Drug Pricing Investigation

Novartis—*Gleevec*

Selected Investigation Documents

Staff Report
Committee on Oversight and Reform
U.S. House of Representatives
October 2020
oversight.house.gov

Novartis Selected Documents

Document #	Citation	Short Description
Novartis 1	CTRL-0003501, at Page 6	August 2016 Presentation Excerpt
Novartis 2	CTRL-0118195, at Slide 3	October 2014 Presentation Excerpt
Novartis 3	CTRL-0007100	2013 Presentation Excerpt
Novartis 4	CTRL-0096280, at Slide 4	November 2012 Presentation Excerpt
Novartis 5	CTRL-0029114, at Slide 1	June 2013 Presentation Excerpt
Novartis 6	CTRL-0007430	July 2013 Emails
Novartis 7	CTRL-0130193, at Slide 8	October 2016 Presentation Excerpt
Novartis 8	CTRL-0027659, at Slide 29	April 2014 Presentation Excerpt
Novartis 9	CTRL-0084047, at Slide 4	July 2015 Presentation Excerpt
Novartis 10	CTRL-0004074	February 2018 Emails
Novartis 11	CTRL-0025801, at Slide 12	January 2015 Presentation Excerpt
Novartis 12	CTRL-0088408, at Page 1	2014 Draft Messaging Document
Novartis 13	CTRL-0061584, at Page 1	Financial Analysis
Novartis 14	CTRL-0095459, at Slide 19	July 2013 Presentation Excerpt
Novartis 15	CTRL-0092356, at Slide 1	Presentation Excerpt

U.S. Oncology WAC Price Comparison among Branded Agents

Therapeutic Area	Current (Apr 2016)	Competitor 1	Competitor 2	Competitor 3	Competitor 4	Novartis Brand 2015	Novartis Brand 2016	Competitor 1 2015	Competitor 1 2016	Competitor 2 2015	Competitor 2 2016	Competitor 3 2015	Competitor 3 2016	Competitor 4 2015	Competitor 4 2016
CML	Gleevec $10,123	Sprycel $11,299	Iclusig $15,334	Bosulif $12,014	Synribo $12,768	Jan: 9.9% Jul: 9.9%		Mar: 7.50%	Jan: 4.90% Jul:4.00%	Feb: 8.99% Sep: 5.94%	Jan: 9.00% Apr: 8.01% Jul: 9.00%	Jan: 6.0% Jun: 9.4%	Jan: 5.0% Jun:5.00%	Aug: 4.07%	Apr: 4.95%
Iron Chelators	[redacted]														
CLL - First Line															
ITP															
Multiple Myeloma															
GIST	Gleevec $10,123	Sutent $10,093	Stivarga $13,843			Jan: 9.9% Jul: 9.9%		Jan: 7.0% Jun: 5.0%	Jan: 5.0% Jun:5.0%	Jan: 8.0% Jul: 5.9%	Jan: 6.0% Jul: 4.5%				

Discount to Novartis product
Premium to Novartis product
+/- 2% of Novartis product

1 Pricing as of 7/7/2016

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Novartis Product Lifetime & 10 Year Price Increases and CAGRs as of 8/31/2016

Brand Name	Strength	Launch Date	Launch Price	Current Price	Lifetime CAGR	Lifetime PI
[redacted]						
GLEEVEC	400 mg	11/15/2003	$ 2,120.41	$ 10,122.43	13.0%	377.4%
[redacted]						

Brand Name	Strength	Initial Date	8/31/2006 Price	Current Price	10YR CAGR	10YR PI
GLEEVEC	400 mg	8/31/2006	$ 2,641.90	$ 10,122.43	14.4%	283.1%
[redacted]						

6 | Pricing as of 7/7/2016

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Oncology Product WAC Price Change

Novartis and some newly launched non-NVS products review

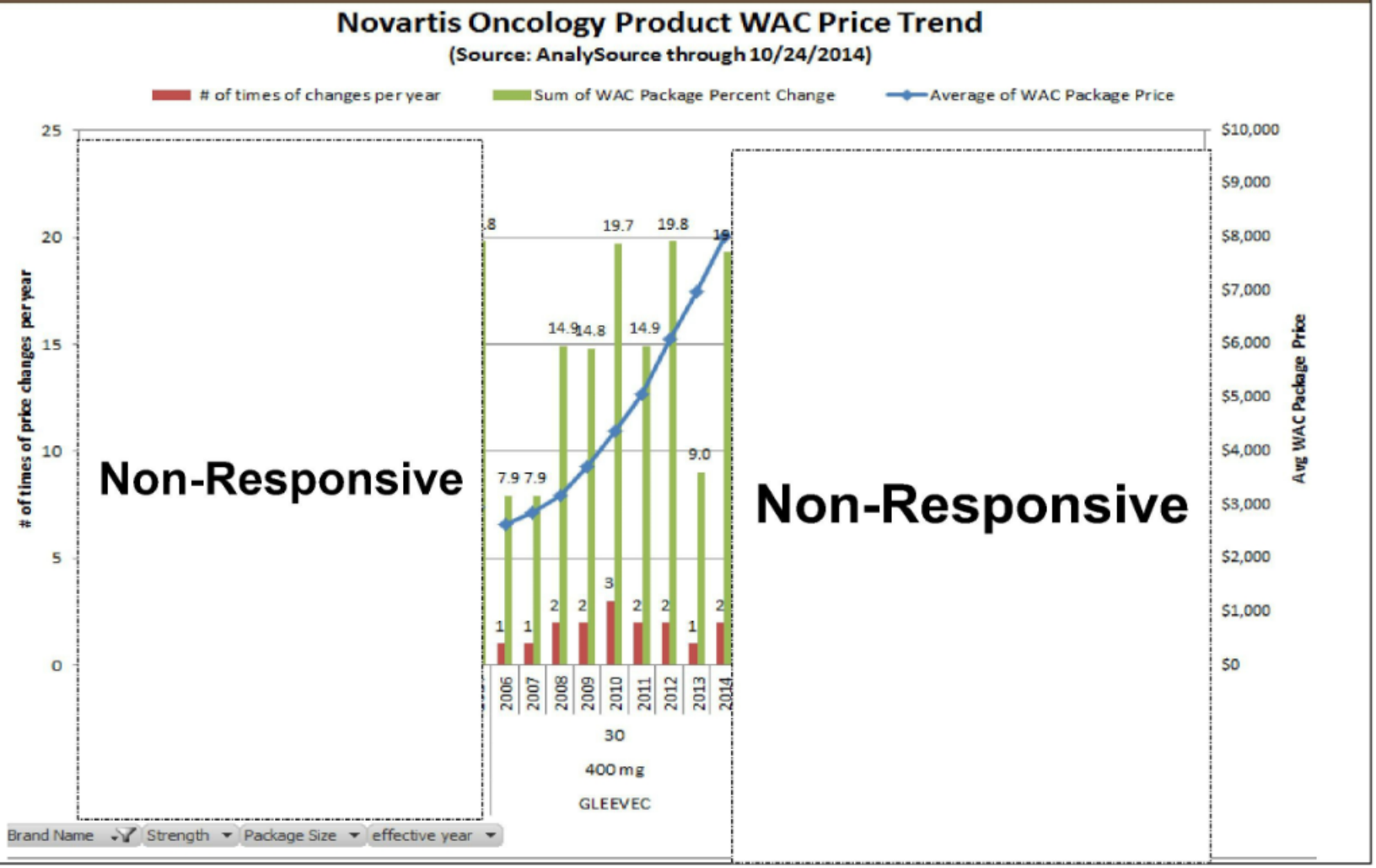
[redacted]

October 24, 2014

NOVARTIS

Gleevec prices increased as it approaches LOE

Non-Responsive

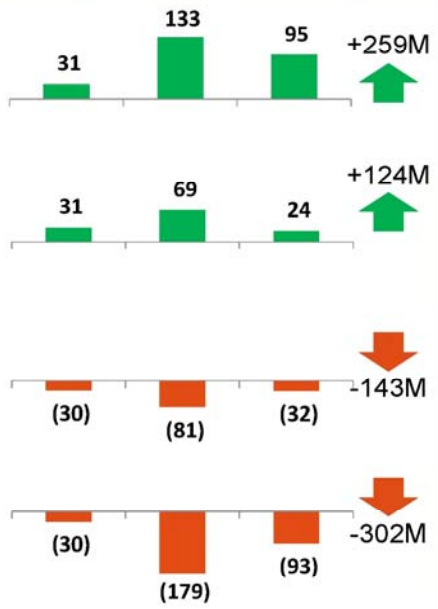


Gleevec Pricing Scenarios

Risk to Strat Plan if Action Not Taken in 2013

	2013	2014	2015
Strat Plan	4.9% Jul	9.9%	9.9%
Aggressive	9.9% Jul	9.9% Jan, 9.9% Jul	9.9% Jan, 9.9% Apr
ST Management	9.9% Jul	9.9% Jan	9.9% Jan
ST Management, hold strat	0% Jul	9.9% Jan	9.9% Jan
No Price	0% Jul	0%	0%

Net Sales vs Plan



Comments

- Delivers greatest upside while keeping single increases below 10% threshold Given July increase, recommend enhancements to patient support programs.
- Delivers value in line with strat plan, while delaying increase to late 2013/early 2014. However 15.9% single increase levels may bring greater negative reaction.
- Eliminates mid-year increase, but creates sizeable gap vs plan as compounding effect impacts outer years
- Limits PR risk but creates significant gap in plan.

one3 Patient. Team. Solution.

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CML Market: WAC Based Pricing
July Pricing Action Discussion with Brand Team

Prepared by

[redacted] Oncology Managed Markets

Actuals Updated Nov 28, 2012

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Tsg/Glv Pricing Strategy Discussion

Current Pricing Strategy

- Decrease the pricing gap between Gleevec and Tasigna
  - Recommendation was to only take price increase on Gleevec
- 2013 Budget: 4.9% July Gleevec, none for Tasigna

Discussion Points

1. Does the current pricing strategy apply given the recent market insights?
   - Decreasing Tasigna's premium vs Gleevec was important given our payer strategy
   - Market insight from the recent Gleevec LOE workshop indicated that payers are going to prefer generic Gleevec anyway and that pricing/contracting will not impact decision
2. What level of Gleevec price increase is acceptable?
   - Are we prepared for media scrutiny
   - What messaging/value story will be communicated
3. When should we take a price increase on Tasigna?

Recommendation

- Gleevec: Maximize value of brand prior to LOE-9.9% in July
  - Need to be prepared to respond to external customer/media
- Tasigna: Take smaller (2-3%), more frequent price increases . Could start as early as July.
  - Minimizes pricing gap vs Sprycel if BMS decides not to follow suit and customer/public reaction

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.

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From: [redacted]

Sent: Friday, July 12, 2013 9:29:17 PM

To: [redacted]

Subject: Fwd: For your approval: Gleevec pricing action at end of July

Dear All,
In terms of stakeholder management, we will be ready to go with pricing action on July 31st. [redacted] does this date work for finance team?

Sent from my iPhone

Begin forwarded message:

From: [redacted] CCFI: Confidential Commercial & Financial Information
Date: July 12, 2013, 8:16:13 AM CDT
To: "[redacted] CCFI: Confidential Commercial & Financial Information
Cc: "[redacted]
Subject: Re: For your approval: Gleevec pricing action at end of July

Thanks [redacted]
I agree with end of July.

I don't like the plan on key messages. They are the old, stale, nonimpactful blah blah blah.

Suggest the patient access approach with our increasing commitment to copay foundation at $25M, dollar value of PAP etc

[redacted]

On Jul 11, 2013, at 11:36 PM, "[redacted] CCFI: Confidential Commercial & Financial Information wrote:

Hi [redacted]
I recommend we go with option A which is to take the price increase at the end of July. It will be very challenging to complete all the actions described in scenario A in the attached plan, but i think we can get most of it done in next two weeks. We will have to streamline the approvals as we discussed.

Please let me know if you agree.

Thanks!

[redacted]
Sent from my iPhone

Begin forwarded message:

From: "[redacted] CCFI: Confidential Commercial & Financial Information
To: "[redacted], [redacted]
CCFI: Confidential Commercial & Financial Information, "[redacted]n"
e"
CCFI: Confidential Commercial & Financial Information
Cc: [redacted] CCFI: Confidential Commercial & Financial Information
Subject: RE: Draft GLEEVEC Scenarios Memo

All,

We have incorporated your feedback into the final version of the memo, attached here for your review. Thank you for your input.

[redacted]
Consultant

APCO Worldwide
700 12th Street, N.W.
Suite 800
Washington, D.C. 20005

CCFI: Confidential Commercial & Financial Information

----- Original Message -----
From: [redacted]
Sent: Thursday, July 11, 2013 05:44 PM Eastern Standard Time
To: [redacted]
Cc: [redacted]
Subject: RE: Draft GLEEVEC Scenarios Memo

Dear All,

Please find my edits in blue. I updated the document sent around by [redacted] As you will see, I changed PAP to patient access programs throughout the document to incorporate all the support programs offered to patients.

If you need to get in touch with me tonight, you can call my cell at [redacted]

Best,
[redacted]

[redacted]
Executive Director, Patient Advocacy and Access Public Affairs and Communications Novartis Oncology One Health Plaza East Hanover, NJ 07936-1080 USA

CCFI: Confidential Commercial & Financial Information
Fax +1 973-781-2362
CCFI: Confidential Commercial & Financial Information
www.novartis.com

-----Original Message-----
From: [redacted]
Sent: Thursday, July 11, 2013 3:47 PM
To: [redacted]
Cc: [redacted]

US Pricing Scenarios

ECN project update
October 17, 2016

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Scenario 2: Major federal level healthcare reform

Worst case "possible" scenario with very low probability

Potential actions	2020 NVS revenue impact ($ Billions)
• **International net price referencing for specialty products.** CMS requires companies to **self-report US and ex-US** net prices for all specialty products; **mandates a glide path** towards ex-US net prices over a 5-10 year period. ➢ Assume implementation begins 2018	**$2.0 – 3.0 B[1]**
• **Personal importation approved for non-specialty, oral drugs** (up to 90 day supply) from select countries beginning in 2019. Assume that ex-US CPOs increase sales from importation, so US business impact is ~2x Novartis Group impact. ➢ Assume implementation begins 2019	**$0.5 - $0.7 B[2]**
• All actions from **Scenario 1**	**$1.5 - $2.0 B**
	$4.0 - $5.7 B

CCFI: Confidential Commercial & Financial Information

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CCFI: Confidential Commercial & Financial Information

Gleevec LOE: Payer Contracting Workshop

April 23, 2014

Workstream Lead: [redacted]

Core Team: [redacted]

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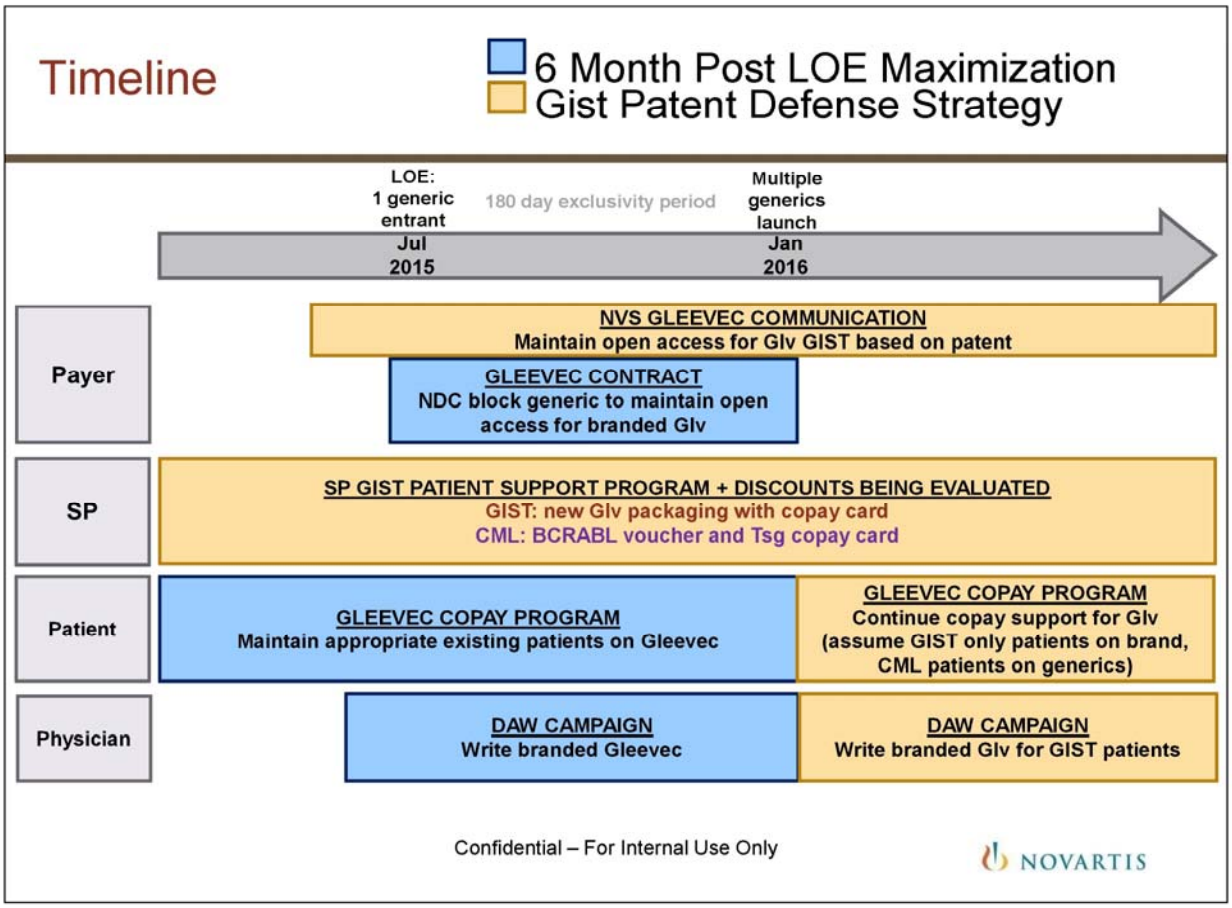

Novartis Document 8

gleevec®
(imatinib mesylate) tablets

US Gleevec LOE

Working Cross-Functionally to Ensure Success

July 16, 2015

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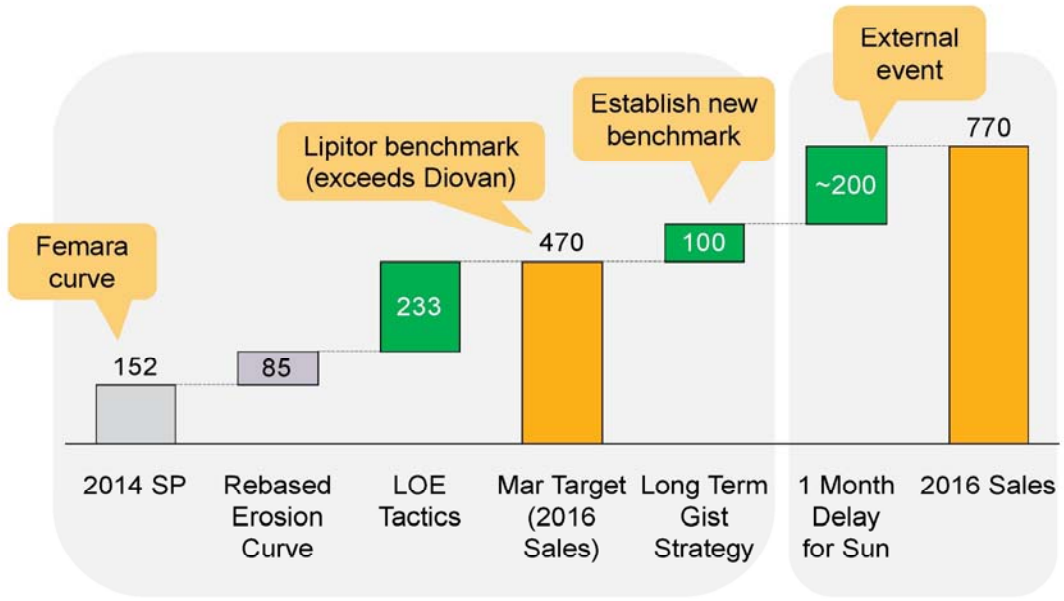
Organizational Expectations

LOE Tactics, Long Term GIST Patent Strategy, and Potential Delay in 1st Generic Launch Are Needed to Reach $770M Net Sales in '16

Evolution of Gleevec Net Sales for 2016 (*$ Millions*)



Note: Average daily sales pre LOE ($7M), 6 months exclusivity ($2.5M) and rest of the year ($1M)

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From: [redacted]

Sent: Monday, February 19, 2018 5:56:09 PM
To: [redacted]
Subject: RE: Gleevec LOE team Recognition background

Sorry to have to ask again. I will take action now.

Regards,

[redacted]

From: [redacted]
Sent: Monday, February 19, 2018 11:48 AM
To: [redacted]
Subject: FW: Gleevec LOE team Recognition background

Here you go. Thanks.

From: [redacted]
Sent: Thursday, February 1, 2018 12:39 PM
To: [redacted]
Subject: Gleevec LOE team Recognition background

[redacted]

Below is the information around the Gleevec LOE team performance and subsequent recognition. Appreciate your willingness to try and address with [redacted] on behalf of the team.

The Gleevec LOE team started working 2 years prior to LOE and for some of us up until now.
There were weekly senior management meetings after normal working hours for over a year and extensive global reporting and communication that took place in addition to developing and executing our strategy. Extensive time (almost 2 years) spent with Sandoz to counter their interest to launch AGx. In a video conference with Joe, to explain why the gleevec LOE went so well in late 2016, Joe said "I now understand why launching an AGx would have been a disaster"

For 2016 the brand came in over $400MM over a stretch budget target of $770 MM, retaining nearly 50% or prior year's nets sales with a Feb 1 generic entrant. In December of 2016 [redacted] was told by [redacted] "thank you for saving the company this year". The team was eventually recognized with a Global CEO award in May of 2017 which awarded 10 team members $1,000 each, payable at end of July 2017. When [redacted] announced the award to the team back in May he indicated that he was not sure what the award amount was and that if it was not sufficient the US OBU would supplement. 2017 results were also above expectations with net sales of $627 MM. Team has worked extensively with other brands both within Oncology and Pharma to share learnings in preparing for future LOEs.

Team members currently with company: **CCFI: Confidential Commercial & Financial Information**

CCFI: Confidential Commercial & Financial Information

Details from award submission:

- Situation – US business was facing significant challenge due to expected entry of generics for Gleevec in the market. Gleevec is an important product not only for the organization (generated $2.5B in '15 net

sales in US) but more importantly for patients/HCPs community who have relied on Gleevec for more than 15 years since approval in 2001 CML, GIST, and other rare cancers and diseases

- Objectives – Generation Gleevec team was charged to *"establish a new benchmark in lifecycle management"* by ensuring patients and HCPs are aware of the options they have with generics entering the market place.

- Tactics – The cross functional team focused on 3 main areas of focus

    1. Maximize patient access and support – Gleevec patient support program, educate on generic imatinib entering the market, educate on options to stay on Brand (DAW), Co-pay support for eligible patients, Package and Tablet Change

    2. Optimize market access –general contracting for brand vs generic and also optimizing decision for launching an AGx with Sandoz

    3. Establish long term GIST strategy – appropriately enforce GIST patent, GIST ICD-10 code, and assessing GIST related contracting

- Accomplishments – Generation Gleevec team focused on educating and informing patients and establish new benchmarks on multiple fronts – highest level of DAW (>65% of brand Rx maintained over 6 months), success in contracting (>25% of business at just 31% RD rate-twice as much business under contract and half the rate of GenMeds LOE products), brand share of >50% with multiple generics in the market, copay utilization of >7,000 and Patient Hub enrollment of >5,000. Nov LO for US sales is $1,187M, $417M above budget ($770M was the stretched budget target for the year, compared to $470M which was in line with Lipitor analogue). The team is on track to establish a new benchmark in lifecycle management.

Describe the actions which demonstrate the Value & Behavior (Maximum 750 characters). *Describe the actions of the team that role modeled the Values & Behaviors, and why you think this particular program goes above and beyond what is expected.*

- V&B category: Performance

- The cross functional Generation Gleevec team was able to achieve exceptional results while managing Gleevec LOE by innovating, prioritizing and making things happen with urgency.

- All the team members individually and together went above and beyond to bring solutions and information to patients/HCPs quickly and effectively over the past 2 years before and through generic entry

- Some key highlights that demonstrate team delivering exceptional results – innovative Med D messages for one of the first high priced Med D product to face generic competition, enrollment of >5,000 patients in the support program in less than a year, >7,000 copay card utilizations within year of launch, collaboration with Sandoz to optimize AGx decision, regular communication with the VA, targeted copay comparison messages for the field force within a week of Sun Pharma's launch of copay offer, highest level of contracting with plans/pharmacies and many others

- Finally, the team is formally sharing lessons learned across key stakeholders to help ensure the experiences inform other future LOEs within the OBU and rest of Novartis

CML Management

Wednesday

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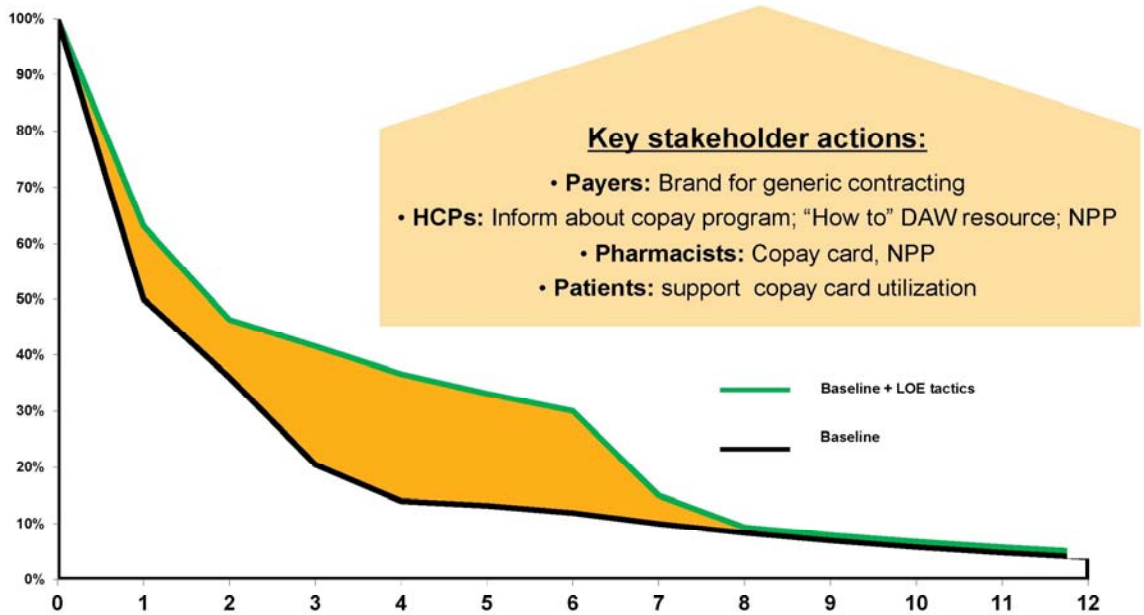
The Science of Medicine
The Art of Access

OMA ONCOLOGY MARKET ACCESS

LOE Contracting Can Provide Significant Upside



Key stakeholder actions:

- **Payers:** Brand for generic contracting
- **HCPs:** Inform about copay program; "How to" DAW resource; NPP
- **Pharmacists:** Copay card, NPP
- **Patients:** support copay card utilization

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

NPP = Non-personal promotion.

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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?

Novartis Document 12

Customer's First Initiative Financial Details - Incremental Revenue				
Initiative Name	**Initiative Description**	**Project Owner**	**Project Timing**	**Divisions Included**
US15411_Gleevec Packaging	Assessing the impact of the new Gleevec packaging with the blister packs. Key Learnings from the Diovan LOE are leveraged as we prepare for the Gleevec LOE. Key learnings shared on Divoan for the Gleevec packaging to blister pack.	[redacted] General Medicines:	Continued through 2015 to 2016	US General Medicines US Oncology

Financial Methodology and Assumptions

Improved packaging can have 2 effects on Gleevec sales.
1) Improved packaging can increase adherence.
2) Improved packaging can slow generic erosion (impact would occur in 2016).

Initiative Assumptions

[redacted]
Non-Responsive

Financial Calculations

2.5 billion x 1% adherence increase x 6 months (2nd half of year) = $12,500,000.

Management Results Calculations

Completed by:	[redacted]
Reviewed by Finance:	[redacted]

CML Pricing

Task Force Message Data Sources and Key Takeaways

July 12th, 2013

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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]**

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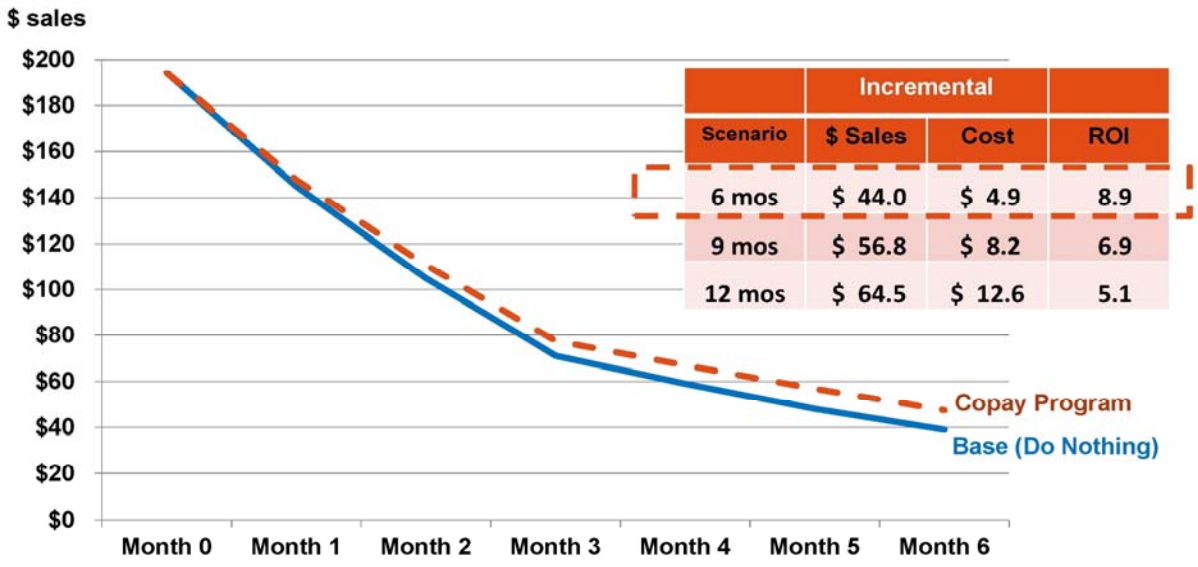
The Optimal Scenario is a 6 month Pre-LOE Start for the Enhanced Copay Program



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

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