma treatment, best response achieved to 2nd line anti-myeloma treatment, cytogenetic findings and quality of life. Patients will participate in the trial until disease progression up to the time all patients have been followed for at least 5 years from randomization or have died. This trial is part of a global registration strategy for REVLIMID in the newly diagnosed multiple myeloma elderly population.

Strategic Considerations

In June 2008, Millennium Pharmaceuticals (now Millennium: The Takeda Oncology Company) received an expanded indication based on the VISTA trial results comparing MPV to MP in the NSCT patient population. Despite this new approval, use of the MPV regimen within the United States has not grown significantly and currently there is no standard of care (SOC) for newly diagnosed NSCT patients. In the United States, market research indicates that Rd, MPT and MPV are the regimens most often prescribed for this patient population at 16%, 10% and 16% respectively (ATU study, Feb 2009).

The FIRST TRIAL has the potential to establish Rd as the SOC in the previously untreated multiple myeloma NSCT market. Should the non-alkalator couplet of Rd demonstrate superior efficacy and safety/tolerability to the traditional alkalating triplet (MPT), the commercial organization anticipates significant growth in Rd market share at the expense of not only MPT, but also MPV. In the United States, Rd is currently the most prescribed regimen in the autologous stem cell transplant (ASCT) eligible patient population (ATU study, Feb 2009). The net effect of a positive outcome in the FIRST TRIAL would be the establishment of REVLIMID as the preferred agent across all segments of the previously untreated multiple myeloma market. Additionally, future studies of novel agents would almost exclusively be conducted with Rd as the control arm compared with the three drug combination of Rd plus the novel agent. Establishing Rd as the base regimen for all future combinations for the treatment of previously untreated MM is a principle endorsed by SWOG through the just initiated phase 3 trial of RVd (V is Velcade) vs. Rd also known as S0777.

The FIRST TRIAL is aligned with the long term strategy for the Revlimid brand in multiple myeloma which is to *provide REVLIMID to as many patients worldwide earlier in the course of the disease for the duration of their disease.*

In addition, the FIRST TRIAL plays a critical role in meeting each of the five key long term strategic imperatives established by the Revlimid Global Project Team. Theses strategic imperatives are:

- To establish REVLIMID as the base therapy for all patients with multiple myeloma
- "De-segment" the treatment of patients with multiple myeloma
- Ensure patients with multiple myeloma are treated continuously until disease progression or unacceptable toxicity
- Differentiate REVLIMID from other IMiDs®
- Expand Celgene leadership in multiple myeloma with key opinion leaders

The FIRST TRIAL is strategically important to Celgene for the following reasons:

Registration Opportunity

The FIRST TRIAL is a central part of the REVLIMID worldwide newly diagnosed clinical, regulatory and commercial strategy. It has been repeatedly endorsed by PDC because positive results will lead to the following outcomes:

- Provide the only Celgene sponsored phase 3 study with the global opportunity to achieve marketing authorizations for Revlimid in combination with low dose dexamethasone within the previously untreated myeloma patient population
  - Back-up registration opportunity in NDMM should MM-015 not reach its primary endpoint

BMS-Celgene Document 7

- Broaden the labeled indication within the previously untreated population should MM-015 prove successful (Rd in addition to MPR)
  - Of particular importance to EU market and other markets that reference EMEA marketing authorizations
- Addresses the key clinical question of appropriate length of treatment duration for Revlimid
  - Should MM-015 support continuous REVLIMID maintenance, there is an opportunity to discontinue fixed cycle arm of MM-020
  - Should MM-015 not support continuous REVLIMID maintenance (inferior or stopped early), MM-020 provides a back-up opportunity to support treating to disease progression in newly diagnosed patient population
  - Should MM-015 and MM-020 continuous treatment arms prove inferior, the FIRST TRIAL establishes 18 cycles as the standard length of treatment for REVLIMID

Market Access

With the one payer system already in place in Europe and most of the top 20 global markets, with the strong possibility of such a system coming in the United States, we can anticipate continued reimbursement and pricing pressures. The US is already realizing payer driven step therapy requiring the clinical use of THALOMID before the use of REVLIMID. Success with the FIRST trial will clearly help to mitigate potential barriers to prescribing created by private or government payers that may require comparative cost-effectiveness of REVLIMID in the setting of newly diagnosed multiple myeloma.

Current Clinical Profile

Relative to the competition and THALOMID, there is limited clinical data on REVLIMID in the newly diagnosed multiple myeloma setting. The following table demonstrates the emerging clinical profile of Rd in untreated MM.

Phase III Newly Diagnosed Multiple Myeloma Clinical Trials

Study	Age	Regimen	1 year Survival Rate	2 year Survival Rate	3 year Survival Rate
Rajkumar, E1A00	Med = 65	TD v. D	80%	72%	<70%
Rajkumar, MM003	Med = 65	TD v. D	83%	71%	~60%
Palumbo	Med = 72	MPT v. MP	~87%	~83%	~60%
Facon	Med = 68	MPT v. MP v. M100	88%	~78%	~65%
Attal, IFM	< 65	Auto v. Chemo	~88%	~80%	~65%
Child, MRC	< 65	Auto v. Chemo	~87%	~75%	~70%
Barlogie, S9321	≤ 70	Auto v. Chemo	84%	~78%	~60%
Attal, IFM	< 60	Single v. Double Auto	~90%	~75%	~65%
Barlogie, TT2	< 75	TT2 +/- Thalomid	92%	~84%	~75%
San Miguel, VISTA	Med = 71	MPV v. MP	~90%	83%	72%
Rajkumar, E4A03 (Arm A)	Med = 65	Rev / Dex (high dose)	88%	78%	75%
Rajkumar, E4A03 (Arm B)	**Med = 65**	**Rev / dex (low dose)**	**96%**	**88%**	**74%**

While the Rd data from the ECOG E4A03 trial compares favorably with other regimens in the newly diagnosed patient setting, it remains relatively undifferentiated. Direct comparisons of the CR, VGPR, TTP, OS and safety profiles of MP-based regimens have had significant influence on the market perception and use of Velcade and THALOMID. In order to increase the competitiveness of REVLIMID in multiple myeloma, it is critical that Celgene produce strong scientific evidence for its use as well as direction on its appropriate use relative to THALOMID.

The FIRST trial will:

- Provide scientific support and/or confirmation for the superiority of REVLIMID over THALOMID
  - Provides back-up support for REVLIMID superiority over THALOMID should ECOG E1A06 (MPR vs. MPT) prove unsuccessful
- Provide the most comprehensive clinical evidence on Rd in the previously untreated patient population
  - Addresses a weakness of the ECOG E4A03 study – primary endpoint being response rates after only 4 cycles
- Provide scientific evidence that will address the inevitable comparison clinicians will try to make between REVLIMID/dexamethasone and Velcade/dexamethasone within the previously untreated population
  - IFM 2005-01 (VD vs. VAD)
  - UPFRONT (VD vs. VTD vs. VMP): particularly important given the comparison between Velcade based couplet versus triplet therapy
- Create a steady flow of data to be presented at major medical meetings (ASCO, ASH, EHA, IMW) that will continuously shape and defend Rd as a global standard of care in NDMM
- Create publication opportunities providing additional global promotional opportunities
- Provide the clinical evidence and raw data sets required as inputs for health economic models used by various governments and payers

Key Opinion Leaders / Institutions

Establishing and expanding meaningful scientific relationships with key institutions and thought leaders is vital to the reputation of Celgene and our expansion into new areas within hematology and oncology.

- Enables Celgene to establish and expand relationships with key thought leaders and accounts worldwide. This trial is expected to accrue 1590 patients across 151 sites.
  - As of April 17, 2009 there were 229 patients enrolled across 145 sites in EU, US and Australia/New Zealand.
- Given that Celgene proactively approaches the IFM regarding this trial and converted the trial from a pure French cooperative group IIT to a Celgene sponsored international trial, any attempts to scale back or discontinue this trial would severely damage the Celgene relationship with this pivotal EU group and its individual membership.
- MM-020 sites represent key thought leaders and institutions not only for myeloma, but other related disease areas in which REVLIMID and other Celgene compounds are currently or planned to be studied

Financial Opportunity

The newly diagnosed patient population is equally split between those patients that are considered eligible for stem cell transplantation and those that are considered ineligible for transplantation. However, the newly diagnosed non-stem cell eligible patient population represents the largest commercial opportunity for the multiple myeloma franchise as the anticipated duration of therapy is longer within this segment (ASCT eligible – 8 months vs. NSCT – 15 months).

As a result, the projected total global net revenue exceeds $8.6 billion over the patent life of REVLIMID (expiry in 2026). The anticipated worldwide peak sales for this patient segment are reached in 2021 and are approximately $915 million. Finally, the REVLIMID Global Project Team estimates that the NPV for aggressive pursuit of this patient segment is nearly $1.5 billion, which represents an internal rate of return on investment of 114%.

No other current or planned Celgene program approaches the financial value represented by realizing the assumptions in our current newly diagnosed multiple myeloma global sales forecast.

Summary

As Celgene continues to build upon its MM franchise, The FIRST TRIAL is one of the most important studies in the overarching previously untreated multiple myeloma strategy for the Revlimid brand. Patients and physicians want the answers only The FIRST TRIAL is asking and will answer.

The completion of this study is essential in positioning Revlimid across all patient segments of the previously untreated multiple myeloma market and establishing R d as the SOC in the previously untreated multiple myeloma NSCT market. Positive results for Rd will complete the differentiation of REVLIIMD from all current and future anti-myeloma therapies. Our global markets will be able to expand their commercialization efforts through significant primary and secondary publications developed and delivered by the many of the most important global myeloma key opinion leaders. Our global market access teams will be able to make direct clinical benefit and cost comparisons in the assessments used to establish and maintain reimbursement. Most importantly, the FIRST TRIAL is likely to be the only randomized trial that will ever be conducted to determine if the non-stem cell toxic regimen Rd is superior to a stem-cell toxic alkylator-based regimen MPT for the treatment of patients with previously untreated multiple myeloma. Celgene's reputation as an innovator and scientific leader in hematology will either continue to expand or may significantly erode depending on our commitment to the FIRST TRIAL.

List Price Adjustment Proposals

PRA Steering Committee
December 12, 2011

Lilly
Answers That Matter.

Eli Lilly 1

Insulin Current List Price Comparison

Brand	Package	NWP per ml
Novolog	Pen	$15.79
	Vial	$12.26
Humalog	Pen	$15.79
	Vial	$12.26
Apidra	Pen	$11.98
	Vial	$9.31
Levemir	Pen	$14.01
	Vial	$11.38
Lantus	Pen	$12.80
	Vial	$9.94
Humulin U100	Pen	$12.57
Humulin U100	Vial	$5.95
Humulin U500	Vial	$3.79
Humulin Relion	Vial	$1.815

Source: Analy$ource.com 11/22/11

Message

From: Enrique A Conterno [[redacted]@lilly.com]
Sent: 6/1/2014 11:59:38 AM
To: [redacted]
CC: [redacted]
Subject: RE: Humalog and Humulin - list price

While the list price increase is higher than we had planned, I believe it makes sense from a competitive perspective.

Enrique

From: [redacted]
Sent: Friday, May 30, 2014 5:36 PM
To: Enrique A Conterno
Cc: [redacted]
Subject: Fwd: Humalog and Humulin - list price

Enrique:

As you know we have been discussing a price increase in June. Attached is our proposed price increase.

Let me know if you have any questions.

[redacted]

P.S. We learned from public sources on Thursday that Novo took a 9.9% price increase across their Insulin portfolio.

Sent from my iPad

Begin forwarded message:

From: [redacted]
Date: May 29, 2014 at 2:22:35 PM EDT
To: [redacted]
Cc: [redacted]
Subject: Humalog and Humulin - list price

[redacted]

Per our conversation this morning, I propose +9.9% list price adjustments for all NDCs of Humalog family and Humulin family effective for orders received after 5pm on Wednesday evening June 4.

The resulting list prices:

- Humalog = $184.30 WAC per 10ml vial versus $184.85 for Novolog
- Humulin = $99.80 WAC per 10ml vial versus $99.65 for Novolin

Of course, the insulin category is among if not the most price competitive class at the contracted price level. Please let me know if you have additional questions or would like to meet to discuss this price adjustment.

Project Quincy
Preliminary Forecasts - US

Global Business Insights and Forecasting

March 5th , 2014

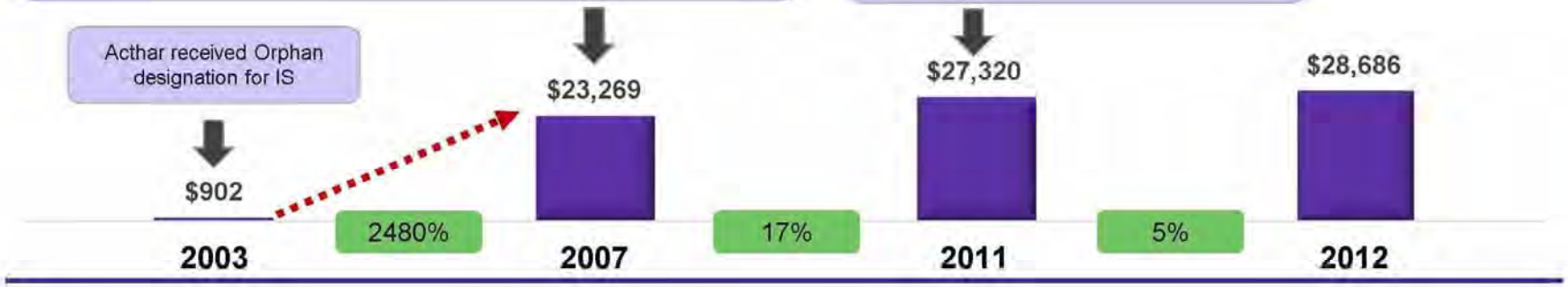
Mallinckrodt Pharmaceuticals

Pricing and Reimbursement

Acthar Pricing Action[1]

- Non approval of Acthar in IS (Orphan designation)
- Change in management of Quincy (CEO)
- New CEO adopted aggressive pricing strategy based on Orphan designation
- Pricing strategy contributes to company's growth
- Price increment due to orphan designation for IS; same leveraged for other indications (MS and NS)

- In 2010 Acthar got approval for IS and Orphan drug exclusivity (7 years)
- There after in Q1 2001 price increases by 5% after every 6 months



Reimbursement Update[1]

Payers	% Share for IS	IS	Non IS
Health Plan of Nevada	45%	Covered	Covered
United Healthcare		Covered	Covered
BlueCross BlueShield*		Covered	Covered
Aetna	5%	Covered	Not Covered
Cigna	50%	Covered	Covered
CMS		Covered	Covered
Emblem		Covered	Covered

- In Sep 2012, Aetna announced it would no longer be covering Acthar beyond IS
  - It stated there is no clinical evidence that the Acthar is more effective than steroids
  - Quincy estimates ~5% of its prescriptions are sold through Aetna
- Quincy reduced subsidy for Medicaid prescriptions for 100% to 23%

Price growth %

* Regions covered – Kansas, Michigan, Arizona, Montana, North Carolina, Tennessee

Please check note section for sources

Preliminary review of opportunity "Quincy"

Prepared exclusively for Mallinckrodt Pharmaceuticals by Strategic Clinical Development, LLC

Robert M. Elfont

Mallinckrodt 2

Sociopolitical

- Public, turned to political, reaction to high prices of drugs in general, and drugs for rare, life-threatening, diseases in particular, amplified by "over night" price escalation of Acthar.
- Questcor's defense: price was necessary solely to insure supply for IS, but was then followed by an unforeseeable expansion in use. Once successful at high price-point, fiduciary responsibility to shareholders precluded price reduction.
- The same narrative cannot be used with the same degree of plausibility by an acquirer of Questcor.
- Third party payers using Affordable Health Care Act as cover for jettisoning policies and programs they have begrudgingly accepted before – distributing the high cost of orphan drugs amongst these

Stakeholder Assessment of Proposed Price Actions

Public Relations	• Heightened risk of media coverage for any mid-year price action on Gleevec and Tasigna following *Blood* article; less risk for Afinitor. Risk in CML may be less by year end. • *If taking price in CML this July, should enhance Patient Support Programs to reduce potential patient burden and further develop communication plan to address PR concerns.* • *Preference is for larger increases (<10%) at lesser intervals rather than several smaller repeated increases throughout year.*
Payers	• Low risk that product reimbursement will be negatively impacted in any of the scenarios considered based on relative product value and historical trends of manufacturer mid-year price actions in CML, RCC and Breast Cancer
Patients	• Low risk of increased patient out of pocket costs from price increases (XX / % of pts) and largely mitigated by co-pay assistance programs, foundation support or Novartis' Patient Assistance Program. Enhancements to program to address patient gaps recommended.
Providers	• Low risk of reduced prescribing; physician concern over price tends to be focused on patient out of pocket cost rather than product list price, most of whom are unaware of price. Should develop key communication messages for field force to address if issue is raised by customer.

CML Management

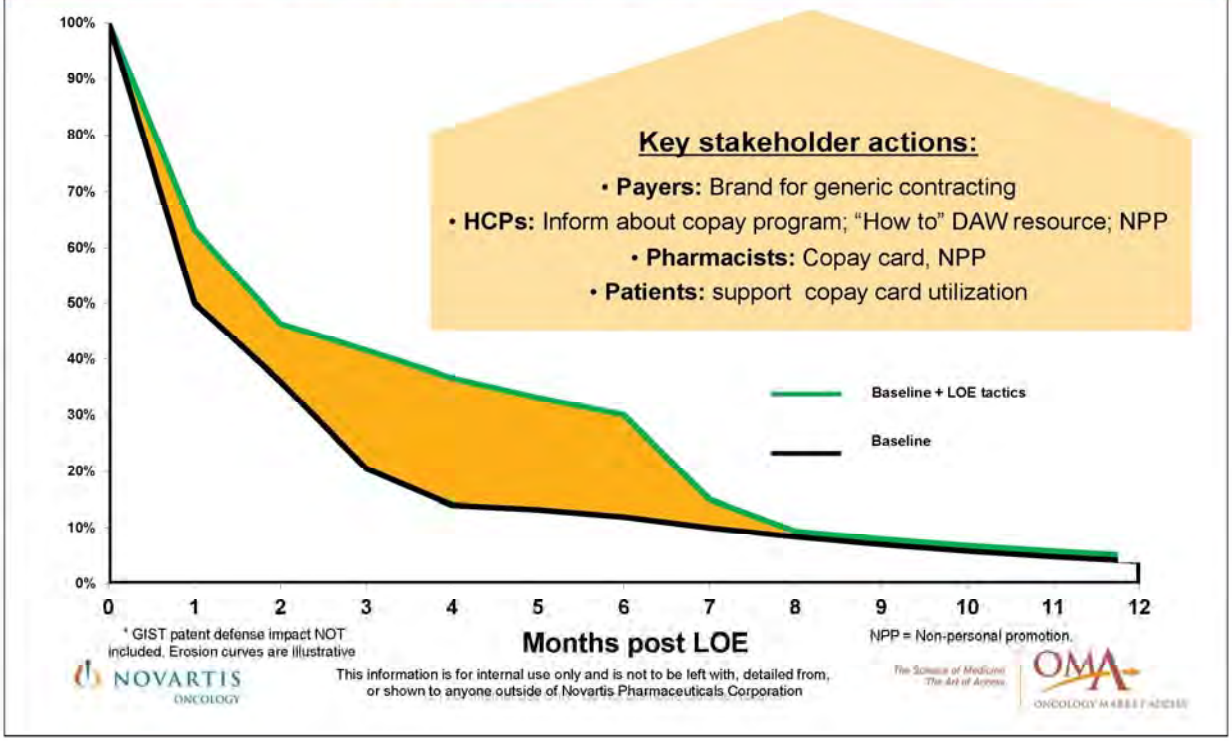
Wednesday

NOVARTIS ONCOLOGY

The Science of Medicine
The Art of Access

OMA ONCOLOGY MARKET ACCESS

LOE Contracting Can Provide Significant Upside



* GIST patent defense impact NOT included. Erosion curves are illustrative

NPP = Non-personal promotion.

NOVARTIS ONCOLOGY

The Science of Medicine. The Art of Access.

OMA ONCOLOGY MARKET ACCESS

Message Audience	Access/Co-Pay	Heritage/Clinical	Patient Support	Loyalty/DAW	Gx Consideration
Patient/HCP	• Save big on Gleevec – Pay as little as $10 • Gleevec gives • @LOE (once we know OOP for Gx): With brand Gleevec, you may save $XXX/ year vs with generics.	• Gleevec is the only imatinib approved for GIST • Sarcoma specialist: "Gleevec changed the way doctors treat cancer" • Gleevec changed the life of your patients. Don't let pharmacists change what you intend for your patients • Comfort/ predictability of the imatinib studied in clinical trials • 15 years of efficacy and safety data in more than x patients, x patient years experience, x clinical trials, x indications, x trials ongoing, • The #1 prescribed brand for GIST • The brand most trusted for treating GIST • Novartis #X largest R&D company • After GIST surgery, ensure the consistency you expect by sticking with Gleevec • Branded Gleevec is produced in a single factory	• We're here for you and your loved ones to help you stay with branded Gleevec • We support your choice of branded Gleevec • Gleevec, helping patients beyond their prescriptions • Stand up 2 Cancer, Stand Up for Gleevec – we'll support you • Discuss with HCP if your payor or pharmacy is switching • Do not risk losing patient response – resources are available for them to stay on Gleevec	• Generic imatinib does not have the Gleevec name imprinted on the tablet • Stay on a drug you know and trust • It's your right to ask your pharmacist for branded Gleevec. Tell them to dispense as written. • There is no diagnostic test in GIST to assess efficacy of Gleevec or generics • Gleevec your trusted partner through your journey • There are things worth changing in your life – is your Gleevec one of them? • Stick with what works for you • The power is in your hands – demand the brand • What is worse than telling the patients their cancer is back? • Make the milestones in life	• Multiple generics can lead to patient confusion • If you get generic, your medication may change shape, color, size from month-to-month • Generic drugs have the same active ingredients but not necessarily the same fillers • Generic drugs are bioequivalent to brands but NOT to each other • Dosages vary (80-120%) with generic, unlike branded drugs • Disease can recur. Is it physiological or is it loss of efficacy of the medication?

CML Pricing

Task Force Message Data Sources and Key Takeaways

July 12th, 2013

NOVARTIS
ONCOLOGY

Novartis Document 4

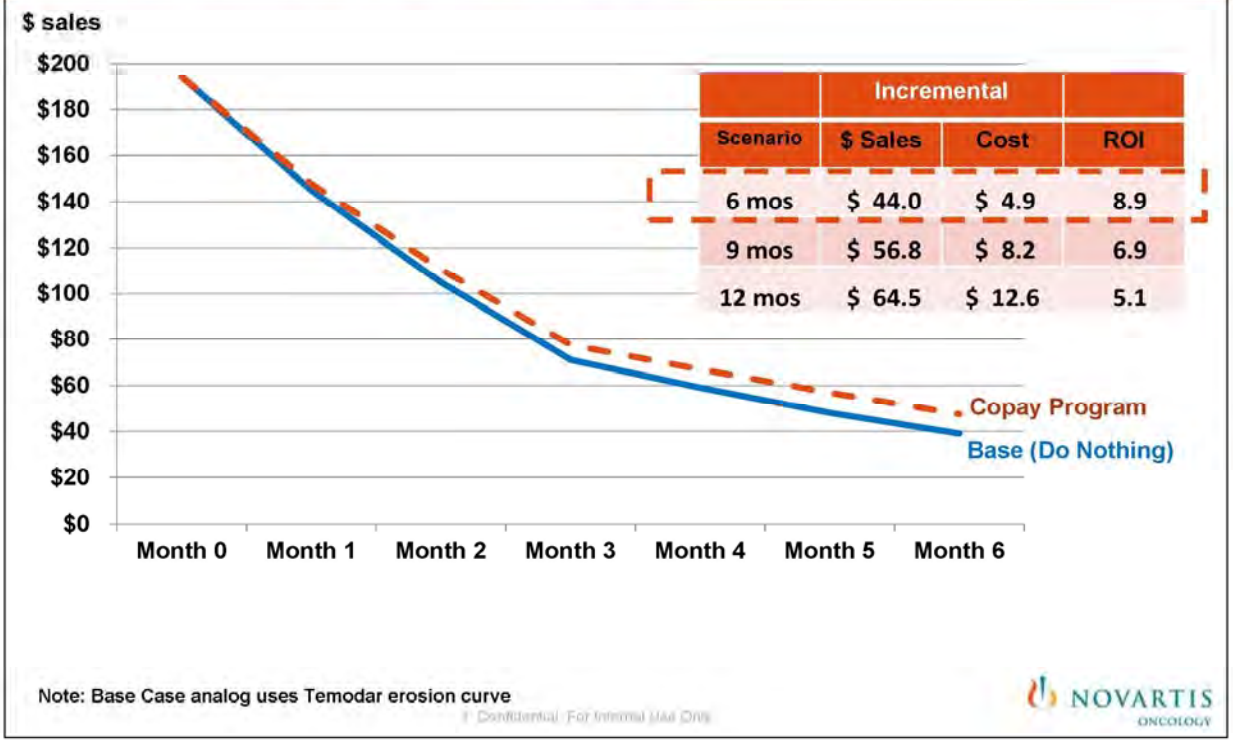
Cost & Patient Adherence

Evidence for the impact of copayments on CML patient adherence. Very few US patients will have a co-pay over $100 per month for Tasigna or Gleevec

- **The current data regarding TKI shows that copays are low for most patients.**
  - **In studies of TKI use in CML, the median copay is $25-30, (75th percentile: $63, 95th percentile: $122) [6, 7]**
- **However for the patients who have higher copays, cost is a risk factor for non-adherence.**
  - **In a study of patient adherence to imatinib, 1/3 of patients were shown to be poorly adherent. Risk factors include high starting dose, a longer time lag between CML diagnosis and prescription fill, and a higher percentage of copayment.[9]**
- **There is some data that suggests higher copays may have a "designer drug" effect and lead to improved adherence, however most studies refute this finding.[10]**
- **Because oncologic drugs are a necessity for patients, there is less sensitivity to price increases. However, research shows that there is an upper limit of OOP costs ($200-$500 per claim) at which patient adherence begins to decline. [5, 6, 8, 9]**

NOVARTIS ONCOLOGY

The Optimal Scenario is a 6 month Pre-LOE Start for the Enhanced Copay Program



Scenario	Incremental $ Sales	Incremental Cost	ROI
6 mos	$ 44.0	$ 4.9	8.9
9 mos	$ 56.8	$ 8.2	6.9
12 mos	$ 64.5	$ 12.6	5.1

Note: Base Case analog uses Temodar erosion curve

PCWG Update to: NNI Executive Team August 2016

Price Communication Work Group (PCWG)

[redacted]; [redacted]; [redacted]; [redacted]; [redacted]; [redacted], in April [redacted] was added.

- PCWG Leadership will be reassigned from [redacted] to [redacted] effective 1 Sept.

Input to Pricing/Transparency Legislation:

Workgroup has helped to shape NNI's position on and engagement around state-level pricing/transparency legislation and ballot initiatives, providing input on proposals and implications for NNI.

- This included recurring review and analysis of multiple successive versions as language evolved through the legislative process
- As a result of subsequent efforts by NNI's state Government Affairs team, and our Trade organization PhRMA and BIO, nearly all threats in 2016 were defeated or mitigated, with no direct impact to NNI to date.

Patient Affordability Messaging:

Quantitative research shows that Qualified Patient Affordability messages should be proactively communicated to patients as it persuades them to request our brands from their doctor.

- "NNI's ultimate goal is to find the cure for diabetes. To make that a reality, we invest 15% of every dollar we earn on conducting promising research to find a cure"
- "We have also helped hundreds of thousands of people cover the cost of their medication through our company-funded patient assistance programs. This includes programs for insured patients to assist with monthly co-pays".
- Next step is to align on appropriate communication channels (eg., NPR in rotation with 90 years, NNI Corporate site, end of Branded ads in rotation with 90 years, at retail, etc..) and communicate with Sense of Urgency communication platform.

Increasing Employee Awareness & Understanding

Integrated messages into existing communication opportunities, highlighting news coverage along with NN position

- 3 NovoNews articles – amongst top read in each quarter
- Participation on ET panel at May Vision 2020 meeting
  - 82% of employees agreed the ET panel helped improve their understanding
- Reinforced ongoing leadership communication
  - JESH earnings email, LT touch points/summit, and communication tool kits

Field Training:

Trained DBMs, RBDs, DEP Managers and others attending Pre-POA II to provide prospective on industry pricing challenges and NNI's ongoing strategic response.

- Overview of the pricing landscape was presented as part of the breakout rotations
- Key takeaway from training: NNI is managing pricing pressures while taking an empathizing with patient concerns

Levemir®
Price Increase Timing

Pricing Committee

March 30, 2015

STRATEGIC PRICING | SP

novo nordisk®

Levemir® price strategy is follow market leader

Levemir®

Brand strategy built on marketing clinical equivalence (w/additional benefits), maintaining access, and optimizing profits

A Marketing

- Levemir® positioned as equivalent to Lantus, with additional benefits
- List price parity reinforces brand messaging
- With Toujeo in the market, do we want to be in a defensive position about price?

B Access

- Levemir® currently at net price discount (higher rebates) vs Lantus
- List price parity maintains current access
- [redacted] 2016 Commercial RFP's expected in April, so do we want to risk losing 2016 access?

C Profits

- AB15 2015 ARP baseline is $1.91B and is predicated on 9% April price increase *(value of increase is $6M-$7M per month; Levemir® daily sales tracking down $20M)*
- [redacted] Levemir® annual net sales are ~$160M and ~$286M respectively, but a hypothetical 10% volume loss could mean $45M downside in 2016

RISK: What will the competition do?

US market structure and dynamics

- ~20-25 min breakout session presentation followed by Q&A

Slide	Title	Key message
1	North American organisation has continued to expand with increased growth	Expanding commercial presence in the entire region through continued investments
2	Healthcare spending in the US continues to soar with increased pressure on the payers	Healthcare expenditure of GDP in the US continues to increase leading to increased pressure on payers, however spending on prescription medicines only remains a small share of total US healthcare spending (around 10% of total spend)
3	The US healthcare system involves multiple payers and intermediaries with complex interactions	The US healthcare system involves multiple payers and intermediaries with complex interactions
4	Medicaid, Medicare and Managed Care will continue to cover the bulk of the insured US population	Despite shifting macro and socioeconomic trends in insurance coverage, Medicaid, Medicare and Managed Care will continue to be the largest payer channels and biggest drivers of sales growth
5	Medicare and Managed Care accounts for ~75% of the insulin value market	Medicare and Managed Care continues to comprise the majority of insulin sales, hence why Novo Nordisk will continue to mainly invest and focus on these channels
6	Prescription and money flow in the US healthcare system	PBMs are a key intermediary and control centre in the flow of prescription medicines and a key link between health plans and the pharmaceutcial industry. PBMs either control national formularies on behalf of health plans or simply just adjudicate prescriptions
7	Not all health plans are alike	Novo Nordisk needs to build different relationships with different health plans given their differences in approach to cost control and interest in controlling formularies

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novo nordisk®

US market structure and dynamics

- ~20-25 min breakout session presentation followed by Q&A

Slide	Title	Key message
8	Contracting decisions is a balance between preserving quality and value vs. volume	Several factors always need to be considered in contracting. Different approaches to customer types, either: Protect (be aggressive in holding onto wins), Pick (prioritize open accounts based on size, share, and other factors), Concede (allow competition to keep their wins)
9	Multiple perspectives required to effectively engage the entire marketplace	Novo Nordisk actively engage with all payers, intermediaries, prescribers and patients through multiple sales force perspectives
10	Novo Nordisk maintains a competitive presence despite an increasingly competitive environment	As example of the sales force efforts Novo Nordisk's Share of Voice remains very competitive despite the increased competitive landscape
11	Focused promotional activities enforce continued strong commercial presence by Novo Nordisk	Another tactical example is DTC: strong Levemir and NovoLog performances is supported by the continued investments in sales force and other promotional activities
12	Formulary coverage is an integral, but not superseding part, of successfully operating in the US	Despite shifts in contracting dynamics, Novo Nordisk maintains good market access for all key products, reflected the continued solid performance
13	Despite increased scrutiny and pressure, the US pricing environment still remains favourable	Despite increased US rebates, payer scrutiny and pricing pressure net sales has continued to increase
14	The US diabetes market remains very attractive	Despite all the challenges with increasing healthcare spending, increased payer pressure and scrutiny the US diabetes care market will remain very attractive
15	Key opportunities and challenges impacting mid-term outlook in the US	Solidify diabetes market position, ensure obesity launch readiness, navigate payer and environment including, continue strong focus on compliance and advance relationship with FDA

CAPITAL MARKETS DAY 2013

novo nordisk

From: [redacted]
To: [redacted]
CC: [redacted]
Sent: 12/24/2015 3:05:27 PM
Subject: Re: Competitor List Price Increase - Modern NIAD (Trulicity)
Attachments: image001.png

Ho Ho Ho!!!

[redacted]
Sr Director Market Access - National Accounts

On Dec 24, 2015, at 9:39 AM, [redacted] PII wrote:

Nope, I actually started a drinking game- I have to take a shot for every response that says "what about Sanofi"

My poor liver…

From: [redacted]
Sent: Thursday, December 24, 2015 9:24 AM
To: [redacted]
Cc: [redacted]
Subject: RE: Competitor List Price Increase - Modern NIAD (Trulicity)

You getting tired of these yet?…maybe Sanofi will wait until tomorrow morning to announce their price increase…that's all I want for Christmas..

[redacted]

PII

From: [redacted]
Sent: Thursday, December 24, 2015 8:42 AM
To: GM_MarketAccess_StrategicPricing; NNI Diabetes Pricing; NNI Forecasting; NNI PCOR; NNI Trade; [redacted] SLS_Market Access Business Support Team; NNI SLS_Market Access SA Health Plans; NNI SLS_Market Access SA PBMs; NNI SLS_MarketAccessNationalAccounts; NNI SLS_MarketAccessRegionsEast; NNI SLS_MarketAccessRegionsWest; [redacted] NNI MM Team; NNI HEOR; IRofficer
Cc: [redacted]
Subject: Competitor List Price Increase - Modern NIAD (Trulicity)

Good Morning – the following list price increase became effective on **12/23/2015:**

Product Name	% Change
Trulicity	**+8.1%**

An updated Modern NIAD price comparison can be found below:

<image001.png>

[redacted]

[redacted]

Novo Nordisk Inc.
800 Scudders Mill Road
Plainsboro, NJ 08536
USA

PII

Emergent: Healthcare Reform, U.S. – State Initiatives

Risk description

The severity of the state legislative and policy threats significantly increased in 2017 and is expected to continue in 2018, with the political and policy debate evolving from drug pricing transparency to direct price controls. In 2018, we expect bills to include reporting and disclosure requirements, advance price increase notification requirements, and attempts at price controls. These issues will build upon the efforts in Nevada and California that were successful in 2017. There are now three states with reporting requirements: Vermont that introduced legislation to justify price hikes in 2016, Nevada is in the process of implementing a new diabetes-focused transparency bill, which does not protect all information as proprietary, and California where the transparency bill also includes advance price increase notification requirements. There is a risk of transparency measures and direct price controls adversely impacting NNI's operating model and profitability.

Mitigating actions

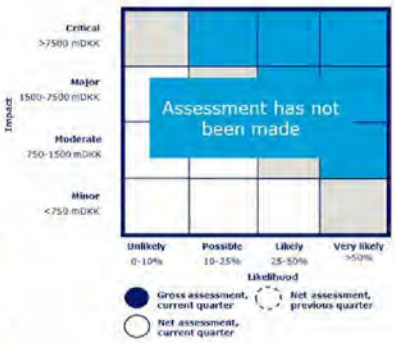
- Ongoing Public Affairs activities, including trying to shape the transparency bills to look like that of the Vermont bill.
- Significant advocacy efforts by PhRMA and BIO.

Next milestones

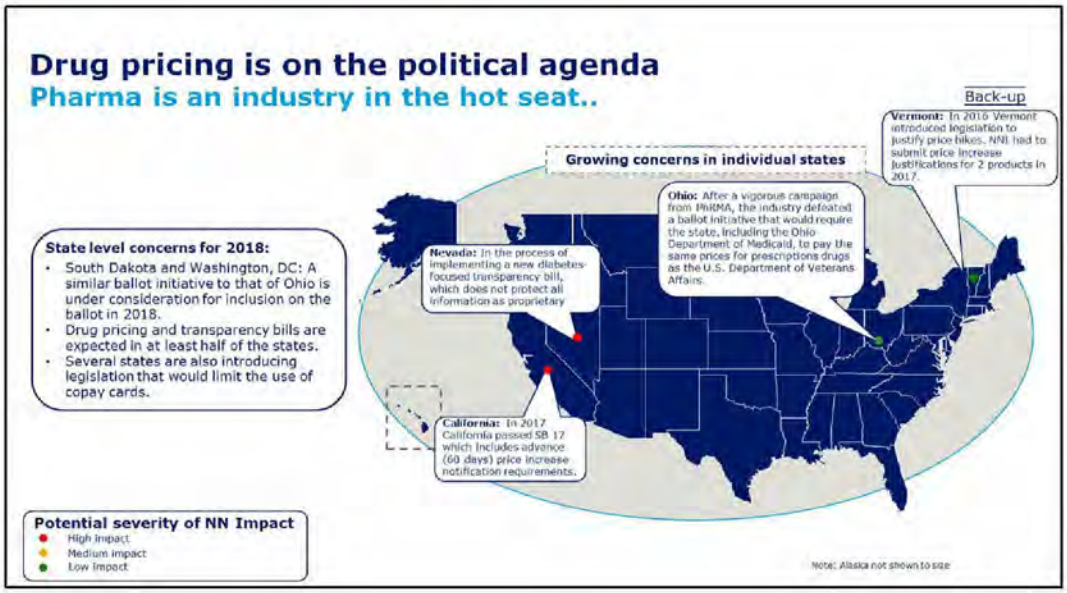
- A similar ballot initiative to the one defeated in Ohio is under consideration in South Dakota, and is possible in DC, for inclusion on the ballot in 2018. It would require the state, including the Department of Medicaid, to pay the same prices for prescriptions drugs as the U.S. Department of Veterans Affairs.

Update

- PhRMA has filed litigation against the Nevada and California legislation, but NNI is preparing to comply with the legislation if it moves forward. Further, after a vigorous campaign from PhRMA, the industry defeated a ballot initiative in Ohio that would require the state to pay the same prices for prescriptions drugs as the U.S. Department of Veterans Affairs.
- Two NNI products (Novolog and Novolog Flexpen) were selected for reporting requirements in Vermont, the report from the Attorney General is expected in January 2018.



RMB: The risk will be updated prior to the BoD submission.


Drug pricing is on the political agenda
Pharma is an industry in the hot seat..
Back-up
Growing concerns in individual states
State level concerns for 2018:
South Dakota and Washington, DC: A similar ballot initiative to that of Ohio is under consideration for inclusion on the ballot in 2018.
Drug pricing and transparency bills are expected in at least half of the states.
Several states are also introducing legislation that would limit the use of copay cards.
Vermont: In 2016 Vermont introduced legislation to justify price hikes. NNI had to submit price increase justifications for 2 products in 2017.
Ohio: After a vigorous campaign from PhRMA, the industry defeated a ballot initiative that would require the state, including the Ohio Department of Medicaid, to pay the same prices for prescriptions drugs as the U.S. Department of Veterans Affairs.
Nevada: In the process of implementing a new diabetes-focused transparency bill, which does not protect all information as proprietary
California: In 2017 California passed SB 17 which includes advance (60 days) price increase notification requirements.
Potential severity of NN Impact
High impact
Medium impact
Low impact
Note: Alaska not shown to size

Medicare Part D

Channel Update

October 2013

[redacted]

changing diabetes®

novo nordisk®

changing diabetes®

novo nordisk®

Why does Medicare Part D Matter?

- Medicare Part D accounts for about 30% of retail sales
- Part D is the most profitable market for the Novo Nordisk insulin portfolio
- Insulin volume for the Part D market is growing 3 times faster than the commercial market
- Almost **27% of people aged 65 or older have diabetes**, where as approximately 11% of people aged 20-64 have diabetes

changing diabetes

novo nordisk

From: [redacted]
To: [redacted]
Sent: 8/20/2014 12:49:54 PM
Subject: FW: Levemir realised price request

Concerning. Especially given the investment we make in Sales force. How can we better execute formulary pull-through? [redacted]

From: [redacted]
Sent: Tuesday, August 19, 2014 9:42 PM
To: [redacted]; [redacted]
Cc: [redacted]; [redacted]
Subject: RE: Levemir realised price request

Hi [redacted],

We had a chance to read through the broker report, which was pretty accurate when it came to price splits, etc., and then [redacted] and [redacted] connected and put together some facts together for you.

From the US perspective, price really did save the day overall because without price, Diabetes growth would have been -4% and total NNI -3%.

With **respect to the broker's comment around Levemir saving the day**, it was a significant contributor to our Q2.14 results compared to Q2.13, but volume growth of Levemir helped as well. If we were to exclude Levemir price, we would have seen NNI's total growth cut in half, to 6%. So in short, price really did save the day on our Q2 results and Levemir price contributed to half of our growth.

Here's a little more granular perspective on the Q2.14 vs Q2.13 growth is provided in the table below. Note that price has been a positive contributor whereas volume has been negative in some cases.

	Total Growth	Due to Price	Due to Volume	
Levemir®	56%	35%	21%	*Both price and volume aided brand growth, but you'll notice that price was a bigger contributor.*
NovoLog®	3%	15%	-12%	*Volume down, but offset by price*
Victoza®	15%	11%	4%	
Diabetes	13%	17%	-4%	*Overall diabetes volume was down, but price brought us back to growth*
Total NNI	12%	15%	-3%	*Total US volume was down, but again price brought us back to growth*

Regarding Levemir® realization (your questions in the below email), it's been shrinking over time. Despite taking price increases, we've had to enhance rebates, offer price protection, and pay for coverage gap, which has eroded what flows through to ARP. So, while price has helped with our performance, it's becoming a less effective lever. Levemir® realization over time:

- 61% 2012
- 57% 2013
- 53% 2014 (RE2 estimate)
- 50% 2015 (RE2 estimate)

Any other questions please don't hesitate to reach out.
[redacted]

From: [redacted]
Sent: Thursday, August 14, 2014 10:07 AM

To: [redacted]; [redacted]
Cc: [redacted]
Subject: Levemir realised price request

Hi [redacted], [redacted],
Below is an excerpt from a broker report on Q2.14 results (full broker report attached). As you can see Levemir price is noted to have "saved the day" with our results.

Can I get an understanding of how much of the increase is realized – (1) in 2013 total price increase vs total realized, (2) most recent increase and (3) forecasted in the future, vis-à-vis impact of price protection.

Thanks,
[redacted]

The premium end of the market is still the target – US price is the driver
For all the talk of the diabetes epidemic, 2Q showed again how dependent Novo is on US price increases. Levemir's US price rises led it to beat consensus by 7%, and Levemir US price alone contributed half of Novo's 10% operating profit growth in 2Q.

Different views on the US pricing outlook
Novo's US cost base has already been tightly reined in, in response to the top-line hit from losing ESI (payer) coverage in the US. Kare Schulz, COO, had a more bullish outlook: net pricing growth should continue: yes, rebates are increasing sharply, but so are list prices. Novo are confident in the insulin market's status quo remaining till 2016 (only 3 significant players), and we agree. We still remain concerned over potentially dramatic shifts in basal insulin (pricing) in 2016, once Lilly's glargine launches.

[redacted]
Novo Nordisk Inc.
800 Scudders Mill Road
Plainsboro, NJ 08536
USA
PII

2018 Key Accomplishments for Public Affairs

Stakeholder Engagement

- Partnered with ADA and AHA to launch a public awareness campaign on the link between diabetes and CVD
- Through the Diabetes Advocacy Alliance, worked to allow for Medicare coverage of Continuous Glucose Monitors (CGM) linked to smart devices, and to introduce Diabetic Self-Management Training (DSMT) legislation
- Worked collaboratively with Sales and Market Access to support WVU in development of the state's first Diabetes Action Plan (DAP), and engaged in IL and NJ to improve the quality of their upcoming DAPs
- Secured sustainability of Cities Changing Diabetes for 3 of 5 projects in Houston, continued interest of additional cities coming onboard

Direct Government Business Implications

- Actively engaged with PhRMA to make changes to Part D donut hole provision in BBA, helped secure signatures of 204 Members (50% of the House) for a letter expressing support for making changes to Medicare Part D
- Submitted NNI comments and helped shape PhRMA comments to the Administration's drug pricing proposal
- Continued engagement with ADA, AMA, JDRF, Endocrine Society on drug pricing, including balanced release of ADA's white paper with policy recommendations
- Worked with industry partners to defeat price transparency legislation: over 40 bills introduced in 22 states failed to pass and provided mitigating language in enacted bills in CT*, ME, NH, and OR.
- Prevented adverse pricing related recommendations in the SC DAP
- After successful advocacy with VT Attorney General, shaped new process for drafting VT state transparency report to focus on net, rather than list price

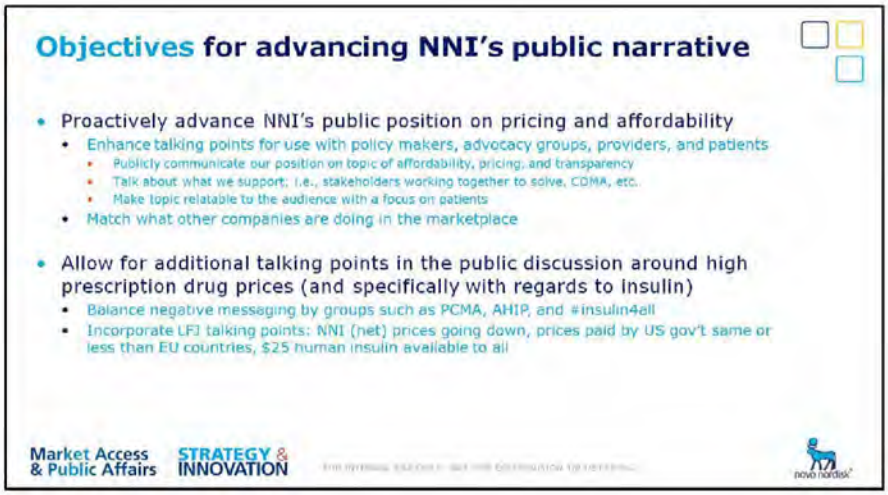
Non-Responsive


customer focused
model
novo nordisk


Top two questions we always hear from you
We are always looking to improve our approach and welcome your feedback
QUESTION
ANSWER
1. Why do we keep raising list prices?
• Management expects 10%+ YoY growth
• Payer negotiations focused on net price
• Non-contracted volume optimization
2. Why can't we go after more accounts?
• Sanofi and Lilly able and willing to fight back
• Volume upside at much lower margins
• Price war = steep price erosion

PPT represents work by the Pricing Workgroup…cross functional team across multiple functions (Finance, Legal, CE, MAPA, Communications).

NNI 10



From: LFJ (Lars Fruergaard Jørgensen)
To: [redacted]
Sent: 5/8/2017 1:22:58 PM
Subject: RE: Novo Nordisk (Buy, DKK 320): Lilly raises US list prices by ~8% across its injectable diabetes drugs portfolio (Trulicity, Humalog, Humulin)

Thanks – let's discuss on our call Thursday.

Lars

PS: Have just send a welcome note to [redacted]

From: [redacted]
Sent: 8. maj 2017 13:54
To: LFJ (Lars Fruergaard Jørgensen)
Subject: RE: Novo Nordisk (Buy, DKK 320): Lilly raises US list prices by ~8% across its injectable diabetes drugs portfolio (Trulicity, Humalog, Humulin)

Lars,

LLY followed our increase on NOVOLOG®, so we're at parity here, so no action from us. They led with Trulicity® and based on our strategy, we will follow which will likely be on June or July 1st (PC to approve). Our budget timing was September prior to Non-Responsive launch (again based on strategy).

Does that help?

[redacted]

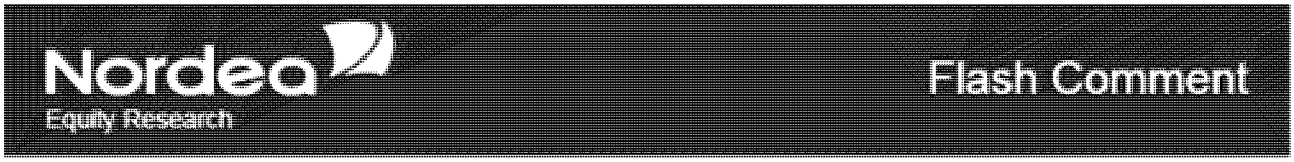
From: LFJ (Lars Fruergaard Jørgensen)
Sent: Monday, May 08, 2017 1:53 AM
To: [redacted]
Subject: FW: Novo Nordisk (Buy, DKK 320): Lilly raises US list prices by ~8% across its injectable diabetes drugs portfolio (Trulicity, Humalog, Humulin)

[redacted]

What is our price increase strategy?

Thanks
Lars

From: PII
Sent: 8. maj 2017 07:50
Subject: Novo Nordisk (Buy, DKK 320): Lilly raises US list prices by ~8% across its injectable diabetes drugs portfolio (Trulicity, Humalog, Humulin)



8 May 2017

Novo Nordisk (Buy, DKK 320): Lilly raises US list prices by ~8% across its injectable diabetes drugs portfolio (Trulicity, Humalog, Humulin)

According to pricing data from First Data Bank and Bloomberg Industries (Symphony), Lilly has taken broad-based list price hikes (around 8%) by early May across its portfolio of injectable diabetes drugs in the US. Normally, competitors follow suit with list price hikes, but we have not noted the same price hikes across Novo's portfolio yet.

Trulicity (GLP1):

As of 2 May, Lilly raised the price/wholesale acquisition cost for a unit of 1.5mg/0.5 auto or pen injector of Trulicity by 8% to USD 338 from USD 313. We have already described this price hike in our post Q1 note on Novo Nordisk last Friday.

Humalog (fast-acting insulin analogue):

As of 2 May, Lilly raised the price/wholesale acquisition cost for packages of 100/ml insulin pens of Humalog rose by 7.8% to USD 35.36 from USD 32.80. We have not earlier commented on this insulin price hike.

Humulin (human insulin):

As of 2 May, Lilly raised the price/wholesale acquisition cost for packages of 500/ml injectable vials of Humulin by 7.8% to USD 74.35 from USD 68.95. We have not earlier commented on this insulin price hike.

Full year results and estimates

DKKm	2016	2017E	2018E	2019E
Total revenue	111,780	115,847	121,497	128,681
EBITDA	51,624	53,487	56,358	60,911
- margin	46.2%	46.2%	46.4%	47.3%
EBIT (adj.)	48,432	50,299	52,859	56,086
- margin	43.3%	43.4%	43.5%	43.6%
Pre-tax profit	47,798	48,542	53,002	56,229
Net profit from cont oper	37,925	37,911	41,713	44,590
Shareholders' equity	45,269	48,591	52,745	57,494
Net debt	-18,411	-15,623	-15,033	-14,398
Net gearing	-41%	-32%	-29%	-25%
Net debt/EBITDA	-0.4	-0.3	-0.3	-0.2
Free cash flow before A&D	41,348	32,186	38,938	39,176
No. of shares (m)	2,511	2,444	2,372	2,303

Source: Company data and Nordea Markets

Per share data and multiples

DKK	2016	2017E	2018E	2019E
EPS (adj.)	15.10	15.51	17.59	19.36
- growth	11%	3%	13%	10%
DPS	7.55	7.76	8.79	9.68
BVPS	18.0	19.9	22.2	25.0
P/E (adj.)	16.9	14.9	13.2	12.0
EV/Sales	6.6	4.8	4.4	4.0
EV/EBITDA	12.0	10.3	9.5	8.5
EV/EBIT	12.8	10.9	10.1	9.3
P/BV	14.1	11.8	10.4	9.3
Div. Yield	3.0%	3.3%	3.8%	4.2%
FCF Yield	6.3%	5.7%	6.7%	7.3%
ROE after tax	82.2%	80.8%	82.3%	80.9%
ROIC after tax	111.0%	108.6%	99.2%	93.8%

Source: Company data and Nordea Markets

Completion date: 08 May 2017, 07:49CET

[redacted]

PII

Web: nordeamarkets.com

LIST PRICE Framework, Optimization, & AB16 Planning

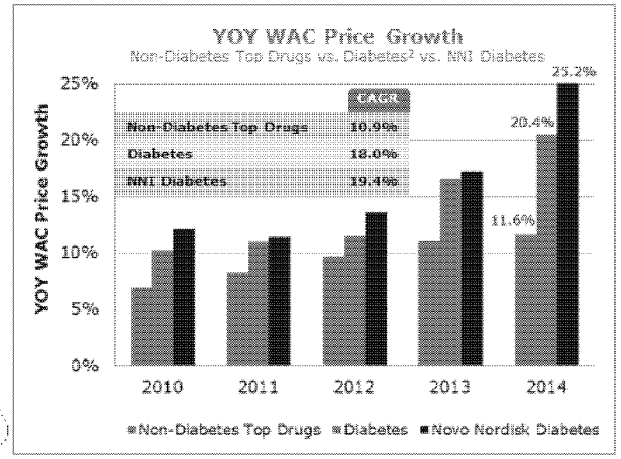
Pricing Committee

June 29, 2015

STRATEGIC PRICING | SP

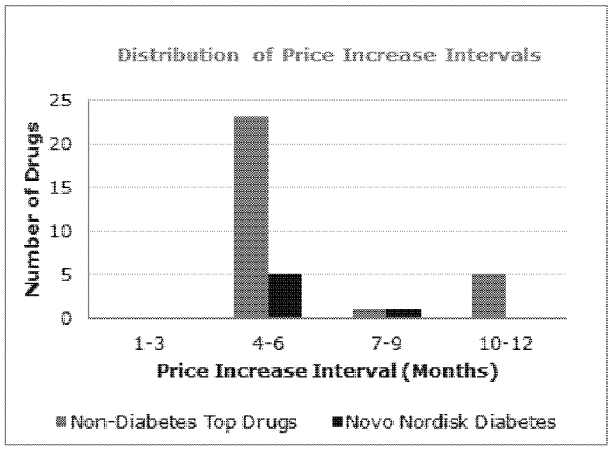
2 Pricing Landscape: Industry Benchmarks

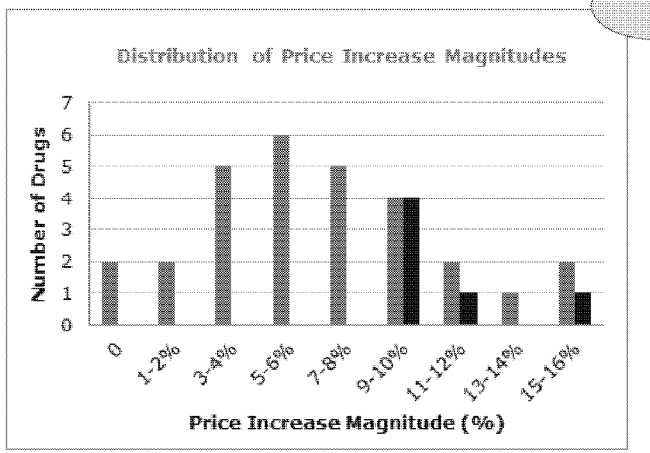
Illustrative Examples



	Criteria	
	Magnitude within industry norms?	Frequency within industry norms?
Option 1	●	●
Option 2	●	●

If data is available, other possible benchmarks:
- Medical cost inflation
- Insurance premium growth
- CPIU





Note: Prior to taking any price increase, Novo Nordisk undertakes a review of all factors relevant to the price increase to ensure that the increase remains consistent with brand pricing strategy

Price Increase – Risk Assessment – Apr 2016
Lyrica

Attribute	Risk Level Assessment
Brand Strategy	• Price increase aligned with key brand strategy to maximize Net Sales in years prior to LOE
Payer Mix	• ~80% of volume is Comm/Medicare. Very little in Cash channel so minimal impact to Patient. • Plans that have enough control to meaningfully manage utilization have already restricted LYR • Top PBM's are heavily reliant on rebate revenue and unlikely to move against LYR • Top Insurers that don't already restrict LYR are unlikely to restrict LYR moving forward as they have been historically unable to substantially reduce LYR utilization via restrictions. As a result, they are also unlikely to forego rebates.
Brand Price and Market Share / Competition	• Significant price protection in Medicare channel will reduce GTN in out years if current price increase trend is maintained • Since significant portion of gross sales is unrebated, price increases will offset impact of price protection among top accounts in Commercial and Medicare
Stakeholder Impact	• Past price increases have not prompted any major shift in how Payers cover LYR • Contracts w/ most major payers have been agreed upon through LOE but are subject to change • Main risk is poor optics related to drug price increase given election year dynamics, etc.
Overall	**Low – Limited risk that payers will move against LYR due to continuation of current price increase trend. Payers are either reliant on LYR rebate revenue, or they are not confident that they can sufficiently impact utilization through restriction. Potential risk of poor external optics associated with pharma drug prices increases on mature products.**

Risk Levels: Low Medium High

ILLUSTRATIVE

Pfizer GLOBAL HEALTH & VALUE

Price Increase - Risk Assessment - Apr 2017
Lyrica

Attribute	Risk Level Assessment
Brand Strategy	• Price increase aligned with key brand strategy to maximize Net Sales in years prior to LOE
Payer Mix	• ~80% of volume is Comm/Medicare. Very little in Cash channel so minimal impact to Patient. • Plans that have enough control to meaningfully manage utilization have already restricted LYR • Top PBM's are heavily reliant on rebate revenue and unlikely to move against LYR • Top Insurers that don't already restrict LYR are unlikely to restrict LYR moving forward as they have been historically unable to substantially reduce LYR utilization via restrictions. As a result, they are also unlikely to forego rebates.
Brand Price and Market Share / Competition	• Significant price protection in Medicare channel will reduce GTN in out years if current price increase trend is maintained • Since significant portion of gross sales is unrebated, price increases will offset impact of price protection among top accounts in Commercial and Medicare
Stakeholder Impact	• Past price increases have not prompted any major shift in how Payers cover LYR • Contracts w/ most major payers have been agreed upon through LOE but are subject to change • Main risk is poor optics related to drug price increase given political environment, etc.
Overall	**Medium - Limited risk that payers will move against LYR due to continuation of current price increase trend. Payers are either reliant on LYR rebate revenue, or they are not confident that they can sufficiently impact utilization through restriction. Potential risk of poor external optics associated with pharma drug prices increases on mature products.**

Risk Levels: Low Medium High

ILLUSTRATIVE

- CONFIDENTIAL -

Lyrica CR Pricing Recommendation

May 2017

Pfizer Innovative Health

Pfizer Internal Medicine

The closer that Lyrica CR launches to IR LOE, the more likely payers will expect higher rebates and/or limit the ability to achieve preferred access

Recommendation	Launch Lyrica CR leaving as much time prior to IR's LOE minimizing payer's perception of a lifecycle/LOE strategy and leverage for increased rebating

Rationale

- Payers state that similar rebate levels that are currently provided to Lyrica IR (about 5-10% for most preferred plans) could result in comparable access for Lyrica CR based on a launch timing of 18 months prior to Lyrica IR LOE
- However, payers may require more aggressive rebates because of impending IR LOE, but Pfizer should not exceed a 5% net price discount for Lyrica IR to maximize the Lyrica portfolio
- Distancing Lyrica CR from a LOE strategy, minimizes payer leverage for greater rebates to preferred access
- The closer the Lyrica CR launch is to Lyrica IR LOE, the more payers are likely to see CR as a LOE strategy and likely to push for higher rebates for preferred access

A parity net price for Lyrica CR will optimize revenue for the Lyrica franchise over time (pre-IR LOE and post-IR LOE)

Recommendation	Launch Lyrica CR at $14.50/day WAC and provide similar levels of rebates that are currently provided to plans for Lyrica IR

Rationale

- $14.50/day WAC is a parity price to Lyrica IR based on DACON assuming semi-annual price increases of 9.44% per year up through 2017 and accounts for 20% of patients who would require 2 doses of Lyrica CR/day
- Pricing at a premium to Lyrica IR will result in broad non-preferred access with a step which will reduce volume, and sub-optimize revenue
- Pricing at a discount to Lyrica IR does not result in significant preferred access or an increase in volume, and so sub-optimizes revenue
- Following Lyrica IR LOE, many plans will move Lyrica CR to a non-preferred tier with a step through generic agent (which now includes Lyrica IR)
- Plan on providing similar rebate levels that are currently provided to Lyrica IR (about 5-10% for most preferred plans) **with a cap at 15% (to minimize the revenue impact of Lyrica IR pre-LOE) as some plans may negotiate slightly higher rebates compared to existing contracts**.

Note: Assumes 9.44% price increases in 6/2016, 1/2017, 6/2017

WINDROSE

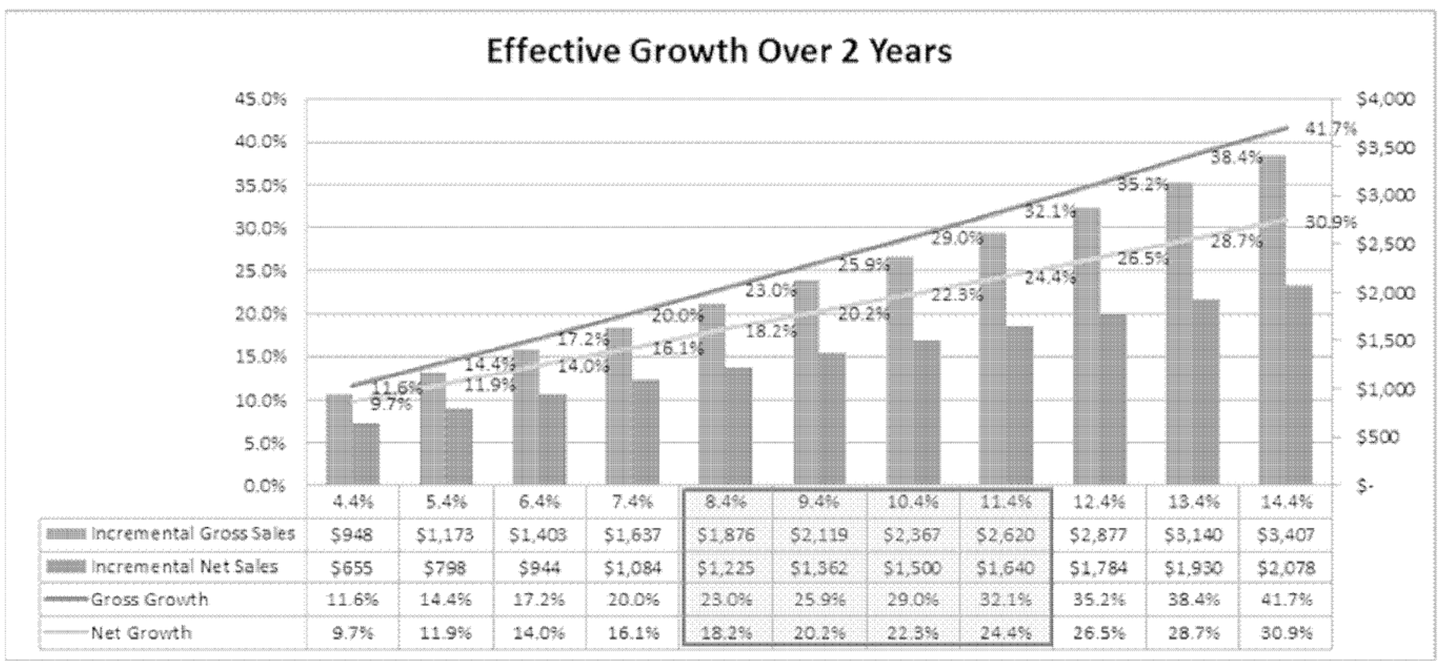
From: [redacted]
Sent: Wednesday, July 06, 2016 9:13 PM
To: [redacted]
Cc: [redacted]
Subject: RE: Pricing Scenarios

Follow Up Flag: Follow up
Flag Status: Flagged

[redacted]

We have run some scenarios that didn't make into the last version of the deck and I think this might help with the scenarios you are looking for. Please see highlighted area below, we ran scenarios with 1% increments (twice a year) and compared them to no price increase scenarios. In short, **every 1% incremental price increase (twice a year) provides roughly 140M additional Net Sales over 2 years with all segments except Medicaid and Military.** Medicaid and Military are 100% price protected. Feel free to let me know if you want me to take you through this.
The 10.44% twice a year scenario is very close to option 1, the 11.44% twice a year scenario is very close to Option 2, and the 8.44% twice a year scenario is very close to Option 3.
Please note that these scenarios assume [redacted] commercial contracted with no price protection. We are currently updating the analysis with the two [redacted] views that [redacted] outlined as well as the [redacted] sensitivities, please let us know what are the options/scenarios you want for the final presentation.

Thanks,
[redacted]



	4.4%	5.4%	6.4%	7.4%	8.4%	9.4%	10.4%	11.4%	12.4%	13.4%	14.4%
Incremental Gross Sales	$948	$1,173	$1,403	$1,637	$1,876	$2,119	$2,367	$2,620	$2,877	$3,140	$3,407
Incremental Net Sales	$655	$798	$944	$1,084	$1,225	$1,362	$1,500	$1,640	$1,784	$1,930	$2,078
Gross Growth	11.6%	14.4%	17.2%	20.0%	23.0%	25.9%	29.0%	32.1%	35.2%	38.4%	41.7%
Net Growth	9.7%	11.9%	14.0%	16.1%	18.2%	20.2%	22.3%	24.4%	26.5%	28.7%	30.9%

From: [redacted]
To:
Sent: 8/26/2016 6:14:33 PM
Subject: RE: Lyrica - $78M

Hi [redacted]

I like the pricing option to be honest as ~4% is too aggressive for a brand in its last year of promotion. We will discuss these options with [redacted] next week and come back to the team with a plan.

Thanks and have a great weekend.

[redacted]

From: [redacted]
Sent: Friday, August 26, 2016 1:28 PM
To: [redacted]
Subject: Lyrica - $78M

Hi [redacted] and [redacted]

For Lyrica to deliver +$78M vs. my submission yesterday, TRx growth in 2018 would have to be 3.75%.

One other (and possibly preferred) option to close that gap would be to increase price in 2018. Remember that we are all only assuming a 6% increase in 2018.

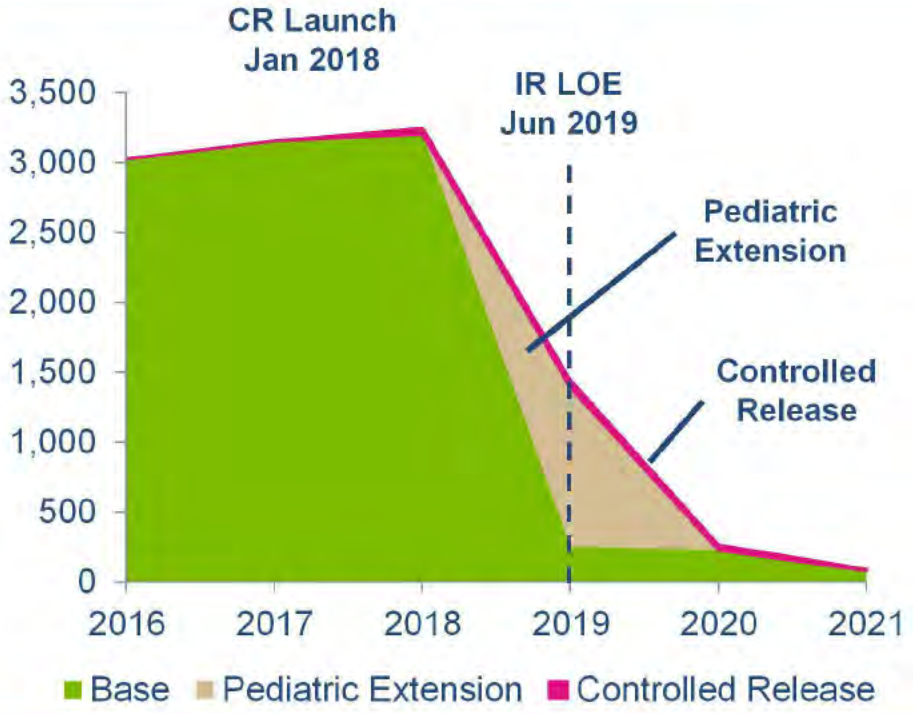
[redacted]@pfizer.com
PI

CR Expected to Deliver Modest Incremental Volume With or Without FM Indication

Pfizer Internal Medicine

Goal: Launch CR to Maximize LYRICA Franchise Value in US Through IR LOE

US Revenue $M (2017 LRF)



Key Assumptions

- **Launch:** Jan 2018, 18 months pre-IR LOE
- **IR LOE:** June 2019
- **CR LOE:** June 2021
- **Price:** Parity to IR (per day)

	Peak Revenue ($M, 2019, non-risk adj.)	Peak Revenue ($M, 2019, risk adj.)	PTRS	eNPV ($M)
2017 - Current LRF	$63M	$53M	~85% *(50% FM and 90% DPN/PHN)*	$30M

PATIENTS FIRST

* Incremental are additional Rxs from existing patients and new volume from new users

Non Responsive Information

At this point in our Lifecycle, we have no new data so CR affords us the opportunity to drive renewed interest in the franchise and offer patients a more convenient proposition with once daily dosing. To HCPs the CR proposition is simple and they see the value of an extended release product. Access will be a challenge with higher tiering vs. IR but that is reflected in our forecast.

We are anticipating a January 2018 launch – 18 months prior to IR LOE with the additional six months of exclusivity if we are granted the pediatric extension. CR will have 3 years of exclusivity, specific to this formulation plus an additional six months if IR receives the pediatric extension.

LYRICA Operating Plan

August 7, 2018

Pfizer Innovative Health

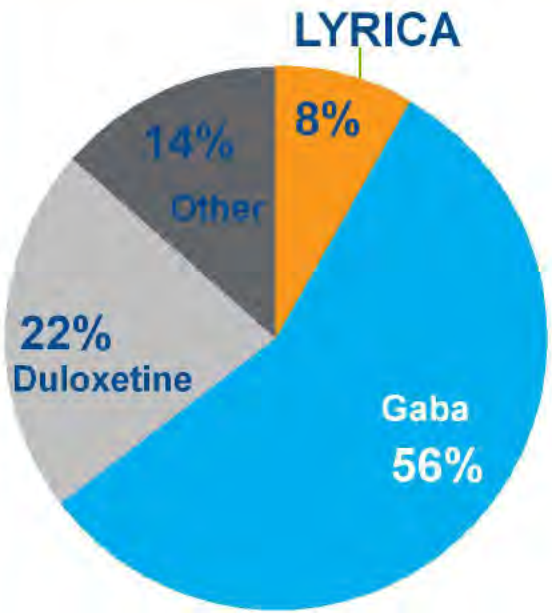
Pfizer Internal Medicine

With Generics Continuing to Dominate LYRICA's Market, Field Force Levers Are Essential and Effective at Driving LYRICA Rx

IM PROUD

Genercized Market Highlights Continued Need for LYRICA Differentiation

Current LYR Market Share



LYRICA Still Wins on Efficacy vs. Key Generic Competitors

HCP Perception by Attribute

LYR significantly better than Gaba

Gaba significantly better than LYR

Provides meaningful DPN pain relief	52%
Relieves pain to help patients feel better	46%
Effective relief for moderate-severe DPN patients	50%
Improves overall FM patient functioning	39%
Favorable combo of efficacy and formulary access	28%

Field Force Tactics Remain Critical to Driving LYRICA Rx

LYR Detailing ROIs*

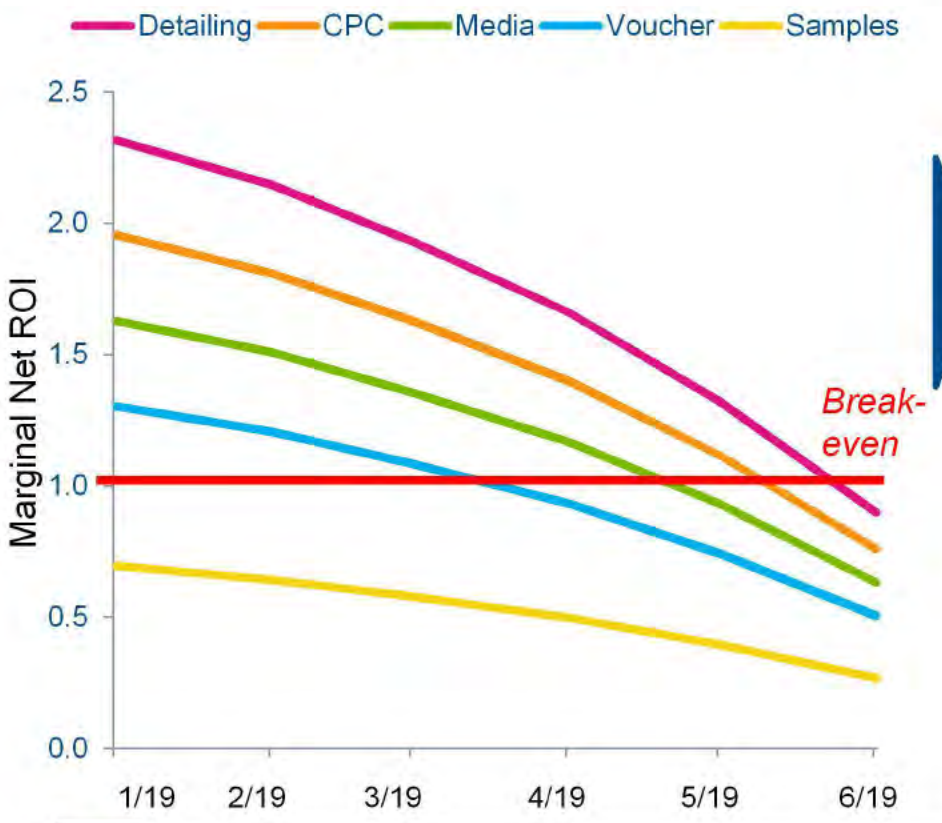
*Gross ROIs, reflect full 3 year payoff

Detailing Remains Strongest HCP Promotional Lever – Messaging and Tactics Will Evolve to Meet Needs through 2019

IM PROUD

Marginal ROIs Demonstrate Impact of Key Levers Approaching LOE and Drive Investment

LYRICA HCP Net Profitability Analysis



Details Anchor with Most Impactful Messages Across FM/DPN Treatment Considerations…

1. Infuse efficiency into Winning Formula detail
2. Own LYRICA opportunities throughout FM/DPN treatment continuum
3. Leverage and maximize relationships in HCP offices to set Pfizer up for the future

…While Surround Sound Tactics Support Details and Prepare Post-LOE Promotion

$4 Copay Card

Vouchers & Samples

HCP Targeting

Post-LOE

MCM

Lyrica LOE Workshop

Pre-Reads for Workshop on 17 May 2018

Pfizer Innovative Health

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Pfizer Internal Medicine

LOE HCP Strategic Questions

Pfizer
Internal Medicine

Strategic Questions for Op Plan

	1H 2019	2H 2019
HCP Objective	• Continue driving overall Lyrica prescribing • Maximize new patient starts on LOE CPC	• Drive prescribing of branded Lyrica via DAW
Messaging	• CPC / LOE claims	• Continued LOE claims
Targeting	• Allocate more details to "Protect/Maintain" vs. "Grow" • Add Loyalists to UVP and MCM	• Prioritize MCM on Loyalists
FF Execution	• Dec POA direction through June	• *Some FF if detailing CR** • *Sampling** • *Customer care representatives**

* Still under evaluation

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Stakeholder LOE Insights Summary

Pfizer
Internal Medicine

Consumer

- Because consumers defer to their HCP on treatment, knowledge of pending LOE will not motivate Lyrica users (or non-users) to alter their behavior, either pre or post LOE
  - However, Lyrica users assume they would continue receiving branded Lyrica post-LOE unless notified otherwise
- Most consumers would stick with the gx if switched, but a small subset would pay more for branded Lyrica
- A co-pay card would encourage Lyrica users to look into remaining on the brand (despite a negative reaction to the term "eligible"), but would not motivate non-Lyrica users to ask for a change in medication
  - Other programs aside from cost savings do not provide sufficient motivation to staying on brand

Lyrica Controlled Release (CR)

pregabalin Extended Release Tablets

On-Boarding Session

May 16, 2016

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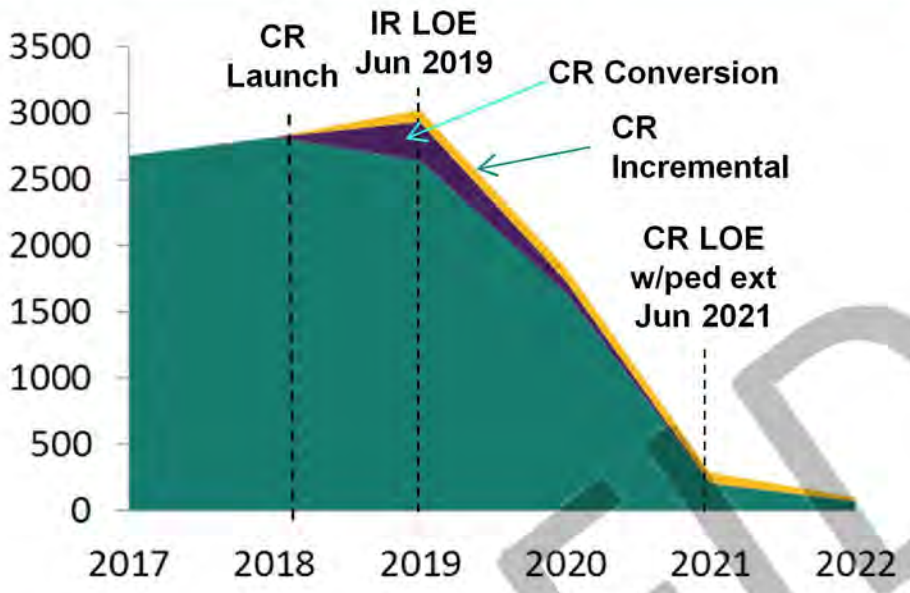
Any claims are dependent on adequate substantial evidence from clinical trials.

Strategies contained in this document are subject to regulatory and legal review and approval before implementation.

CR Is Expected To Deliver Modest Incremental Value with Low Risk

Revenue $M



Key Assumptions

- **Launch**: Jan 2018, 18 months pre-IR LOE
- **IR LOE**: June 2019
- **CR LOE**: June 2021
- **Price**: parity to IR (per day)
- **IR-CR Conversion rate**: 10% peak rate (BOP range: 3% - 25%)
- **Incremental* CR growth**: 3%
- **Erosion post IR LOE**: 66% retained year 1 (based on adjusted CR/ER analog erosion rate analysis)
- **Erosion Post CR LOE**: 24% year 1 retention (PFE standard)

Peak Revenue ($M, 2019, non-risk adj.)	Peak Revenue ($M, 2019, risk adj.)	PTRS	eNPV ($M)
$98M	$88M	90%	$109M

*Incremental are additional Rxs from existing patients and new volume from new users

So when we turn to the forecast, we do not see the huge numbers that we would like to see or potentially anticipate given the size of the IR business, yet we still see modest incremental value with low risk, now that the program is nearly complete, and we want to go get that value. The peak revenues in 2019, risk adjusted or non-risk-adjusted are slightly shy of $100M and the eNPV is $109M. And these are the revenues submitted in this year's op plan after a reassessment by a cross-functional team this spring/summer. What comprises this forecast if you look at the graph is a portion of IR business that we convert to CR (the purple) and the incremental business (the yellow) that we gain directly by having the CR offering (the incremental includes either more Rxs/refills from IR patients who convert (more than they would have refilled on IR) and new volume from completely new-to-LYRICA users). And then we hold on to some of that total volume post IR's LOE.

So looking at the key assumptions, the strategy calls for launching CR in Jan 2018, 18 months pre-IR LOE which we see as that sweet spot mentioned earlier to support conversion but also have some CR exclusivity post IR LOE; for both IR and CR, we assume the exclusivity periods incl the 6 month ped extension which places CR LOE in June 2021. The IR to CR conversion rate in the forecast is 10% at peak and the incremental growth is 3% of IR. These were derived by adjusting past volumetric forecasting work to account for updates to the assessment of key influencers of volume since that time (and we will review these shortly). And while CR has will have exclusivity post IR LOE, there will still be erosion of CR at IR's LOE given anticipated payer action (so in year 1 post IR-LOE we have removed approximate a third of the CR volume; and finally at CR LOE we have applied standard erosion rates.

North America Internal Medicine

Operating Plan 2017

27th September 2016

Pfizer Innovative Health

Pfizer Internal Medicine

Pfizer
Internal Medicine

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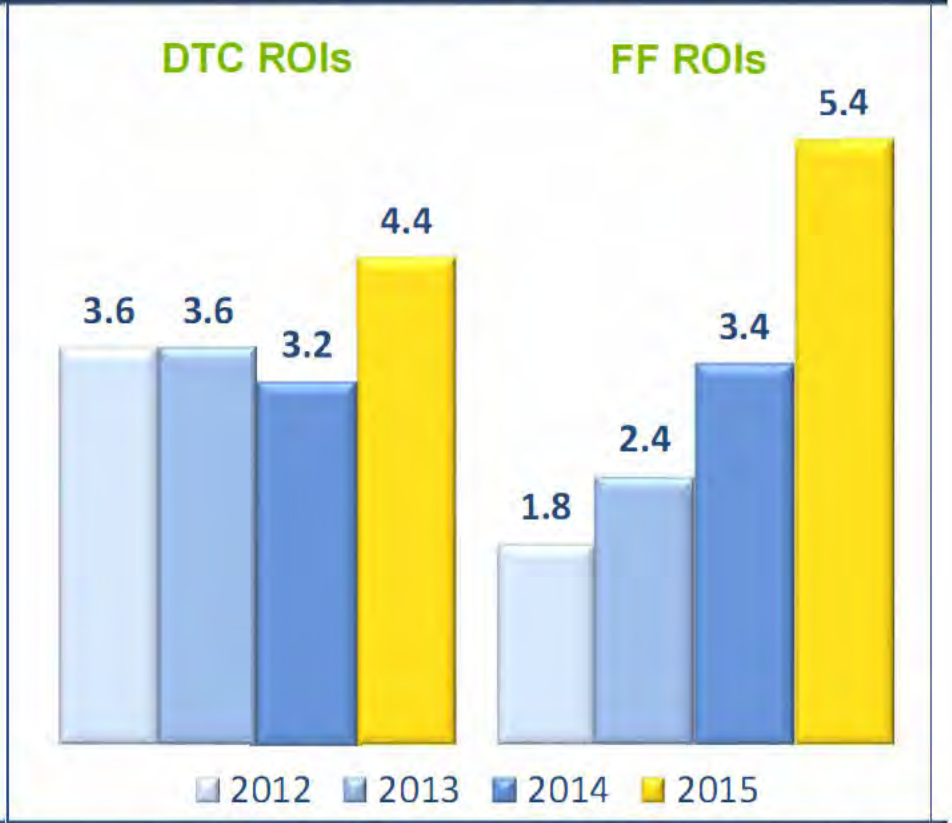
Primary Drivers of DTC and Field Force Delivering Strong and Improving ROIs

Pfizer
Internal Medicine

Both DTC and FF ROIs Surpassed Aspirational Goal of 4:1



Lyrica Detail Impact Grew 29% In 2015

Sales Force Driving 4.8% YoY Growth Among Detailed HCPs

In Absence of Sales Force, Lyrica Volume Declines In 90% Generic Market

Lyrica Business Review

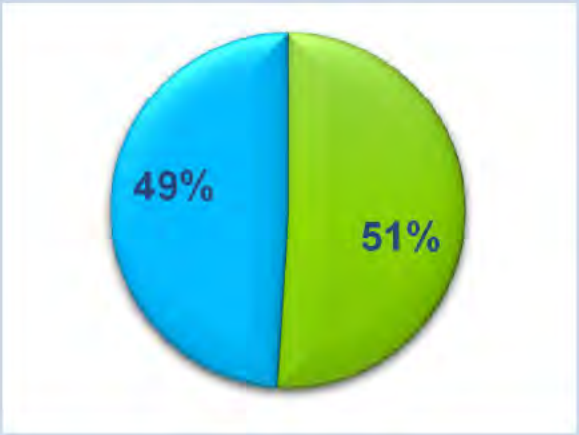
February 13, 2017

Pfizer Innovative Health

Pfizer Internal Medicine

Lyrica – Maximizing the Value, Unlocking the Power

Pfizer Internal Medicine



Lyrica Represents Close To Half of IM Revenue

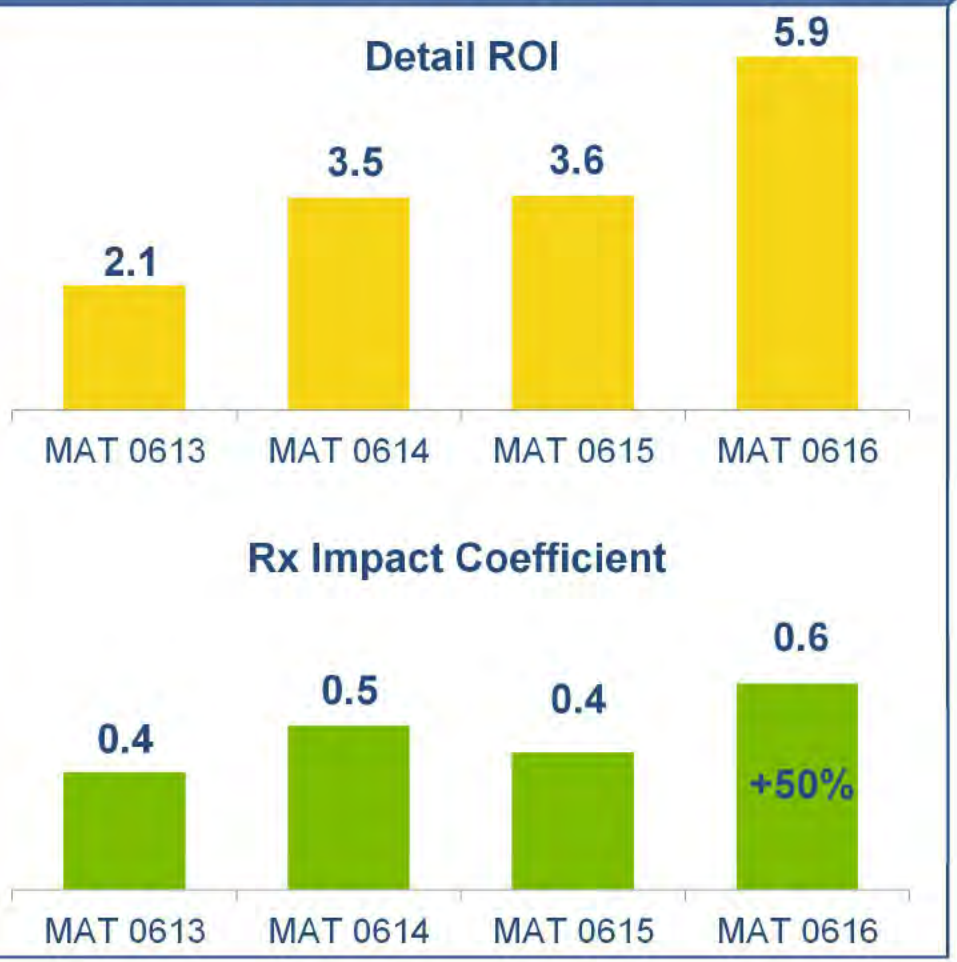
Solid Strategy and Execution Continue to Drive Results

Opportunity Exists to Maximize the Asset prior to LOE

Primary Drivers Of Growth Delivering Strong Performance

Pfizer
Internal Medicine

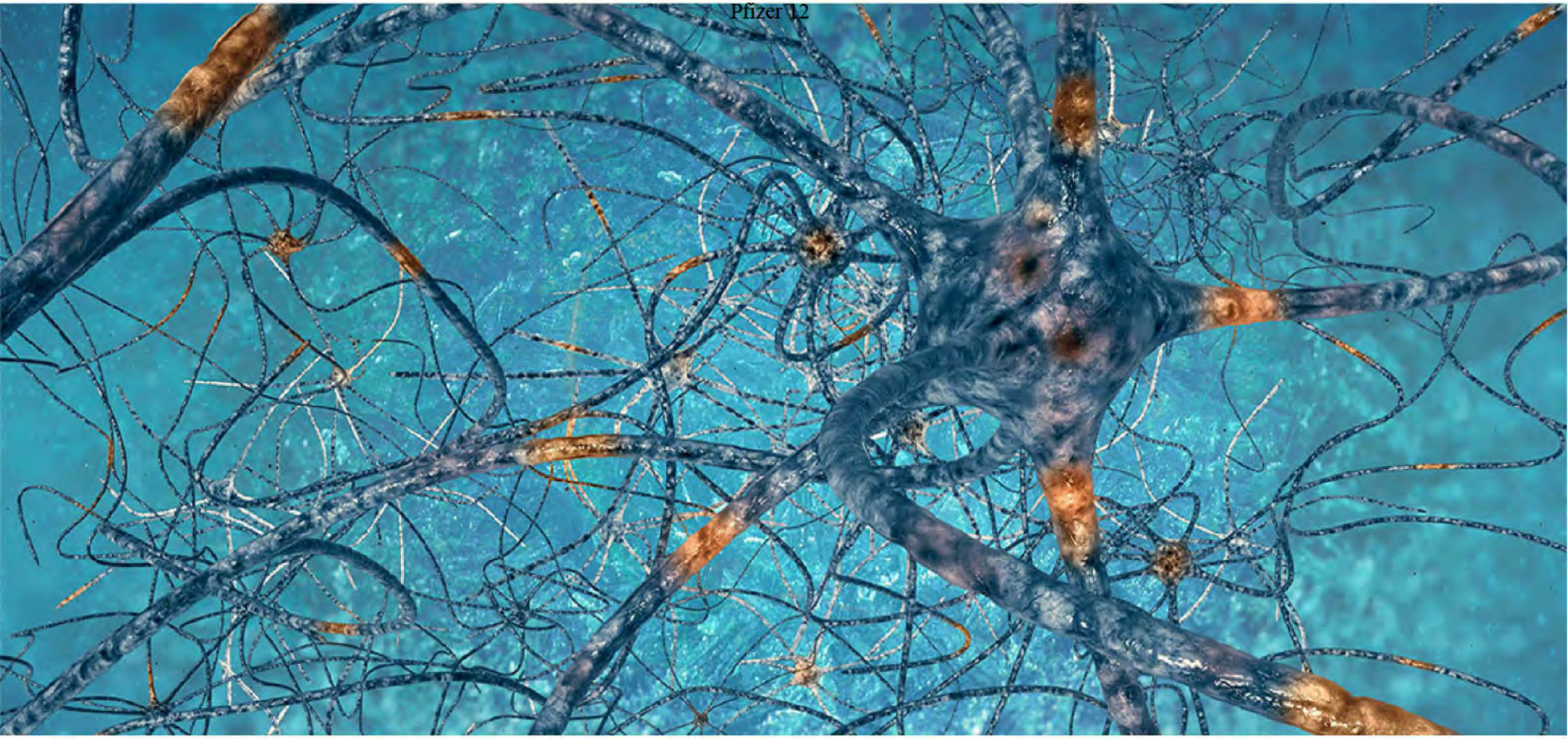
Sales Force ROIs and Detail Impact Continue To Grow



As Are TV ROIs and GRP Impact, Even w/ Significant Media Spend

Aspirational Goals Exceeded for Both Sales Force Details and DTC

*Assumes FY'15 TV media excluding CHE



LYRICA 2018 Op Plan

August 8, 2017

Pfizer
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Health

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Internal Medicine

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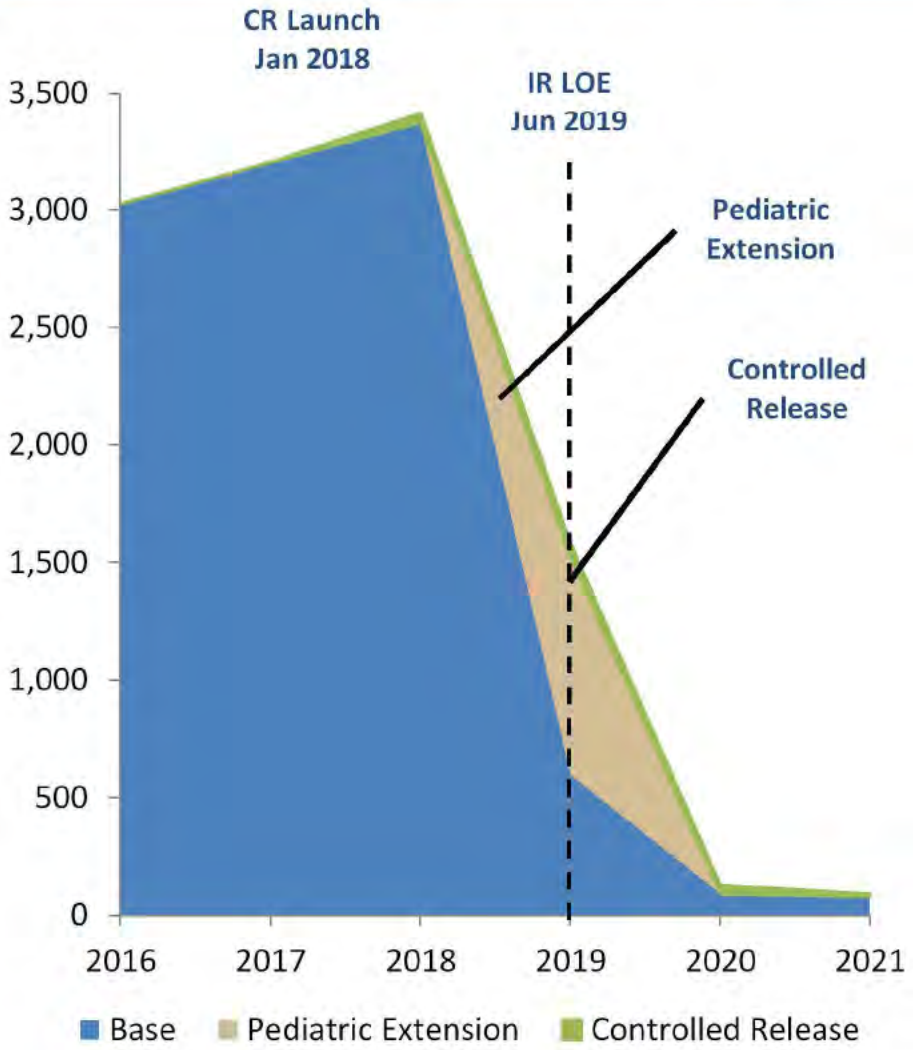
Two-Year Window Exists to Maximize Value of LYRICA

Pfizer Internal Medicine

US Revenue $M (2016 LRF with New CR)



Controlled Release Formulation

Launch On Track for December '17 Managers' Mtg

- CR Value Totals $184M, and has 3 years exclusivity
- Payer Coverage Likely To Be <15% UR

Pediatric Program

Pediatric Program Success Results In ~$1.6B

- Subject enrollment significantly behind schedule
- Regulatory team has identified multiple strategies to reduce submission times

Lifecycle Planning

Evaluation of Best Practices Underway

- Multisource generics at LOE date

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* Adjusted assuming Phase 3 success 100%, PRS 90% – consistent with current Scenario valuations
** Incremental are additional Rxs from existing patients and new volume from new users

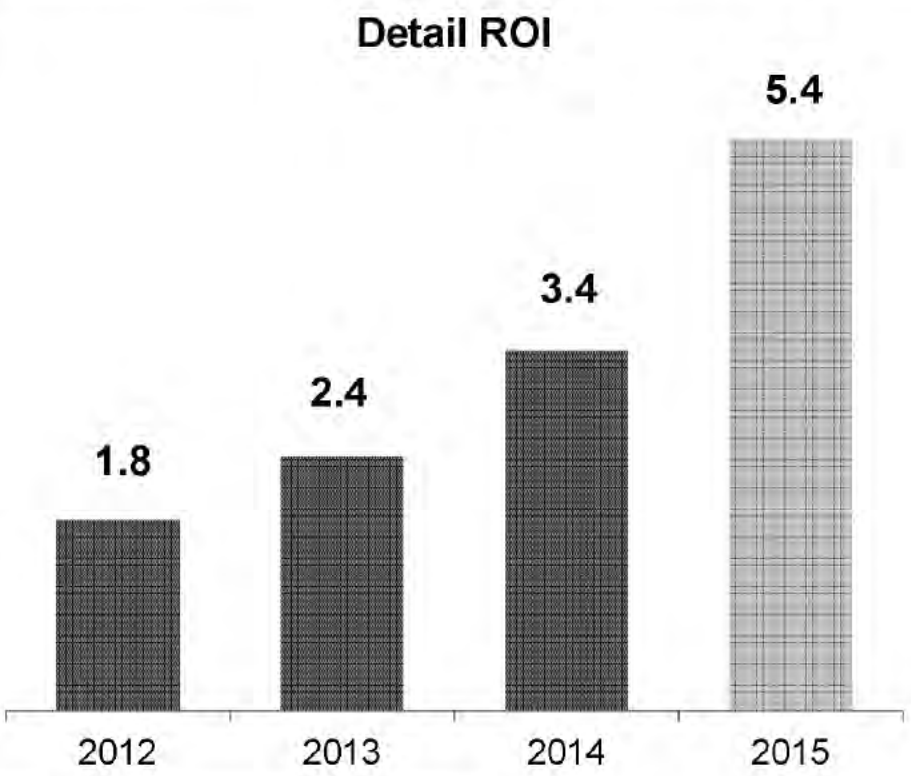
Lyrica Operating Plan
Maximizing The Value

May 3, 2016

This presentation represents the strategic vision for Lyrica. Strategies contained herein are NOT necessarily endorsed by Pfizer senior management, and the presentation is NOT intended to be implemented without further review. Strategies contained herein are subject to regulatory and legal review and approval before implementation.

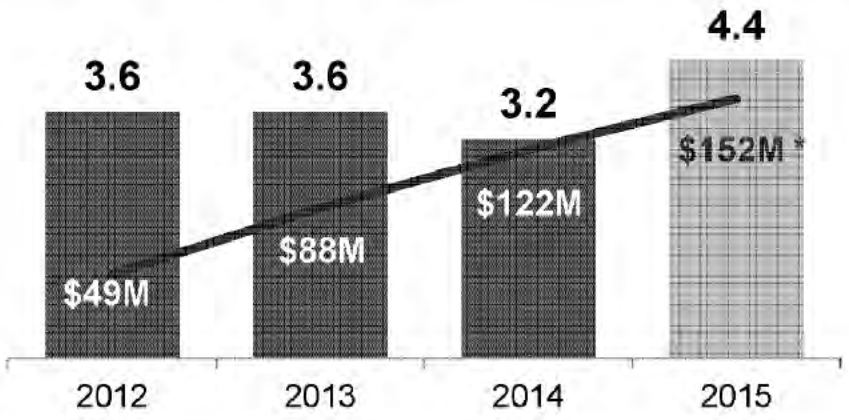
Primary Drivers of Growth Continue to Deliver Strong and Improving Performance

Sales Force ROIs Continue to Grow



Rx Impact Per Detail +25% YoY

TV ROIs Have Increased Despite Significant Increase In Media Spend



[redacted]

*Assumes FY'15 TV media excluding CHE

Lyrica LOE Co-Pay Card Offer

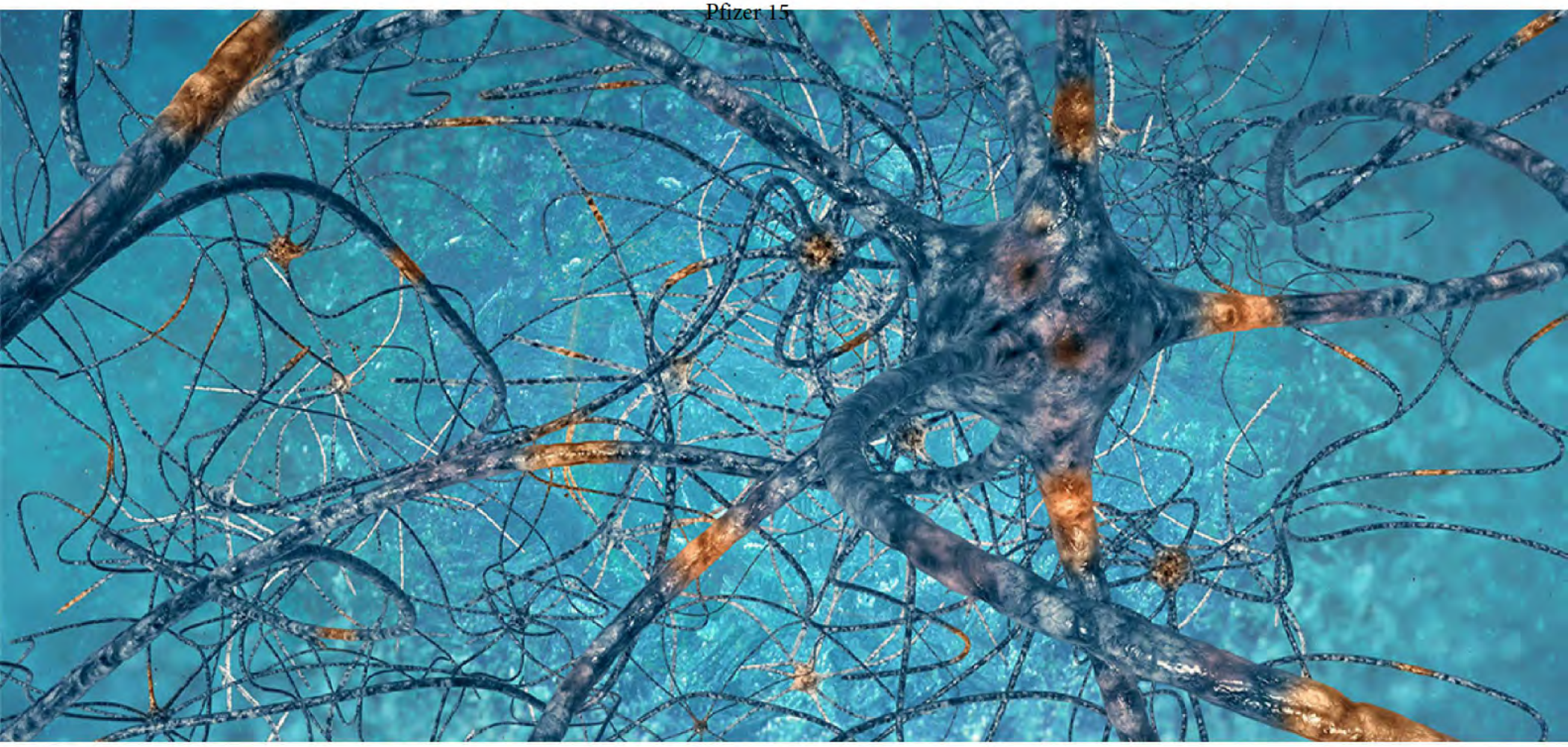
Recommendation

Recommendation (based on detailed model)

Pfizer
Internal Medicine

- **Launch new CPC 6 months prior to LOE**
  - Pre-LOE 6 mo revenue = -$2.0M to -$5.6M
    - Least negative if new offer is not extended to all for first 4 months
    - Jan POA CPC launch is easiest to execute
  - Post-LOE 6 mo revenue = +$5.5M
  - Post-LOE 24 mo revenue = +$13.0M

- Subsequent key decisions
  - Offer value and cap
  - Desired impact on FF engagement
  - Effect on CR CPC offer
  - Promotional channels other than FF



LYRICA 2018 Op Plan

August 8, 2017

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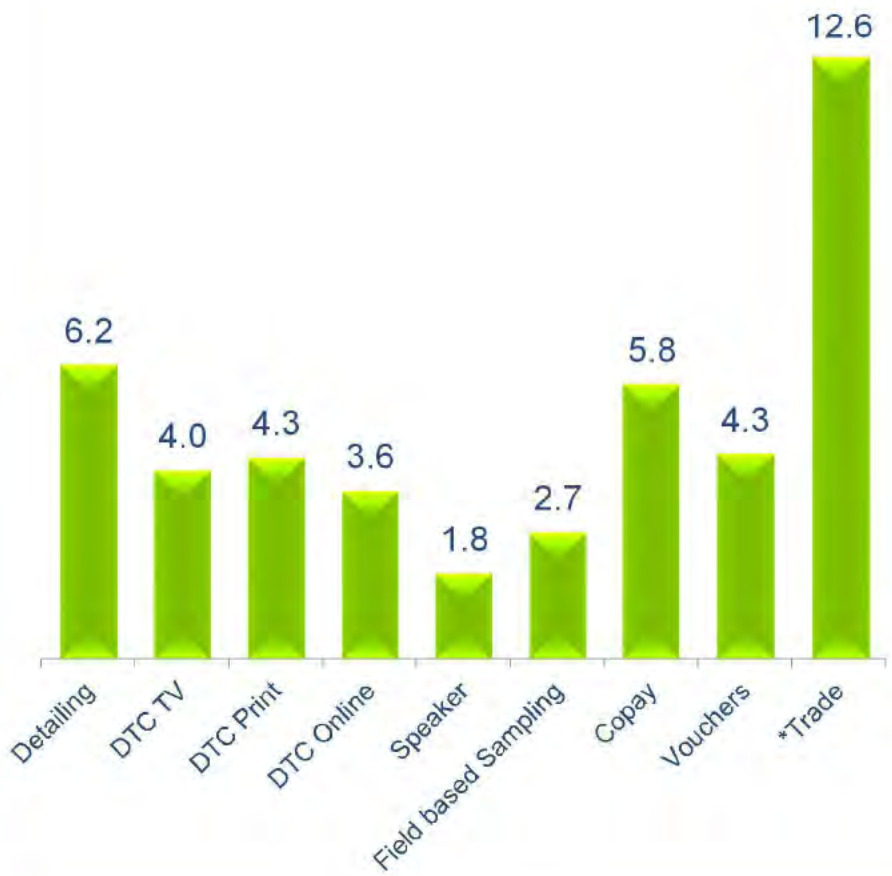
Despite Environmental Challenges, LYRICA ROIs Continue Deliver Across All Promotional Levers

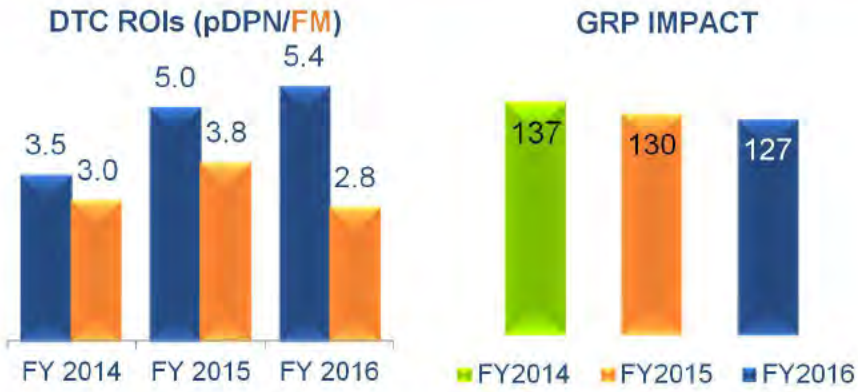
Pfizer
Internal Medicine

With Major Drivers Deliver ROIs ≥4:1



FF ROIs and Impact Up Significantly

DTC ROIs Strong But Vary By Indication



ROI	3.2	4.1	4.0
Spend	$122M	$152M	$183M

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Lantus Price Action for Dec 2013

November 19, 2013

All price increases have the potential to subject the organization to public scrutiny from payers, physicians and patients. Any decision on price increases must be done with this understanding.

Sanofi 1

Executive Summary

Vote: Move the planned January '14 WAC Price increase to December 13, 2013

		WAC per ML		
	Proposed Increase	Lantus (Proposed)	Lantus (current)	Levemir (current)
Vials	14.94%	$19.13	$16.64	$16.64
Pens	9.94%	$20.21	$18.38	$18.38

Situational Overview:

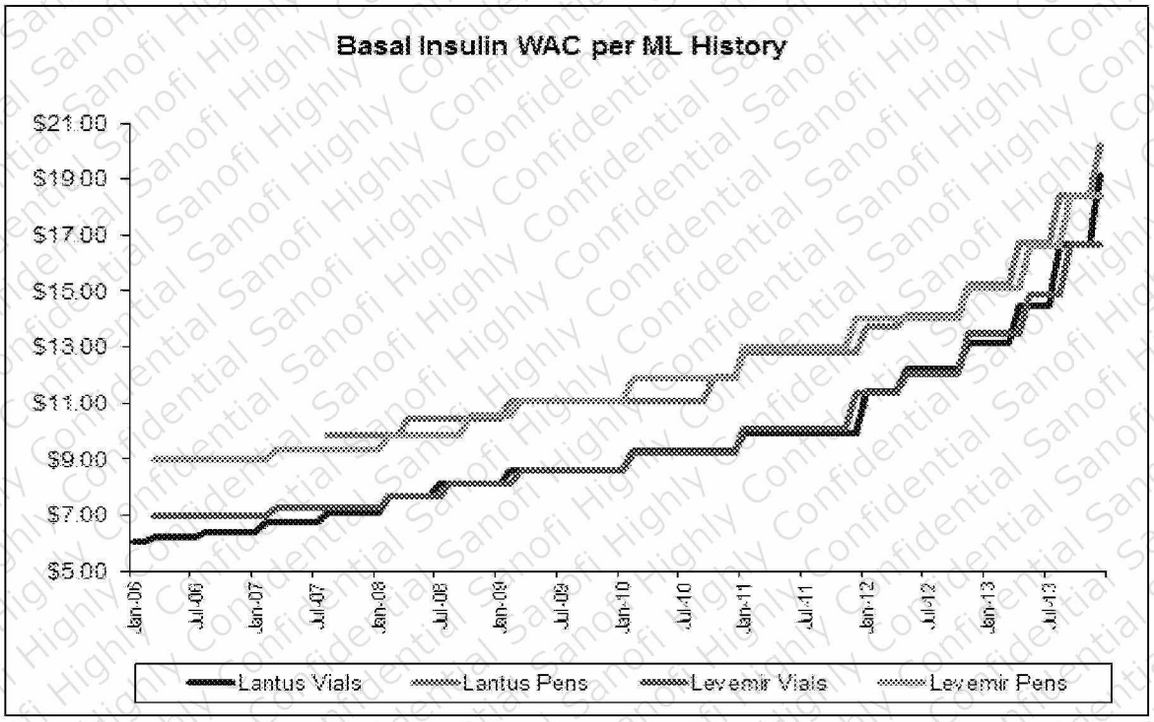
- Trigger Event
  - **Positive financial impact in '13 & '14 moving the planned January '14 increase up to December '13 without altering the magnitude of the increase**
    - '13: +$59 million vs. budget
    - '14: +$69 million vs. budget

SANOFI North America Pharmaceuticals

All price increases have the potential to subject the organization to public scrutiny from payers, physicians and patients. Any decision on price increases must be done with this understanding.

Pricing Dynamics

- Lantus & Levemir pricing has been comparable historically
- Rate of increase has accelerated recently
  - **Proposal would be the 3rd pricing action of '13.**
  - **Vial ranked #1 in cumulative YTD price increases (26.8%) out of the Top 25 most commonly dispensed drugs***
  - **45% cumulative vial increase since April '13 (including the proposed increase)**
  - **Rebate pressure expected and planned for in '14**



Therapy Class: DIABETES THERAPY		BASKET: Basal		
Basal	WAC$ /ml	Chg Date	Chg %	mo's Since Last Chg
Lantus vial*	$ 16.64	08/02/13	14.9%	3.2
	$ 14.48	04/26/13	9.9%	6.7
SANOFI-AVENTIS	$ 13.18	10/05/12	7.9%	5.3
	$ 12.21	04/27/12	7.0%	4.4
	$ 11.42	12/16/11	14.9%	12.0
	$ 9.94	12/17/10	7.0%	11.2
Lantus Solostar	$ 18.38	08/02/13	9.9%	3.2
	$ 16.72	04/26/13	9.9%	6.7
SANOFI-AVENTIS	$ 15.22	10/05/12	7.9%	5.3
	$ 14.10	04/27/12	3.0%	4.4
	$ 13.69	12/16/11	7.0%	12.0
	$ 12.80	12/17/10	7.0%	3.1
Levemir vial	$ 16.64	08/27/13	12.1%	3.8
	$ 14.85	05/03/13	9.9%	7.0
NOVO NORDISK	$ 13.51	10/03/12	12.0%	6.0
	$ 12.06	04/04/12	6.0%	4.4
	$ 11.38	11/22/11	13.0%	11.0
	$ 10.07	12/21/10	9.0%	11.5
Levemir Flexpen	$ 18.38	08/27/13	10.5%	3.8
	$ 16.63	05/03/13	9.9%	7.0
NOVO NORDISK	$ 15.13	10/03/12	8.0%	10.4
	$ 14.01	11/22/11	8.0%	11.0
	$ 12.97	12/21/10	9.0%	11.5

*Source: Analysource "Top 200 US Brand Drug Report – October 2013"

SANOFI North America Pharmaceuticals

All price increases have the potential to subject the organization to public scrutiny from payers, physicians and patients. Any decision on price increases must be done with this understanding.

From: [redacted]
Sent: Tuesday, November 18, 2014 3:29 PM
To: [redacted]
Subject: RE: Levemir price increase?

[redacted] – Just to follow-up…as I mentioned last night NN has not yet increased the price of Levemir. Over the past four price increases on Lantus they have typically followed within 1 month. Here are the dates for your reference…

Lantus Levemir
4/26/13 5/3/13

8/2/13 8/27/13

12/13/13 12/19/13

5/30/14 5/31/14

If you have questions let me know.

[redacted]

From: [redacted]
Sent: Monday, November 17, 2014 18:45
To: [redacted]
Subject: Levemir price increase?

[redacted] – Did Novo increase the price of Levemir following our price increase on Lantus last week? I just want to confirm we can still say that Lantus and Levemir are still priced at parity on a WAC basis.
Thanks,
[redacted]

SANOFI
Detroit Region

Turbo Charge Call Flow and Outline

Opening [redacted]

- Discuss the regions success in 2013 and thank team for a solid year
- Review call outline and objectives of the call
  - Bring clarity around Turbo Charge and what it means to you.
  - What it means to the region
  - What is means for representatives
  - How we will be successful

Current Situation [redacted]

[redacted] **Current situation**

•Last year's sales goal was hit primarily because of two price increase totaling almost 18% growth in total revenue for Lantus.

••A large study was conducted by an outside agency (McKenzie) showing that we were not operating as well as our competitors. This included all areas of the company, not just field sales.

•This is another important year for the company because the finances of our current portfolio fuels our future

•The company has a strong pipeline but the new products are not yet ready to launch.

•The Diabetes Division remains a bright spot for the company and represents about 50% of global profit.

•Sales of Lantus are critical to hitting the quarterly earnings expectations that keeps our stock price growing. Demand is down for Lantus so far for Q1. Growth in TML volume is behind expectations. `70m behind QTD

- Intro [redacted]

[redacted] **Why are we not meeting earnings expectations?**

Growth and Competition

SANOFI
Detroit Region

- If you have room to improve we need to do that now and do it quickly to ensure our success in the region and overacheive so we can deliver the bottom line sales to the organization.
- We are clearly not in maintainance mode but continued growth mode with Lantus. And we need everyone to sell with passion and enthusiasm.

Recap and Path Forward [redacted]

[redacted] **recap quick. And discuss how we are going to get there.**

- We have the plan
  - Strategic messaging
- We have the resources
  - Strategic Messaging tool
  - 850m V 225m in 2013
  - We are doing a great job with engaging customers with webcasts, programs, and 1:1 engagements!
  - And in some cases I feel we may need more resources but we need to own what we can control and drive and not look in the rearview mirror of what we don't have but focus on what we do have and maximize it immediately.
- We simply need to execute our strategy on every sales call, with passion and pride and show our competition exactly who we are.
- The leadership team is here to support your efforts and we will joining you with renewed energy and efforts towards executing with excellence.
- How do we plan to execute with excellence and really Turbo charge the business?
  - Making sure our operational and sales calls principles/expectations are in order.
  - Making sure we as a leadership team are stretching to meet exceed our deliverables and coaching you and each other to expect greatness.

Bottomline we need to execute our plan with excellence and do it quickly.

- Intro [redacted]

DCV DIABETES & CARDIOVASCULAR

Glargine and the Diabetes Portfolio and Position of Leadership in the U.S.

Goal:

Analyze the value of Lantus to the US portfolio as we build our US DCV transformation

SANOFI

Sanofi 4

Speaker Notes for Slide 2

For the best of the Sanofi overall diabetes revenue, we should be spending less time and resources trying to "genericize" Lantus and more time trying to think about how to keep Lantus in the payer space. This will best serve Lantus and Toujeo.
Important to note, Toujeo and Lantus are forever entangled in the US because of how they were launched and the payer strategy to date. If one understands the US payer market, you understand that you cannot degrade Lantus and not have downside for Toujeo.

[redacted]

Lantus is important to our payer strategy

DCV DIABETES & CARDIOVASCULAR

Leveraging the entire insulins portfolio (size/contracts/PMPM) provides more Value to Payers

- Lantus is the **preferred 1st generation basal insulin.** We have succeeded at leveraging the size of Lantus to **unlock preferred access for Toujeo**
  - **Toujeo maintains 76% Coverage in Commercial & 74% in Medicare** despite recent exclusions at [redacted] in both Commercial & Medicare
- **100% of our Toujeo contracts are tied to Lantus**
  - In instances where Lantus has lost coverage, Toujeo has also been removed
- Our competitors are leveraging their **entire diabetes portfolio** to provide the most optimized value to Payers/PBMs
  - **Removing Lantus** from our basal portfolio contracting strategy **would put us at a competitive disadvantage**
- **Externally, value can be offered to payers by bundling the entire Insulins portfolio* in to a PMPM model,** particularly since Lantus and Toujeo are already tied together

[redacted]

** Lantus, Toujeo, Admelog, Apidra, and SARA*

SANOFI

From: [redacted]@sanofi.com>
Sent: Thursday, February 15, 2018 11:21 PM
To: [redacted]
Subject: RE: 2018 PRB Admelog Lantus Copay Slide - 2.14.18 v2.pptx

Hi guys – assuming he is talking about the copay topic below, here is a proposed response. Feel free to tweak it.

[redacted]

Sensitivity analysis (see slide 10 in attached deck) is showing that we would need an incremental 11% Lantus share in the cash market with minimal increase in copay card usage to break-even (10% card usage in total). This is unlikely to happen as copay card utilization will increase with the new program. Assumptions noted by the brand are that we will see a 7% increase in Lantus share in the cash market by implementing the new program with a copay card utilization of 25% or greater, causing the negative sales impact. The brand is recommending a change to some of the current copay programs to offset the costs. In particular, potentially adding a cap to the Relay Health evoucher program (used for commercially insured patients), or increasing the patient pay copay amount on the Relay Health program that is used for not covered patients (denial voucher). The brand team, including [redacted] is meeting with [redacted] on Tuesday to discuss further which changes to current programs will appropriately offset the expected costs.

We will circle back with you on Tuesday once the meeting with [redacted] takes place. Thanks.

From: [redacted]
Sent: Thursday, February 15, 2018 5:57 PM
To: [redacted]
Subject: FW: 2018 PRB Admelog Lantus Copay Slide - 2.14.18 v2.pptx

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From: [redacted]
Sent: Thursday, February 15, 2018 3:52 PM
To: [redacted]
Cc: [redacted]
Subject: Re: 2018 PRB Admelog Lantus Copay Slide - 2.14.18 v2.pptx

I may have to drop. We need some estimate of upside. Also, what's the break even?

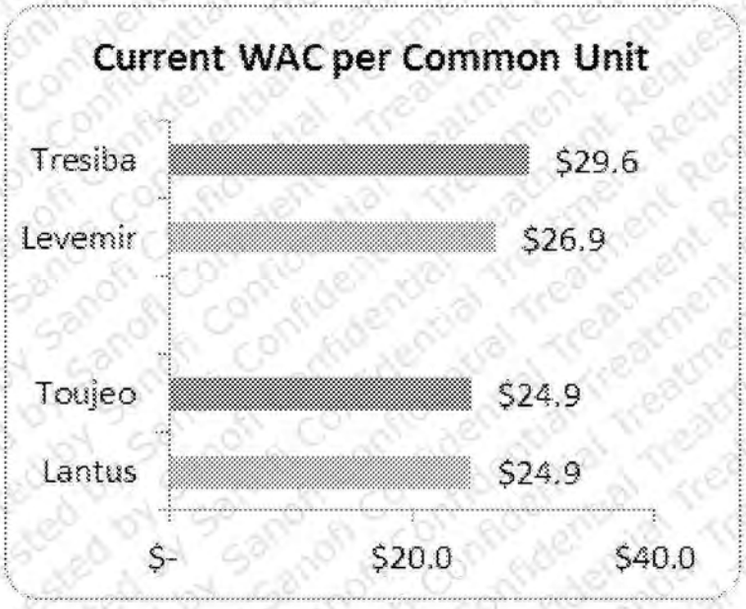
On Feb 15, 2018, at 12:01 PM, [redacted] /US <[redacted]@sanofi.com> wrote:

> FYI on copay program from [redacted] Best regards, [redacted]
>
> **Why this initiative has negative GTN impact?**
> People who are currently using Lantus will pay less for their Lantus scripts when we implement this program. IMPORTANT: our analysis did not include any assumptions for these people to have increased adherence since we wanted to present a conservative case. In reality we should see some improvement in adherence with decrease in OOP. This increase in adherence will help to offset negative GTN impact further.

Why are we proposing "negative GTN" program?

We plan to have a strong marketing push behind this initiative to have a positive impact on Sanofi insulins image as a company that truly cares about patient affordability. Long term effect of the image improvement is not accounted for in the calculations.

Basal Insulin Price Evolution



Lantus			Levemir		
Date	% Incr Vial	% Incr Pen	Date	% Incr Vial	% Incr Pen
			08/25/15	8.2%	8.2%
11/07/14	11.9%	11.9%	11/18/14	11.9%	11.9%
05/30/14	16.1%	9.9%	05/31/14	16.1%	9.9%
12/13/13	14.9%	9.9%	12/19/13	14.9%	9.9%
08/02/13	14.9%	9.9%	08/27/13	12.1%	10.5%
04/26/13	9.9%	9.9%	05/03/13	9.9%	9.9%

* No price increases for Toujeo & Tresiba since launching

- Parity was obtained on the 5/30/14 price increase for Lantus Vial & Pen
- Tresiba currently at 19% premium and to Sanofi Glargine
- Levemir currently at 8% premium to Sanofi Glargine

SANOFI

US Pharmaceutical Operations
Diabetes PCU
2015 Operational Plan and Budget

September 30, 2014
12:45 – 3:20

SANOFI DIABETES

Sanofi 7

Glargine family imperatives

Establish Toujeo and convert the franchise

- **Lantus to Toujeo switch is required to maximize the glargine family and defend our leadership position**
- **The organization's imperative to switch is captured in Toujeo's strategy and launch plan**
  - Toujeo has a core goal around switch: convert basal insulin, especially glargine users to Toujeo
  - Launch plan includes key tactics (e.g., pharmacy programs, co-pay offset) and necessary investment to ensure switch before biologic follow on entry

Drive Lantus in Q1 and then optimize total glargine for Q2-4

- **Leading up to Toujeo launch, Lantus brand objectives are to build and protect the patient base**
  - Focus will be to accelerate profitable patient acquisition and retention through differentiating our offering as the first injectable of choice
- **Post Toujeo launch, the primary focus of Lantus will be to appropriately support the current patient base**
  - Lantus will provide reactive HCP and patient support with samples through the web and address any questions with Lantus PI
  - Lantus appropriate support will continue within select hospital / LTC channels given the predominant use of vial and Part D formulary access

SANOFI DIABETES

Teva 17	TEVA_HCO_IC_005233185	December 2008 Emails
Teva 18	TEVA_HCO_IC_005234121, at Slide 4	July 2008 Presentation Excerpt

Healthcare Costs in the U.S. Talking Points

Intended for use by Corporate Communications,

IR and Teva Leadership with media and analyst audiences only (Oct 18, 2016)

Background

Recent events have placed an increased focus and request for commentary on healthcare costs in the U.S., including:

- Mylan Inc. has come under sharp criticism from a variety of stakeholders, including political candidates and patients, for the recent dramatic price increase of EpiPen, as well as the salary increases for top executives, especially CEO Heather Bresch
    - In September 2016, Heather Bresch testified before the House Oversight and Government Reform Committee, justifying that the profits the company has collected compared to the price is not what people assume
    - The Committee called for a Justice Department investigation to determine if the company acted illegally when it classified EpiPen as a generic drug and qualified for lower rebate payments to states
    - In response to the criticism, Mylan announced a series of measures to mitigate the cost to consumers, including the release of their own generic version and a direct-ship option, which allows consumers to buy the product directly from the company instead of through pharmacies
        - While positioned as a positive from Mylan's perspective, there is still a focus on the extremely high price of the branded EpiPen, as well as scrutiny surrounding the company making a generic version of its own branded product and ultimately, still profiting
- Shortly following the Mylan issues, Allergan CEO Brent Saunders posted commentary on the company's position on drug pricing on his executive blog
    - Resulting response has been factual and mostly positive
- In May 2016, Valeant issued a press release announcing the formation of a committee to oversee drug pricing following their pricing scandal and subsequent Senate hearings in October 2015
- In addition to highly critical media response to these events, several Federal and State legislative proposals are currently being floated whose professed aim is lowering prescription drug spending, and there is increasingly negative election rhetoric surrounding the upcoming U.S. Presidential election.

Key Messages – Teva Overall:

- Teva is a diversified, world-leading pharmaceutical company dedicated to the development of safe, effective and quality medicines. Upholding our commitment to maintaining a fundamental focus on patients and improving their treatment experiences has been, and remains, at the core of Teva's heritage.

- Teva acknowledges that the pharmaceutical industry as a whole needs to be mindful and responsible as to what the healthcare system can tolerate when pricing medications and each company's role in keeping down healthcare costs.

- Teva is committed to the development and production of high-quality, affordable generic medicines and innovative specialty medicines for doctors, pharmacists, and most importantly, patients.
    - With nearly 600 generic medicines available, Teva has the largest portfolio of FDA-approved generic products on the market.

  - Teva is disciplined in our R&D and branded commercial strategies and our approach has resulted in research treatments and technologies that have fundamentally changed the way diseases are understood and treated.

- The pharmaceutical industry as a whole provides tremendous overall value to the healthcare system.

- Recent attention on the cost of medications in the U.S. stemming from both the political arena and specific actions by select companies raises an important issue to the forefront of today's conversation– but also paint a narrow view of industry practices and undermines the important strides Teva and other companies are making through investment in research and drug discovery to prevent and treat complex life altering disorders.

- Industry pricing decisions are largely reflective of investments made to research, develop and commercialize high quality, safe and effective products, the health benefits of products and the invaluable patient services companies provide.

Generics-Specific Messages:

- Generics, specifically, create tremendous additional savings.
- As the largest generic drug manufacturer in the U.S. market, Teva is responsible for 12.7 percent of the total savings accruing from generic drugs. This amounts to approximately $214 billion in savings in the last decade attributable to Teva. Of the $214 billion in generic healthcare savings attributable to Teva, $82 billion accrued to the federal government, $62 billion to Medicare, and $20 billion to Medicaid (state and federal)..[i]
- It is a misconception that the overall cost of generic drugs is increasing.
  - Recent data shows that the generic cost trend continues to decline. In fact, drug costs are a small portion (approximately 10%) of overall health system costs and generic drugs are an even smaller fraction of that expenditure.
  - To date, we continue to see depreciation of our generic product prices year over year.
- Like all commodity markets, the generic drug market is dynamic and prices fluctuate based on external factors.
  - The number of competitors in the market.
  - The cost of ingredients can fluctuate based on supply and demand (i.e., fewer suppliers in the market, the cost of ingredients increases).
  - The cost of production can change due to requirements by the FDA.
- Generic drug manufacturers can proudly point to a legacy of savings and access that brings expensive treatments within reach for millions of people:
  - The IMS Institute for Health Informatics found that generic drugs were responsible for $254 billion in health system savings in 2014, bringing the total savings over the last 10 years to $1.68 trillion. A May 2015 report from AARP notes that retail prices for generic drugs dropped an average of 4% in 2013, marking nearly a decade of consecutive years of decreasing generic drug costs. The report also notes that 73% of generic drugs in the study experienced price decreases.
  - An August 2015 Drug Channels blog noted that in the second quarter of 2015 almost half (44%) of generic drugs experienced a decline in cost.

Key Messages - Specialty:

- We will continue to make calculated investments to research, develop and commercialize safe and effective treatments in areas of true unmet need and innovation aimed at improving the treatment experience for patients. For example:
    - Teva has invested in numerous development programs in CNS focused on complex high unmet need areas such as neurodegeneration and movement disorders which include orphan diseases like Huntington's disease, as well as Tourette syndrome, Parkinson's disease, multiple sclerosis, and tardive dyskinesia. Teva is currently developing Redacted - Other Product Information pridopidine, Redacted - Other Product Information and other undisclosed assets in the neurodegenerative category.
    - Further, Teva works to ensure proven safe and effective treatments, such as a COPAXONE® (glatiramer acetate injection), are available to patients. Through continued innovation to the product to enhance the patient experience, three-times-a-week COPAXONE® 40 mg/mL now offers the same proven COPAXONE® that patients and physicians know and trust with 60 percent fewer injections compared to the daily injection regimen with COPAXONE® 20 mg/mL.

Copaxone Specific Pricing-Related Messages (*reactive only*):

- The current wholesale acquisition cost (WAC) for COPAXONE® (glatiramer acetate injection) is competitive relative to other therapies in the category. COPAXONE® 40 mg/mL offers a strong value proposition when compared to Glatopa™.
- Teva continually evaluates the needs of MS patients to ensure our supportive services, like Shared Solutions®, appropriately meet patient needs. We believe that patients should not have to choose, interrupt or discontinue their MS therapy because of financial reasons. As a part of Shared Solutions®, COPAXONE Co-Pay Solutions® is one of several financial assistance offerings that help people living with a relapsing form of MS start and/or stay on COPAXONE®.

- For more than 30 years, Teva has pursued its MS research with the goal of providing effective, safe and tolerable therapies for MS patients. This ongoing commitment to patients was evidenced by the development of three-times-a-week COPAXONE® 40 mg/mL, thereby expanding the suite of COPAXONE® formulations and services to benefit patients with relapsing forms of MS.

Questions & Answers/Generics:

Q1: Why is Teva pricing its generic drugs higher, when generics are supposed to be affordable alternatives to branded therapeutic options?
A1: It is a misconception that the overall costs of generic drugs are increasing. Like all commodity markets, the generic drug market is dynamic and prices fluctuate based on external factors. Generic medicines continue to be an affordable alternative to brand therapies.

Q2. What are the circumstances that cause Teva to increase price on a generic drug?
A2: As a commodity market, the generic drug market is dynamic and prices fluctuate based on external factors. A generic drug price is adjusted (either up or down) because the market demands a change.

Q3: What percentage are prices usually increased?
A3: It is a misconception that the overall cost of generic drugs is increasing.

- Express Scripts Prescription Price index shows that generic drug prices have been cut in half since 2008. Compared to generic drug prices in December 2012, in December 2013 generic drug prices were15.9% lower.
- According to a recent survey of insurance plan benefit designs, the average copay for generic drugs is generally one-third the copay for preferred brand drugs and one-fifth the copay for non-preferred brand drugs. Similarly, research from the Department of Labor's Bureau of Labor Statistics shows that the median copay for generic drugs in 2012 was $10 and for brand drugs, $30. Despite price fluctuations that could affect pharmacy costs, median generic drug copays have remained constant in recent years.
- To date, we continue to see depreciation of our generic product prices year over year.

Q4: What impact does a generic price increase have on patients?
A4: For patients with insurance, there is no impact based on the pre-determined copay with the insurance provider. For patients that pay out-of-pocket for medicines, they pay the price that each pharmacy sets for a product, and not a price set by Teva.

Question & Answers/Copaxone (Specialty):

Q1: What is the current price of COPAXONE®?

A1: The current wholesale acquisition cost (WAC) for COPAXONE® (glatiramer acetate injection) is competitive relative to other therapies in the category. COPAXONE® 40 mg/mL offers a strong value proposition when compared to Glatopa™.

Q2: Will you take further pricing actions?

A2: We do not comment on future pricing actions.

Q3: Can you explain the COPAXONE® gross profit margin in relation to the cost of the therapy?

A3: The profit margin associated with COPAXONE® (glatiramer acetate injection) is similar to other branded molecules in this category, and is largely reflective of investments made to research, develop and commercialize a safe and effective relapsing MS product. We plan to continue to focus on innovation aimed at improving the treatment experience for patients.

Q4: Why is COPAXONE® 40 mg/mL priced lower than COPAXONE® 20 mg/mL?

A4: COPAXONE® (glatiramer acetate injection) remains competitively priced within the category, particularly considering it is the market leading product. Three-times-a-week COPAXONE® 40 mg/mL offers an outstanding value proposition and a co-pay assistance program that will allow eligible commercial patients to access the product with no out-of-pocket cost. Certain terms and conditions apply.

Q5: What was the most recent price increase for COPAXONE® and when did it happen?

A5:

The current wholesale acquisition cost (WAC) for COPAXONE® (glatiramer acetate injection) is competitive relative to other therapies in the category. COPAXONE® 40 mg/mL offers a strong value proposition when compared to Glatopa™, as there is only a XX% difference on annual wholesale acquisition cost of therapy.

- ***IF PRESSED*:** As of January 1, 2016, the WAC for a 30 day package of COPAXONE® (glatiramer acetate injection) 20 mg is $6,593.23 and a 28 day package of COPAXONE® 40 mg/mL is $5,403.00.

Q6: Why did Teva increase the price of COPAXONE®?

A6: The decision to increase pricing is determined by a number of factors as we constantly evaluate the marketplace and needs of our patients. We work hard to ensure the price of COPAXONE® - the global market-leading treatment for patients with relapsing forms of MS - reflects the clinical utility of the drug, while maintaining our commitment to ongoing clinical research.

- ***If pressed:*** We do not comment on specifics of our pricing strategy.

Q7: What are the factors that determined this price increase?

A7: We do not comment on specifics of our pricing strategy. We remain committed to ensuring the price of COPAXONE® reflects the clinical utility of the drug, while maintaining our commitment to ongoing clinical research.

Q8: Why is there a difference in the out-of-pocket costs for daily COPAXONE® 20 mg/mL and three-times-a-week COPAXONE® 40 mg/mL?

A8: The co-pay assistance for COPAXONE® 40 mg/mL was enhanced to help patients maintain financial access to the therapy.

Q9: How can you justify the price escalation of COPAXONE® over the last decade?

A9: COPAXONE® remains competitively priced within the category, particularly considering it is the market leading product. While COPAXONE® was approved for relapsing forms of MS in 1996, Teva's investment in the MS category spans three decades. Teva works to ensure we meet patient's needs and we continue to invest in researching new developments that directly translate to increased options for COPAXONE® patients. This is evidenced by:

- A robust ongoing clinical trial program designed to continue innovation that has included studying alternative dosing options such as the FORTE (double dose) and 0.5 mL studies, investment in the GALA study to bring three-times-a-week COPAXONE® 40 mg to market, plus continued investment in our overall MS program with 4 major trials for Redacted - Other Product Information
- Research has also led to an evolution in the way COPAXONE® in administrated with advances taking COPAXONE® from a frozen product to a pre-filled syringe and now the availability of the **auto***ject*®*2 for glass syringe*
- We have also invested in the Shared Solutions® network of personalized support, education, and training with free tools to help patients stay on track of their therapy with the goal of enhancing compliance and a co-pay assistance program allow eligible commercial patients to access the product with no out-of-pocket cost.

If pressed: Three-times-a-week COPAXONE® 40 mg/mL offers an outstanding value proposition based on the efficacy, safety, and tolerability that the medicine offers patients and physicians. Further, COPAXONE® 40 mg/mL offers a strong value proposition when compared to the one available generic, as there is only a 2-3% difference on annual wholesale acquisition cost of therapy, but an enhanced patient experience with three-times-a-week COPAXONE® 40 mg/mL with 208 fewer injections per year as compared to daily COPAXONE® 20 mg/mL.

Q10: What is Teva doing to help patients who cannot afford COPAXONE®?

A10: Teva continually evaluates the needs of MS patients to ensure our services, like Shared Solutions®, appropriately meet patient needs. We believe that patients should not have to choose, interrupt or discontinue their RMS therapy because of financial reasons. As part of Shared Solutions®, COPAXONE Co-Pay Solutions® is one of several financial assistance offerings that help people living with a relapsing form of MS start and/or stay on COPAXONE®. These efforts contribute to helping patients maintain financial access to COPAXONE®.

Patients who require financial assistance are invited to call the Shared Solutions® team at 1-800-887-8100. Shared Solutions® has assisted thousands of patients for more than a decade and has completed more than two million patient calls.

###

[i] Matrix, "Teva Pharmaceuticals: Providing Critical Health and Economic Benefits in the United States." June 2016.

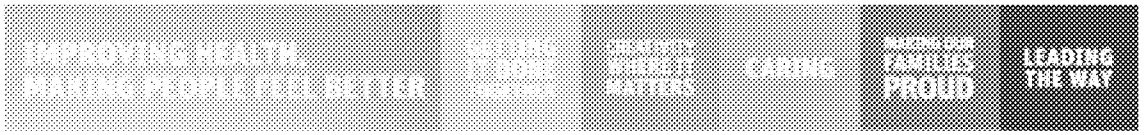
COPAXONE Highlights - Changes on August 3 from June Submission and Subsequent August 21st Changes

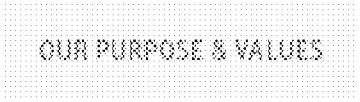
Summary of Changes	Total 2018 expense reduction of $71M (31%), $159M vs. original submission of $229M
Key Areas of Change	• Sales Force reduced by $[redacted] *- Assumes Sales Force COPAXONE weighting reduced from 60% to 50%* • Marketing Direct Tactical reduced by $2M • Medicare Donation reduced by $22M– *Donation reduced a further $21M to $0M* • Commercial Operations reduced by $3M • Patient Solutions reduced by $11M *- Anticipate 75% reduction in call center capacity* • *Market Access reduced by $3M* • *Marketing other reduced $1M*
Risk to Topline (Net Sales) By Areas of Change	• Sales Force: [redacted] • Marketing Direct Tactical: $5 - $14M • Medicare Donation: $0 - $128M– *revised impact $0M-$261M* • Patient Solutions: $50 - $80M
Overall Risk to Topline	• *$75M - $413M (revised total impact)*

From: Brendan O'Grady
Sent: Wednesday, January 31, 2018 4:05 PM
To: [redacted]
Subject: RE: CONFIDENTIAL: ***FORMULARY UPDATE*** Insurer Commercial/MPD & COPAXONE 40mg

I have to get up in 2.5 hours to fly to Switzerland. I may just stay up and work on email.

Best regards,





From: [redacted]
Sent: Wednesday, January 31, 2018 3:05 PM
To: Brendan O'Grady
Subject: Re: CONFIDENTIAL: ***FORMULARY UPDATE*** Insurer Commercial/MPD & COPAXONE 40mg

I know that! I guess I am missing my pint in texting. We will talk live someday. Safe travels

Sent from my iPhone

On Jan 31, 2018, at 4:02 PM, Brendan O'Grady Highly Confidential wrote:

> No as last I understood, Specialty Pharmacy only ships brand Copaxone no matter how it is written or what the formulary states. That is why this has little impact. Then again, my knowledge may be dated.
>
> Best regards,
>
> <image001.png>
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>
> <image002.png>

From: [redacted]
Sent: Wednesday, January 31, 2018 3:01 PM

To: Brendan O'Grady
Subject: Re: CONFIDENTIAL: ***FORMULARY UPDATE*** Insurer Commercial/MPD & COPAXONE 40mg

Ok- thanks. I thought they only received that for non- mail order and since 95% of Insurer is mail order through Specialty Pharmacy it doesn't sound so great, so I obviously need to understand it better

Sent from my iPhone

On Jan 31, 2018, at 3:56 PM, Brendan O'Grady Highly Confidential wrote:

> Because PBM is getting an additional rebate to fill all "glatiramer" or Copaxone scripts with Copaxone…if a doctor orders generic glatiramer or the pharmacy benefit mandates it be filled as a generic, it will come in a plain box with Copaxone inside. Win-win for all…
>
> Best regards,
>
> <image001.png> **Brendan P. O'Grady** EVP and Head of North America
> **Highly Confidential**
>
> <image002.png>

From: [redacted]
Sent: Wednesday, January 31, 2018 2:54 PM
To: Brendan O'Grady
Subject: RE: CONFIDENTIAL: ***FORMULARY UPDATE*** Insurer Commercial/MPD & COPAXONE 40mg

Sorry for the question – I worked it out in my piddly little mind today, and kind of understand it better. Just don't know how PBM benefits from this, as they are the PBM for Insurer I get how Specialty Pharmacy and Insurer would benefit …….oh well – another learning curve will possibly keep my mind young.

Warm Regards,

<image001.png> [redacted]
Highly Confidential

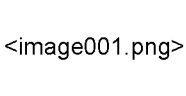
<image002.png>

From: Brendan O'Grady
Sent: Wednesday, January 31, 2018 3:52 PM
To: [redacted]
Subject: RE: CONFIDENTIAL: ***FORMULARY UPDATE*** Insurer Commercial/MPD & COPAXONE 40mg

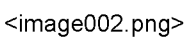
Because they are looking at the future…this has almost zero impact on actual prescriptions – I will explain later. Also, the NP status means little as we buy the patients copay down to zero anyway. Unless they NDC block Copaxone 40mg, we are fine. That is why they did not inform the reps because the actual impact is very low and it would just confuse them.

Best regards,

Brendan P. O'Grady EVP and Head of North America



Highly Confidential



From: [redacted]
Sent: Wednesday, January 31, 2018 1:02 PM
To: Brendan O'Grady
Subject: FW: CONFIDENTIAL: ***FORMULARY UPDATE*** Insurer Commercial/MPD & COPAXONE 40mg

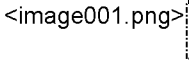
Hi,

I thought I would take you down five million levels and let your brain totally veg out on things so below your pay grade.

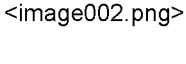
I realize we have the Specialty Pharmacy House Brand Strategy that will lessen the blow on this Insurer decision, but – do why would a plan of this size make this type of move if they were being offered a rebate that made a brand drug more economical than a generi? (at least I am assuming that is the case, but haven't spoken to [redacted] about it yet, as it is not official that this is my account.)
Wish you weren't so important and busy with higher level decisions and control – I need you as my mentor! Ahahahha!

Warm Regards,

[redacted]



Highly Confidential



From: [redacted]
Sent: Thursday, January 18, 2018 6:37 PM
To: USKAN_DIST_MANAGED_MARKETS_FIELD
Subject: CONFIDENTIAL: ***FORMULARY UPDATE*** Insurer Commercial/MPD & COPAXONE 40mg

Greetings,

In follow-up to our discussion on this topic from last Friday's call, [redacted] the COPAXONE brand team, [redacted] and I agreed that **the house brand strategy with** Specialty Pharmacy **that impacts this formulary change should not be formally shared with the sales team**. We did agree, however, to communicate this detail with [redacted] and the ASDs personally - which I completed yesterday. I also confirmed with the COPAXONE IC team that representatives WILL get credit for scripts getting filled with the brand at Specialty Pharmacy through **Insurer**

When supporting the TN sales force on this coverage change, please align to the confidential nature of the Specialty Pharmacy House Brand strategy and encourage representatives to use DAW as their reactive response in the field.
Don't hesitate to reach out to [redacted] or me if you would like to discuss further.

Best regards,

<image003.png> [redacted]
Highly Confidential

<image004.jpg>

From: [redacted]
Sent: Thursday, January 18, 2018 3:33 PM
To: TevaUS_TNS_Sales_Regional_Managers
Cc: USKAN_DIST_MANAGED_MARKETS_FIELD
Subject: ***FORMULARY UPDATE*** **Insurer** Commercial/MPD & COPAXONE 40mg

Greetings TN Sales Leadership,
See below for a COPAXONE 40mg coverage update. Effective immediately, **Insurer** Commercial and Medicare Part D will move COPAXONE 40mg to *non-preferred* status. This change impacts new starts immediately, and current COPAXONE patients will be grandfathered until annual PA re-submission. Providers should document DAW on the PSR to ensure highest probability of a branded fill.

Please don't hesitate to contact me if you have any questions about this coverage change.
Best regards,

<image003.png> [redacted]
Highly Confidential

<image004.jpg>

Effective 1/1/17, COPAXONE 40mg is Non-Preferred on Insurer Commercial & Medicare Part D

Effective immediately, COPAXONE 40mg is Non-Preferred on **Insurer** Commercial & Medicare Part D (representing ~15 million and ~1 million lives respectively).

- This formulary change impacts new patients where HCPs should request DAW on the PSR
- Current COPAXONE 40mg patients will be grandfathered until their annual PA submission, then will also be subject to restrictions listed below

Restrictions:

- Requests for Brand Copaxone 20mg/ml or Brand Copaxone 40 mg/ml must meet the following criteria:
    - Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one of the following:
        - One preferred beta interferon agent (Avonex, Betaseron Plegridy) or
        - Tecfidera or
        - Glatiramer 20mg/ml, glatiramer 40mg/ml, or Glatopa 20mg/ml
- Current COPAXONE patients will be grandfathered until their annual PA submission, then will also be subject to the step edit through generic GA
- Providers should document DAW on the PSR to ensure highest probability of a branded fill

Effective Date: January 1, 2018

Plan Details:

- **Insurer** Commercial Pharmacy Benefit represents ~15 million lives (includes health exchange)
- **Insurer** Medicare Part D represents ~1 million lives
- This announcement does not impact **Insurer** Managed Medicaid (~5 million lives) as branded COPAXONE 40mg is non-formulary
- **Insurer** formulary decisions impact the following health plans:

Health Plans

Contact your manager if you have any questions about this formulary change.

From: Katie Hiett
Sent: Friday, April 7, 2017 11:56 AM
To: [redacted]
Subject: RE: Question

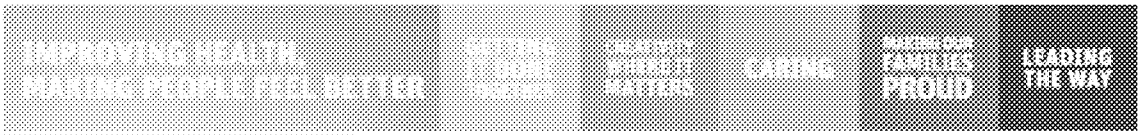
[redacted]

[redacted] is probably not aware that I am raising the issue but he is aware of the issue itself. We get hammered by prior period corrections from Medicaid going back years and we are getting hammered with duplicate claims between Medicare and Medicaid and I know I am not finding all of it. Looking forward to doing something other than just taking it.

Best regards,

Katie Hiett, CPA Vice President - US Market Access Pricing and Contracting

Highly Confidential



OUR PURPOSE & VALUES

From: [redacted]
Sent: Friday, April 07, 2017 8:58 AM
To: Katie Hiett
Cc: [redacted]
Subject: RE: Question

Good Morning Katie,
Thank you for the outreach—you've come to the right place. I am going to ask [redacted] to set you and I up with a call to discuss this a bit further. We are also in the process right now of developing proactive policy strategy for Teva and these may fit well into that effort. I have a meeting with [redacted] a week from Monday where we will be discussion some of the policy options we are considering including—is he well aware of this pain point?

Look forward to speaking soon.

[redacted] please find at least 30 minute for Katie and I as soon as possible (Katie I am on vacation next week).

[redacted]

Highly Confidential

From: Katie Hiett
Sent: Thursday, April 06, 2017 4:21 PM
To: [redacted]
Subject: Question

[redacted]

I am looking for some direction on who can help me with some policy changes I would like to see Pharma start pushing for when it comes to the Medicaid program and Medicaid Expansion.

There are two issues I would like to see Pharma start lobbying for.

- There is no statute of limitation on the states on when they can submit Medicaid. They can go back forever and we have no way of knowing about these liabilities. We continue to get hit with surprises and if Medicaid continues to expand this will only get worse. This is millions of dollars for Teva and I know all other pharma gets hit with the same amounts. It has been referenced on some earnings calls when they miss earnings.
- Medicaid currently collects 100% of the rebate even if they only pay a penny against the claim. We are seeing more and more of this with the aging population. They have dual coverage so we get hit with the rebate from the payer claim and then we get hit with the full rebate from Medicaid even though Medicaid was the secondary payer. Currently Teva has several products that have 100% rebate in Medicaid due to best price and a long history of price increases or just being on the market for a long time. Copaxone 20, [redacted - Other Product Information] are all at 100% WAC rebate in Medicaid meaning we don't ever cover our COGS or other GTN discounts.

I think we need to start advancing some of these changes given the massive increase in this program since ACA and our voice needs to be heard. Don't know where to start.

Best regards,

[redacted]

Katie Hiett, CPA Vice President - US Market Access Pricing and Contracting

Highly Confidential

From: [redacted]
Sent: Saturday, February 18, 2017 8:46 AM
Subject: Fwd: generic Copaxone 40 mg delayed because of fill/finish issues
Attachments: image001.png; ATT00001.htm; image001.png; ATT00002.htm; MYL, TEVA - Quick Take Teva, Mylan - Another Hanukkah miracle; but will it last (Bernstein Research) 7 Pages - 17-Feb-17.pdf; ATT00003.htm

Best regards
[redacted]
Sent from my iPhone

Begin forwarded message:

From: [redacted]
Date: February 18, 2017 at 7:23:58 AM EST
Subject: Fwd: generic Copaxone 40 mg delayed because of fill/finish issues

Might be good for cash flow and debt pay down and some of your bonuses :)

Best regards
[redacted]
Sent from my iPhone

Begin forwarded message:

Subject: Fwd: generic Copaxone 40 mg delayed because of fill/finish issues

Begin forwarded message:

From: TevaInvestorRelations [redacted]
Date: February 17, 2017 at 10:33:54 PM EST
Subject: generic Copaxone 40 mg delayed because of fill/finish issues

Below is Evercore' s note, and attached is a Bernstein report on the matter.

In a press release filed by MNTA just now, it seems that Copaxone generic is delayed

As a reminder, at least 5 generics are in development for Copaxone. However, only MNTA/Sandoz was approved for 20 mg generic (where patent expired already).

Street has widely expecting an approval of 40 mg generic - at least from MNTA/Sandoz (mostly because their 20 mg is already approved). In fact, i was hearing investor feedback that a generic 40 mg from MNTA/Sandoz is likely launching in 1Q17 (and Novartis' Sandoz had actually put up a slide on this on recent earnings call).

As per press release just now, here's what MNTA is saying:

1. **MNTA's contract manufacturer (Pfizer) got a warning letter**

2. The warning letter does NOT restrict the 20 mg generic

3. However, the approval of 40 mg generic depends on successful resolution of this warning letter. Thus MNTA/Sandoz generic is delayed

We also touched base with Momenta who aren't giving additional details until Tuesday's press conference

This is very good news for Teva - for now. At the very least, it delays MNTA/Sandoz for few months (am waiting to hear back from MNTA).

In some ways, it explains why MNTA did not get approved when 30-month stay on Copaxone 40 mg expired last week.

In light of Teva/MNTA news just now (generic Copaxone 40 mg delayed because of fill/finish issues), we thought it would be helpful to look at precedents.

Here's what we just did:

1. Look at all warning letters in last 20 yrs
2. Zoom in specifically on warning letters relating to CGMP issues on finished pharmaceuticals

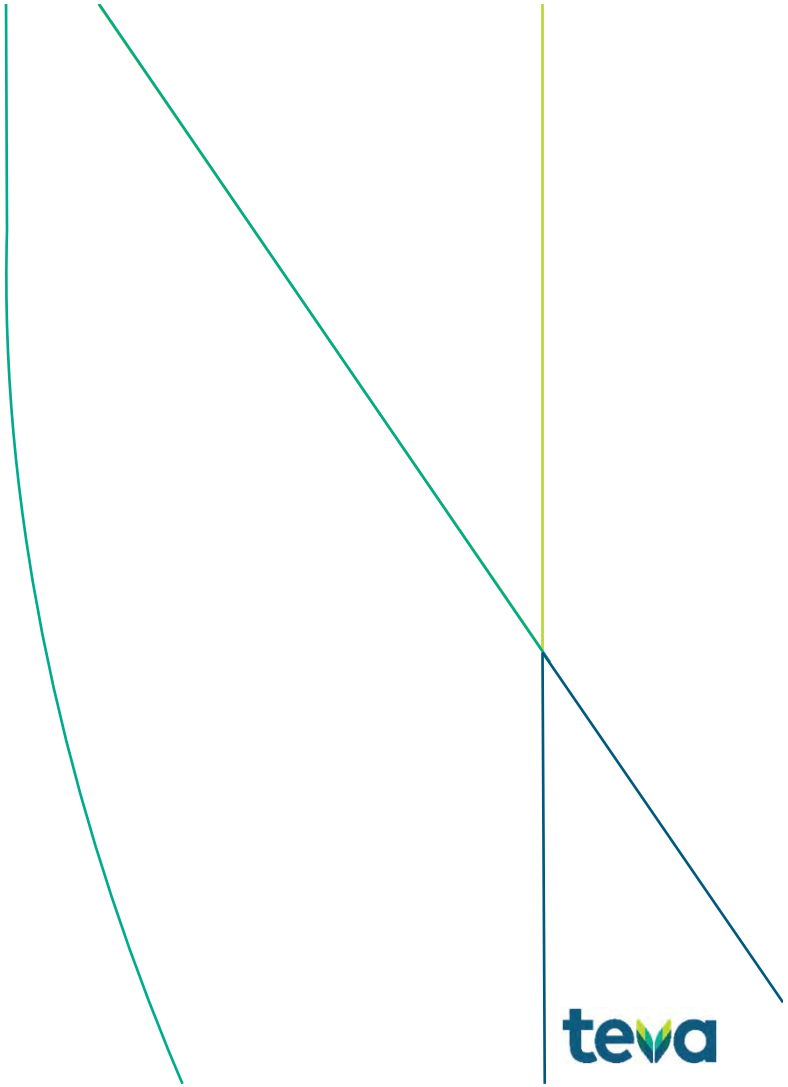
- The implied sample size was 31 cases

Here's what we're seeing: ~13-17 months for resolution (median/avg) … and minimum of 5 months

Generic COPAXONE 40mg Update*

Board, October 2017

*first preliminary analysis – for internal use only



Key Activities to Defend Against Generic Erosion

Brand over Generic (House Brand) Contracting Strategy

- Contracting with major payors, PBMs and pharmacies
- Contracts range from Brand over Generic terms (all 40mg Rx will be switched to Brand), to loyalty allowing access to COPAXONE 40mg alongside generic

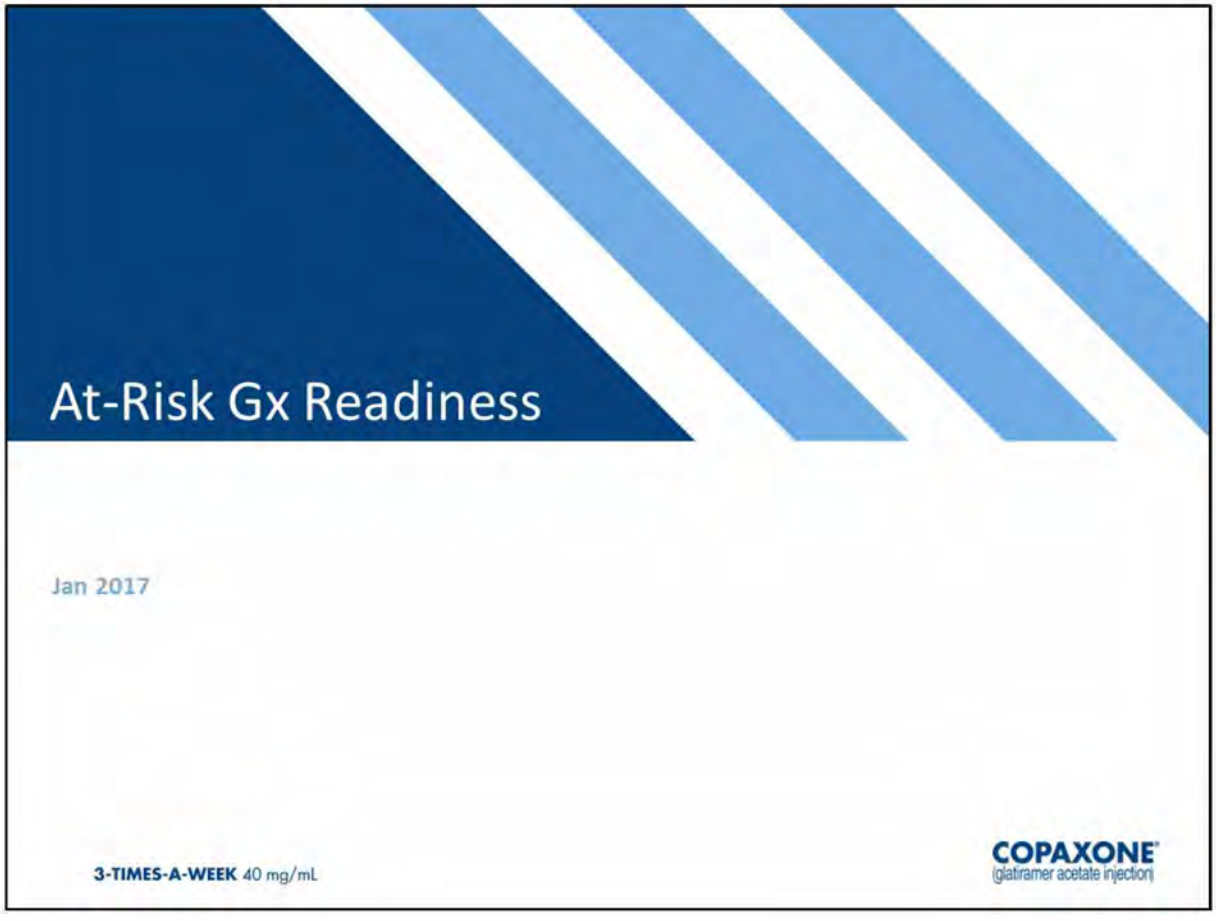
Sales force DAW messaging and activities

- Sales force proactively messages to HCP customers the need for "Dispense as Written" on all new Rx and refills
- Working with office accounts to ensure they have the capabilities and resources need to communicate DAW through verbal, written and electronic means

Outbound efforts to 40mg patients through Shared Solutions

- Call center outbound effort to contact all current 40mg patients with active marketing authorization
- Emails to all patients with DAW messaging
- Ability to produce current 40mg patient lists for HCP offices to proactively DAW scripts

Legal pathways also being explored


At-Risk Gx Readiness
Jan 2017
3-TIMES-A-WEEK 40 mg/mL
COPAXONE
(glatiramer acetate injection)

Market Access Update

- House Brand Accounts:
  - Contracting Strategy for Brand over Generic. Discussions have taken place with these designated accounts.
    - 2 of the House Brand target accounts will be executed at the formulary level. Blocking the generic via formulary restriction.
    - 2 of the House Brand target accounts will be executed at the specialty pharmacy level. Pharmacy will fill brand regardless if prescribed as generic.

- Loyalty Accounts:
  - Contracting for continued formulary access, without any step edits through Gx. These plans may decide to add Gx to their formulary. Assume modest increases in rebate for this strategy (1-5 points)
    - HCP loyalty and DAW strategy will help retain many of these branded units.
    - Assumed retention of 50% of 40mg units


Go To Market Action Plan (GTMAP)
COPAXONE
Launched
Relapsing Forms of Multiple Sclerosis
PRIVILEGED AND CONFIDENTIAL – DRAFT FOR INTERNAL DISUCSSION ONLY

Marketing: Supporting Activities and Spend

KBQ: What supporting activities are needed to successfully execute key tactics?

$ million

SI	CSF	Key Tactics	Supporting Activities	Owner	Start Month	End Month	Budget
1	a.	HCP Personal HCP Promotion	*Field Sales and Materials*	*US Sales*	Jan	Dec	2
			Speaker Programs	*US Marketing / US Sales*	Jan	Dec	7
			Conventions	*US Marketing*	Jan	Dec	1
1	a	HCP Non Personal Promotion	*COPAXONEHCP.com*	*US Marketing*	Jan	Dec	4
			MSKnowledgeSeries.com (unbranded)				
			Email and other Digital Media				
2	a	Medicare Donation	-	*US Marketing*	Jan	Dec	40
1	a	*Advocacy*	*Charitable Donations and Sponsorships*	*US Marketing*	Jan	Dec	2

Continued on next slide

GSP & GHE Kick-Off

Sheraton Valley Forge Hotel

13th & 14th September, 2016

What does Teva do well in Pricing? (Overall GSM & GGM)

- Pricing negotiation strategy and able to increase prices successfully
  - Influenced heavily by US being allowed to hike prices p.a
- We have dedicated pricing negotiation packages & strategy for all key accounts and tenders
- We apply more frequent price changes
  - Once, twice a year and many on a continuous basis - adaptive
- Teva pricing organization set-up in the right place
  - Pricing established as a business partner
  - Reporting directory to CEO, Marketing or Business Unit
  - Organized by Pricing activity or Business Unit
- Timely, reliable and actionable market intelligence data in place, feeding into pricing strategy and models

Teva Document 9

From: [redacted]
Sent: Tuesday, August 26, 2008 8:26 PM
To: [redacted]
Cc: [redacted]
Subject: Re: brief update from GIR meeting on GA LCM

Thanks for the update. A few points:
1. The limiting step with GA is the density of the solution. I assume that [redacted] has the information for the 60mg back from the days we have worked on the 80mg.
2. Please consider the ISR we saw in the rats with the 80mg (so we may not want to go to high).
3. In addition, we have currently a 5 fold safety ration based on monkeys only and excluding the ISRs - we should consider whether this should guide us when choosing the next dose.
4. What is the TPP - efficacy as 20mg?
5. Can we patent the frequency?
6. This is also a long term plan, assuming Phase II and Phase III bringing us to 2016 - still relevant?

[redacted]

[redacted]
26/08/2008 18:55

To [redacted]
cc
Subject brief update from GIR meeting on GA LCM

Dear all,
In the Gir meeting today the following decisions were made:
1. 0.5 ml GA 20 mg - Go decision. However it was decided that TN will run the clinical trial in parallel to the 6 M stability to see if indeed we get better /same injection side reaction and not worse.

2. Gir accepted the LCM recommendation not to pursue the 40 mg every other day. Instead of that it is requested that we prepare a development plan with GA 50 mg or even higher if feasible for once or twice weekly injections. My input was that the highest feasible dose is 60 mg and therefore the 50 mg was accepted. A CDP for this product should be developed as well.

3. New formulations/pumps etc.. - the concept of looking on new GA products of such kind was accepted. we need to work with [redacted]nd TN, map the relevant options and make a recommendation for these products developments. Vera, it will be very helpful to organize a CMC meeting asap.

Thank you all,

[redacted]

Senior Director,

Special Innovative Projects
Innovative R&D
Tel: Highly Confidential
Fax: Highly Confidential
Mobile: Highly Confidential

CONFIDENTIAL ATTORNEY CLIENT PRIVILEGE

Gx GA Readiness Work Team

November 18, 2014

COPAXONE®
(glatiramer acetate injection)

Marketing: Deliverables

Deliverables	Status	Responsible Party	Start Date	Completion Date
Pre-Gx Launch				
Gx Strategy	Complete	Jeff	8/14	9/14
Tactical Plan	In Development	Jeff / Marcy	8/14	10/14
Field Communications / TPs	Complete	Scott / Karen	2/14	4/14
Discontinue 20mg Financial Programs (Patient Services)	In Process	Karen / DeAnne	8/14	12/14
Post-Gx Launch				
Tactical Plan	In Development	Jeff / Marcy	8/14	10/14
Field Communications / TPs	In Development	Marcy / Karen	9/14	12/14

COPAXONE®

2009-2011 WP Review

USMT and LT
2008.08.06

Downside to Plan V1

Probable Net Sales	1,742	1,957	2,150
Downside Events:	2009	2010	2011
No Pricing Action	(144)	(324)	(517)
Discount Rx - No Impact on Compliance	(53)	(74)	(75)
Eliminate Medicare PAP investment	(16)	(33)	(45)
[redacted]			
Private PAP Programs does not increase Patients	(14)	(26)	(35)

Probable Contribution	894	1,390	1,671
Downside Events:	2009	2010	2011
No Pricing Action	(94)	(272)	(468)
Discount Rx - No Impact on Compliance	(34)	(63)	(68)
Eliminate Medicare PAP investment	(11)	(28)	(41)
[redacted]			
Private PAP Programs does not increase Patients	(9)	(22)	(31)

Teva Neuroscience
2012-2014 Workplan
August 18, 2011

COPAXONE Expense Drivers

Expense Driver	Budget	ROI (>0 is considered positive)
Patient Assistance	$81M direct	▪ Returns for commercial patients average 451% with a range of 205% to 761% ▪ Medicare D grants are not included in the assessment
Sales Force	$41M people related	▪ 178% short term ROI ▪ 95% carryover at 6 months
Patient Services	$14M direct $17M people related	▪ 29M invested in 2011 generated $363M with a ROI of 1152% ▪ PAP is not included in this ROI
Opportunity and Educational Funds	$17M direct	▪ Not tracked, but assumed similar to Peer to Peer
Peer to Peer	$10M direct	▪ AHM is the surrogate metric ▪ Average ROI for AHM programs is 701%
Scientific Communications	$7M	▪ Not Tracked

TEVA PHARMACEUTICAL INDUSTRIES LTD.

TEVA PHARMACEUTICAL INDUSTRIES LTD.

Copaxone LCM - Mid Term Initiatives

1

Development of High dose/ low frequency formulation of GA

- **Situation**
  - There is a need to develop a low frequency formulation of GA to:
    - Ensure the competitiveness of Copaxone in the future and to address the market unmet need for less frequent injections
    - Prepare a mid-term solution as an insurance policy in case [redacted] fail and our next launch is not before 2016 / 17
- **Complications**
  - No supporting clinical data for the selected dose or dosing regimen
  - Regulatory authorities may request a dose range finding study and comparison of the new formulation to daily GA and placebo
  - The new formulation must be approved no later than 2014
- **Possible Resolution**
  - To conduct a 2 -arm PC study, using the 40mg/ml configuration e.g. 32-40 mg GA 2-3 times a week
  - Do not consult with regulatory authorities before study initiation – they will most probably not accept this design
- **Risks**
  - The cost of the study is $52 M
  - Regulatory authorities may not approve the new formulation based on a single study results
  - Recruitment to a PC study will be slow and the TTM may be later than 2014

High dose /low frequency formulation Challenges

- No supporting data for the selected dose or dosing regimen
  - There is no supportive clinical data - no POC study
  - Less frequent injections may delay the onset of action
  - Overall, the data available to date do not support going to higher doses
  - Immunogenicity - twice weekly injections may induce a different antibody response – it is not clear how it would affect the clinical efficacy since the correlation was never proven
- In the absence of rationale for dose selection, the regulatory authorities may not approve the product based on a single study exploring only one dosing regimen
- No market exclusivity in Europe

Multiple Sclerosis Franchise Strategy

"MS Disease Area Strategy"—Confidential Working Draft

February, 2017

Pricing Trends

Generitization of multiple classes on the 5 year horizon potential to change the pricing paradigm

	US dynamic	EU dynamic
Current pricing dynamic	• Premium prices are available – current list prices average $80k per patient per year • But payers demand competitive discounting – highest discounts for older DMTs, lower for newer DMTs - but averaging ~25% in GTN w/ COP 40 at 40% GTN • HEOR is a key lever for preferred plan coverage • Payers do not generally dictate prescribing despite high cost	• Health technology assessment is the firmly established P&R gatekeeper • Current list price (average $13k per patient per year) much lower than US price • With discounts averaging ~10 to 15% • H2H comparisons against SoC are expected, but do not guarantee success (if no H2H comparator – DMT is relegated to lowest priced DMT or reference pricing) • Country-specific eligibility guidelines and prescribing restrictions may be narrower then EMA labeling
Future pricing dynamic	• Generitization of oral (small molecule) DMTs could potentially drive pricing erosion of ~85% within two years[1] • Biosimilars expected to drive pricing erosion of only ~35% within two years[1] • Rebate range for biosimilars are not expected to be significantly different from the originator rebate; biosimilars are hampered by volume-based contracts and longer originator contracts • Payers are interested in piloting outcomes-based contracts • Potential HHS negotiation power for Medicare and Medicaid	• (Compared to the US,) generic or follow on products drive significantly less price and sales erosion happening over a significantly longer period of time • Possible move to rejection of placebo-controlled studies for reimbursement consideration (e.g., Italy) • More focus on cost-effectiveness analysis; budget impact management • To reduce spending, focus on simpler contracts (e.g., straight discounts) over risk-sharing and outcome-based contracts (where administrative cost and compliance decrease effectiveness)

Sources: Evidera Policy Change presentation, Feb 2017; Decision Resources Disease Landscape & Forecast, November 2016 BY2015
1. Decision Resources Market Forecast Assumptions, November 2016 BY2015

From: Ronit Weiss
Sent: Monday, December 29, 2008 3:41 AM
To: Yifat Shorer
Cc: Ety Klinger; Yossi Gilgun
Subject: Re: GA Infrequent injection proposed study

Totals added. Yossi and I will compere the numbers between projects tomorrow as soon as Vera will give as the allocation for the CMC FTEs.

Yifat Shorer Highly Confidential
28/12/2008 21:50

To Ronit Weiss Highly Confidential
cc Yossi Gilgun Highly Confidential
Klinger Highly Confidential
Subject

DocLink1.ndl

Re: GA Infrequent injection proposed study

Thanks, Ronit.

Could you please add the 'total FTEs' for each stage?

Thanks,
Yifat

Ronit Weiss Highly Confidential
28/12/2008 13:56

To Yifat Shorer Highly Confidential
cc Yossi Gilgun Highly Confidential
Subject

DocLink2.ndl

Re: GA Infrequent injection proposed study

Hi

Here are the number of FTEs per department from the Copaxone 40mg development per stage:
1. From G/NG to FPI (2-9/2006):

2. From FPI to LPO (10/2006-5/2008):

3. From LPO to Results - (6-7/2008):

Teva Document 16

Yossi - as you can see the CMC allocation is far from zero and this needs to get attention here as well. I think we need to sit on this together.

Regards,
Ronit

Yifat Shorer Highly Confidential
24/12/2008 22:38

To Yossi Gilgun Highly Confidential
cc Ronit Weiss Highly Confidential
Subject


DocLink3.ndl

Re: GA Infrequent injection proposed study

Ronit,
Can you please check how many FTEs were invested in 40mg for MS (+ in which department, globally)? do you think it might be used as a benchmark?
Best regards,
Yifat

Yossi Gilgun Highly Confidential
24/12/2008 12:13

To Ronit Weiss Highly Confidential, Shorer Highly Confidential
cc
Subject GA Infrequent injection proposed study

Dear both,

Please find below the presentation prepared for the discussion in the GA LCM meeting one month ago (the relevant study design can be found in slides 7-9- Option 2- Superiority study GA 32 mg thrice a week vs, placebo, and the appropriate FTE slide can be found in slide 14).

I would like to make it clear that the IR&D management, led by [redacted] are **strongly against the study** since it has no scientific rationale/ value. The IR&D decision was conveyed to the GA LCM team; however, the GA LCM members, though agree with IR&D decision, think that such a study has its business value.

I know from [redacted] that a GIR meeting is planned for 08-09 Jan 09, so I assume that a final decision will be taken then by [redacted]

Please contact me if you need any further clarifications.

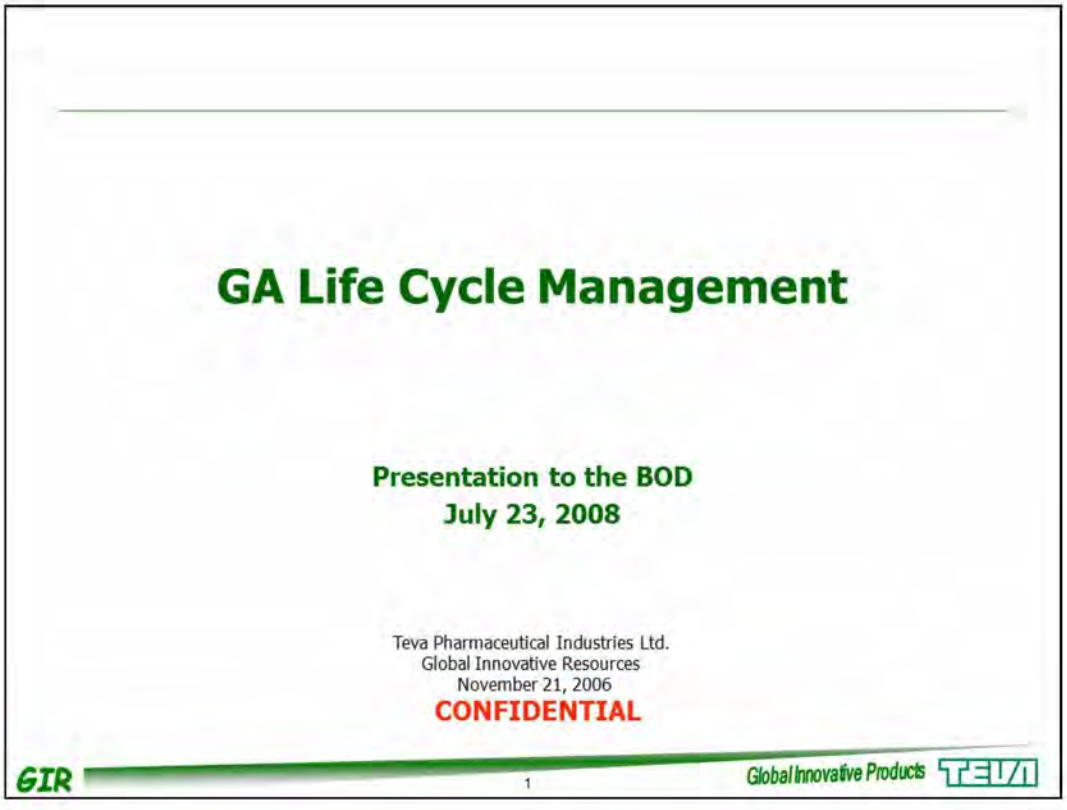
All the best

[redacted]

[attachment "GA infrequent injection- Optional scenarios- 19 Nov 08.ppt" deleted by Yifat Shorer/NTA/TEVA/IL]

Yossi Gilgun-Sherki, Ph.D.
Global Clinical Leader
Clinical Development Section
Global Innovative R&D
Teva Pharmaceutical Industries, Ltd.
Netanya, Israel

Highly Confidential


GA Life Cycle Management
Presentation to the BOD
July 23, 2008
Teva Pharmaceutical Industries Ltd.
Global Innovative Resources
November 21, 2006
CONFIDENTIAL
GIR
1
Global Innovative Products
TEVA

GA Life Cycle Initiatives
Lower frequency of injections

No formal dose ranging or frequency humans studies (PK/PD) have been performed to link with clinical outcomes

- **40 mg every other day**
  - Based upon "sameness" of 40mg to 20mg in the FORTE trial
  - **Issue**: existing data from every other day with Copaxone may prompt patients using generic COPAXONE every other day
- **Higher doses in less frequent dose regimen (i.e once weekly)**
  - How do we justify the use of higher doses after Forte?
  - Solubility of a higher dose, increased injection site reactions
  - Once weekly injections of 15 and 30 mg TV-5010 in MS patients provided equivocal MRI results, anti TV5010 antibodies profile looks different from that induced by daily GA
- **Issue for consideration : costs of yearly treatment of the lower frequency regimen compared with COPAXONE daily**