Drug Pricing Investigation

AbbVie—*Humira and Imbruvica*

Selected Investigation Documents

Staff Report
Committee on Oversight and Reform
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AbbVie Selected Documents

Document #	Citation	Short Description
AbbVie 1	ABV-HOR-00042146	April 2008 Strategy Document
AbbVie 2	ABV-HOR-00042168	October 16, 2008 Strategy Document Titled: "Humira and Hidradenitis Suppurativa"
AbbVie 3	ABV-HOR-00030706	July 2010 Presentation Excerpt
AbbVie 4	ABV-HOR-00032081	October 8, 2018 Emails
AbbVie 5	ABV-HOR-00031271	January 19, 2011 Memorandum
AbbVie 6	ABV-HOR-00032430	March 8, 2011 Emails
AbbVie 7	ABV-HOR-00032366	April 26, 2011 Emails
AbbVie 8	ABV-HOR-00034291	June 2011 Presentation Excerpt
AbbVie 9	ABV-HOR-00136539	January 2012 Emails
AbbVie 10	ABV-HOR-00034241	2012 Strategy Document
AbbVie 11	ABV-HOR-00033937	February 2013 Presentation
AbbVie 12	ABV-HOR-00032882	March 8, 2013 Emails
AbbVie 13	ABV-HOR-00036813	June 11, 2013 Presentation
AbbVie 14	ABV-HOR-00032198	February 2014 Presentation
AbbVie 15	ABV-HOR-00033966	August 2014 Presentation
AbbVie 16	ABV-HOR-00040491	November 2014 Presentation
AbbVie 17	ABV-HOR-00138392	February 2015 Presentation Excerpt
AbbVie 18	ABV-HOR-00033181	July 2015 Presentation Excerpt
AbbVie 19	Public Document	October 30, 2015 Board Presentation Excerpt
AbbVie 20	ABV-HOR-00036196	January 8, 2016 Emails

AbbVie 21	ABV-HOR-00039140	April 6, 2016 Email
AbbVie 22	ABV-HOR-00048274	September 2016 Presentation Excerpt
AbbVie 23	ABV-HOR-00033663	September 2016 Presentation Excerpt
AbbVie 24	ABV-HOR-RR-00012724	October 2016 Presentation Excerpt
AbbVie 25	ABV-HOR-00033572	December 2016 Presentation
AbbVie 26	ABV-HOR-RR-00001539	October 29, 2017 Email
AbbVie 27	ABV-HOR-00039036	November 28, 2017 Email
AbbVie 28	ABV-HOR-00032081	October 8, 2018 Email
AbbVie 29	ABV-HOR-00092105	October 2018 Presentation Excerpt
AbbVie 30	ABV-HOR-RR-00006005	October 2018 Presentation Excerpt
AbbVie 31	ABV-HOR-RR-00000739	November 5, 2018 Letter to Vermont Attorney General
AbbVie 32	ABV-HOR-00172913	Rick Gonzalez 2018 Bonus Document

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

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- *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.

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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.

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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

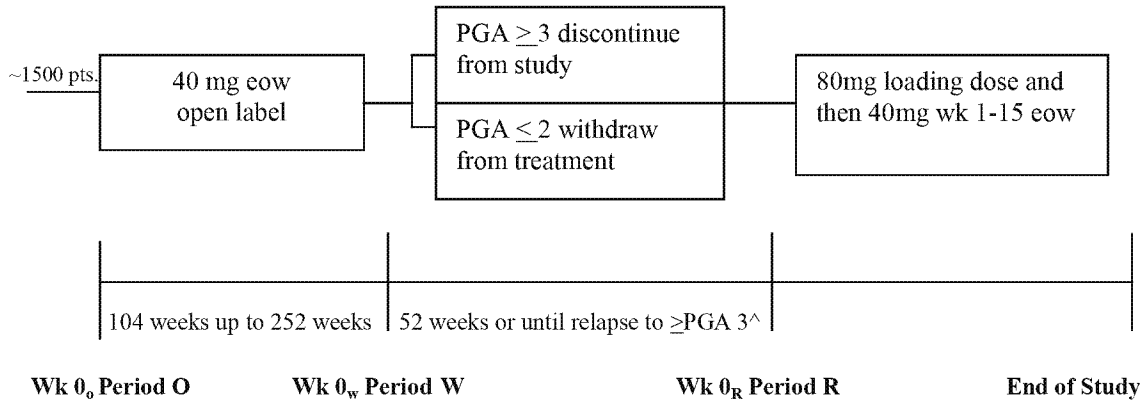
Ongoing Studies in Humira Dermatololgy

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).

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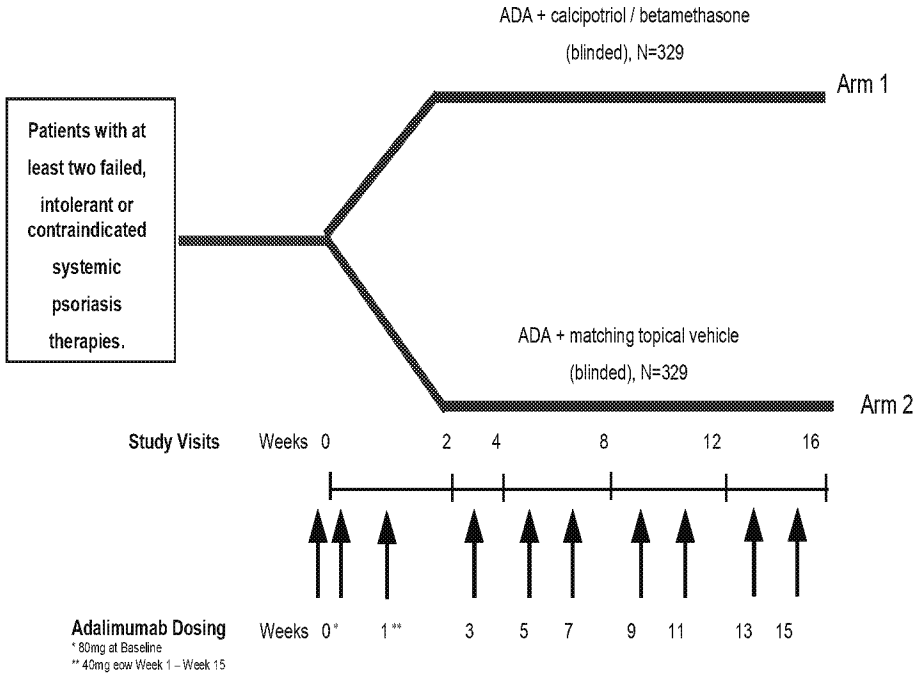

Since concomitant high potency steroids were excluded from the phase 3 program, this study will provide information to prescribers on the whether there is additional benefits to continuing these therapies while a patient is on adalimumab, and to confirm there are no safety concerns with such a combination.

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

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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.

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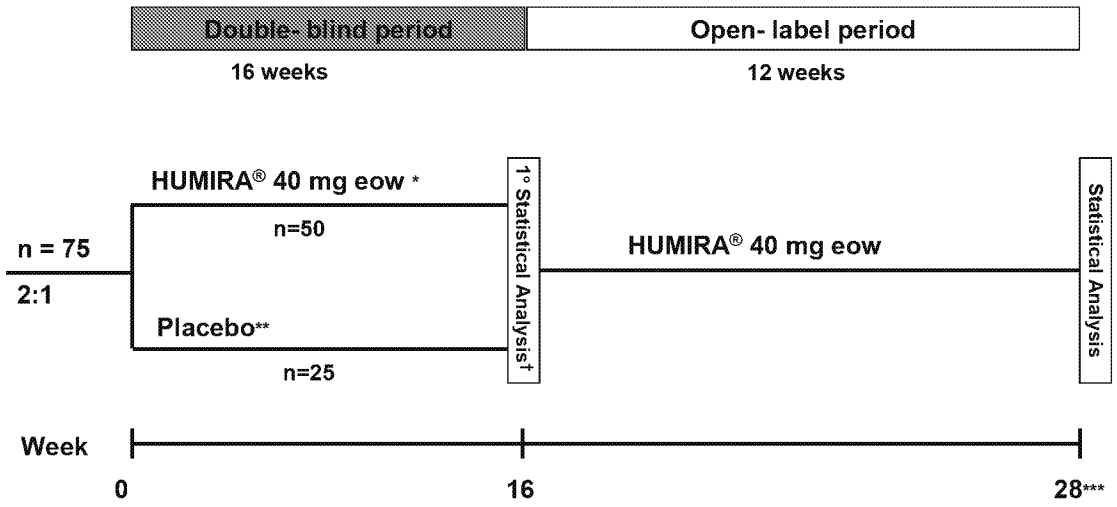
The study includes an initial 16-week double-blind placebo-controlled period, which will be followed by an open-label 12 week period. Randomization will be 2:1 (adaliumumab:placebo). The open-label period will allow patients on placebo to receive adalimumab treatment as well as to provide information 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

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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.

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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.

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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.

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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.

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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

AbbVie 2

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).

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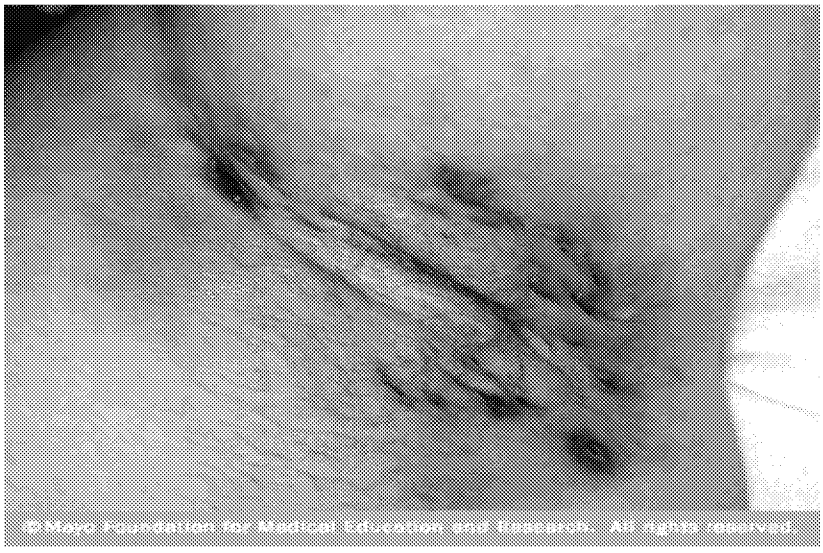
HS Disease Overview

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.

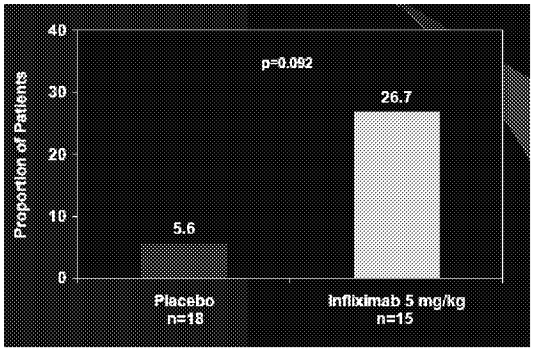
HSSI Scoring Table

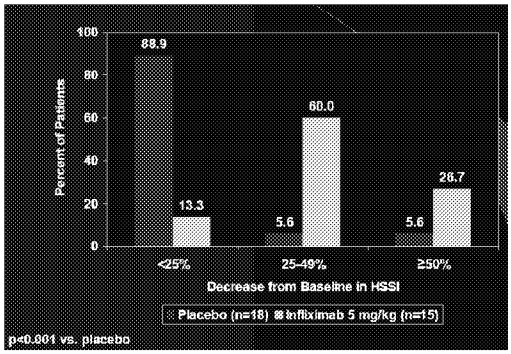
	Number of Sites	Body Surface Area (%) SAGE	# Lesions (erythematous, painful)	Drainage (# dressing changes/working hours)	Pain (VAS)
0	0	0	0	0	0-1
1	1	1	1-2		
2	2	2-3	2-3	1	2-4
3	3	4-5	3-4	>1	5-7
4	>4	>5	>5		8-10

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.

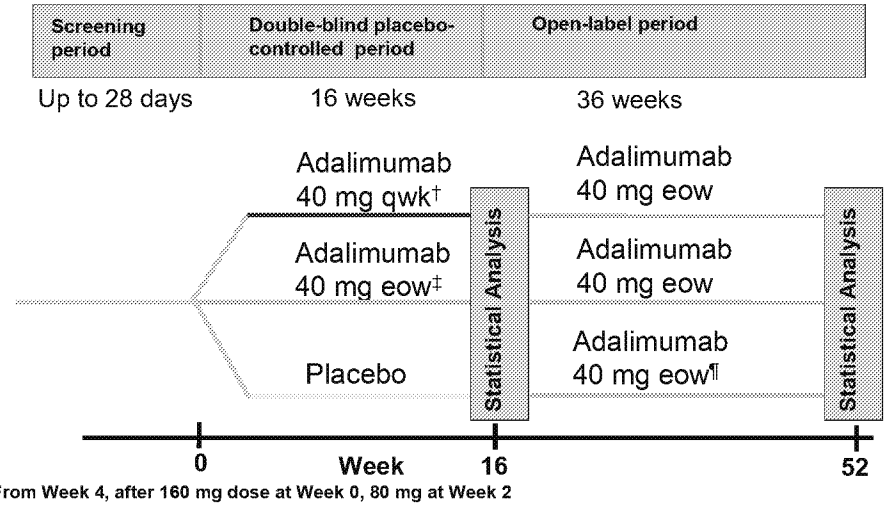
An advisory board with key opinion leaders in the field of HS in both US and Europe was assembled on June 3, 2008. Consensus was reach on the trial design along with the proposed primary endpoint definition.

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.

References

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2011 GPRD Plan Portfolio Development Project Review

Project Detail Reference Binder

July 16, 2010

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2011 GPRD Plan Prioritization

Gastroenterology: HUMIRA Mild to Moderate CD

Overall Project Objective	• Two Multicentre, Randomised, Double-blind Studies of the Human Anti-TNF Monoclonal Antibody Adalimumab for the Induction and Maintenance of Clinical Remission in Adult Subjects with elevated inflammatory markers, and with symptom scores that may be defined as mild/moderate • To demonstrate the efficacy and safety of adalimumab administered subcutaneously in adult subjects who have elevated inflammatory markers regardless of symptoms scores
Strategic Rationale	• This study would open a new patient pool of patients who could benefit from anti TNF • This supports earlier use of HUMIRA in what is estimated to be a large population of patients and is well aligned with other initiatives supported by Abbott (disability index, disease progression score, calprotectin strategy)
2011 Project Objective	• To obtain regulatory approval for treatment of subjects with elevated biomarkers independent of symptomatic status
Target Product Profile; or Success Criteria	**Efficacy:** Study A: Clinical Remission, CDAI ≤ 150 at 52 weeks Study B: Clinical Remission, CDAI ≤ 150 at 52 and 104 weeks In the combined studies of M02-404 and M05-769, subjects with baseline CDAI <= 300 has remission rates of 13% for placebo and 30% for ADA eow **Safety:** In all clinical trials, rate of infection in patients treated with Humira is similar to patients treated with placebo •Injection site reactions are mild and transient, occur in ≤ 20% of patients
Key Project Risks, Issues and Opportunities	• Regulatory success of study will be dependent on obtaining and following regulatory agency (FDA and EMA) advice prior to study initiation, specifically regarding risk/benefit in study population and long-term safety • Symptoms scores are mostly driven by subjective assessments; inflammatory markers may be more reflective of true disease activity, and more predictive of relapse and mucosal damage

Key Dates:		Project External Cost, $MM		2011 External Cost, $MM		Key Value Metrics	
Launch Date	2015	2010 LBE	0.0	Committed by 5/31/10	0.0	Risk-adj NPV (20 yr, $MM)	$923
Redacted		2011 Est	11.5	Remaining to be committed by 12/31/10	0.0	Prob Success, %	60%
		2012 – End	23.1	Uncommitted	11.5	Risk-adj IRR, %	75%
Key G/NG Milestones (7/10 – 12/11)		Total, '10-end	34.6			Peak Sales, $MM (US/ExUS)	$336 / $244
		Contractual Commitment				Cum risk-adj sales, '11-'15	$92
		No				Cum risk-adj sales, '16-'20	$1,308

Key 2011 Activities:	Activity:	Brief Description
	Clinical	Study A: 1:1 Active:PBO, 175 subjects in each arm followed for 52 weeks
	Regulatory, HEOR and Other (Data Management/Statistics, Global Drug Supply Management, Research QA, Clinical Project Teams, etc	Study B: 1:1 Active:PBO, 228 subjects in each arm, followed for 104 weeks. At week 52, re-randomization and de-escalation of ADA for subjects meeting criteria
	Regulatory, HEOR and Other (Data Management/Statistics, Global Drug Supply Management, Research QA, Clinical Project Teams, etc	Standard support, submission activities, and preparation for Regulatory commitments such as the Global Registry

New Project for 2011

Key Clinical Studies / NonClinical Activities Ongoing/Proposed for 2010/2011
Gastroenterology: HUMIRA Mild to Moderate CD

Activity	Brief Description	Timeline (mo/yr)		Ext. Cost, $MM	
		Start	Finish	2010 LBE	2011
Clinical Studies (from IMPACT)	See next page for detail			$ -	$ 11.53
Total Portfolio Project Ext Expense				$ -	$ 11.53

Product Code: ABT-D2E7

TA: Immunology

Indication: Mild / Moderate CD

Study Number	Study Phase	Description	Planned No. Pts	Actual No. Pts	FSFD	LSLV	DBL	CSR	Ext Budget 2010 LBE	Ext Budget 2011
Study Status: Proposed									-	11.53
12489	Phase III	Phase 3 Mild Moderate Study 1 - 12489	350	0	Apr 4, 2011	Apr 4, 2013	Apr 18, 2013	Jul 31, 2013	-	6.21
12490	Phase III	Phase 3 Mild Moderate Study 2 - 12490	350	0	Apr 4, 2011	Apr 7, 2014	Apr 21, 2014	Jul 31, 2014	-	5.32
Grand Totals									-	11.53

2011 GPRD Plan Prioritization

Gastroenterology: HUMIRA Tight Control Study / CALM

Overall Project Objective	• Answer multiple questions regarding the optimal use of HUMIRA in Crohn's disease
Strategic Rationale	• Show that tight control of disease activity via more intensive therapy based on objective parameters such as biomarkers in combination with clinical symptoms leads to better outcomes vs conventional therapy • Generate date in a bio-naïve population and differentiate from competitors and early biosimilars • Work collaboratively with KOLs to execute the study and eventually influence ECCO guidelines that will advocate early biologic therapy as standard-of-care, and highlight Humira as potentially the biologic of choice
2011 Project Objective	• Show that Utilizing a therapeutic algorithm that allows for treatment intensification based on objective parameters will lead to improved patient outcomes vs a standard, symptoms-based, approach • Objective parameters include calprotectin, CRP, and CDAI remission • Continue study conduct and enrollment
Target Product Profile; or Success Criteria	**Efficacy:** Improved mucosal healing rates vs conventional therapy **Safety:** Same as label **Convenience:** Same as label
Key Project Risks, Issues and Opportunities	• Publication only • May impact Crohn's disease guidelines ex US • Humira is being used to compare methods of treatment, thus there is no type of 'failure' that can be attributable to treatment • Dose escalation to EW may be higher than anticipated - Slow study enrollment

Key Dates:		Project External Cost, $MM		2011 External Cost, $MM		Key Value Metrics	
Launch Date	ECCO 2012: Initial look at data 2Q/2014: Primary Manuscript	2010 LBE	2.6	Committed by 5/31/10	0.1	Risk-adj NPV (20 yr, $MM)	$750
Redacted		2011 Est	6.1	Remaining to be committed by 12/31/10	5.8	Prob Success, %	90%
		2012 – End	5.1	Uncommitted	0.1	Risk-adj IRR, %	186%
Key G/NG Milestones (7/10 – 12/11)	N/A	Total, '10-end	13.8			Peak Sales, $MM (US/ExUS)	$240
		Contractual Commitment				Cum risk-adj sales, '11-'15	$425
		No				Cum risk-adj sales, '16-'20	$1,065

Key 2011 Activities:	Activity:	Brief Description
	Clinical	Continue study conduct and enrollment

Ongoing Project for 2011

Key Clinical Studies / NonClinical Activities Ongoing/Proposed for 2010/2011
Gastroenterology: HUMIRA CD Tight Control Study/ CALM

Activity	Brief Description	Timeline (mo/yr)		Ext. Cost, $MM	
		Start	Finish	2010 LBE	2011
Clinical Studies (from IMPACT)	See below for detail			$ 2.61	$ 6.09
Total Portfolio Project Ext Expense				$ 2.61	$ 6.09

Clinical Studies (in IMPACT) Ongoing/Proposed for 2010/2011

Product Code: ABT-D2E7

TA: Immunology

Indication: CD Tight Control Study

Study Number	Study Phase	Description	Planned No. Pts	Actual No. Pts	FSFD	LSLV	DBL	CSR	Ext Budget 2010 LBE	Ext Budget 2011
Study Status: Protocol Number Assigned									2.61	6.09
M11-271	Phase III	Ph III Tight Control Study	240	0	Sep 15, 2010	Oct 10, 2012	Oct 24, 2012	Dec 18, 2012	2.61	6.09
Grand Totals									2.61	6.09

Message

From: [redacted]

Sent: 10/8/2018 5:34:00 PM
To: [redacted]
CC: [redacted]
Subject: RE: Humira 15-Day Price Action Key Plus/Minus
Attachments: Reval Slide 10.8.18.pptx

See attached

From: [redacted]
Sent: Monday, October 8, 2018 4:26 PM
To: [redacted]
Cc: [redacted]
Subject: RE: Humira 15-Day Price Action Key Plus/Minus

[redacted] - several key points to maximize revaluation at wholesale:

- Price action effective date on a Monday (either 1/7/19 or 1/14/19) enables full recapture of ABC's Monday order – this revaluation value is worth ~ $17MM. ABC orders product on Mondays -- if new price is not effective at the time of ABC placing their order (on Monday), this value is lost to Abbvie.
- Also need to weigh the sellouts that occur from wholesale to pharmacy. Each day during the week Abbvie delays, the more product that is sold out the door at wholesale – and the lower the amount of inventory available at wholesale for revaluation capture (as will sit @ pharmacy).

Call me @ 5, thanks.

From: [redacted]
Sent: Monday, October 8, 2018 4:13 PM
To: [redacted]
Cc: [redacted]
Subject: RE: Humira 15-Day Price Action Key Plus/Minus

There are two components. The first is the change in net sales without reval change. The second is the reval change.

The initial downside of a 15 day delay (January 15th) is approx. ($54MM) before reval change. This includes an estimated reval of $70MM (in Plan). There is no change in reval per [redacted] with a Jan. 15 date.

If we were to delay 14 days (Monday, Jan 14th), the downside is ($47MM) before reval change and the reval benefit would be $17MM, so the total net sales downside would be $34MM.

[redacted]

abbvie

ABV1/Dept. 0303
1 North Waukegan Road
North Chicago, IL 60064
OFFICE [redacted]

EMAIL [redacted]

abbvie.com

From: [redacted]
Sent: Monday, October 08, 2018 2:41 PM
To: [redacted]
Cc: [redacted]
Subject: Humira 15-Day Price Action Key Plus/Minus

[redacted]

Are you closed to calculating the 15 day delay on the Price action for Humira?

Thanks

[redacted]

abbvie

Dept 309, Bldg. ABV1-5SE
26525 North Riverwoods Blvd.
Mettawa, IL 60045
OFFICE [redacted]
CELL
EMAIL
abbvie.com

	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 5

- 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

Message

From: [redacted]
Sent: 3/18/2011 7:46:00 AM
To: [redacted]@abbott.com]
Subject: Re: HUMIRA price acceleration

He caught me yesterday and asked, so I did let him know.

[redacted]

----- [redacted] wrote: -----

To: [redacted]
From: [redacted]
Date: 03/17/2011 05:22PM
Subject: Re: HUMIRA price acceleration

Thanks. I'll let [redacted] know.

[redacted]

[redacted]
200 Abbott Park Road
AP30-1W / D0303
Abbott Park, IL 60064
[redacted]
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[redacted]---03/17/2011 11:27:28 AM---A one month acceleration of HUMIRA 6.9% from September to August would yield $22.6MM in Net Sales, $

From: [redacted]
To:
Date: 03/17/2011 11:27 AM
Subject: HUMIRA price acceleration

A one month acceleration of HUMIRA 6.9% from September to August would yield $22.6MM in Net Sales, $19.2MM in Margin.

[redacted]

AbbVie 6
Dept. 0303, AP30

[redacted]

From: [redacted]
Sent: Tuesday, April 26, 2011 9:35 AM
To: [redacted]
Cc: [redacted]
Subject: Re: Pricing deck
Attachments: 2011 Update Price Actions Pkg_04.25.11 with products.ppt

There are many many issues that impact the 1.7% stated below such as product mix, customer mix, higher rebate rates. I added the following bullet to the presentation to describe why not all price falls through. I think this may be clearer.

VALUE OF PRICE ACTION:

• We capture only a fraction of the WAC price action. Varying by product, between 10-50% of sales do not receive the benefit of the price action (i.e. government channels allow only CPI increases, many Managed Care plans have price protection). This reduces the value of the price action.

(See attached file: 2011 Update Price Actions Pkg_04.25.11 with products.ppt)

[redacted] Dept. 0303, AP30 [redacted]

[redacted]--04/26/2011 05:11:11 AM--- [redacted] mentioned an analysis was done recently showing the effective increase for 2010 net of re

From: [redacted]

To: [redacted]@abbott.com>

Cc: [redacted]

Date: 04/26/2011 05:11 AM

Subject: Pricing deck

AbbVie 7

[redacted] mentioned an analysis was done recently showing the effective increase for 2010 net of rebates was like 1.7 percent. Can you confirm? If so add to the talking points to the deck you did yesterday...

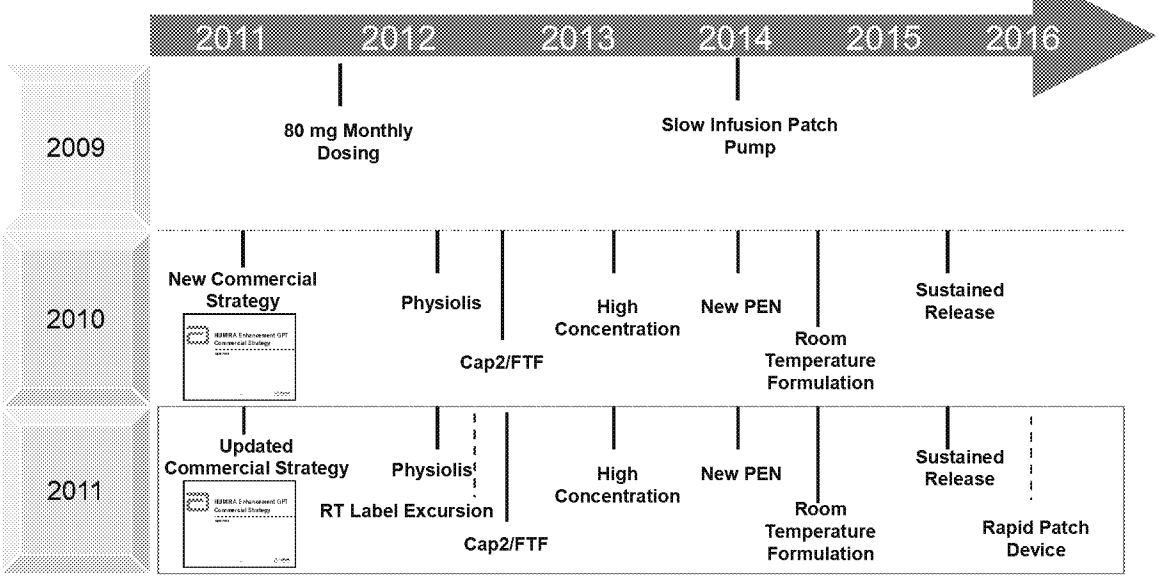
[redacted]

AbbVie 7

7/28/2020 11:20 AM

7/28/2020 11:20 AM

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



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7/28/2020 11:20 AM

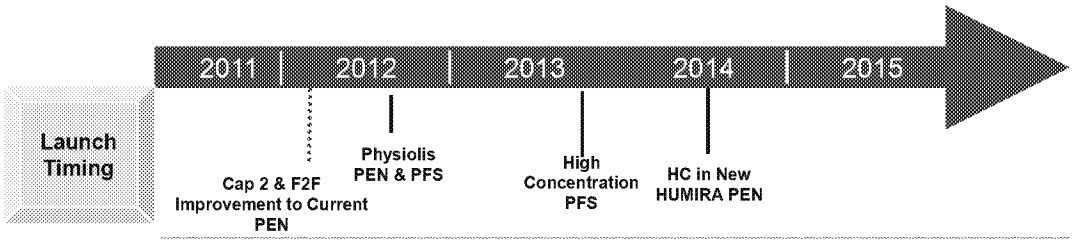
HUMIRA Enhancement Strategy and Commercial Launch Plan in 2011

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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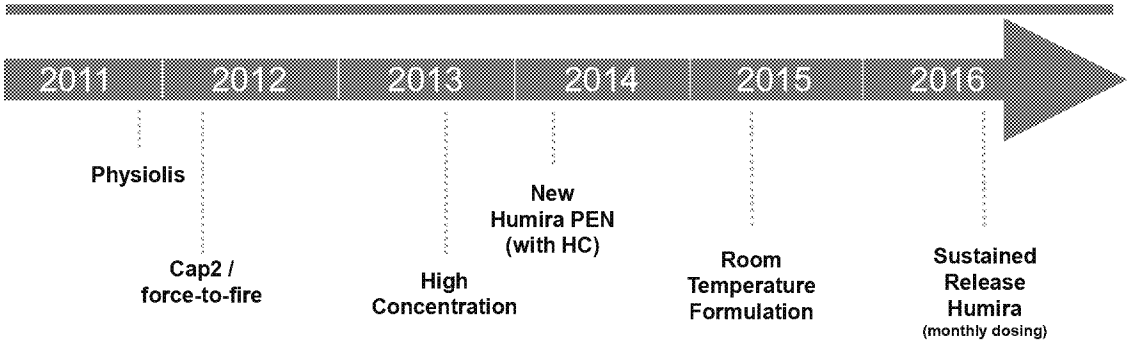
7/28/2020 11:20 AM

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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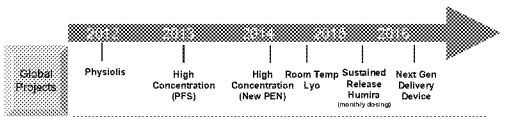
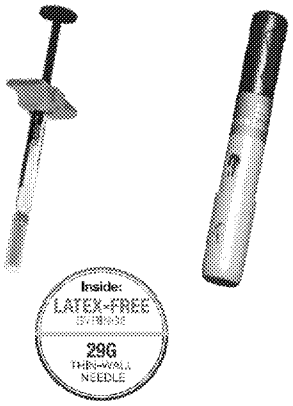
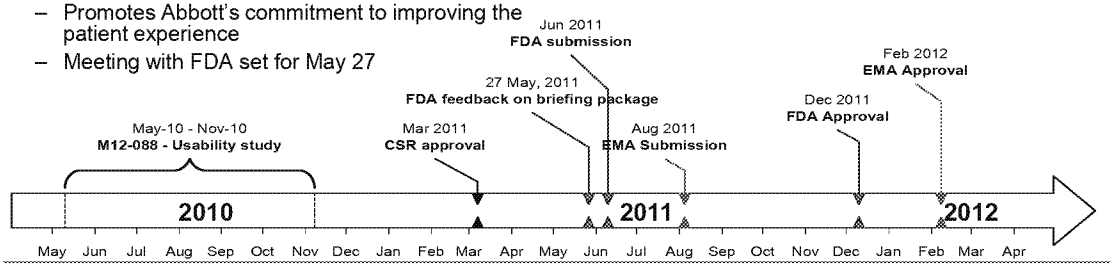
HUMIRA
Physiolis – PFS & PEN



- 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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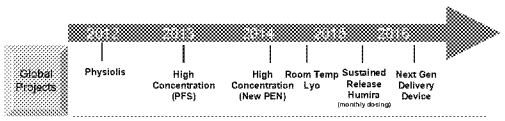
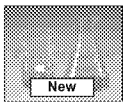
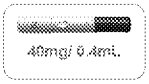
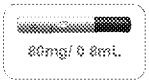
HUMIRA
High Concentration Formulation

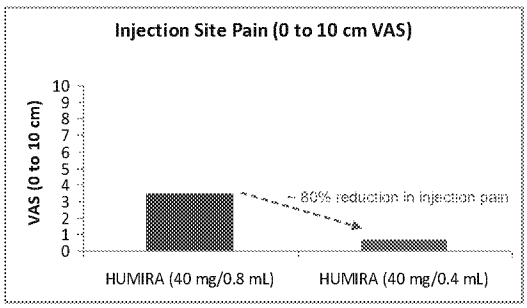


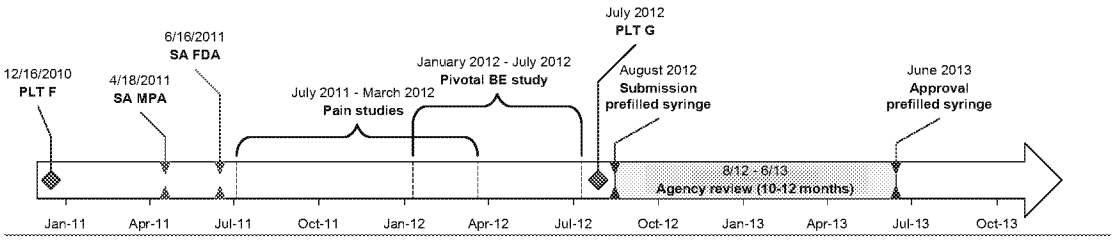






- **Project Description**
  - HUMIRA New Formulation is associated with reduced pain (e.g. stinging/burning) than current formulation
  - New Formulation has a 2-fold higher protein concentration (100mg/mL vs. 50mg/mL) to reduce the dose volume in half.
  - It is likely that the New Formulation will **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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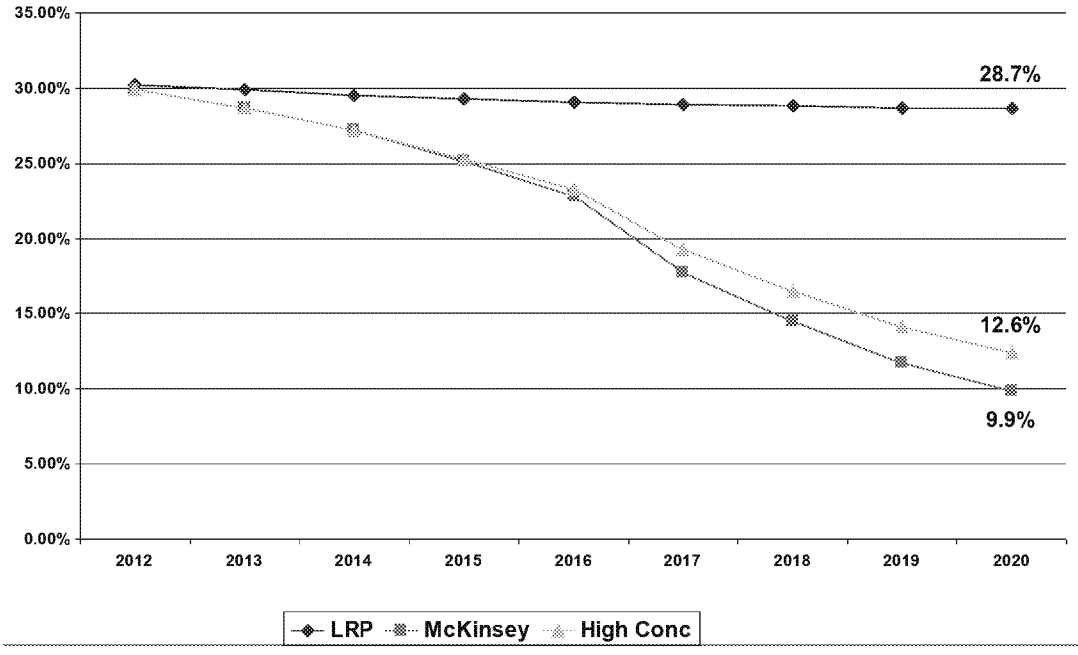
PPD
Market Share Retention with High Conc. Product



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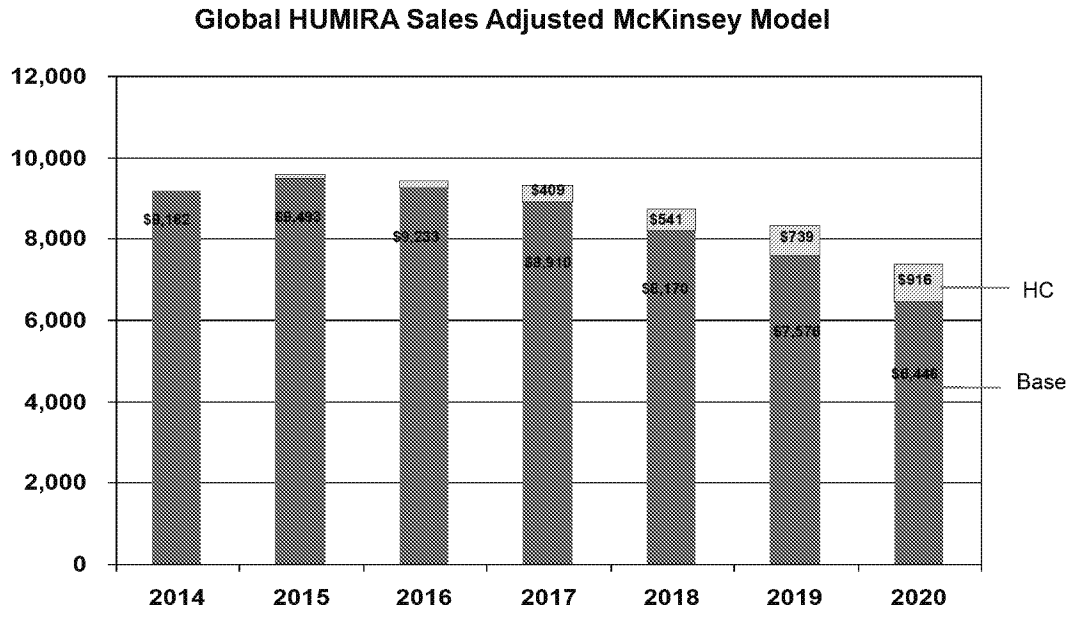
HC HUMIRA will retain $0.9B in Global Sales in 2020 (cumulative sales retention 2014-2020 of $2.9B)



[DateTime] Company Confidential 15

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7/28/2020 11:20 AM

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]
[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]

AbbVie 9

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
Abbott Park, IL 60064

Office: [redacted]
Mobile: [redacted]
Fax: [redacted]
[redacted]@abbott.com

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Memo

HUMIRA

adalimumab

Global LRP Strategy 2012

Table of Contents

Abbott recognizes that laws and regulations change often, and, that they vary by country/region across the world concerning the marketing, promotion, and sale of prescription drugs, and also concerning disease awareness and scientific exchange. Accordingly, Abbott is committed to adjust this plan as necessary prior to execution in each country/region to ensure compliance with local laws and regulations. In particular for the US Market, Abbott will execute upon the US Brand Plans for HUMIRA in case of conflict with this Global Brand Plan

This document was developed in collaboration with Medical, Regulatory, GHEOR, Commercial, Market Access, Public Relations, GPO, Strategic Initiatives and other key functional areas

Biologic Market Dynamics

In 2011, HUMIRA surpassed Enbrel and Remicade as the #1 anti-TNF globally reaching $7.9B in sales and achieving YOY growth of 21.2%. In the U.S., HUMIRA sales reached $3.4B with growth of 19.3% and a Q4 overall TRx market share of 29.1% placing the brand nearly in a tie with Enbrel in the total market. The international sales were $4.5B with a growth of 22.6%. HUMIRA remained the clear market leader with 33.3% (vs. Enbrel's 28.6%)

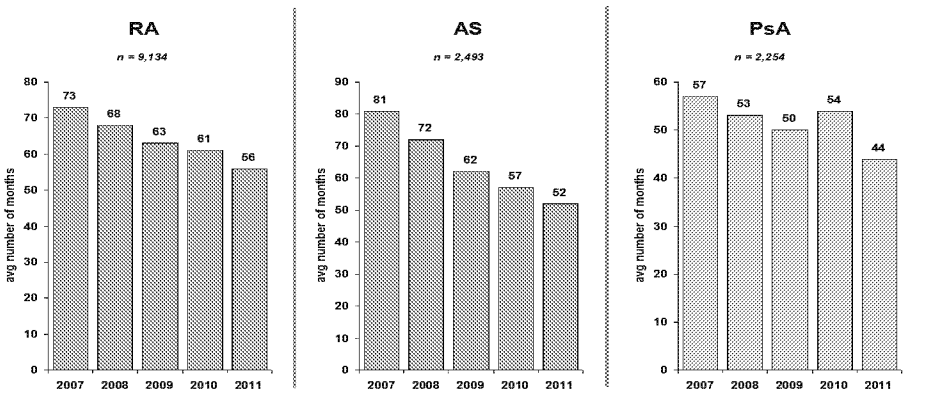
Analysts project HUMIRA will become the #1 selling pharmaceutical worldwide by 2013 with sales in excess of $10B+ worldwide. Abbott has been a recognized key contributor in growing the biologic market by supporting field-changing initiatives to improve patient management and clinical outcomes. As a result, HUMIRA has consistently grown at high double digits, outperforming the anti-TNF market.

With anti-TNFs now constituting a significant portion of healthcare budgets, their cost draws increasing attention from payers and policy makers. Cost containment measures continue to be implemented such as making reimbursement/insurance criteria stricter than label and/or clinical guidelines, limits on prescribing freedom, reference pricing, reimbursement caps and centralized tendering. Over the LRP it is anticipated that cost containment measures will remain important and will encourage interest in lower cost options, such as biosimilars.

Market growth has slowed in most major markets in the past year. However, in the US, market growth has increased from 6.3% in 2010 to 6.9% in 2011, while in WEC market growth has slowed to the mid teens (from 18.6% in 2010 to 16.1% FY 2011). Contributors to this, aside from cost containment measures and maturing penetration rates, include a clinical practice environment that lags behind guidelines (e.g. number of non-biologic therapies tried before a biologic is initiated) and ongoing safety concerns that limit the treatment of DMARD patients that could benefit from biologic therapy. This contributes to very heterogeneous, penetration rates of biologics across indications thereby representing an important growth opportunity in most key markets.

Time to First Biologic has reduced significantly over the last 5 years – but still far from T2T recommendations

Number of treatment months from initiation on first DMARD Rheumatology



Source: Therapy Knowledge, EU only, Q2 2011 Database

Abbott

Between 2007 and 2011 the time to the first biologic has improved significantly (in RA from 73 to 56 week or -23%. *Source: Therapy Knowledge, EU only, Q2 2011*).

Despite this improvement most patients are far from being treated according to T2T principles. In all indications we start to see a shift in the standards of care start towards treat-to-target principles and a need to treat these chronic, progressive diseases beyond just clinical symptoms. While the KOL backing of such principles is increasing, the acceptance and currently low level of adaptation in daily practice remains a key issue.

A recent publication in ARD showed that individual treat to target recommendation are followed in daily practice between 50 and 75%, but physicians apply all T2T recommendations in only about 25% of all patient. The same publication shows that patients who are consistently treated to target have a 50% lower rate of functional disability, adding to the evidence of long term benefits of the T2T approach.

In all indications HUMIRA's share gains have slowed due to an increasingly crowded competitive landscape: anti-TNFs (Enbrel, Remicade, Simponi, Cimzia) compete in first line with the newest agents taking advantage of limited perceived differentiation within the class, and new MoAs (Actemra/RoActemra, Stelara, Orencia, MAbthera/Rituxan) are gaining ground in second line by promoting early switch from first line agents like HUMIRA. Enbrel benefits across the rheumatology and dermatology markets as a result of a perceived safety advantage, despite an inferior efficacy profile. The cost-pressure from payers described above pose a significant challenge in many markets, as new anti-TNFs are offering significant discounts to improve adoption.

Beyond 2012, two new groups of products, novel oral DMARD compounds and biosimilars, will challenge anti TNFs and more specifically HUMIRA share and growth performance over the LRP. The launch of the first oral BID JAK inhibitor is anticipated for Q4 2012 in the US with other geographies and indications coming on in 2013 and beyond. The latest published data shows that the new compound does not add any additional efficacy benefit, on the other hand some potential new safety signals were reported (e.g. anemia, dyslipidemia, creatinine elevation)
The development of biosimilar has accelerated over the past year. Both EMA and FDA are working on defining clearer paths forward for the regulatory approval of biosimilars of monoclonal antibodies. The filing of the first biosimilar of Infliximab in March 2012 with EMA marked a milestone in this potential game changing development.

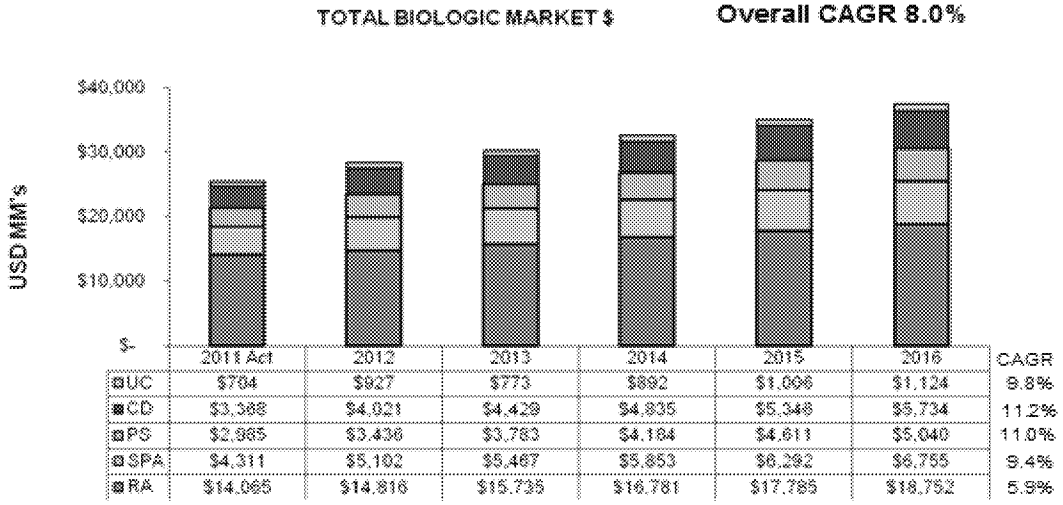
Biologic market dynamics and issues
In Q3 2011 HUMIRA was for the first time the leading biologic product globally and the largest pharma product in 9 countries. Immunology remains an interesting growth market with a recovering US market growing at 6.9% in 2011, while the international markets grew overall at 18%. Despite this growth, biologic penetration rates among treated patients remain conservative with a range of about 5% in Psoriasis to approximately 25% in highly developed RA markets.

The Immunology Market

Overall Growth Expectations (2016 WW Sales of $37B; 5-Year CAGR 8.0%)

Over the LRP, the global biologic market will reach $37B (Figure 1).

Figure 1: Global Biologic Immunology Market



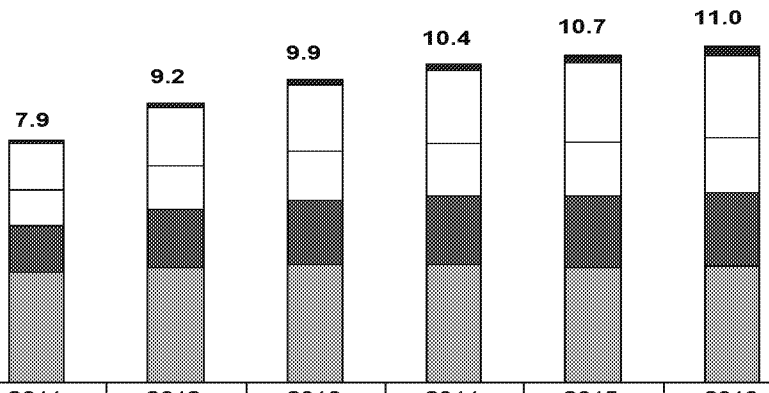
	2011 Act	2012	2013	2014	2015	2016	CAGR
UC	$784	$827	$773	$892	$1,006	$1,124	9.8%
CD	$3,388	$4,021	$4,429	$4,935	$5,348	$5,734	11.2%
PS	$2,985	$3,436	$3,783	$4,184	$4,611	$5,040	11.0%
SPA	$4,311	$5,102	$5,467	$5,853	$6,292	$6,755	9.4%
RA	$14,065	$14,816	$15,725	$16,781	$17,785	$18,752	5.9%

Note: Financials have not been eroded for JAK and Biosimilars

RA will continue to be the largest contributor of HUMIRA's franchise sales achieving $4.6B by 2016. CD and PS indications contribute the highest CAGR's of 11.2% and 11.0% respectively.

Global HUMIRA Projected Immunology Sales by TA

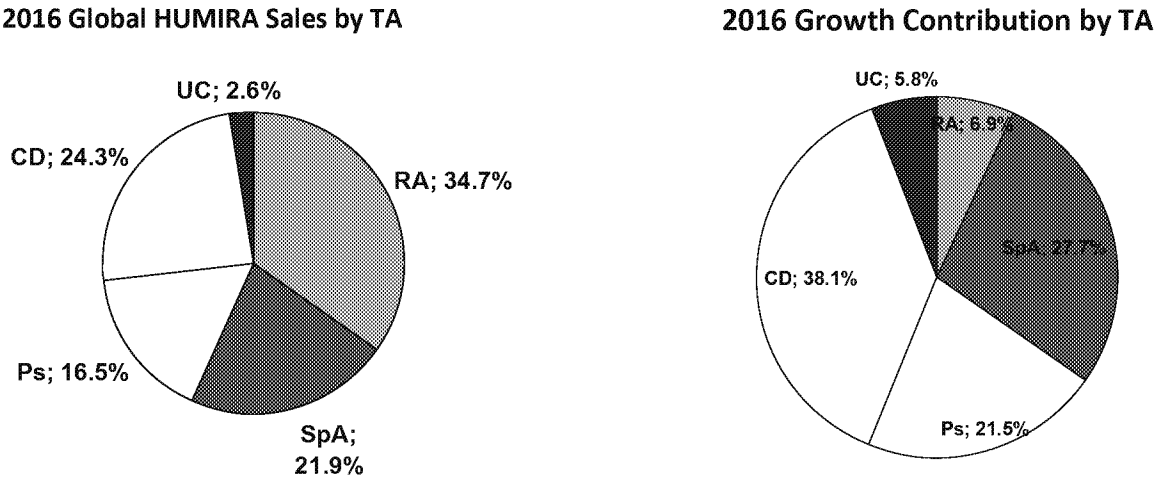
Risk-Adjusted ($B) (Overall CAGR = 6.8%)



$MM's	2011	2012	2013	2014	2015	2016	CAGR
UC	108	154	167	213	253	285	**21.5%**
CD	1504	1912	2171	2378	2581	2674	**12.2%**
Ps	1155	1414	1608	1713	1764	1814	**9.4%**
SpA	1564	1921	2102	2251	2374	2413	**9.1%**
RA	3602	3761	3881	3871	3757	3814	**1.2%**

Note: Financials have been eroded with Biosimilar/JAK impact. Numbers of PRIOR to RAG review and not final

Figure 2: Therapeutic Area Sales Contribution of Immunology Franchise



Note: Financials have been eroded with Biosimilar/JAK impact. Numbers of PRIOR to RAG review and not final

Key Franchise Global Strategies to Drive Brand & Market Growth

Brand Vision
HUMIRA, as the treatment of choice, will inspire the continuous improvement in the standard of care and help millions of patients to address the long term damage of their disease. Therefore HUMIRA will become the number one drug in the pharmaceutical market across all indications and geographies

Brand Positioning
HUMIRA delivers deep and sustained response, which leads to lasting control that helps to prevent long term impact in a broad range of immunological disorder and enables physician and patients to reach their treatment goals.

Opportunities
Moving forward Abbott/AbbVie can support effort to generated appropriate evidence to change the Standard of Care by pro-actively engaging in the continuous evolution of T2T principles and the local implementation in all indications. Broad acceptance of the new standards of care will create a new definition of the patient population that might be appropriately treated with anti-TNFs: **Every appropriately eligible patient who does not reach the treatment goal on the first line treatment within a defined time frame is eligible for treatment with HUMIRA.**

We need to further generate differentiating data through driving **strategic trials** that show HUMIRA's benefit in treating to target and treating beyond symptoms and link treatment strategies to improved long term and economic outcomes.

Our long standing experience helps to establish a positive **benefit-risk profile** for HUMIRA and the whole anti-TNF class and create market advantages vs new mode of actions. Recent positive data with anti-TNF treatments in reducing the **cardio vascular impact** in patients with chronic inflammatory disease prompted a lot of interest in the medical community and is an opportunity to generated further

evidence and potentially strengthen the argumentation about early intervention. In addition we can be the driver behind the generation of scientific data around adherence and take a role in generating data to support improved physician – patient communication.

Over the LRP we will be able to launch multiple **enhancements** to HUMIRA as a **product** but also to different **services** surrounding the product. All these investments have the goal to improve the physician and patient **experience with HUMIRA** and will give us an additional competitive edge.

Brand Objectives

- Maintain overall market leader position over the LRP, reach market leadership in each indication and improve the benefit-risk differentiation.
- Become the best selling pharmaceutical product in 2013, by reaching $10B in sales and have the ambition to become the product with the highest peak sales ever (>US$13.5B)
- Achieve widespread use of treatment targets in daily practice
- Shorten the time to biologics for appropriate patients
- Improve the on-boarding process to anti-TNF therapy and improve adherence
- Gain market access for new indications and for new standards of care

LRP Critical Success Factors

- **Redefine the markets**: alignment of all stakeholders that patients who are not reaching a low disease activity target after one first line treatment should be switched to anti-TNF treatment, if appropriate
- **Collaborate with organizations to pursue new standards in care: I**ntegration of treat-to-target principles in daily clinical practice across all therapeutic areas
- Change in Communication: **improved patient – HCP interaction** that address appropriatly practical and emotional hurdles of treatment initiation and continuation
- Generate data to establish an **improved benefit-risk profile** vs. new MoA and distance from anti-TNF competitors through strong **efficacy perception**, leveraging the long term, well **defined safety profile** and integrating evidence based **CV protection** into overall risk evaluation
- Increase the value perception: proof that early HUMIRA treatment leads to a change in the course of the disease and prevent long term damage and changes the course of the disease
- Improve the **HUMIRA experience** for patients and physicians through flaw-less roll out of **product and service enhancements**
- Advocate that biosmilar entrants are held to high standards of quality and patient safety
- Harness the power of the consumer in US with effective mix of DTC to drive awareness, consideration and action in favor of HUMIRA.

Brand Strategies

To realize the vision of making HUMIRA the top selling pharmaceutical we need a strong strategic platform and outstanding execution. During the LRP we need to consolidate HUMIRA as #1 anti-TNF and support the growth of the market for TNF-mediated disorders by executing on 3 key core strategies that are common to all therapeutic areas:

1) Create an Unsurpassed Value Proposition around deep and sustained response

HUMIRA needs to build the most competitive profile around **deep response and sustainability** across all current & new indications by defining and generating data about treatment targets that help to position HUMIRA as the optimal drug for treating to therapeutic target and by leveraging the most comprehensive long term data set in the market. In addition the launch of new indications, where HUMIRA will be the first licensed biologic treatment, such as axial and peripheral SpA, Uveitis and HS will help to consolidate the differentiation halo of HUMIRA.

Patient adherence is a complex multi-dimensional issue and will require a focused investment over time. Significant adherence improvement opportunities are available in acceptance, onboarding and continuation phases of the patient journey. Even a small improvement in adherence can yield significant returns for patient outcomes and product revenue. We must first create a sense of urgency with health care professionals so they understand adherence is an issue and an important component of Treat to Target guidelines. We want to stimulate the scientific acceptance of the importance of adherence through clinical studies which demonstrate the impact of non-adherence & improved adherence with HUMIRA. We will create new health care professional tools such as the adherence screener and H-Link to ease the burden of discussing, starting and continuing HUMIRA therapy. We will address patient motivation through innovative programs that leverage technology and address the patient's individual needs and concerns thereby differentiating the brand and retaining our patient base.

We need **to create market advantages versus BID JAK and advocate for quality and patient safety for biosimilar entry** by generating strong data of HUMIRA's Benefit Risk profile and messaging, mainly around generating **evidence on cartilage and bone protection.** In addition, continue to explore opportunities and generate evidence on the potential impact of anti-TNF and HUMIRA on cardiovascular risk reduction of patients and on the predictability of a **well defined safety profile**. In order to ensure a fair competitive environment when biosimilar enter, we need to lobby for principles to establish high quality and patient safety standards for the development and post-marketing surveillance of biosimilar

2) Collaborate with organizations to pursue new standards in care through treatment goals

In order to further develop standards of care in all indications and improve adaptation in daily practice, we will support scientific and commercial partners to devise meaningful targets and new diagnostic and monitoring tools (e.g. the development of the IBD damage score with IPNIC, the further development of an ultrasound target with TUI and General Electric's or the policy changing Fit4Work coalition)

There is still a need to drive game-changing programs that define **higher treatment targets** and ensure that these **treat to target principles** are integrated into local guidelines and clinical practice through the established platforms in the different therapeutic areas (T2T in Rheumatology, SDR in IBD and PPI in Dermatology)

The scientific community increasingly accepts treatment targets and the notion of treating chronic auto-immune diseases beyond mere clinical symptoms. In a next step we need to focus on the **increase acceptance** of biologic treatment for patients not yet reaching their treatment target by generating a strong, positive benefit risk profile. This is partly based on the existing wealth of our clinical and registry data, combined with newly generated data on improved efficacy (joint

protection, sustained deep remission) and adding, once fully established, the evidence of the cardiovascular protective impact of early intervention with anti-TNF treatments. In order to bring this story to the patients, we are supporting KOL's in the communication of the improved understanding of the benefit risk of early treatment to their HCP colleagues and we need to support the development of pioneering tools to **enhance benefit risk communication between patient & HCPs**

In a world where every patient gets treated to target, we need to look differently at our market and every appropriately eligible patient who does not reach the treatment goal on the first line treatment within a defined time frame could become eligible for treatment with HUMIRA. Therefore we need to advocate among payers on **new treatment goals,** which need first to be integrated into local guidelines. Our value story to payers needs to reflect the benefit of early treatment and the treat to target approach.

3) Demonstrate HUMIRA's impact in reducing the burden of immune modulated diseases

In order to elevate the **importance of effectively treating TNF-mediated diseases** we work on showing the risks & costs to patients and society of under-treating these diseases by generating global & local evidence on the burden of the disease and the consequences of under-utilization of effective interventions. Based on a strong, fact supported argumentation package, we need to roll-out multi stakeholder lobbying programs that shape the discussion of budget allocation and integrate societal impact of diseases into the health care policy discussion.

In order to maintain the recognition on the value for HUMIRA we need to provide payer relevant, localized data and develop Key Account specific value propositions and leverage the broad range of indications. In addition we need to generate data that help to improve the predictability of outcomes, e.g. by conducting thorough analysis to determine the patient populations most likely to fail MTX and subsequent DMARDS and by researching the optimal timing of treatment initiation and characterize patient populations with strong response in our trials such as OPTIMA, TUI, FLEX RA, POCCER or CALM

The ultimate goal is to show a **change in the disease course** for patient populations treated by HUMIRA and generate evidence that shows the positive societal and economic impact of early treatment beyond the individual patient and beyond only clinical improvements. We will establish process & tools to effectively measure & monitor changes in long term outcomes and regularly publish updates to demonstrate trends in morbidity, mortality and cost reduction

Issue	Changes vs. 2011	LRP Implications
Competitive Landscape	• Pfizer JAK profile becomes clearer in RA and shows consistent new safety signals. Development of new indications seems delayed vs. 2011 assumptions. • Biosimilar development has accelerated with the first compound (Infliximab) submitted to the EMA in Q1, 2012, creating a potential launch in non-IP protected markets in mid 2013. FDA has issued draft guidance and first biosimilar is expected to launch in 2015 • Increasing number of H2H trials against HUMIRA. Next to the recent Tofa trial, 8 industry sponsored H2H programs are ongoing	• Need to further improve benefit risk profile with focus on joint protection, long term, predictable safety and trying to leverage cardiovascular protection • Biosimilar launches are forecast earlier in non-IP protected countries than in 2011 LRP. High urgency to ensure that high standards are established for substitution, interchangeability, etc. • Need to strengthen need for comprehensive disease control as a treatment goal
Franchise Expansion	• UC and axial SpA launch delay in US due to challenging path forward with FDA	• Indications are at risk in the US
Change in Safety Perceptions	• Cardiovascular risk management becomes a new hot topic in chronic inflammatory diseases, especially RA and Psoriasis with an increasing body of evidence of anti-TNFs might have a positive impact on CV events and the risk	• Opportunity to generate additional evidence that would support a stronger benefit-risk profile of anti-TNFs and for differentiation from new MoA with unclear impact on lipid profiles a
Economic Downturn	• Continued pressure on public health care systems leads to a increasingly fast shift from clinical to economic decision making	• Increased need to protect HUMIRA value within different payer systems and to manage tenders effectively

The Rheumatology Franchise

Rheumatology (Sales 2016: $7.2MM; 2011 – 2016 CAGR: 6.9%)
RA (Sales 2016: $4.6MM; 2011 – 2016 CAGR: 4.9%)
SPA (Sales 2016: $2.6MM; 2011 – 2016 CAGR: 11.0%)

Market Dynamics and Competitive Environment

The current worldwide rheumatology market is estimated to be ~$20B with the U.S. representing almost 48%, or approximately $9.5B. In RA the current market growth is in the high teens in many International Markets and less than 10% in the U.S. Despite new competitors, it is projected that RA market growth will slow considerably throughout the LRP to less than 5% by 2016. The high level of current and upcoming competition especially in the RA market suggests that commoditization will further intensify, increasing further the need for driving innovative concepts to enhance HUMIRA's product profile in RA. Driving the development and implementation of new standards of care (e.g. T2T) is essential to reduce time to biologic treatment and protect HUMIRA's leadership in biologic naive patients. Throughout the LRP, the RA market will face even further intensified competition with the introduction of new oral DMARDs predicted to enter as early as Q4 2012, and subsequently with Biosimilars, which are predicted to have a impact on established brands such as HUMIRA.

The SpA Market continues to grow > 20% in most major markets. There is still significant opportunity for growth over the LRP with gaining approval for new indications (Axial and Peripheral SpA), earlier diagnosis and more aggressive treatment of these patients. The new ASAS disease classification criteria for Axial & Peripheral SpA have at least in Europe lead to more progressive treatment recommendations to date. However there is still a significant gap in early referral and diagnosis, due to the lack of easy to apply tools and guidance. Especially in the US, the rate of Axial SpA patients (incl. AS) treated by rheumatologists is significantly lower than in Europe, despite increasing evidence about comparable prevalence rates. Increased support of KOLs across the globe and intensified international collaboration is expected to continuously raise the level of awareness and acceptance for the improved management of these diseases. HUMIRA and our organization aiming for first approvals in these indications are expected to benefit from being the first mover and main supporter of this process. This will drive share growth beyond current differentiation dynamics which are already stronger in As & PsA compared to RA.

Critical Success Factors

- Package HUMIRA's unique attributes to define and generate additional data around comprehensive disease control in alignment with the T2T principles in a compelling way to physicians, patients, and payers to successfully differentiate vs. existing and new competitors.
- Achieve a leadership position for HUMIRA in SpA through the approval of new indications in Axial & Peripheral SpA and providing a compelling story that differentiates HUMIRA, ensuring maximum benefit prior to competitor launches
- Ensure local implementation of Treat to Target into daily clinical practice via tight disease control models and increased acceptance of biologic treatment and protect Abbott/AbbVie's leading role
- Gain consensus on the ASAS criteria, on the need to treat, burden of the disease and the risk of under-treatment within all stakeholder groups (4 Ps) and drive their adoption into local treatment and reimbursement guidelines and ensure their use in daily clinical practice
- Reinforce the physician's choice for HUMIRA and drive adherence by developing evidence-based therapeutic guidance for HUMIRA patients that have sub-optimal response.
- Improve the communication between physicians and patients, to ensure that a better understanding of HUMIRA's favorable benefit/risk profile is resulting in better adherence and patient outcomes.
- Develop and strengthen Abbott/AbbVie's capabilities to understand payers and address their needs with HUMIRA's value proposition that resonates to ensure payers reimburse the management and treatment of SpA
- Harness the power of the consumer in US with effective mix of DTC to drive awareness, consideration and action in favor of HUMIRA.(US)

Rheumatology Key Strategies

RA

Create an Unsurpassed Value Proposition around Deep and/or Sustained Response

1. Make Comprehensive Disease Control* (CDC) the ultimate treatment goal & demonstrate HUMIRA's unique capabilities.
2. Optimize treatment in tough to treat HUMIRA patients to reinforce the preferred choice of physicians & patients via best in class on-boarding and patient support.

   **as defined by clinical remission, inhibition of radiographic progression and/or normal physical function. The individual components are part of the HUMIRA label, but CDC is currently not approved for promotion yet.*

Collaborate with organizations to pursue new standards in care through treatment goals

1. Address the suboptimal patient flow by implementing Treat to Target principles to reduce time to HUMIRA /anti-TNFs.
2. Optimize RA patient management to increase adherence on HUMIRA.
3. In the US, find opportunities to remove the financial barrier to HUMIRA use for Medicare patients

Demonstrate HUMIRA's Impact in Reducing the Burden of Immune-Modulated Inflammatory Disease

1. Evolve HUMIRA's value proposition to payers, patients & public (according to country specific rules) based on deeply understanding their needs, which avoids commoditization of biologics and guarantees access for all eligible patients and recognizes the value of HUMIRA.
2. Effectively measure & monitor trends in morbidity, mortality and cost reduction due to TNF treatment and communicate risk & cost of under-treated disease to patients and society (according to country specific rules).
3. In the US, activate patients to request HUMIRA as the drug of choice that stops joint damage

SpA

Create an Unsurpassed Value Proposition around Deep and/or Sustained Response

1. Strengthen HUMIRA's 1st line position compared to current and new competitors
2. Improve on-boarding & adherence by stakeholders' education on SpA,

Collaborate with organizations to pursue new standards in care through treatment goals

1. Definitively establish Axial and Peripheral SpA as well-defined and recognized diseases
2. Optimize Axial and Peripheral SpA diagnosis
   - Accurate pre-identification and referral
   - Universal adoption of ASAS classification/diagnosis algorithms
3. Define SpA treatment targets and algorithms
4. In the US, drive patient awareness of inflammatory back pain to seek treatment by a rheumatologist as a hallmark of AS, and when approved, Axial SpA

Demonstrate HUMIRA's Impact in Reducing the Burden of Immune-Modulated Inflammatory Disease

1. Convince of the need-to-treat SpA diseases
    - Because of the high burden of disease and long-term impact of late diagnosis and delayed treatment
    - Strengthen advocacy networks
2. Get full Market access and reimbursement

The Gastroenterology Franchise

Gastroenterology (Sales 2016: $3.1B; 2011 – 2016 CAGR: 14.2%)
CD (Sales 2016: $2.8B; 2011 – 2016 CAGR: 13.6%)
UC (Sales 2016: $0.3B; 2011 – 2016 CAGR: 22.0%)

Market Dynamics and Competitive Environment

The value of the current worldwide IBD market is estimated at $4.9B, with the U.S. representing 49% or approximately $2.4B. The lack of understanding about the progressive nature of the disease and the associated disability remain the challenge in the treatment of IBD. Many patients are not accurately diagnosed or treated effectively for many years after the onset of the first symptoms. Conventional therapies are the first line of treatment and are primarily used to achieve symptom control, rather than address the underlying cause of inflammation to achieve remission. Furthermore, optimization of conventional therapies is not standard practice, impacting the appropriate and timely advancement to biologics to treat moderate to severe Crohn's disease. Also impacting an appropriate time to biologic are pervasive safety concerns among patients and conventionalist physicians. Despite these challenges, the Crohn's market is currently growing greater than 15% for many markets. This growth will slow throughout the LRP but will remain strong as strategic programs are executed to raise awareness and drive earlier appropriate use of biologics. During this period it is not anticipated that new biologic competition will impact the market.

Previously, the Ulcerative Colitis market had only one approved biologic product (Remicade) and a very low biologic penetration. In contrast to Crohn's Disease, Ulcerative Colitis is a disease of the mucosa, with flares shorter in duration and symptoms often subsiding for a longer period of time. Conventional therapies dominate the UC market, as they are indicated to induce remission in patients with mild to moderate UC. Additionally, physicians cite the disease as more controllable and less progressive. Biologics are mostly reserved for severe patients prior to surgery, which is still viewed as curative by an important number of physicians. The launch of the HUMIRA UC indication will increase attention to biologics as a viable approved treatment option for this disease and will increase both growth and penetration. The recent approval of HUMIRA in Europe addresses an unmet need as a self-injectable biologic option, especially for appropriate moderate patients when conventional therapy has failed. Physicians perceive both biologic treatment options as similar in efficacy for moderate to severe UC, although Remicade stands as the treatment of choice for severe hospitalized patients. The UC submission in Japan has been realized by mid march and US review process should finalize by the end of Q3.

Critical Success Factors

1. Accelerate Market Growth
   - Collaborate with organizations to pursue new treatment goal of treating beyond symptom control to long term remission (Sustained Deep Remission). Sustainability must become the key driver for prescriber decisions, demonstrating that Crohn's Disease is progressive and may lead to cumulative damage and disability.
   - Generate evidence around the benefit of earlier use of biologic treatment in a step up approach for appropriate patients, after timely optimization of conventional therapy
   - Generate evidence around the benefit of earlier and appropriate use of biologics within the UC Treatment algorithm, positioning HUMIRA as the most appropriate treatment for moderate UC.
   - Elevate disease awareness to increase biologic utilization in appropriate patients across relevant HCP segments, patients, payers and key policy decision makers
   - Increase patient empowerment to challenge the status quo of current therapy and understand that biologics are safe, efficacious and accessible/affordable

2. Grow Share through generation of new, potentially differentiating data
   - Enhance the HUMIRA value proposition through the expansion of label to moderate in EU and development of new data supporting the impact of HUMIRA on the current burden of both CD & UC
   - Increase awareness of HUMIRA as a therapy that offers the possibility of remission to drive patient requests
   - Improve patient on-boarding and increase persistency

Gastroenterology Key Strategies

Collaborate with organizations to pursue new standards in care through treatment goals

- Drive disease awareness & educate HCP, payer and policy stakeholders on the benefit of earlier, continuous biologic treatment.
- Educate patients via disease awareness efforts about the link between damaging inflammation and symptoms. Provide personalized one on one disease education with patients to encourage productive conversations with HCPs about treatment goals and expectations. Expand US disease awareness campaign into international markets, based upon initial US success which demonstrated strong patient engagement.
- Further develop the Join the fight campaign ex –US, which helps with the dissemination of the IMPACT survey results and other patient surveys realized in Europe. Almost 80 journalist from 34 countries have already produced over 500 articles focusing on the burden of disease and the new standard of care
- Support the generation of data to establish the benefits of rapid step-up therapy and tight control in clinical practice through strategic clinical studies such as the CALM study and REACT 1 & 2 studies. Invest in studies that demonstrate treatment optimization to facilitate the monitoring of the new treatment goal by developing an easy to use tool (PREDICT).

- Support global initiatives such as the International Program to develop New Indices for Crohn's Disease (IPNIC) that advances the science of IBD and allows a broader base of physicians to effectively to treat, assess and monitor Crohn's patients. Systematic measurement is projected to lead to earlier treatment with Biologics and HUMIRA over the LRP.
- Highlight the medical & societal cost of the progressive nature of CD and the burden of UC thru studies and publications.
- Develop predictive factors and collect data to build audit and benchmark activities that contribute to accelerate adoption by identifying intervention points that support more ambitious treatment goals.
- Expand use and improve the service model to provide continuous product innovations, enhanced patient on-boarding and improved retention support services to differentiate HUMIRA from currently available biologic agents and ultimately creating cost barriers to entry for future competition.

Create an Unsurpassed Value Proposition to Make HUMIRA First choice for HCPs & Patients

- Drive a multi-stakeholder platform around "sustained deep remission", "disease modification" and ease of use e.g. promotional campaign
- Provide Commercial strategic objectives to align medical education initiatives towards new treatment goals, treatment algorithm and optimization of conventional therapy and monitoring
- For payers, elevate the value proposition of HUMIRA by demonstrating a link between IBD & secondary manifestations, in immune-mediated diseases, such as arthralgia and arthritis
- Through a comprehensive communication campaign to HCPs, ensure thorough understanding of the benefits of starting on the proper dose to achieve optimal treatment outcomes and develop a complete benefit/risk educational campaign
- Execute clinical studies to generate data that demonstrates the value of structured treatment algorithms to optimize outcomes with HUMIRA
- Successfully launch new indications: UC (2011) and reshape the treatment algorithm to establish HUMIRA as first line in the moderate of moderate to severe patients, in order to avoid hospitalization and colectomy
- In the US, invest significantly to surround patients with integrated branded DTC messaging to raise awareness of HUMIRA and drive patient requests

Demonstrate HUMIRA's impact in reducing the burden of IBD to improve the value understanding of Payers

- Through studies and Immunology Account Executives (US), demonstrate the cost effectiveness of HUMIRA vs. infusion
- Demonstrate cost effectiveness versus conventional therapy and HUMIRA superiority versus Remiade where appropriate
- Collect data on surgery and hospitalization reduction to further establish the long term impact of HUMIRA in changing the course of the disease

The Dermatology Franchise

Dermatology WW Sales 2016: $2.2B; 2011 – 2016 CAGR: 13.2%; Figure includes HS sales of $86MM in 2016

Market Dynamics and Competitive Environment

- 125 Million people suffer from Psoriasis worldwide. In the G7, 15 million people have psoriasis with 2.8 million considered moderate to severe. The current worldwide biologic psoriasis market is estimated to be around $3.4B with the U.S. representing 55%, or approximately $1.9B.

- Biologic penetration rates in the moderate to severe psoriasis population continues to grow but remains low across most markets, it is expected to reach >12% in 2016 in the top 7 markets globally.

- A significant number of dermatologists do not prescribe biologics to treat moderate to severe psoriasis. This is due to a combination of continued safety concerns and the fact that psoriasis is not perceived to be a progressive disease that leads to irreversible harm in patients, despite an increased recognition that psoriasis is a systemic disease caused by chronic inflammation associated with increased cardiovascular risks. Dermatoligists still largely rely on topical therapies and conventional systemics for the majority of patients regardless of disease severity.

- Despite limited penetration rates, the HUMIRA Dermatology business has reached global market leadership, surpassing $1.1 billion in sales in 2011. Stelara and Enbrel continue to be strong competitors, although Enbrel continues to lose share in most markets and Stelara is reaching a plateau in some major countries.

New agents in Development, Pfizer's JAK inhibitor and anti-IL-17 agents have the potential to impact naïve patient recruitment. If priced attractively to payers, newer small molecules (Pfizer's JAK BID) may reduce the market opportunity as more patients are successfully managed ahead of biologic prescribing. Later in the LRP, newer biologics (e.g. anti-IL-17) may enhance biologic growth, but this will depend on the safety profile

Critical Success Factors

Generate data that allow for differentiation

- Establish a strong benefit/risk profile vs. competitors, by creating a compelling, sustainable positioning in the customers' minds where HUMIRA delivers superior treatment of inflammation *'on and below the skin'.*
- Establish consumer loyalty with a unique, comprehensive patient experience that result in the best possible HUMIRA outcomes.

Redefine the market

- Drive acceptance that Psoriasis is a multifaceted disease, where the right solution provides benefits inside and out.
- Align stakeholders to the goal that patients who are not reaching the target (low disease activity) after the first-line treatment need to be switched to HUMIRA.

Collaborate with organizations to pursue new standards in care

- The objective is to have absolute treatment goals and treatment transition to improve patient outcomes, driving adoption into clinical practice.

Enhance the Communication

- Improve the interactions between patients and their dermatologists to address practical and emotional hurdles of treatment initiation, persistency and to seek optimal quality of care.
- Encourage patients to demand better results through direct-to-consumer advertising and coaching in the US.

Increase the value of HUMIRA

- Maximize and generate new data to enhance the value of HUMIRA (including label enhancements) as the complete solution for a multifaceted disease for all stakeholders.

Establish hurdles to new MOA

- Influence clinical guidelines & payer assessments so that systemic co-morbidities are integrated into disease management and treatment goals requiring new market entrants to prove outcomes similar to HUMIRA as a cost of entry.

Dermatology Key Strategies

1) Create an Unsurpassed Value Proposition around Deep and Sustained Response

a. Create a compelling positioning for HUMIRA around skin and commonly associated co-morbidities of psoriasis
   - Build a competitive profile that reinforces HUMIRA with dramatic, sustainable and re-treatable skin clearance and effectiveness in commonly associated manifestations (PsA, Nails, Scalp, Palmo/ Plantar).
   - Launch a global campaign to position HUMIRA as the optimal solution '*on and below the skin'* to treat the multifaceted systemic disease 'insight out'
   - Drive label enhancements to solidify HUMIRA's market leadership position and meet customer needs (Nails, Palmo-plantar, HS)

b. Improve on-boarding & adherence, maximize the HUMIRA patient benefit, and protect patient base
   - Transform current patient support program into patient adherence programs addressing patients' practical and perceptual barriers to treatment.
   - Revolutionize the HUMIRA treatment experience to include simplification of initiation of HUMIRA and personal one-to-one support education that engages patients to remain on therapy delivering an improved clinical outcome. (US focus in the beginning)
   - Demonstrate the benefit of adherence and persistency in real world clinical outcomes.
   - In the US activate patients to request HUMIRA, leveraging mass media, digital and CRM channels to increase awareness of HUMRIA's efficacy and drive patients to talk with a dermatologist and demand higher expectations of treatment.

c. Improve HUMIRA profile to raise the bar for new competition, ensure quality and patient safety with bio-similar entry;
   - Continue to support clinical studies and leverage independent data demonstrating that HUMIRA / Anti-TNF class improves CV surrogate markers in psoriasis patients.
   - Highlight high prevalence and burden of PsA in mod to severe psoriasis patients
   - Improve delivery system and other enhancements (high concentration) to differentiate the brand from bio-similar

d. Launch HS new indication to consolidate the differentiation HALO of HUMIRA around deep responds in Dermatology

2) **Collaborate with organizations to pursue new standards in care through treatment goals**
   - Use established standards of care to trigger decisions based on treatment goals used in clinical practice
   - Support behavior changing initiatives that integrate co-morbidity management in treatment goals and communicate the risks of untreated/under-treated systemic inflammation
   - Continuously support efforts to improve treatment goals, encourage their inclusion into local guidelines and adoption into clinical practice
   - Support the optimization of treatment algorithms to improve patient outcome
     - Drive global consensus of treatment standards, optimizing disease management
     - Facilitate the implementation of standards in clinical practice to better identify bio-eligible patients

   a. Establish a CME program to enhance physician biologic experience and confidence in centers of excellence that treat to target
   b. Increase acceptance of biologic treatment and clearly define bio-eligible patients
      - Communicate the long-term safety profile and benefit /risk of the anti-TNFs
      - Activate and empower psoriasis patients to seek improved quality of care from a dermatologist.
        - Improve the dialogue between patients and their doctors addressing treatment expectations.
        - Educate that psoriasis is not just a skin condition
        - Elevate the importance of being treated by a dermatologist

3) **Demonstrate HUMIRA's Impact in Reducing the Burden of Immune Modulated Diseases**
   a. Continue to build the body of evidence of the burden of commonly associated co-morbidities and of under-treated patients
      - Establish psoriasis as a risk factor for worsened morbidity, mortality and other real world outcomes (Health Registry)
      - Conduct an independent global survey to demonstrate the burden of the disease, impact of under-treatment and influence key stakeholders
      - Strengthen multi stakeholder engaging programs (Under the Spotlight, World Psoriasis Day, Psoriasis Uncovered)
   b. Link treating to target & optimization of treatment algorithm to better outcomes in patients treated with HUMIRA
      - Capture improvements in real world psoriasis co-morbidities through appropriate treatment with HUMIRA
      - Develop evidence to support the transitioning from systemic to biologics
   c. Elevate HUMIRA value proposition to payers
      - Update and broadly communicate the Value Proposition of HUMRIA reflecting the systemic multifaceted nature of psoriasis and the new standard of care
      - Communicate sustained efficacy of HUMIRA on the skin & the efficacy in commonly associated co-morbidities of psoriasis
      - Leverage HUMIRA's favorable benefit/risk profile and cost per responder data to drive preferred positioning in guidelines and mitigate impact of healthcare reforms

Hidradenitis Suppurativa

Hidradenitis Suppurativa (HS) is a very debilitating chronic inflammatory skin disease with painful deep-seated lesions (nodules or abscesses) and purulent drainage. Main locations are the armpits, groin and inframammary. It has a non-infectious etiology, associated with elevated cytokine levels in lesional tissue. The disease is complicated by the formation of fistulas, sinus tracts, and scarring. The prevalence rate is about 1%, but the disease is highly underdiagnosed. Currently there are no approved medical therapies.

Based on the high prevalence, the severity of the disease and the absence of effective therapy this is a very attractive market. Phase II trials with HUMIRA have shown promising results and the phase III trials have started. If approved, HUMIRA will be the first biological on the market, with very little competition. Due to the nature of the disease (including sinus tracts, fistulas and scarring) HS can be seen as a systemic disease. Therefore the efficacy of HUMIRA in HS will support the overall concept of deep response in dermatology.

Pre launch activities have started with focus on 4 key strategies:

1. Support efforts to define diagnostic criteria and ensure physicians knowledge of the optimal treatment of HS
2. Generate data that support the creation of a value proposition which can make HUMIRA first choice for HCP's for appropriate patients
3. Demonstrate HUMIRA's impact in reducing the disease burden of HS
4. Increase stakeholder awareness through disease awareness programs and doctors / patient education

The Competitive Landscape and Impact on HUMIRA

Over the LRP, the HUMIRA franchise will face imminent and increased competition from the launch of oral DMARDs, primarily Tofacitinib and biosimilars. We describe what we believe to be the expected impact of these new competitive threats to HUMIRA. This analysis is constituted from a cross-functional view from Regulatory, Medical/Development, IP/Legal, Commercial and other key areas to ensure all relevant factors and arguments provide us the most accurate assumptions on the launch dates, product profile and impact on the HUMIRA franchise/LRP.

Projected Impact of Novel Oral DMARDs and Biosimilars

The level and nature of competition to HUMIRA is expected to evolve over three distinct phases/time-points:

- Phase 1: Entry of Pfizer's novel oral DMARD Tofacitinib for RA in 4Q 2012

- Phase 2: Cross-brand biosimilar launches for biosimilar Remicade in select EU countries with no patent protection in 2Q 2013 and WEC LBUs in 3Q 2014. Biosimilar Enbrel is expected to launch in WEC LBUs 1Q 2015. In the US we expect a biosimilar infliximab launch in early 2015 and for etanercept in 2018, despite the new patent extension that was granted in 2011.
- Phase 3: On-brand HUMIRA biosimilar launch in 2017(US) / 2018 (EU).

Considering key assumptions on the launch dates and product profiles, novel orals and biosimilars can be expected to erode 62% of world-wide HUMIRA sales by 2021.

The primary factors that have impacted the erosion model as compared to the 2011 LRP are listed below. Note that there are other minor changes to the LRP that have been factored into the erosion model.

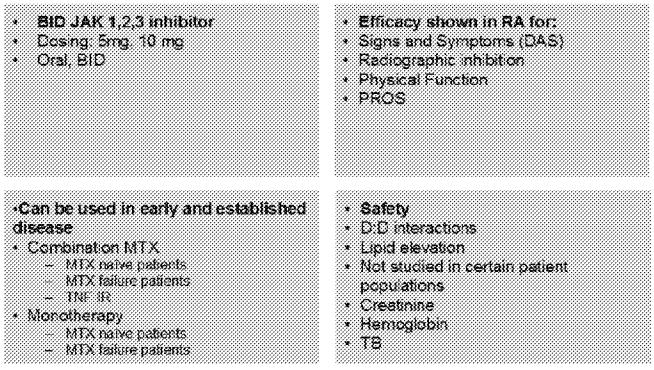
- Key changes that represent upside to 2011 LRP erosion:
  - Lower JAK erosion: This is primarily due to delay in Ps approval from 2Q 2013 to 4Q 2013 as well as no expected launch in the AS indication. The target product profile of Tofacitinib is largely unchanged from last year.
  - US Enbrel patent extension: The USPTO has granted a new patent on Enbrel thus extending patent protection for another 16 years past its 2012 expiration date. But we believe that the patent will be litigated and further challenged and so our assumption is that Amgen/Pfizer will be able to maintain exclusivity in the U.S. market until 3Q 2018
  - Biosimilar ramp-up: After considering key analogs, physician, payer and patient acceptance, we believe the ramp up to steady state will be 4 years (as opposed to 3 years in 2011 LRP)

- Key changes that represent downside to 2011 LRP erosion:
  - Faster cross-brand biosimilar launches: Biosimilar Remicade is expected to be approved in mid 2013 in certain ex-US markets as opposed to Q4, 2014 while biosimilar Enbrel is expected to launch in certain ex-US markets in late 2013 as opposed to Q1, 2015
  - Weaker patent protection for Enbrel and Remicade in ROW: From the information available in 2011, the erosion model extrapolated ROW launches based on the WEC LBUs patent expirations. The 2012 revision takes into account individual country launch dates based on FDA or EMA approvals along with a detailed patent assessment for all markets.

A. Phase I (2012-2014/15) – Novel Oral DMARDs Enter the Market

Entry of the first novel oral DMARD, Tofacitinib from Pfizer, will be phased across markets and indications. In the U.S., tofacitinib is assumed to enter for RA in 3Q 2012 and for Psoriasis in 4Q 2013. Launch in the EU-5 is assumed to occur in a staggered manner 9-15 months following the U.S. launch. Entry into Crohn's is not assumed as part of this erosion model, although new Phase 2 trials are in progress. Additional novel oral DMARDs are likely to follow tofacitinib but we don't expect increased erosion due to the analysis conducted on the Tofacitinib launch, and expected lack of differentiation between these follow on 1st generation novel oral DMARD's.

We believe the following target product profile/label provides our base case for the launch of Tofacitinib:

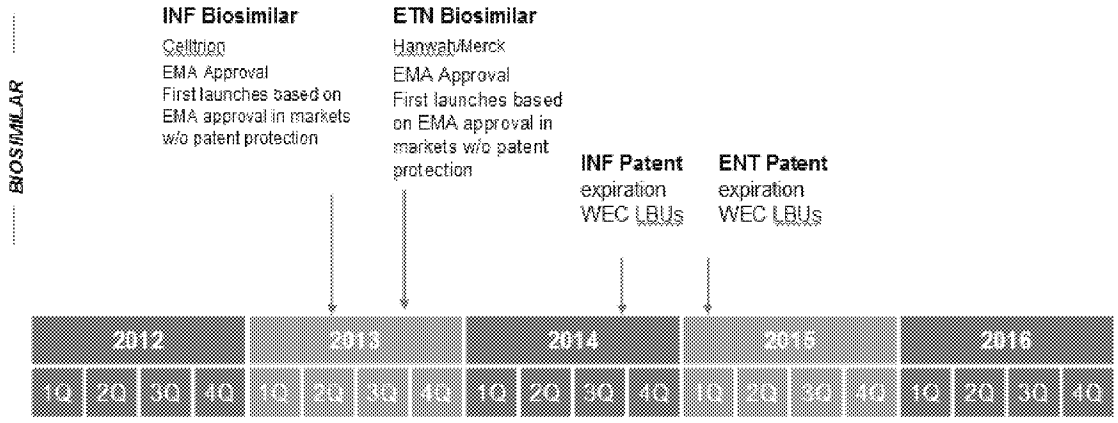


Tofacitinib will represent a new type of competitor for anti-TNFs with an oral route of administration, perceived convenience advantages, new mechanism of action, promising data with efficacy expected to be on par with anti-TNFs in RA, and early excitement among physicians. Pfizer will clearly overweight investment in the launch of this critical product and seek to exploit their strong efficacy data in monotherapy and oral route of administration.

B. Phase II (2014/15-2017/18) – Biosimilar Remicade (EU) and biosimilar Enbrel (U.S. /EU)

We have observed a significant increase in 2011/12 on biosimilar activity primarily around biosimilar collaborations and initiation of new biosimilar clinical trials. 2011 also marked the FDA release of draft guidance on a biosimilar approval pathway. The lead biosimilar players in terms of manufacturing capabilities, commercial presence and advancing clinical trials are Celltrion, Sandoz and Teva. The most advanced biosimilar threat comes from the Korean company Celltrion. Celltrion has completed Phase 3 comparative trials for Infliximab and recently filed their application with the EMA, and has partnerships in place to market biosimilars in the United States and Europe, including with Hospira. Sandoz and Teva have multiple programs underway but are several years behind Celltrion in terms of development. Hanwa in collaboration with Merck are advancing their P3 clinical trials for eternacept and appear to be the leader to reach market with a biosimilar version of Enbrel. Boehringer-Ingelheim has completed Phase 1 adalimumab studies and is projected to initiate P3 clinical trials in Q1, 2013.

The team conducted an analysis of current competitive intelligence, clinical development timelines, regulatory approval assumptions and a global IP/legal assessment, resulting in detailed global launch dates assumptions for biosimilar Remicade and Enbrel. For the U.S. market biosimilar Enbrel is expected to launch in Q3, 2018, while Remicade is anticipated to see biosimilar competition in late 2014 versus 2018, as was assumed in the previous LRP.



C. Phase III (2017-2020) – HUMIRA Biosimilars Enter Market

Biosimilar HUMIRA is expected to enter in 1Q 2017 in the U.S. and in 1Q 2017 in Germany and 2Q 2017 in UK upon patent expiry. The Table below indicates the latest launch assumptions for biosimilar HUMIRA. The earlier launch dates in some key markets is due to the assumption that companies will be able to launch upon IP expiry and not have to wait for pricing/reimbursement and listing approvals.

	Biosimilars (RA) HUMIRA	
US and Top 10 ex-US	2011 LRP	2012 LRP
USA	1H 2017	Q1-17
United Kingdom	2H 2018	Q2-18
Germany	2H 2018	Q1-17
Spain	1H 2019	Q2-18
France	1H 2019	Q2-18
Italy	1H 2019	Q2-18
Netherlands	ROW	Q2-18
Canada	1H 2017	Q1-17
Brazil	2H 2019	Q4-19
Japan	1H 2018	Q3-18
Australia	1H 2019	Q4-18

HUMIRA will likely face significant and more immediate erosion risk once biosimilar HUMIRA is on the market due to several years of physicians experience with other TNF biosimilars. HUMIRA will face peak erosion of the vast majority of naïve/switching patients (>75%) with peak erosion in stable patients more moderate at ~30% due to physician concerns about switching and payers being more restrained in driving uptake in this segment.

Potential Swing Factors

The above projections are related to a "base case" set of assumptions for Oral DMARD's and Biosimilars and there are a number of important swing factors that could positively or negatively impact this 'base case' projection. These factors result in the following downside and upside scenarios:

JAK (the following factors below will have a potential ***upside*** to the base case LRP)

- Less favorable JAK label with restricted use and or prominent safety language
- 3rd line indication (no bio naïve indication) for JAK
- Additional market growth to which HUMIRA has access (JAK failures)

Biosimilars (the following factors below will have a potential ***downside*** to the base case LRP)

- Faster ramp up of biosimilar adoption rate (3 years instead of 4 years to peak sales)
- Extrapolation of indications at launch time for biosimilar Adalimumab
- No enhancements to HUMIRA that result in protective differentiation versus competitors
- Price impact on HUMIRA due to government actions

Addressing the New Competition

A. HUMIRA Enhancements

High Concentration: Projected to launch in 2014/2015 timeframe, HC is designed to significantly reduce the pain associated with the current HUMIRA injection. This development will provide the opportunity for HUMIRA to redefine convenience in the face of an oral competitor (two "virtually painless" injections twice a month vs. two pills per day) as well as differentiate itself from biosimilars.

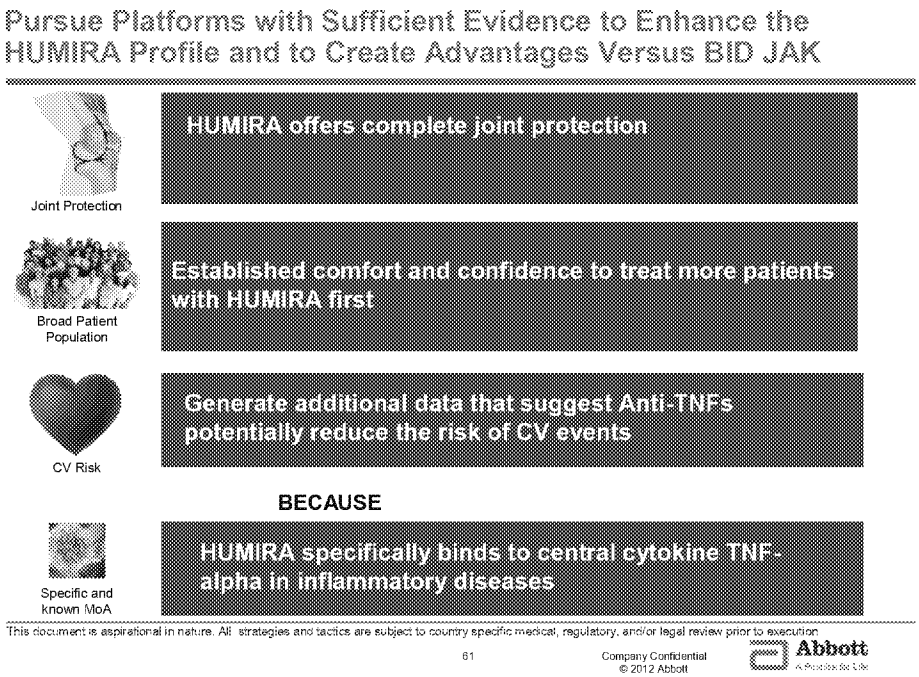
Monthly Dosing: Projected to launch in 2016 prior to entry of biosimilar HUMIRA in 2017, Monthly Dosing provides a once a month dosing option to patients in the RA and Ps segments. This enhancement will build on high-concentration allowing HUMIRA to continue to redefine convenience versus oral and biologic competitors and widen the gap between itself and a biosimilar offering.

Improving Patient Experience: New delivery devices are planned to offer an enhanced patient experience and increase adherence which will further differentiate HUMIRA from novel orals and biosimilars. Smart devices, needle-less injection, improving the current PEN design, etc, are some of the characteristics of the target product profile for next generation devices to deliver HUMIRA. Management has funded key programs/feasibility studies to further identify, analyze, design and launch these devices in time for Monthly Dosing or for future enhancements.

'Other' Manufacturing and Formulation Changes: The team is in process to further define other changes from a manufacturing and formulation standpoint that might potentially provide us benefits from an efficacy and safety standpoint compared to the current product profile. This approach will further provide benefits to our patients and provide additional differentiation to cross-brand and on-brand biosimilars. The possibility of additional IP and potential 12-year data exclusivity provides significant advantages against cross and on-brand biosimilars.

B. Comprehensive Clinical and HEOR Messaging to enhance the profile of HUMIRA and create advantage versus Tofacitinib

The team has identified and is in the process of implementing a comprehensive clinical and HEOR messaging portfolio of projects to support four key messaging platforms listed below



A cross-functional team has been established to continue to disseminate these messages (in compliance with Med Reg, OEC, etc) at various congresses, publications, etc. Also, the team will closely monitor the nature and uptake of Tofacitinib and identify further strategies moving forward.

US Focused Strategies:

There are specific strategies that are currently planned for US:

- HCP:
  - Increasing the SOV in Rheumatology in 2012, incl. the separation of the SF into RA & SpA and significantly increased number of promotional programs
  - Case Studies with HCPs, creating consideration for comorbidities and lab values
  - "Owning" the ACR congress in October 2012
  - Introduction of H-Link, significantly reducing the burden in HCP offices and reducing the time to HUMIRA usage (vs. other therapies)

- Payers
  - Drive preferred position with HUMIRA (67% today) with payers and specialty pharmacies
  - Include contracting to (1) include market basket language for orals and (2) encourage plans w/o specialist restrictions to implement PAs

- Patients
  - Increased DTC investments in 2012 with key message of "……" driving awareness and action favoring HUMIRA. To be continued in 2013.
  - Introduction of H-Link, significantly reducing the time to HUMIRA usage

- Other
  - Accelerate policy & reimbursement in Medicare to shift coverage to Part B (from Part D)

C. Other Key Strategies:

New Indications and Commercial Initiatives: Additionally, a number of existing growth strategies described in Section 1 have the capability to offer protection of HUMIRA against novel oral DMARDs and/or biosimilars. For instance, expansion into niche indications (e.g. Uveitis, Ulcerative Colitis, HS) will differentiate HUMIRA from biosimilar and oral competitors who are not expected to pursue these patients or indications; improving adherence through "high-touch" specialty pharmacy or patient programs (e.g. Pharmacy Solutions, myHUMIRA) will decrease the number of HUMIRA patients lost to novel oral DMARDS and biosimilar anti-TNFs, thereby positively impacting erosion.

Biotherapeutics Advocacy:

- Codify Abbott's position on the key "levers" for biosimilars (e.g., interchangeability, substitution, indication extrapolation, cross-reference filing notification, post approval safety hurdles, etc) with clear articulation of the supporting scientific and legal rationale and execution in the Area's.
- Develop a Global, Regional & National risk assessment and influencer map (regulatory, political, payers, physicians and patient groups) to identify major risks and strategically prioritize resources to build partnerships to influence guideline development at the regional, national and local levels
- Create an external communications and public relations plan and commit internal resources to participate in industry and scientific events, developing a publication plan and proactively influencing external stakeholder to promote Abbott's/Industry position

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2013 LRP

Biosimilar Erosion Modeling

Assumptions Discussion

February 7, 2013

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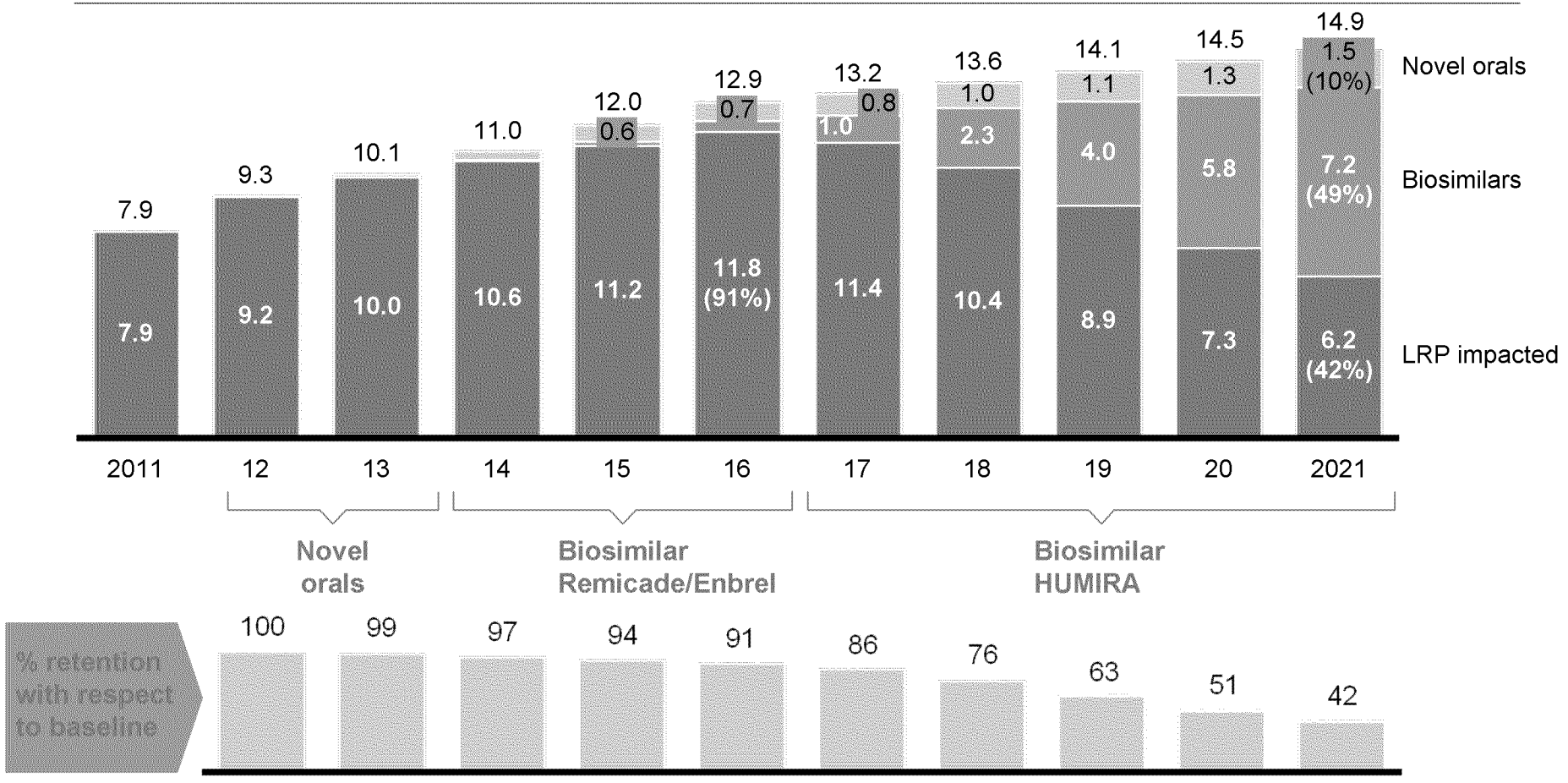
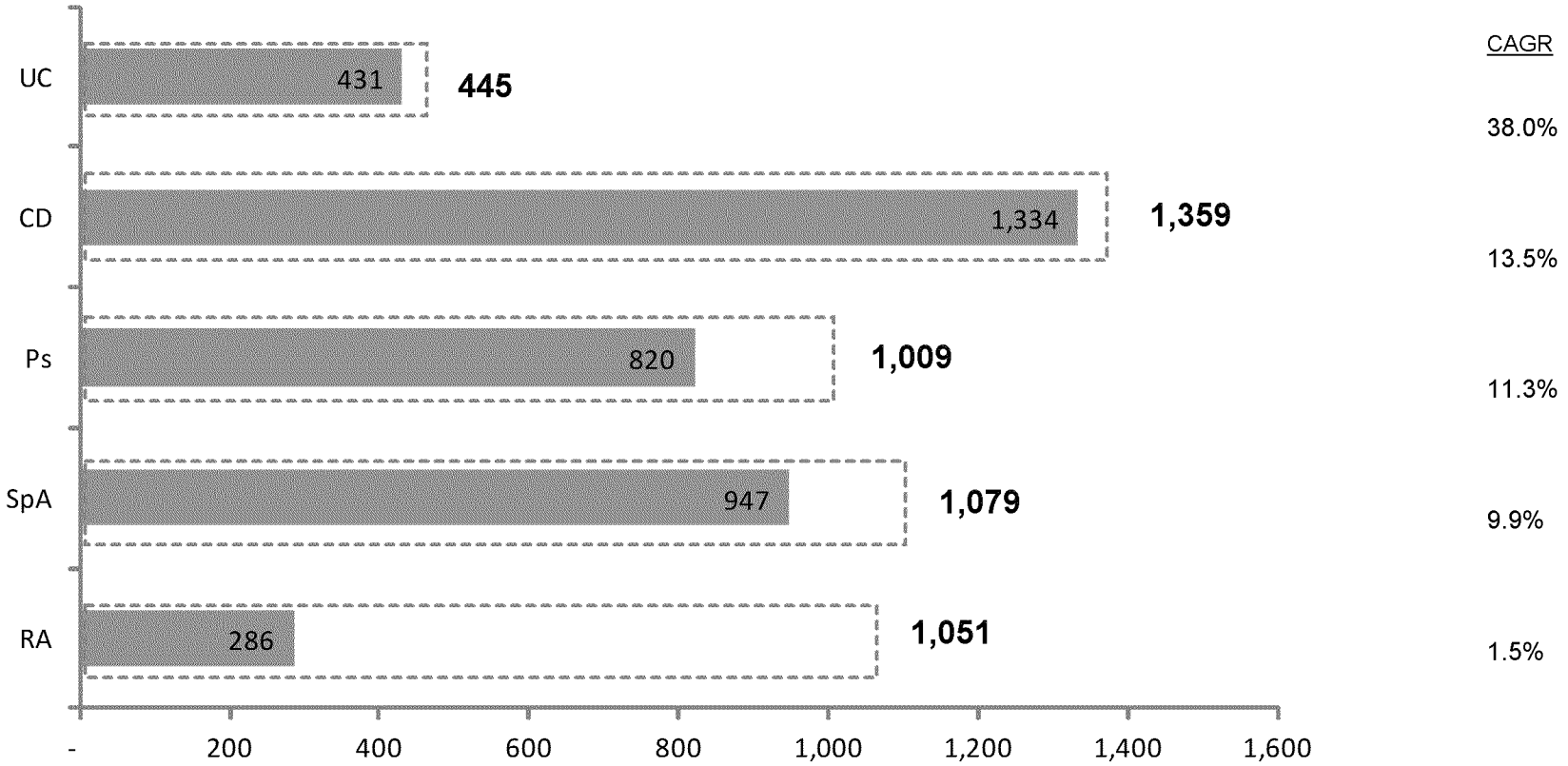
Globally, novel orals and biosimilars are expected to have ($8.7B) (58%) combined impact on global HUMIRA in 2021



SOURCE: Quantitative and qualitative physician research; 2012 erosion model

Gastroenterology is the biggest growth contributor over the LRP due to minimal JAK impact. HUMIRA global growth by Indications/ JAK & Biosimilars

Absolute Sales Value Growth 2011-2016 in $B
TOTAL = $3.8B



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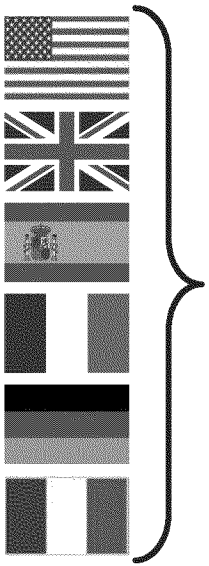
Key Assumptions driving the Biosimilar Erosion of LRP

Launch Dates	Based on Regulatory timelines and Composition of matter patent expiration. Potential delays due to 'non readiness' taken into consideration
Erosion assumptions	Based on market research, with the key variables a. Patient erosion of Naïve, switch and stable patients b. Payer aggressiveness (ability to enforce) *Based on primary data for top 6 markets and proxy assumptions for remaining markets*
Ramp time to Peak Erosion	How fast will biosimilars be fully accepted 4 years to full erosion for cross brand entrance 3 years to full erosion for HUMIRA biosimilars
Indication Extrapolation	Different assumptions depending on a. Agency (EMA, FDA, KFDA) b. Timing of approval (first monoclonal antibody vs later approval0
Automatic substitution	We assume no automatic substitution (payer or pharmacy driven) throughout the LRP This assumption drives the 'erosion assumption of stable patients and the payer aggressiveness assumption:

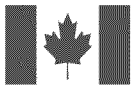
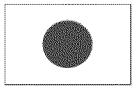
The model assumes a price differential origniator vs biosimilar of 30%. The model can not adjust for volume impact of different pricing scenarios

10 additional countries that will be modeled in detail

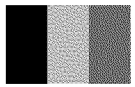
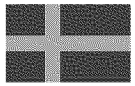
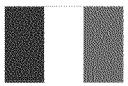
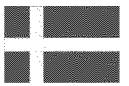
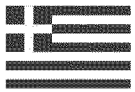
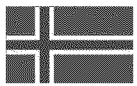
Countries with individual models* in 2012



Primary Market in the respective market drives erosion curve of country

	Proxy Country
	Germany
	Average of EU-5
	UK/high end of EU-5 range
	50% lower than lowest EU-5 country
	France

Countries added for 2013

	Proxy Country
	Average of Italy, Spain, France /Low end of EU-5
	Average of EU-5
	UK/high end of EU-5 range
	Average of EU-5
	Average of EU-5
	Average of EU-5
	UK/high end of EU-5 range
	Average of EU-5
	Average of Italy, Spain, France /Low end of EU-5
	UK/high end of EU-5 range

* Erosion curves, launch date of each product and Indication specific per quarter, country specific naive : switch and retention curves

Launch timing assumptions for Biosimilars key markets

	REMICADE		ENBREL		HUMIRA	
	2012 LRP	2013 LRP	2012 LRP	2013 LRP	2012 LRP	2013 LRP
	Q4 2014	**Q1 2016**	Q3 2018	Q3 2018	Q1 2017	Q1 2017
	Q1 2015	Q1 2015	Q1 2015	**Q3 2015**	Q2 2018	**Q4 2018**
	Q1 2015	Q1 2015	Q1 2015	**Q3 2015**	Q1 2017	**Q4 2018**
	Q1 2015	Q1 2015	Q1 2015	**Q3 2015**	Q2 2018	**Q4 2018**
	Q1 2015	Q1 2015	Q1 2015	**Q3 2015**	Q2 2018	**Q4 2018**
	Q3 2014	Q3 2014	Q1 2015	**Q3 2015**	Q2 2018	**Q4 2018**
	Q1 2015	Q1 2015	Q1 2015	**Q3 2015**	Q2 2018	**Q4 2018**
	Q1 2013	**Q4 2013**	Q3 2013	**Q2 2014**	Q1 2017	Q1 2017
	Q4 2014	*?Q3 2013?*	Q4 2014	**Q2 2014**	Q4 2019	Q4 2019
	Q3 2014	**Q3 2015**	Q3 2015	Q3 2015	Q3 2018	Q3 2018
	Q3 2015	Q3 2015	Q3 2015	Q3 2015	Q4 2018	Q4 2018

1 Based on assumed FDA & EMEA submissions in Sept 2011 2 Best case scenario. PsA included in the SpA therapeutic area
SOURCE: Market access expert interview; IP strategy internal ABT interviews; IP strategy

Delayed launch **Earlier launch**

In 2013 we assume that a number of countries will be able to get biosimilar approval based on the Korean (KFDA) approval (CPP)

2012 Assumptions

- **KFDA approval** — **Q3 2012**
- **EMA approval** — **Q3 2013**
- CPP dependent countries follow EMA with 6 months delay — **Q1 2014**
- **US launch** — **Q4 2014**

2013 Assumptions

- **KFDA approval** — **Q3 2012**
- KFDA CPP dependent countries follow KFDA with 6 months delay — **Q1 2013**
- **EMA approval** — **Q3 2013**
- EMA CPP dependent countries follow EMA with 6 months delay — **Q1 2014**
- **US Launch** — **Q1 2016**

Launch timing assumptions are being verified with each country through the commercial directors.

List of KDFA CPP dependent countries

KFDA CPP:

LatAm: Argentina, Aruba, Brazil, Chile, Colombia, Costa Rica, Dominican Republic, Ecuador, El Salvador, Guatemala, Honduras, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, Trinidad & Tobago, Uruguay, Venezuela

Asia: China, Hong Kong, India, Indonesia, Korea, Malaysia, Singapore, Vietnam

Europe: Croatia, Russia, Turkey, Ukraine

Others: Algeria

RED = Top 20 markets

REMICADE Biosimilar launch date assumptions vs prior year

2012	2013		Scenarios
Launch timing	**Launch timing**		
• **US** patent loss and launch Dec 14 2014	• **US** patent loss and launch Q1 2016	↑	12 months earlier or 12 months later ↑↓
• **EMA** approval Q3 2013	• **EMA** approval Q3 2013	↔	6 months EMA delay ↑
• **EU LBU** patent loss Q3 2014 + 6 month SmPC prolongation due to PIP = **Q1 2015**	• **EU LBU** patent loss Q3 2014 + 6 month SmPC prolongation due to PIP = **Q1 2015**	↔	
• **ROW**: based on EMA CPP	• **ROW**: based **on KDFA** or EMA CPP	↓	

Launch Dates

Enbrel Biosimilar changes since LRP 2012

- All PIP (pediatric investigation plan) trials are completed. We assume therefore that Enbrel will obtain 6 additional month of data exclusivity in EU countries, moving the launch date for patent protected countries from Q1 2015 to Q 3 2015

- Merck decided to end the collaboration with Hanwha in 2012

Scenario 1

- Data was satisfactory for KFDA filing and therefore will be sufficient for EMA filing
- Biosimilar dossier filed with the EMA by Q3 2013
- EMA approval date Q4 2014
- Additional delay of 6 months for countries with NO patent protection and KFDA or EMA CPP dependent approval
    - new partner needed for Hanwah to commercialize product.

Current base case for 2013 LRP

Scenario 2

- Current phase III trial not sufficient for EMA approval:
    - 3 year delay of EMA approval to Q4 2017

- KFDA CCP dependent countries delay 6 months due to need for new commercialization partner

Upside scenario for LRP

Enbrel Biosimilar launch date assumptions vs prior year

2012	2013		Scenarios
US launch Q3 2018	**US launch** Q3 2018	↔	Potential delay of first biosimilar launch by 12 months ↑
EMA approval Q1 2014	**EMA** approval **Q4 2014** due to need of new partner	↑	Hanwah needs additional studies – 24 and 36 months delay ↑
LBU patent loss Q1 2015	**LBU patent loss Q1 2015** + 6 month SmPC prolongation due to PIP (Q3 2015)	↑	
ROW individual, launches as of 2014	**ROW**: based on KDFA or or EMA CPP	↓	

HUMIRA Biosimilar launch date assumptions vs prior year

2012	2013		Scenarios
US patent expiration and launch Q1 2017	**US patent expiration and launch Q1 2017**	↔	
EMA approval Q1 2015	**EMA** approval Q1 2015	↔	
LBU exclusivity loss Q2 2018	**LBU exclusivity** loss Q2 2018 + 6 month SmPC prolongation due to PIP = **Q4 2018)**	↑	Launch during SmPC period (Q3 2017) ↓
ROW based on independent authority or EMA CPP	**ROW**: based on independent authority or EMA CPP	↔	

Erosion assumptions

Ramp time to Peak Erosion

Patient Erosion Assumptions

Scenarios

- **Peak erosion percentages per MD survey (Naïve, Switch, Stable patients)**
  - Cross Brand Biosimilars
    - Aggressive Payors
    - Non-aggressive Payors (MD survey results used here)
  - On Brand Biosimilars
    - Aggressive Payors
    - Non-aggressive Payors (MD survey results used here)

↔

- 15% more erosion ↓
- 15% less erosion ↑
- 30% less erosion ↑

- **Affiliate data used for Naïve-Switch share and persistency curves**
  - Affiliate review currently ongoing

↔

- **Ramp-up to full erosion remains 4 years for first biosimilars**
- **And 3 years for HUMIRA biosimilar**

↔

- 1 year less and 1 year more for ramp up ↑↓

- **Automatic substitution not allowed**

↔

- Automatic substitution = double the peak stable patient erosion ↓

Baselines physician uptake combined with payor aggressiveness will drive up to 78% erosion with Humira biosimilar introduction

Erosion assumptions

Ramp time to Peak Erosion

Impact to Humira

Patient group	Cross-brand biosimilar phase	Humira biosimilar phase
Naïve	26% patient erosion • 34% of KVs aggressive[1] (37% erosion) • 66% of KVs not aggressive[1] (21% erosion) • →34% x 37%[2] + 66% x 21%[2] = 26%	78% patient erosion • 60% of KVs aggressive[1] (90% erosion) • 40% of KVs not aggressive[1] (59% erosion) • →60% x 90% + 40% x 59%[2] = 78%
Failure	33% patient erosion • 34% of KVs aggressive[1] (43% erosion) • 66% of KVs not aggressive[1] (28% erosion) • →34% x 43%[2] + 66% x 28%[2] = 33%	78% patient erosion • 60% of KVs aggressive[1] (90% erosion) • 40% of KVs not aggressive[1] (61% erosion) • →60% x 90% + 40% x 61%[2] = 78%
Stable	17% patient erosion[2]	30% patient erosion • 60% of KVs aggressive[1] (37% erosion) • 40% of KVs not aggressive[1] (20% erosion) • →60% x 37%[2] + 40% x 20%[2] = 30%
Ramp-up to full erosion	4 years	3 years

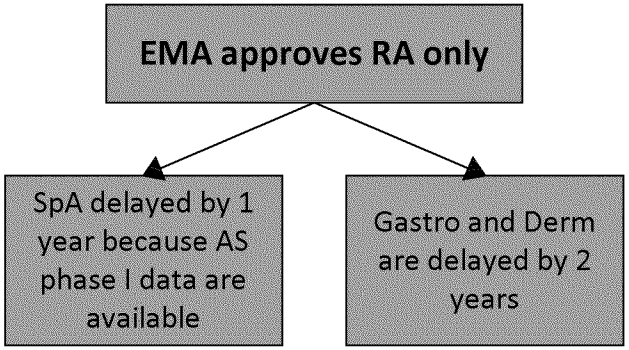
1 Payor interviews and analysis 2 Physician survey

SOURCE: Physician and patient survey; physician interviews, payor interviews; team analysis

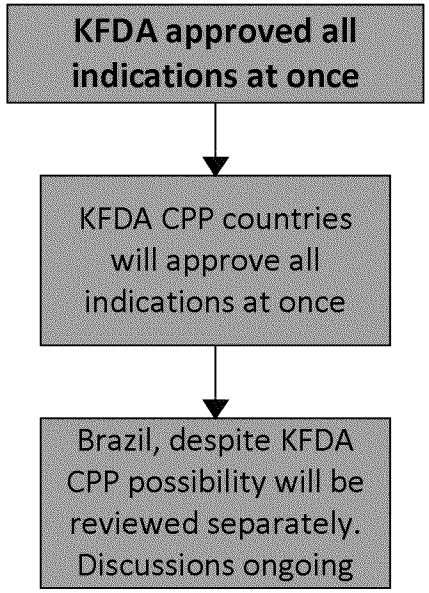
Indication Extrapolation

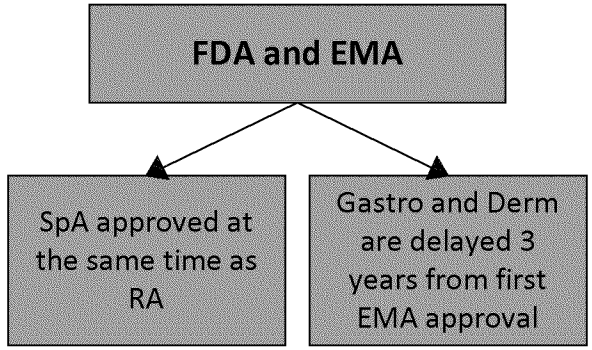
Rational of extrapolation of indications Remicade

2012 Assumptions Remicade



2013 Assumptions Remicade





Based on KOL and expert opinions and fact that AS data are available.

In 2012 we assumed that Derm and Gastro trials would start during 2012. Now we assume that trials will only start after EMA approval and that the trials would take 2 years to enrol and 1 year for approval post submission

Indication extrapolation assumptions vs prior year

2012

Remicade

- No extrapolation of indications
- Delay of SpA indication 1 years
- Delay of Gastro and Derm 2 years

HUMIRA

- Globally:
  1 year delay of all non-RA indications

2013

Remicade

- KFDA depended countries will have extrapolation of all indications
- FDA, EMA and EMA dependent countries will have extrapolation of Rheum indications (RA + SpA)
- FDA, EMA and EMA dependent countries: Gastro and Derm delayed by 3 years (2 year for clinical trials, 1 year for approval)

HUMIRA

- EMA/EMA dependent countries: All indications at the same time (sufficient time to run trials between 2015 and Q4 2018)
- US/FDA: 1 year delay of Gastro indications due to duration and complexity of IBD trials.

Scenarios

Upside if EMA decides against extrapolation

Downside if EMA decides for extrapolation

Impact of 1 year delay of non Rheum indications

Overall Risk Assessment to HUMIRA LRP (from team point of you)

	Cross-Brand Biosimilars	HUMIRA Biosimilars
Launch Dates	Low Risk to LRP / High Risk to LRP EMA first pass approval US Remicade assumption	Low Risk to LRP / High Risk to LRP US Launch Full SmPC exclusivity in EU
Erosion assumptions	No off label use of biosimilars in case of non- extrapolation	
Ramp time to Peak Erosion	4 year ramp up. Payer aggressiveness and HCP adaptation could accelerate	3 year ramp up in a market with biosimilar experience
Indication Extrapolation	KFDA CCP countries full extrapolation at launch EMA/FDA: Rheumatology indications at launch EMA/FDA: Gastro and Derm: 3 year delay after first approval	**Delay of Gastro indication in the US by one year**
Automatic substitution	No Automatic substitution at launch of first biosimilar seems to be a moderate risk assumption	No Automatic substitution at launch of HUMIRA biosimilar bares considerable risk

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2013 LRP

Biosimilar Erosion Modeling

Assumptions Discussion

February 7, 2013

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Biosimilar Remicade assumptions for US

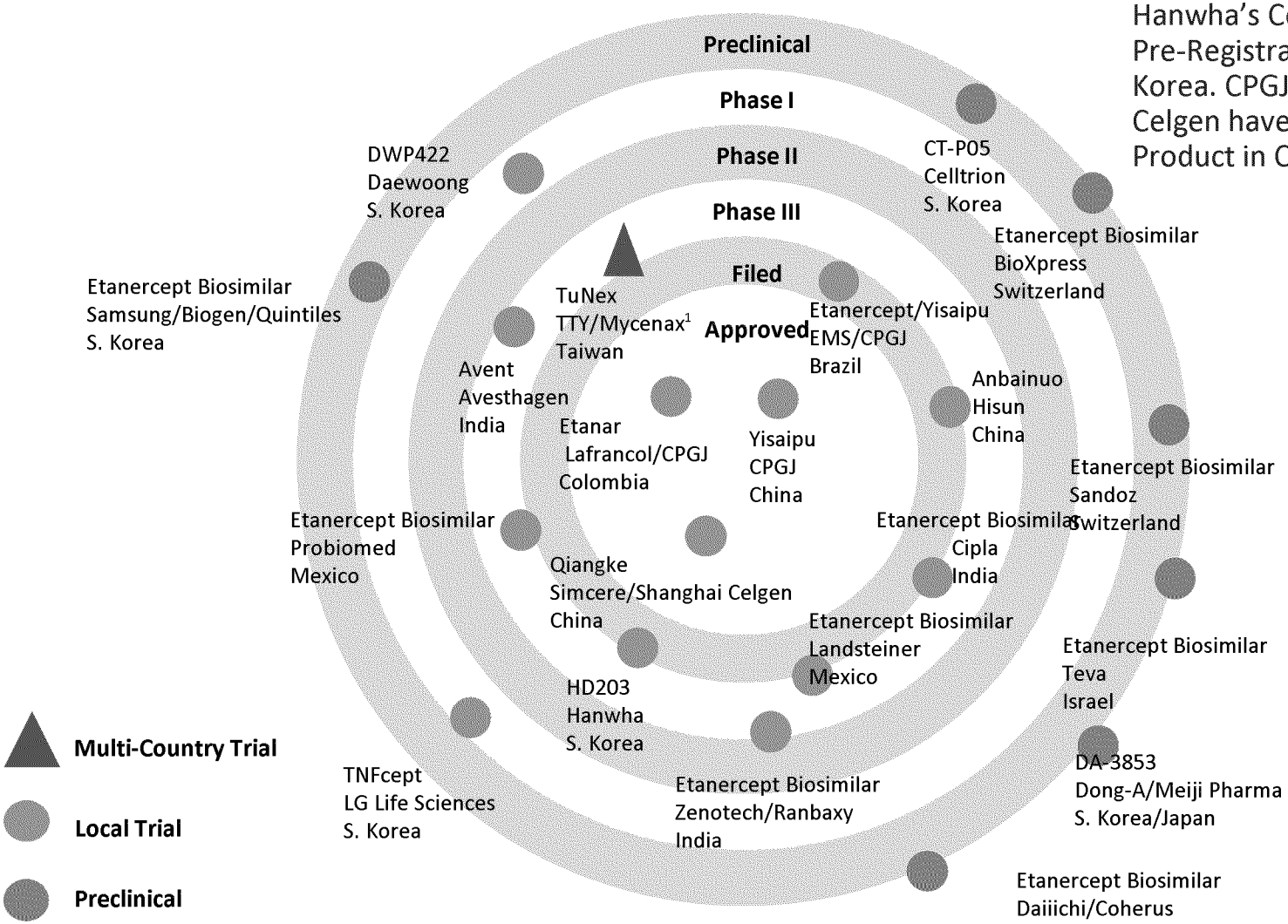
- Centocor will assert additional IP and will engage in litigation against Hospira/Celltrion in Q1 2014.
- No at-risk launch by Hospira/Celltrion at the time of approval and patent expiration in Q4 2014.
- Centocor and Hospira/Celltrion will settle litigation
- Biosimilar product will launch at Q1 2016 under potential settlement agreement.

Launch Dates

Overview of Enbrel biosimilar development programs

Enbrel etanercept

Hanwha's Compound is at the Pre-Registration Stage in South Korea. CPGJ and Shanghai Celgen have an Approved Product in China



[1] India, Taiwan, Argentina

Last updated on January 13, 2013

Baselines physician uptake combined with payor aggressiveness will drive up to 77% erosion with Humira biosimilar introduction

Impact to Humira

Patient group	Remicade biosimilar phase 2014-16	Humira biosimilar phase 2017-21
Naïve	**15% patient erosion** • 15%[1] of payors require step therapy (90% erosion) • 85%[1] of payors do not require step (2% erosion[2]) • →15% x 90% + 85% x 2% = 15%	**77% new patient erosion** • 71%[1] of payors require step therapy (90% erosion) • 29%[1] of payors do not require step (46% erosion[2]) • →71% x 90% + 29% x 46% = 77%
Failure	**2% Switch patient erosion** • 15%[1] of payors aggressive (2% erosion) • 85%[1] of payors not aggressive (2% erosion[2]) • →15% x 2% + 85% x 2% = 2%	**76% patient erosion** • 71%[1] of payors require step therapy (90% erosion) • 29%[1] of payors do not require step (43% erosion[2]) • →71% x 90% + 29% x 43% = 76%
Stable	**2% Stable patient erosion** • 12%[1] of payors aggressive (10% erosion[2]) • 88%[1] of payors not aggressive (1% erosion[2]) • →12% x 10% + 88% x 0% = 2%	**38% patient erosion** • 22%[1] of payors aggressive (39% erosion[2]) • 78%[1] of payors not aggressive (37% erosion[2]) • →22% x 39% + 78% x 37% = 38%

1 Zitter Group survey 2 Physician survey

SOURCE: Physician and patient survey; physician interviews, payor interviews; team analysis

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Baselines physician uptake combined with payor aggressiveness will drive up to 80% erosion with Humira biosimilar introduction

Impact to Humira

Patient group	Cross-brand biosimilar phase	Humira biosimilar phase
Naive	**43% patient erosion** • 50% of payors aggressive[1] (61% erosion) • 50% of payors not aggressive[1] (25% erosion) • →50% x 61%[2] + 50% x 25%[2] = 43%	**80% patient erosion** • 80% of PCTs aggressive[1] (90% erosion) • 20% of PCTs not aggressive[1] (38% erosion) • →80% x 90% + 20% x 38%[2] = 80%
Failure	**25% patient erosion** • 50% of PCTs aggressive[1] (37% erosion) • 50% of PCTs not aggressive[1] (14% erosion) • →50% x 37%[2] + 50% x 14%[2] = 25%	**77% patient erosion** • 80% of PCTs aggressive[1] (90% erosion) • 20% of PCTs not aggressive[1] (25% erosion) • →80% x 90% + 20% x 25%[2] = 77%
Stable	**~0% patient erosion[2]**	**19% patient erosion** • 80% of PCTs aggressive[1] (24% erosion) • 20% of PCTs not aggressive[1] (0% erosion) • →80% x 24%[2] + 20% x 0%[2] = 19%

1 Payor interviews and analysis 2 Physician survey

SOURCE: Physician and patient survey; physician interviews, payor interviews; team analysis

Baselines physician uptake combined with payor aggressiveness will drive up to 78% erosion with Humira biosimilar introduction

Impact to Humira

Patient group	Cross-brand biosimilar phase	Humira biosimilar phase
Naive	26% patient erosion • 34% of KVs aggressive[1] (37% erosion) • 66% of KVs not aggressive[1] (21% erosion) • →34% x 37%[2] + 66% x 21%[2] = 26%	78% patient erosion • 60% of KVs aggressive[1] (90% erosion) • 40% of KVs not aggressive[1] (59% erosion) • →60% x 90% + 40% x 59%[2] = 78%
Failure	33% patient erosion • 34% of KVs aggressive[1] (43% erosion) • 66% of KVs not aggressive[1] (28% erosion) • →34% x 43%[2] + 66% x 28%[2] = 33%	78% patient erosion • 60% of KVs aggressive[1] (90% erosion) • 40% of KVs not aggressive[1] (61% erosion) • →60% x 90% + 40% x 61%[2] = 78%
Stable	17% patient erosion[2]	30% patient erosion • 60% of KVs aggressive[1] (37% erosion) • 40% of KVs not aggressive[1] (20% erosion) • →60% x 37%[2] + 40% x 20%[2] = 30%

1 Payor interviews and analysis 2 Physician survey

SOURCE: Physician and patient survey; physician interviews, payor interviews; team analysis

Baselines physician uptake combined with payor aggressiveness will drive up to 80% erosion with Humira biosimilar introduction

Impact to Humira

Patient group	Cross-brand biosimilar phase	Humira biosimilar phase
Naïve	20% patient erosion • 50% of hospitals aggressive[1] (23% erosion) • 50% of hospitals not aggressive[1] (15% erosion) • →50% x 23%[2] + 50% x 15%[2] = 19%	80% patient erosion • 80% of hospitals aggressive[1] (90% erosion) • 20% of hospitals not aggressive[1] (41% erosion) • →80% x 90% + 20% x 41%[2] = 80%
Failure	14% patient erosion • 50% of hospitals aggressive[1] (20% erosion) • 50% of hospitals not aggressive[1] (7% erosion) • →50% x 20%[2] + 50% x 7%[2] = 14%	79% patient erosion • 80% of hospitals aggressive[1] (90% erosion) • 20% of hospitals not aggressive[1] (35% erosion) • →80% x 90% + 20% x 35%[2] = 79%
Stable	9% patient erosion	18% patient erosion • 80% of hospitals aggressive[1] (20% erosion) • 20% of hospitals not aggressive[1] (9% erosion) • →80% x 20%[2] + 20% x 9%[2] = 18%
Price	0% price erosion	30% price erosion

1 Payor interviews and analysis 2 Physician survey

SOURCE: Physician and patient survey; physician interviews, payor interviews; team analysis

Baselines physician uptake combined with payor aggressiveness will drive up to 79% erosion with Humira biosimilar introduction

Impact to Humira

Patient group	Cross-brand biosimilar phase	Humira biosimilar phase
Naïve	25% patient erosion • 50% of regions aggressive[1] (42% erosion) • 50% of regions not aggressive[1] (9% erosion) • →50% x 42%[2] + 50% x 9%[2] = 25%	79% patient erosion • 80% of regions aggressive[1] (90% erosion) • 20% of regions not aggressive[1] (32% erosion) • →80% x 90% + 20% x 32%[2] = 79%
Failure	27% patient erosion • 50% of regions aggressive[1] (40% erosion) • 50% of regions not aggressive[1] (14% erosion) • →50% x 40%[2] + 50% x 14%[2] = 27%	79% patient erosion • 80% of regions aggressive[1] (90% erosion) • 20% of regions not aggressive[1] (32% erosion) • →80% x 90% + 20% x 32%[2] = 79%
Stable	16% patient erosion[2]	26% patient erosion • 80% of regions aggressive[1] (32% erosion) • 20% of regions not aggressive[1] (0% erosion) • →80% x 32%[2] + 20% x 0%[2] = 26%
Price	0% price erosion	5% price erosion

1 Payor interviews and analysis 2 Physician survey

Baselines physician uptake combined with payor aggressiveness will drive up to 57% erosion with Humira biosimilar introduction

Impact to Humira

Patient group	Cross-brand biosimilar phase	Humira biosimilar phase
Naïve	9% patient erosion • 0% of regions aggressive[1] • 100% of regions not aggressive[1] (9% erosion[2])	54% patient erosion • 40% of regions aggressive[1] (90% erosion) • 60% of regions not aggressive[1] (31% erosion) • →40% x 90% + 60% x 31%[2] = 54%
Failure	16% patient erosion • 0% of regions aggressive[1] • 100% of regions not aggressive[1] (16% erosion[2])	57% patient erosion • 40% of regions aggressive[1] (90% erosion) • 60% of regions not aggressive[1] (35% erosion) • →40% x 90% + 60% x 35%[2] = 57%
Stable	0% patient erosion[2]	12% patient erosion • 40% of regions aggressive[1] (30% erosion) • 60% of regions not aggressive[1] (0% erosion) • →40% x 30%[2] + 60% x 0%[2] = 12%
Price	5% price erosion	15% price erosion

1 Payor interviews and analysis 2 Physician survey

SOURCE: Physician and patient survey; physician interviews, payor interviews; team analysis

Minor countries were modeled using proxies from surveyed countries

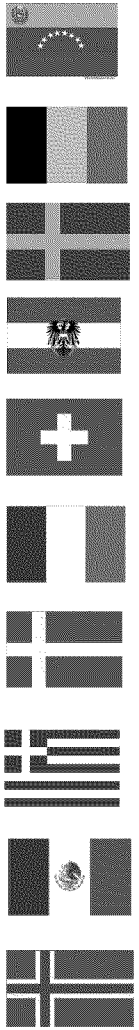
Biosimilars

Proxy country	Rationale
Germany	• Market share for generic medicines similar to Germany (IMS reports)
Average of EU-5	• Generic penetration in Canada more closely matches EU-5 • Proxy confirmed by IMS data
UK/high end of EU-5 range	• Biosimilar regulatory pathway has been approved • Government has shown strong support for biosimilar development and will likely encourage adoption of biosimilars or price concessions from originators • Proxy confirmed by IMS data
50% lower than lowest EU-5 country	• Generics penetration in Japan is low compared to the US and EU-5 • 0% adoption of biosimilar human growth hormone one year after launch • Proxy confirmed by IMS data
France	• Low generics penetration to date (government requires price concessions from originators) • Biosimilars pathway will mirror EMA guidelines • Assumes that Humira will be required to make a price concession of 16% • Proxy confirmed by IMS data

All inputs (e.g., share erosion, payor aggressiveness, ramp-up curves) follow the proxy country unless otherwise noted

SOURCE: Expert interviews; Internal ABT interviews; EGA reports; IMS reports; PPD market research

10 additional countries that will be modeled in detail



Country	Proxy Country	Rationale
Venezuela	Average of Italy, Spain, France /Low end of EU-5	•Low generic penetration
Belgium	Average of EU-5	
Sweden	UK/high end of EU-5 range	•Tender Market
Austria	Average of EU-5	
Switzerland	Average of EU-5	
Ireland	Average of EU-5	
Denmark	UK/high end of EU-5 range	•Tender Market
Greece	Average of EU-5	
Mexico	Average of Italy, Spain, France /Low end of EU-5	•Low generic penetration
Norway	UK/high end of EU-5 range	•Tender Market

Message

From: [redacted]
Sent: 3/8/2013 10:41:21 AM
To: [redacted]
CC: [redacted]
Subject: RE: Feb price-pipeline-demand flash analysis

I think the March price (vs. Plan) may be due to the movement of the price action. Off memory, I think the Plan had a March price action (along with the wipp reval), so vs. the Plan, you would have some unfav. in March (you got benefit of the reval in Jan). Still looks a little high though, but maybe not so far off.

[redacted]

From: [redacted]
Sent: Friday, March 08, 2013 10:36 AM
To: [redacted]
Cc: [redacted]
Subject: RE: Feb price-pipeline-demand flash analysis

Can't see any yellow. I let [redacted] know that I would not expect that much [redacted] unfav...I will look into on Monday.

[redacted], let me know if there is any Medco/VA dialed in for TriCor in March.

Thanks.

[redacted]

From: [redacted]
Sent: Friday, March 08, 2013 10:33 AM
To: [redacted]
Cc: [redacted]
Subject: FW: Feb price-pipeline-demand flash analysis

See below in Yellow. Is this what we're planning in March S&OP? Why do we think we'll have negative price in March?
Thanks

[redacted]

[redacted]

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1 North Waukegan Road
North Chicago, IL 60064

[redacted]

abbvie.com

From: [redacted]
Sent: Friday, March 08, 2013 8:23 AM
To: [redacted]
Cc: [redacted]
Subject: Feb price-pipeline-demand flash analysis

Attached are several files. The first is the price-pipeline-demand February flash as published by [redacted] The second is a file that I put together when we did the February LBE. There are two tabs in that file—for both schedules the Q1 price-pipeline-demand totals equal what we published for our UPD/LBE.

[redacted] would like to get us together this afternoon to review to ensure that what is now being calculated for the March LBE is in sync with what is being submitted for the S&OP.

Two quick examples: When we did the LBE package a few weeks ago, we showed a Feb/March price-pipeline-demand for HUMIRA as being $8MM favorable in demand vs. Plan between February and March. When we dial in the February flash along with January actuals to gait it out it now shows that HUMIRA needs to be $25MM favorable in demand in March to deliver the LBE. Is this in sync with the S&OP?

Likewise, he saw the ($23MM) unfavorability in price fall through in February, much of which should be due to the catch-up of the chargebacks (do we know how much?) [redacted] also wants to make sure there was nothing else weird happening for example in [redacted] in the LBE v Redacted – NR Product However, when we dial in February flash, Redacted – NR Product

Redacted – NR Product

[redacted] understands we may not have the answers today, but he wants to proactively look at this to ensure that we're lining up to deliver the LBE and if the S&OP is coming in different than that (which for Cardio and Specialty Redacted – NR Product Redacted – NR Product to have a brief conversation today so we can begin to collect answers/perspective prior to the LBE submission next Thursday, March 14.

[redacted] will be sending out a meeting invite for this afternoon.

[redacted]

[redacted]

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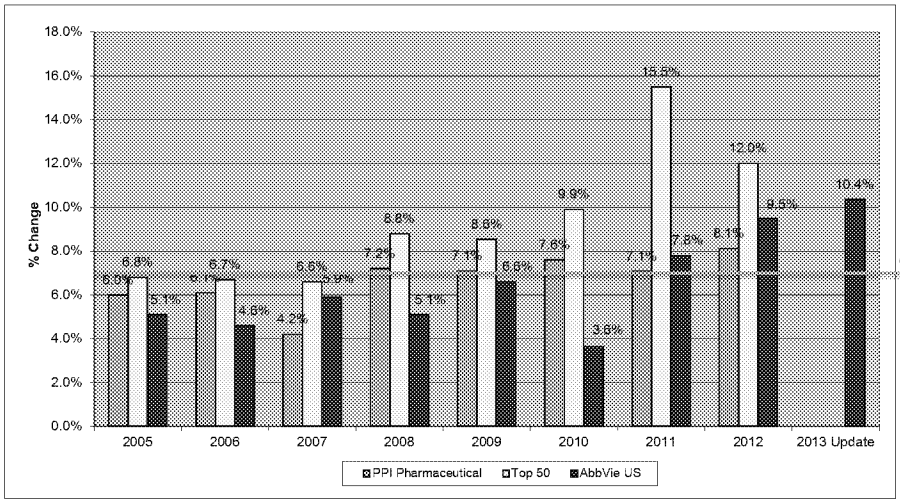
US Commercial 2013 UPD and Proposed Price Actions

June 11, 2013

Comparative Price Indexes – 2013 Update

AbbVie US pricing actions between 2005 and 2012 have been below the average for Top 50 Pharmaceuticals and are below the PPI in five of the last eight years.



Producer Price Index (PPI), Pharmaceuticals for human use, prescription, from the Bureau of Labor Statistics: (12 months ending Dec 31, 2012).

Top 50 price action % based on Analysource WAC prices.

Price Index / Price Actions do not take into account discounts paid to the government and private pay customers.

2013 Update with Proposed Price Actions

US Commercial
2013 Update with Proposed Actions

	Jan	Apr	Jun	Jul	12 Months Cumulative	24 Months Cumulative	Value of June/July Price Actions 2013	Value of June/July Price Actions 2014
TriCor TRILIPIX Niaspan Advicor SIMCOR	Redacted – NR Product							
HUMIRA	6.9%			6.9% **	14.3%	30.6%	153	286
Synthroid								
Zemplar Caps								
Kaletra								
Depakote DR Depakote ER Depakene Depacon								
Nimbex								
Lupron - URO Lupron - GYN Lupron - PED								
AndroGel, 1.62% pump AndroGel, all 1% formulations Creon (Redacted – NR Product Redacted – NR Product	Redacted – NR Product							
Biaxin IR Biaxin XL BOS Cardizem Gengraf Marinol Mavik K-Tab Tarka Teveten Vicodin Survanta Vicoprofen Prometrium								

Redacted – NR Product

* Weighted Average
** Actual price action taken May 8
*** *Proposed, not in Update assumptions*
**** Additional Creon Redacted – NR Product
Redacted – NR Product

Summary: Impact of
-Not Taking Planned June Actions
-Not Taking Planned [redacted]
-Taking Incremental Humira Action
-Taking Incremental [redacted]

Redacted – NR Product	
153	286
Redacted – NR Product	

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Price Action Recommendations – effective date of July 2, 2013

- Humira – an additional 2013 price action (6.9%) would result in $153MM incremental 2013 Net Sales and $132MM Margin
- [redacted] Redacted – NR Product
- [redacted] Redacted – NR Product
- Tricor, Trilipix and Zemplar Caps – Redacted – NR Product
- AndroGel 1.62% pump – Redacted – NR Product

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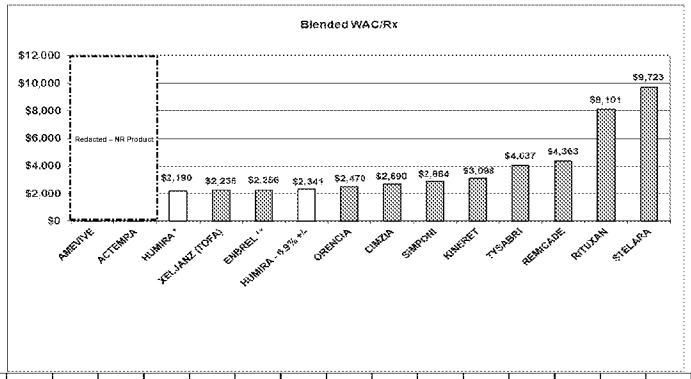
HUMIRA Price Actions vs. Competitors

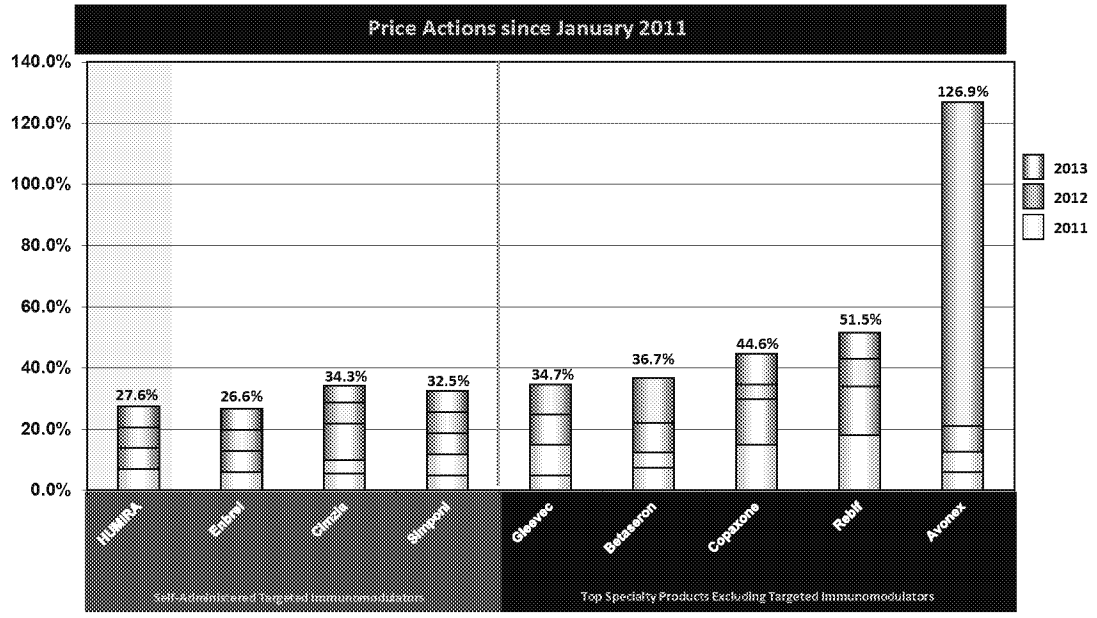
HUMIRA Weighted Average WAC per Rx vs. Competitors – Retail and Mail



	May-11	Jun-11	Jul-11	Aug-11	Sep-11	Oct-11	Nov-11	Dec-11	Jan-12	Feb-12	Mar-12	Apr-12	Jun-12	Jul-12	Aug-12	Sep-12	Oct-12	Dec-12	Jan-13	Feb-13	Mar-13	Apr-13	12 Month Cumulative	24 Month Cumulative
HUMIRA	6.9%								6.9%					6.9%					6.9%				14.3%	30.6%
Enbrel			5.9%						6.9%					6.9%					6.9%				14.3%	29.4%
Orencia***				3.3%						3.3%					3.0%					4.5%			7.6%	14.7%
Remicade					2.9%						4.9%					3.9%					4.9%		9.0%	17.6%
Xeljanz																							0.0%	0.0%
Amevive																							0.0%	0.0%
Cimzia						4.4%			12.0%								6.9%					5.5%	12.8%	31.9%
Kineret		6.9%					4.8%						8.7%			8.9%					25.0%		47.9%	65.7%
Rituxan						2.8%						2.8%					2.8%						2.8%	8.5%
Simponi			6.9%							6.9%					6.9%					6.9%			14.3%	30.6%
Stelara			6.9%							4.9%					4.9%					6.9%			12.1%	25.7%
Tysabri		5.0%						3.9%					6.0%					6.0%					12.4%	22.6%

* HUMIRA Average WAC Price/Rx assumes 2 syringes per Rx.
**Enbrel Average WAC Price/Rx assumes 4 syringes per Rx of the 50mg strength.
*** Orencia – weighted average 4.5% for 3% and 6% on various NDCs on 2/15/13 price action.
12 Month Cumulative: May 2012 – Apr 2013 and 24 Month Cumulative: May 2011 – Apr 2013.
Source – WAC price increase as of 05/15/2013 and Blended WAC/Rx as of 04/30/2013 per Analysource.

HUMIRA Price Actions vs. Competitors / Other Specialty



Source: Analysource.com referenced 4-16-13

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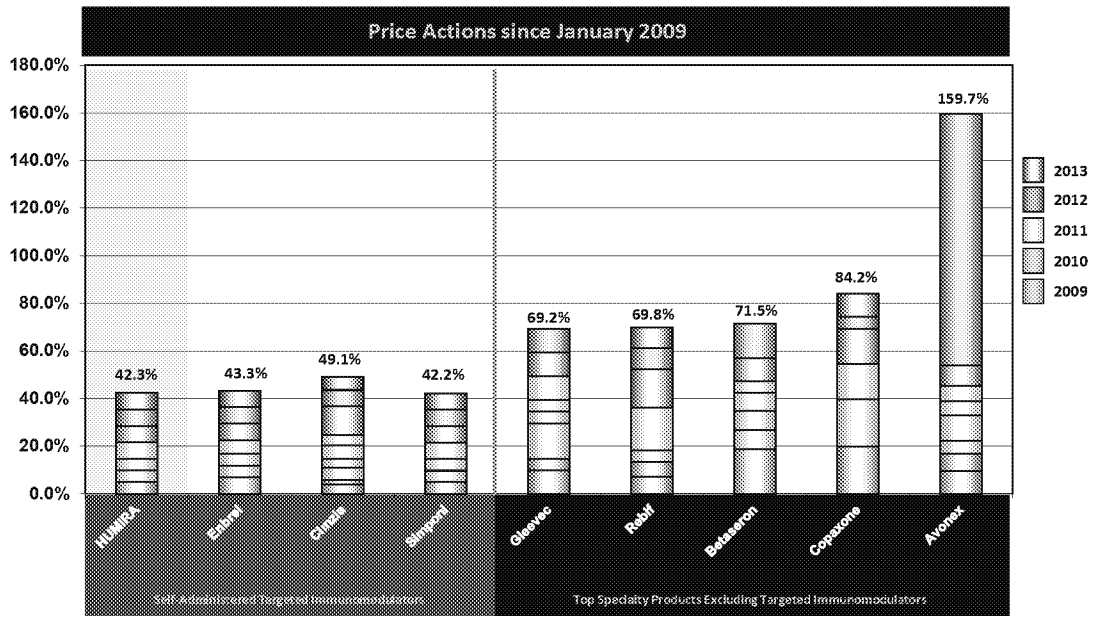
HUMIRA Price Actions vs. Competitors / Other Specialty



Source: Analysource.com referenced 4-16-13

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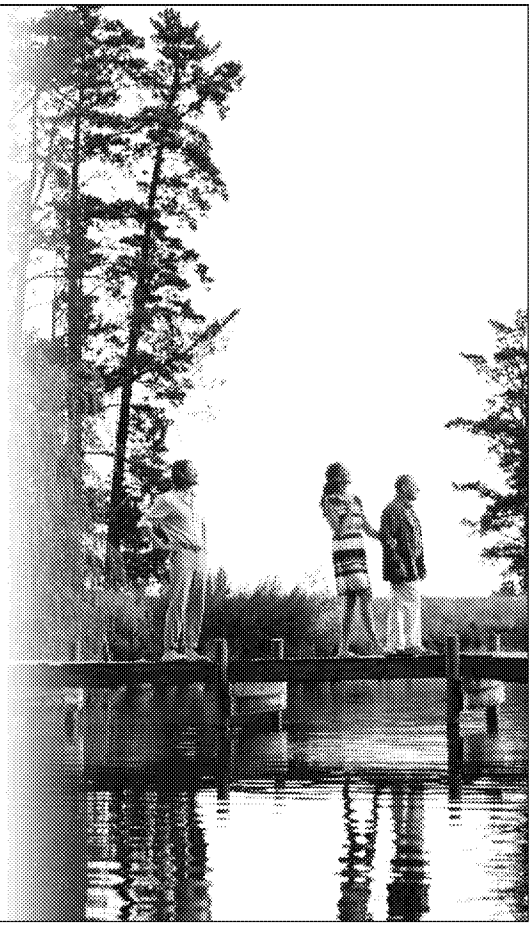
2014 LRP
US HUMIRA Biosimilar Erosion

JRS Review

February 14th, 2014



2014 LRP – US HUMIRA Biosimilar Erosion

Today's Agenda

1) Quick preview of 2014 Base LRP (excluding biosimilars)
   - What's included and what's not
   - Comparison to 2013 LRP
   - More detail will be provided on Feb 25th

2) Review biosimilar erosion modeling approach for 2014 LRP
   - Guiding principles
   - Modeling approach and assumptions
   - Deep dive on select payors
   - Summary comparison to 2013 LRP
   - Ongoing backup analysis

3) Next steps
   - Expectations for Feb 25th JRS review
     - Deeper dive on Base LRP
     - Action items from today's review
   - Discuss deliverables for CA/WJC/RAG reviews

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HUMIRA 2014 LRP - JRS Review Book

What's Included and What's Not

What's Included

1) New indications (HS and UV); reflects latest forecasts from GCD
2) Reflects delay of High Concentration (HC) launch until 2017; project now combined with launch of New Pen
   a) Key +/- to remove based on recent FDA guidance
3) Remaining Portfolio projects (Nail Ps and CD High Dose Induction)
4) One 6.9% WAC increase per year beginning in Jan 2015 (really 12/31/14)
5) MOS remains flat at 0.6 throughout LRP horizon
6) Impact of new competitors currently in Phase 3 trials or later
7) Impact of Remicade biosimilar(s); launch in Q1 2016
8) Impact of HUMIRA biosimilar(s); launch in Q1 2017

What's Not Included

1) HUMIRA 40mg Vial
   a) Key +/- to include incremental impact
2) HUMIRA Ambassador expansion
   a) Blue Plan to include impact

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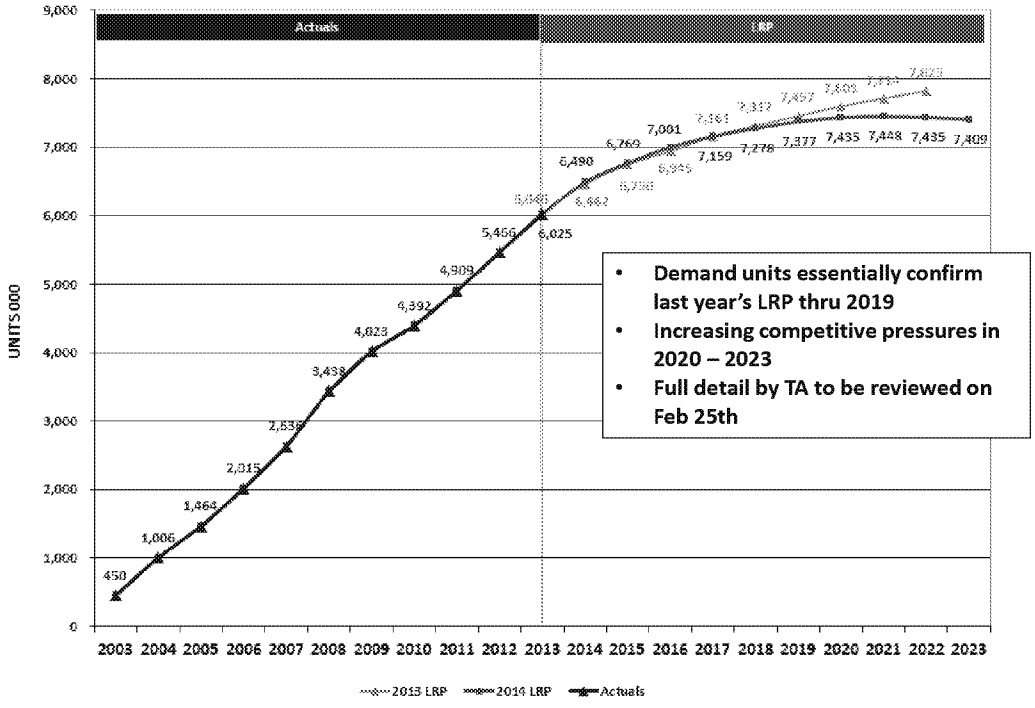
HUMIRA 2014 LRP – Excluding Biosimilar erosion

Demand Units comparison vs. 2013 LRP



- **Demand units essentially confirm last year's LRP thru 2019**
- **Increasing competitive pressures in 2020 – 2023**
- **Full detail by TA to be reviewed on Feb 25th**

HUMIRA 2014 LRP – Excluding Biosimilar erosion

Sales Comparison vs. 2013 LRP

EXCLUDES BIOSIMILARS EROSION

RISK ADJUSTED SALES $MM

	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	5 YR CAGR '13 - '18	10 YR CAGR '13 - '23
2013 LRP SALES	$ 5,124	$ 5,705	$ 6,119	$ 6,512	$ 7,166	$ 7,557	$ 7,952	$ 8,325	$ 8,669	$ 9,004		***8.1%***	**n/a**
% Y-O-Y Growth	*17.1%*	*11.4%*	*7.3%*	*6.4%*	*10.0%*	*5.5%*	*5.2%*	*4.7%*	*4.1%*				
2014 LRP SALES	$ 5,236	$ 6,357	$ 6,969	$ 7,504	$ 7,896	$ 8,297	$ 8,732	$ 9,129	$ 9,461	$ 9,778	$ 10,058	***9.6%***	***6.7%***
% Y-O-Y Growth	*19.6%*	*21.4%*	*9.6%*	*7.7%*	*5.2%*	*5.1%*	*5.2%*	*4.5%*	*3.6%*	*3.4%*	*2.9%*		
Variance	**$ 113**	**$ 652**	**$ 850**	**$ 992**	**$ 731**	**$ 740**	**$ 780**	**$ 803**	**$ 792**	**$ 774**			
VARIANCE DUE TO:													
Demand	**$ (19)**	**$ 27**	**$ 20**	**$ 69**	**$ 13**	**$ (20)**	**$ (60)**	**$ (156)**	**$ (279)**	**$ (441)**			
% Var	*-0.4%*	*0.5%*	*0.3%*	*1.1%*	*0.2%*	*-0.3%*	*-0.8%*	*-1.9%*	*-3.2%*	*-4.9%*			
Pipeline	**$ (208)**	**$ 29**	**$ (10)**	**$ (3)**	**$ (9)**	**$ (5)**	**$ (6)**	**$ (9)**	**$ (10)**	**$ (12)**			
% Var	*-4.1%*	*0.5%*	*-0.2%*	*0.0%*	*-0.1%*	*-0.1%*	*-0.1%*	*-0.1%*	*-0.1%*	*-0.1%*			
Price	**$ 340**	**$ 596**	**$ 840**	**$ 925**	**$ 727**	**$ 765**	**$ 846**	**$ 968**	**$ 1,080**	**$ 1,227**			
% Var	*6.6%*	*10.4%*	*13.7%*	*14.2%*	*10.1%*	*10.1%*	*10.6%*	*11.6%*	*12.5%*	*13.6%*			
Grand Total	**$ 113**	**$ 652**	**$ 850**	**$ 992**	**$ 731**	**$ 740**	**$ 780**	**$ 803**	**$ 792**	**$ 774**			
% Var	*2.2%*	*11.4%*	*13.9%*	*15.2%*	*10.2%*	*9.8%*	*9.8%*	*9.6%*	*9.1%*	*8.6%*			

Demand: Essentially confirms 2013 LRP thru 2019. Unfavorability in 2020+ reflects combined impact of loss of Axial and Peripheral SpA projects, increasing competitive pressure in PsA, and Ps market and share headwinds.

Pipeline: Reflects destock in 2013 to 0.6 MOS and then held flat through 2023. 2013 LRP was held flat at 1.0 MOS.

Price: Primarily reflects flow-through of two additional 6.9% price actions (July 2013 and July 2014) not comprehended in 2013 LRP. Partially offset by removal of 3.6% rebate "harvesting" taken in 2013 LRP beginning in 2017.

HUMIRA 2014 LRP – Excluding Biosimilar erosion

Sales Comparison vs. 2013 LRP

EXCLUDES BIOSIMILARS EROSION

RISK ADJUSTED SALES $MM

	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	5 YR CAGR '13 - '18	10 YR CAGR '13 - '23
2013 LRP SALES	$ 5,124	$ 5,705	$ 6,119	$ 6,512	$ 7,166	$ 7,557	$ 7,952	$ 8,325	$ 8,669	$ 9,004		*8.1%*	n/a
% Y-O-Y Growth	*17.1%*	*11.4%*	*7.3%*	*6.4%*	*10.0%*	*5.5%*	*5.2%*	*4.7%*	*4.1%*				
2014 LRP SALES	$ 5,236	$ 6,357	$ 6,969	$ 7,504	$ 7,896	$ 8,297	$ 8,732	$ 9,129	$ 9,461	$ 9,778	$ 10,058	*9.6%*	*6.7%*
% Y-O-Y Growth	*19.6%*	*21.4%*	*9.6%*	*7.7%*	*5.2%*	*5.1%*	*5.2%*	*4.5%*	*3.6%*	*3.4%*	*2.9%*		
Variance	**$ 113**	**$ 652**	**$ 850**	**$ 992**	**$ 731**	**$ 740**	**$ 780**	**$ 803**	**$ 792**	**$ 774**			

VARIANCE DUE TO:

Growth rates appear to dramatically slow down in 2015; however if you normalize for comparable pricing and inventory levels, the growth appears reasonable.

	2012	2013	2014	2015
2014 LRP Sales $MM	$4,377	$5,236	$6,357	$6,969
Y-O-Y Growth	$950	$860	$1,121	$612
% Y-O-Y Growth	27.7%	19.6%	21.4%	9.6%
One-time 2013 Inventory reduction (4 ticks)		$208		
2nd 6.9% price action in 2015 (very rough estimate)				$150
Ambassador Blue Plan				$39
Total Adjustments	$0	$208	$0	$189
2014 LRP Sales $MM (Normalized)	$4,377	$5,444	$6,357	$7,158
Y-O-Y Growth	$950	$1,068	$913	$800
% Y-O-Y Growth	27.7%	24.4%	16.8%	12.6%

This year's approach for modeling biosimilar erosion

Guiding Principles

- Achieve HUMIRA's full potential (one of four key strategies)
  - Continue to drive sustainable growth through new indications and share gains
- Improve HUMIRA planned market erosion (one of ten strategic imperatives)
- Detailed buildup by major payor (RAG request in 2013 LRP)

Operational Guidelines

- Align modeling approach with strategic approach
- Leverage payor grandfathering of stable HUMIRA patients (key assumption)
- Targeted incremental rebating to maintain greater portion of pre-biosimilar volumes
- Maximize NPV of future cash flows

Other Considerations

- Calculated risk which produces greater price erosion early in LRP (investment) offset by significant volume savings in outer years (return)
- To achieve payback, assumes biologic market value is not "materially" impacted by one or more biosimilar manufacturers' pricing strategy / margin profile tolerance
- Competitive advantages for rebate bundling (Amgen)

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Comparison to last year's approach

- **Approach for 2013 LRP (Hold price, lose volume)**
  - All erosion comes via volume loss based on findings of physician market research by TA
  - In addition, HUMIRA "harvested" 3.6% in rebates in Commercial and Medicare channels beginning in 2017 as cost of access reduced as biosimilars become preferred (3.6% = 5% harvest in 71% of these channels)
  - CD and UC indications launch in 2018; 1 year delay for Gastro indications

- **Approach for 2014 LRP (Targeted rebating to maintain select segments)**
  - Targeted incremental rebating to maintain greater portion of pre-biosimilar volumes
  - Total HUMIRA sales segmented into 14 payors
  - 14 payors segmented into one of four different "payor types" (Red, Yellow, Green, Blue (Gov't))
  - Other general assumptions
    - Biosimilars receive full indication extrapolation by 2017
    - Biosimilars set WAC 20% lower (on average) than HUMIRA WAC
    - Biosimilars rebate (on average) such that Net Price is 30% lower than HUMIRA
    - HUMIRA counters with targeted rebating depending on payor type

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Biosimilar Key Calls

		2013 LRP	2014 LRP
1.	Remicade (infliximab) 1st biosimilar launch date	Q1 2016	Q1 2016
2.	HUMIRA (adalimumab) 1st biosimilar launch date	Q1 2017	Q1 2017
3.	Enbrel (etanercept) 1st biosimilar launch	Q3 2018	Q3 2018
4.	Indication extrapolation (FDA and/or payor allowed)	Gastro 1 yr after RA/PS	Yes
5.	Payor grandfathering of stable HUMIRA patients	Yes	Varies by payor
6.	Pharmacy substitution of biosimilars allowed	No	No
7.	Assumed biosimilar adalimumab ASP difference vs. HUMIRA	-30%	-30% initially; targeted rebating
8.	# of biosimilar adalimumab competitors	N/A	3-5*
9.	HUMIRA WAC price increases	1 x 6.9%/yr	1 x 6.9%/yr
10.	HUMIRA MHC rebating levels after biosimilar launch	Harvest 3.6%	Varies by payor
11.	HUMIRA Naïve patient start peak erosion; time to peak	RA -77%; 4yrs	Varies by payor
12.	HUMIRA Switch patient start peak erosion; time to peak	RA -76%; 4yrs	Varies by payor
13.	HUMIRA Stable patient peak erosion; time to peak	RA -41%; 4yrs	Varies by payor

* BI, Sandoz, Amgen, Pfizer, Celltrion

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Payors segmented into four main types

	High Control / HUMIRA premium: Rebate to keep naïve and stable patients	**Protect the Base:** Rebate to keep stable patients	**High Control / No HUMIRA premium:** Harvest Rebates	**Gov't**
% of Base LRP volume	49%	26%	10%	15%
Incremental rebating vs. Base LRP rates	**+16pts (33% vs. 17%)** E.g. [redacted] in 2017	**+11pts (29% vs. 18%)** E.g. [redacted] in 2017	**-23pts (0% vs. 23%)** E.g. [redacted] in 2017	**+9pts (85% vs. 76%)** "Best Price" implications
HUMIRA premium vs. biosimilars ASP	15% in 2017; 5% in 2020	20% in 2017; 10% in 2020	N/A	N/A
% of Base LRP volume erosion *				
Naïve & Switch (20%)	0%	95%; 2 yrs to peak	99%; 2 yrs to peak	100%
Stable (80%)	0%	5%; 3 yrs to peak	75%; 3 yrs to peak	100%
Payors included	[redacted]	[redacted]	[redacted]	Medicaid, PHS, VA, DOD

* Contemplates standard US patient persistency curves and patient flow dynamics

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REDACTED: Non-Responsive

High Control / HUMIRA premium: Rebate to keep new and stable patients

2014 Base LRP using this year's erosion approach

	2017 (Launch Year)			2018			2019			2020		
	HUMIRA	Biosim	% Var	HUMIRA	Biosim	% Var	HUMIRA	Biosim	% Var	HUMIRA	Biosim	% Var
WAC (Gross)	$1,634	$1,307	-20.0%	$1,747	$1,397	-20.0%	$1,867	$1,494	-20.0%	$1,996	$1,597	-20.0%
YoY Growth	*6.9%*			*6.9%*	*6.9%*		*6.9%*	*6.9%*		*6.9%*	*6.9%*	
	-16.5%			-19.7%			-19.3%			-21.9%		
Payor Rebate	($547)	($383)	-30.0%	($675)	($433)	-35.9%	($752)	($490)	-34.8%	($895)	($551)	-38.5%
% of WAC	*-33.5%*	*-29.3%*		*-38.7%*	*-31.0%*		*-40.3%*	*-32.8%*		*-44.9%*	*-34.5%*	
ASP (Net to Payor)	$1,087	$924	-15.0%	$1,071	$964	-10.0%	$1,115	$1,004	-10.0%	$1,101	$1,046	-5.0%
YoY Growth	*-17.3%*			*-1.5%*	*4.3%*		*4.1%*	*4.1%*		*-1.3%*	*4.2%*	
ASP loss due to Biosims	($327)			($406)			($426)			($507)		
% Variance	*-23.1%*			*-27.5%*			*-27.6%*			*-31.5%*		
Weighted Avg Total Patient (Unit) Erosion	*0.0%*			*0.0%*			*0.0%*			*0.0%*		
Factory Units 000 excl biosimilars	1,521			1,545			1,566			1,578		
Biosimilar Impact (Weighted Avg Impact)	-	-		-	-		-	-		-	-	
Factory Units 000 incl biosimilars	1,521	-		1,545	-		1,566	-		1,578	-	
Net Sales $MM Incl biosimilars	$1,653	$0	$1,653	$1,655	$0	$1,655	$1,747	$0	$1,747	$1,737	$0	$1,737
YoY Growth	*-15.5%*		*-15.5%*	*0.1%*		*0.1%*	*5.5%*		*5.5%*	*-0.5%*		*-0.5%*
Price variance vs Scenario #1	($409)			($531)			($564)			($688)		
Vol variance vs Scenario #1	$0			$0			$0			$0		
Total Sales variance vs Scenario #1	($409)			($531)			($564)			($688)		
Checksum	$0			$0			$0			$0		

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REDACTED: Non-Responsive

Protect the Base:
Rebate to keep stable patients

2014 Base LRP using this year's erosion approach

	2017 (Launch Year)			2018			2019			2020		
	HUMIRA	Biosims	% Var vs HUMIRA	HUMIRA	Biosims	% Var vs HUMIRA	HUMIRA	Biosims	% Var vs HUMIRA	HUMIRA	Biosims	% Var vs HUMIRA
WAC (Gross)	$1,634	$1,307	-20.0%	$1,747	$1,397	-20.0%	$1,867	$1,494	-20.0%	$1,996	$1,597	-20.0%
YoY Growth	*6.9%*			*6.9%*	*6.9%*		*6.9%*	*6.9%*		*6.9%*	*6.9%*	
	-11%											
Payor Rebate	($479)	($383)	-20.0%	($613)	($433)	-29.3%	($687)	($490)	-28.7%	($834)	($551)	-34.0%
% of WAC	*-29.3%*	*-29.3%*		*-35.1%*	*-31.0%*		*-36.8%*	*-32.8%*		*-41.8%*	*-34.5%*	
ASP (Net to Payor)	$1,155	$924	-20.0%	$1,134	$964	-15.0%	$1,180	$1,004	-15.0%	$1,162	$1,046	-10.0%
YoY Growth	*-11.1%*			*-1.8%*	*4.3%*		*4.1%*	*4.1%*		*-1.6%*	*4.2%*	
ASP loss due to Biosims	($243)			($325)			($342)			($426)		
% Variance	*-17.4%*			*-22.3%*			*-22.5%*			*-26.8%*		
HUMIRA volume loss by patient segment for this payor												
New (Naïve & Switch) Patient erosion	*-95.0%*	*within 2 years*										
Stable Patient erosion	*-5.0%*	*within 3 years*										
Wgtd Avg Total Patient Erosion (Patient flow	*-9.9%*			*-30.3%*			*-48.0%*			*-60.0%*		
Factory Units 000 excl biosimilars	951			967			980			987		
Biosimilar Impact (Weighted Avg Impact)	(94)	94		(293)	293		(471)	471		(592)	592	
Factory Units 000 incl biosimilars	858	94		674	293		509	471		395	592	
Net Sales $MM incl biosimilars	$991	$87	$1,077	$764	$282	$1,047	$601	$472	$1,074	$459	$620	$1,079
YoY Growth	*-15.9%*		*-8.6%*	*-22.9%*		*-2.9%*	*-21.3%*		*2.6%*	*-23.7%*		*0.5%*
Price variance vs Scenario #1	($176)			($255)			($271)			($351)		
Vol variance vs Scenario #1	($108)			($332)			($555)			($688)		
Total Sales variance vs Scenario #1	($284)			($587)			($826)			($1,039)		
Checksum	$0			$0			$0			$0		

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REDACTED: Non-Responsive

High Control / No HUMIRA premium: Harvest Rebates

2014 Base LRP using this year's erosion approach

	2017 (Launch Year)			2018			2019			2020		
	HUMIRA	Biosims	% Var vs HUMIRA	HUMIRA	Biosims	% Var vs HUMIRA	HUMIRA	Biosims	% Var vs HUMIRA	HUMIRA	Biosims	% Var vs HUMIRA
WAC (Gross)	$1,634	$1,307	-20.0%	$1,747	$1,397	-20.0%	$1,867	$1,494	-20.0%	$1,996	$1,597	-20.0%
YoY Growth	*6.9%*			*6.9%*	*6.9%*		*6.9%*	*6.9%*		*6.9%*	*6.9%*	
Payor Rebate	$0	($383)	#DIV/0!	$0	($433)	#DIV/0!	$0	($490)	#DIV/0!	$0	($551)	#DIV/0!
% of WAC	*0.0%*	*-29.3%*		*0.0%*	*-31.0%*		*0.0%*	*-32.8%*		*0.0%*	*-34.5%*	
	23.0%											
ASP (Net to Payor)	$1,634	$924	-43.4%	$1,747	$964	-44.8%	$1,867	$1,004	-46.2%	$1,996	$1,046	-47.6%
YoY Growth	*35.3%*			*6.9%*	*4.3%*		*6.9%*	*4.1%*		*6.9%*	*4.2%*	
ASP loss due to Biosims	($204)			$375			$438			$508		
% Variance	*-11.1%*			*27.3%*			*30.6%*			*34.1%*		
HUMIRA volume loss by patient segment for this payor												
New (Naïve & Switch) Patient erosion	*-99.0%*	*within 2 years*										
Stable Patient erosion	*-75.0%*	*within 3 years*										
Wgtd Avg Total Patient Erosion (Patient flow	*-20.3%*			*-54.7%*			*-80.7%*			*-89.7%*		
Factory Units 000 excl biosimilars	153			155			157			158		
Biosimilar Impact (Weighted Avg Impact)	(31)	31		(85)	85		(127)	127		(142)	142	
Factory Units 000 incl biosimilars	122	31		70	85		30	127		16	142	
Net Sales $MM Incl biosimilars	$199	$29	$227	$123	$82	$204	$57	$127	$184	$32	$149	$181
YoY Growth	*13.1%*		*29.4%*	*-38.2%*		*-10.0%*	*-53.8%*		*-10.1%*	*-42.8%*		*-1.6%*
Price variance vs Scenario #1	$57			$68			$79			$92		
Vol variance vs Scenario #1	($51)			($148)			($237)			($284)		
Total Sales variance vs Scenario #1	$7			($80)			($157)			($192)		
Checksum	$0			$0			$0			$0		

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Medicaid/PHS/VA/DOD

Gov't

2014 Base LRP using this year's erosion approach

	2017 (Launch Year)			2018			2019			2020		
	HUMIRA	Biosims	% Var vs HUMIRA	HUMIRA	Biosims	% Var vs HUMIRA	HUMIRA	Biosims	% Var vs HUMIRA	HUMIRA	Biosims	% Var vs HUMIRA
WAC (Gross)	$1,634	$1,307	-20.0%	$1,747	$1,397	-20.0%	$1,867	$1,494	-20.0%	$1,996	$1,597	-20.0%
YoY Growth	6.9%			6.9%	6.9%		6.9%	6.9%		6.9%	6.9%	
Payor Rebate	($1,389)	($1,029)	-25.9%	($1,537)	($1,131)	-26.5%	($1,681)	($1,220)	-27.4%	($1,807)	($1,317)	-27.1%
% of WAC	-85.0%	-78.7%		-88.0%	-80.9%		-90.0%	-81.7%		-90.5%	-82.5%	
ASP (Net to Payor)	$245	$278	13.6%	$210	$267	27.3%	$187	$274	46.6%	$190	$280	47.6%
YoY Growth	-37.8%			-14.5%	-4.1%		-10.9%	2.5%		1.6%	2.3%	
ASP loss due to Biosims	($153)			($172)			($204)			($211)		
% Variance	-38.4%			-45.1%			-52.3%			-52.6%		
Wgtd Avg Total Patient Erosion (Patient flow	0.0%			0.0%			0.0%			0.0%	100.0%	
Factory Units 000 excl biosimilars	1,091			1,109			1,124			1,133		
Biosimilar Impact (Weighted Avg Impact)	-	-		-	-		-	-		-	-	
Factory Units 000 incl biosimilars	1,091	-		1,109	-		1,124	-		1,133	-	
Net Sales $MM Incl biosimilars	$268	$0	$268	$233	$0	$233	$210	$0	$210	$215	$0	$215
YoY Growth	-36.4%		-36.4%	-13.1%		-13.1%	-9.7%		-9.7%	2.3%		2.3%
Price variance vs Scenario #1	($167)			($191)			($230)			($238)		
Vol variance vs Scenario #1	$0			$0			$0			$0		
Total Sales variance vs Scenario #1	($167)			($191)			($230)			($238)		
Checksum	$0			$0			$0			$0		

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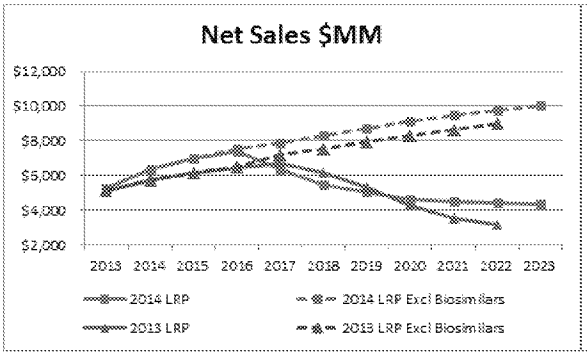
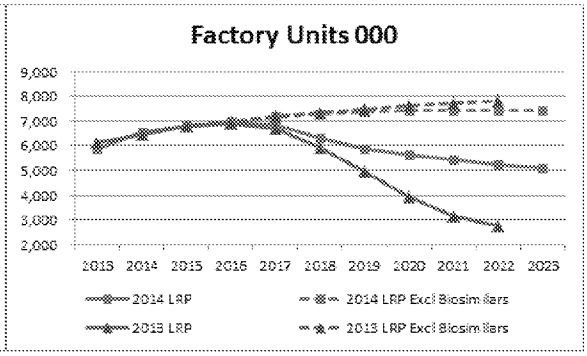
2014 LRP vs. 2013 LRP

Total US HUMIRA





2014 LRP vs 2013 LRP (including Biosimilar erosion)

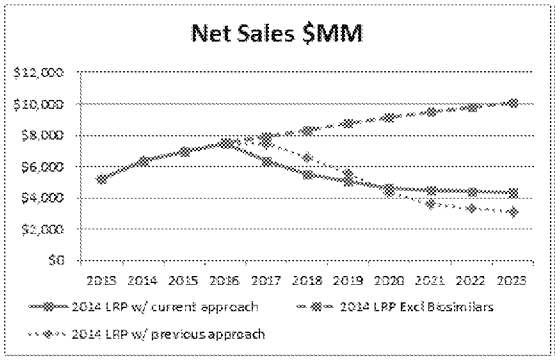
	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Total HUMIRA Var $MM	$113	$652	$850	$966	($351)	($643)	($259)	$286	$962	$1,243
% Var	2%	11%	14%	15%	-5%	-10%	-5%	7%	27%	39%
Price Var	$340	$596	$840	$919	($485)	($966)	($1,029)	($1,086)	($925)	($855)
Vol Var	($227)	$56	$9	$47	$134	$322	$770	$1,372	$1,887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

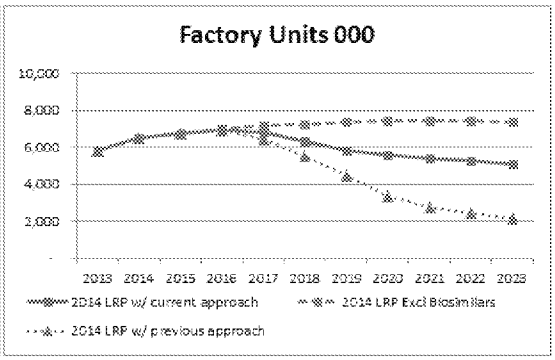
2014 LRP Biosimilar Erosion

	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)

2014 LRP with Biosimilar Erosion

(Current Year's approach vs. Last Year's approach)





2014 LRP including biosimilar erosion (Current approach vs Previous Approach)

	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026
Total HUMIRA Var	$0	$0	$0	($12)	($1,143)	($1,075)	($509)	$266	$854	$1,064	$1,213	$1,200	$1,200	$1,200
% Var	0%	0%	0%	0%	-15%	-16%	-9%	6%	23%	32%	39%	conservative estimate		
Price Var	$0	$0	$0	($8)	($1,496)	($1,759)	($1,691)	($1,567)	($1,370)	($1,308)	($1,261)			
Vol Var	$0	$0	$0	($4)	$353	$683	$1,181	$1,832	$2,225	$2,373	$2,474			

NPV @ 8% as of 1/1/2017 of sales cash flows (2017-2026) $4,547 If positive, then current approach sales are NPV favorable vs previous approach

Next Steps

1) MHC analysis on two payors [redacted] to isolate relative patient erosion (based on Payco score) of each of the following payor levers:
   - Step Edits (Naïve and switch patients)
   - Out of pocket barrier (limit use of Co-Pay cards)
   - Lack of stable patient grandfathering
   - Active non-medical switching (small molecule generic erosion curve)

2) Understand the economics from biosimilar manufacturer perspective
   - Given the volume loss implied in our LRP, is that enough to justify five competitors investment?
     - Margin expectation differences for Hospira vs. Amgen

3) Understand the economics from payor perspective
   - How would economics look like for their customer's perspective (i.e. large employer)

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2014 LRP - Revised Financial Summary

August, 2014

Scenario LRP vs. Original LRP – Summary

$MMs

	2014	2014 LRP 2015	2016	2017	2018
Original LRP					
EBITDA	6,989	7,988	9,590	9,382	9,283
Operating Income	6,621	7,570	9,129	8,903	8,778
Net Income	4,922	5,658	6,900	6,770	6,788
Scenario LRP *					
EBITDA	7,158	8,879	10,413	11,200	11,716
Operating Income	6,791	8,461	9,952	10,721	11,211
Net Income	5,019	6,352	7,540	8,184	8,681
Variance					
EBITDA	170	891	823	1,818	2,433
Operating Income	170	891	823	1,818	2,433
Net Income	97	694	640	1,414	1,893

* Rollforward by causal of Scenario vs. Original LRP on next page.

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Rollforward – Scenario LRP vs. Original LRP
Sales and Operating Income

$MMs

	SALES - Fav/(Unfav) 2014 LRP				OPERATING EARNINGS - Fav/(Unfav) 2014 LRP			
	2015	2016	2017	2018	2015	2016	2017	2018
Original LRP	**21,078**	**23,433**	**23,363**	**23,359**	**7,570**	**9,129**	**8,903**	**8,778**
1) '14 Humira to LBE, '15 10% growth, then grow at LRP rates but hold biosimilar impact	343	370	394	416	313	138	360	385
2) Humira Biosimilars in U.S. delayed 6 months	...	...	639	621	...	...	590	581
3) Humira 2nd price increase in 2016	...	155	299	270	...	143	276	252
4) Assume Norvir	**Redacted – NR Product**							
5) Assume AndroGel	**Redacted – NR Product**							
6) Daclizumab	**Redacted – NR Product**							
7) HCV	**Redacted – NR Product**							
8) SG&A Adjustments					(200)	(200)	(200)	200
Total Revisions	1,233	1,352	2,225	2,472	891	823	1,818	2,433
Scenario LRP	**22,311**	**24,785**	**25,588**	**25,831**	**8,461**	**9,952**	**10,721**	**11,211**

Scenario LRP vs. Original LRP
P&L Comparison

$MMs	ORIGINAL LRP					SCENARIO LRP @ 2014 Plan Exchange Rates				
	14 Plan	2015	2016	2017	2018	2014 Upd	2015	2016	2017	2018
Net Sales	19,042	21,078	23,433	23,363	23,359	19,519	22,311	24,785	25,588	25,831
% vs. PY	*1.3%*	*10.7%*	*11.2%*	*(0.3%)*	*(0.0%)*	*3.9%*	*14.3%*	*11.1%*	*3.2%*	*1.0%*
Gross Margin	15,086	16,844	18,961	18,757	18,858	15,414	17,935	19,984	20,774	21,091
% of Sales	*79.2%*	*79.9%*	*80.9%*	*80.3%*	*80.7%*	*79.0%*	*80.4%*	*80.6%*	*81.2%*	*81.6%*
Research and Development	3,133	3,450	3,540	3,578	3,619	3,267	3,450	3,540	3,578	3,619
% of Sales	*16.5%*	*16.4%*	*15.1%*	*15.3%*	*15.5%*	*16.7%*	*15.5%*	*14.3%*	*14.0%*	*14.0%*
Selling, General & Admin	5,332	5,824	6,292	6,276	6,461	5,355	6,024	6,492	6,476	6,261
% of Sales	*28.0%*	*27.6%*	*26.9%*	*26.9%*	*27.7%*	*27.4%*	*27.0%*	*26.2%*	*25.3%*	*24.2%*
% vs. PY	*4.9%*	*9.2%*	*8.0%*	*(0.3%)*	*2.9%*	*5.3%*	*12.5%*	*7.8%*	*(0.3%)*	*(3.3%)*
Operating Earnings	6,621	7,570	9,129	8,903	8,778	6,791	8,461	9,952	10,721	11,211
% of Sales	*34.8%*	*35.9%*	*39.0%*	*38.1%*	*37.6%*	*34.8%*	*37.9%*	*40.2%*	*41.9%*	*43.4%*
% vs. PY	*(3.0%)*	*14.3%*	*20.6%*	*(2.5%)*	*(1.4%)*	*(0.5%)*	*24.6%*	*17.6%*	*7.7%*	*4.6%*
Net Income	4,922	5,658	6,900	6,770	6,788	5,019	6,352	7,540	8,184	8,681
% of Sales	*25.8%*	*26.8%*	*29.4%*	*29.0%*	*29.1%*	*25.7%*	*28.5%*	*30.4%*	*32.0%*	*33.6%*
EPS	3.05	3.50	4.25	4.15	4.14	3.11	3.93	4.64	5.01	5.30
% vs. PY	*(2.9%)*	*14.8%*	*21.3%*	*(2.4%)*	*(0.1%)*	*(1.0%)*	*26.4%*	*18.1%*	*8.0%*	*5.8%*

	SCENARIO vs. ORIGINAL LRP Fav/(Unfav)				
	2014 Upd	2015	2016	2017	2018
Net Sales	477	1,233	1,352	2,225	2,472
Gross Margin	328	1,091	1,023	2,017	2,233
Research and Development	(134)	...	...	...	...
Selling, General & Admin	(23)	(200)	(200)	(200)	200
Operating Earnings	170	891	823	1,818	2,433
Net Income	97	694	640	1,414	1,893
EPS	0.06	0.43	0.39	0.86	1.16

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Scenario LRP vs. Original LRP
Sales Revision Impacts

$MMs

	ORIGINAL LRP					SCENARIO LRP @ 2014 Plan Exchange Rates				
Key Products	**14 Plan**	**2015**	**2016**	**2017**	**2018**	**2014 Upd**	**2015**	**2016**	**2017**	**2018**
Humira	12,125	13,441	14,264	13,918	13,386	12,531	13,784	14,789	15,250	14,693
% Growth	*13.8%*	*10.9%*	*6.1%*	*(2.4%)*	*(3.8%)*	*17.6%*	*10.0%*	*7.3%*	*3.1%*	*(3.7%)*
HCV	**Redacted – NR Product**									
% Growth										
Memo: Biosimilar Impact	(9)	(103)	(356)	(1,642)	(3,042)	(9)	(103)	(356)	(1,003)	(2,421)
Products Facing LOE	**Redacted – NR Product**									
Androgel										
% Growth										
Norvir										
% Growth										
Pipeline										
Daclizumab										
Total AbbVie	19,042	21,078	23,433	23,363	23,359	19,519	22,311	24,785	25,588	25,831
% Growth	*1.3%*	*10.7%*	*11.2%*	*(0.3%)*	*(0.0%)*	*3.9%*	*14.3%*	*11.1%*	*3.2%*	*1.0%*

	SCENARIO vs. ORIGINAL LRP Fav/(Unfav)				
Key Products					
Humira	406	343	525	1,332	1,307
HCV	**Redacted – NR Product**				
Memo: Biosimilar Impact	-	-	-	639	621
Androgel	**Redacted – NR Product**				
Norvir					
Daclizumab					
Other 2014 Upd Changes	274				
Total AbbVie	477	1,233	1,352	2,225	2,472

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Scenario LRP vs. S-4 and Original LRP Operating and Free Cash Flow

$BN

	PER S-4				SCENARIO LRP			
	2015	2016	2017	2018	2015	2016	2017	2018
Net Earnings - GAAP *	4.8	6.6	6.6	6.6	5.5	7.3	8.0	8.5
Depreciation	0.4	0.5	0.5	0.5	0.4	0.5	0.5	0.5
Amortization	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
Share-based Compensation	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Working Capital Impacts	(0.2)	(0.3)	(0.4)	(0.3)	(0.4)	(0.6)	(0.7)	(0.8)
Operating Cash Flow	5.5	7.3	7.2	7.3	6.1	7.7	8.3	8.7
Capital Expenditures	(0.5)	(0.4)	(0.4)	(0.4)	(0.5)	(0.4)	(0.4)	(0.4)
Free Cash Flow	5.0	6.9	6.8	6.9	5.5	7.3	7.9	8.3
MEMO: Original LRP								
Operating Cash Flow	6.0	7.4	7.1	7.2				
Free Cash Flow	5.5	6.8	6.7	6.8				

	SCENARIO LRP vs. S-4 Inc/(Dec)			
Net Earnings *	0.7	0.7	1.4	1.9
Working Capital Impacts	(0.2)	(0.3)	(0.3)	(0.5)
Operating Cash Flow	0.5	0.4	1.1	1.4

* Net Earnings per S-4 equals Original LRP. Net Earnings per Scenario LRP equals Original LRP + impacts from Scenario changes. Pending deal potential one-time impacts for Project Lightyear in '15/'16 and Acylin and Philogen in '16 are not included.

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Scenario LRP vs. Analysts Forecasts

$MM except EPS

		Scenario	Analysts		
	S-4	LRP	First Call	Bloomberg	Models
SALES					
2015	21,078	22,311	21,713	21,604	22,272
2016	23,433	24,785	23,957	25,367	24,458
2017	23,363	25,588	25,860	25,860	25,636
EBITDA					
2015	7,988	8,879	9,122	9,059	9,036
2016	9,590	10,413	9,785	10,484	10,447
2017	9,382	11,200	10,813	10,850	11,381
CASH FLOW *					
2015	5,533	6,051	NA	NA	7,010
2016	7,305	7,673	NA	NA	8,297
2017	7,242	8,333	NA	NA	9,228
EPS					
2015	NA	3.93	3.87	3.86	4.08
2016	NA	4.64	4.53	4.64	4.83
2017	NA	5.01	5.13	5.13	5.30

* Represents Operating Cash Flow

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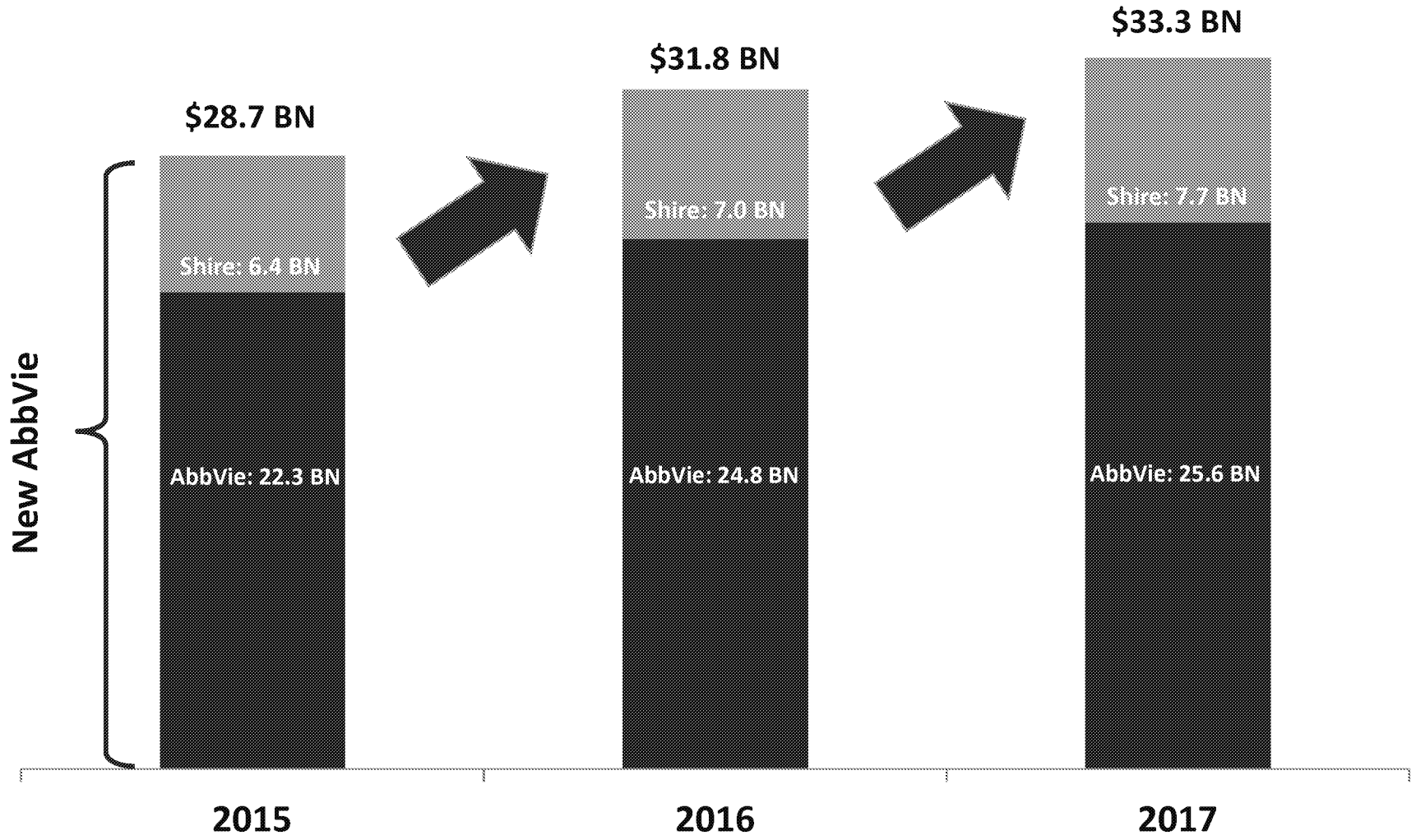
Potential for Significant Top-Line Growth

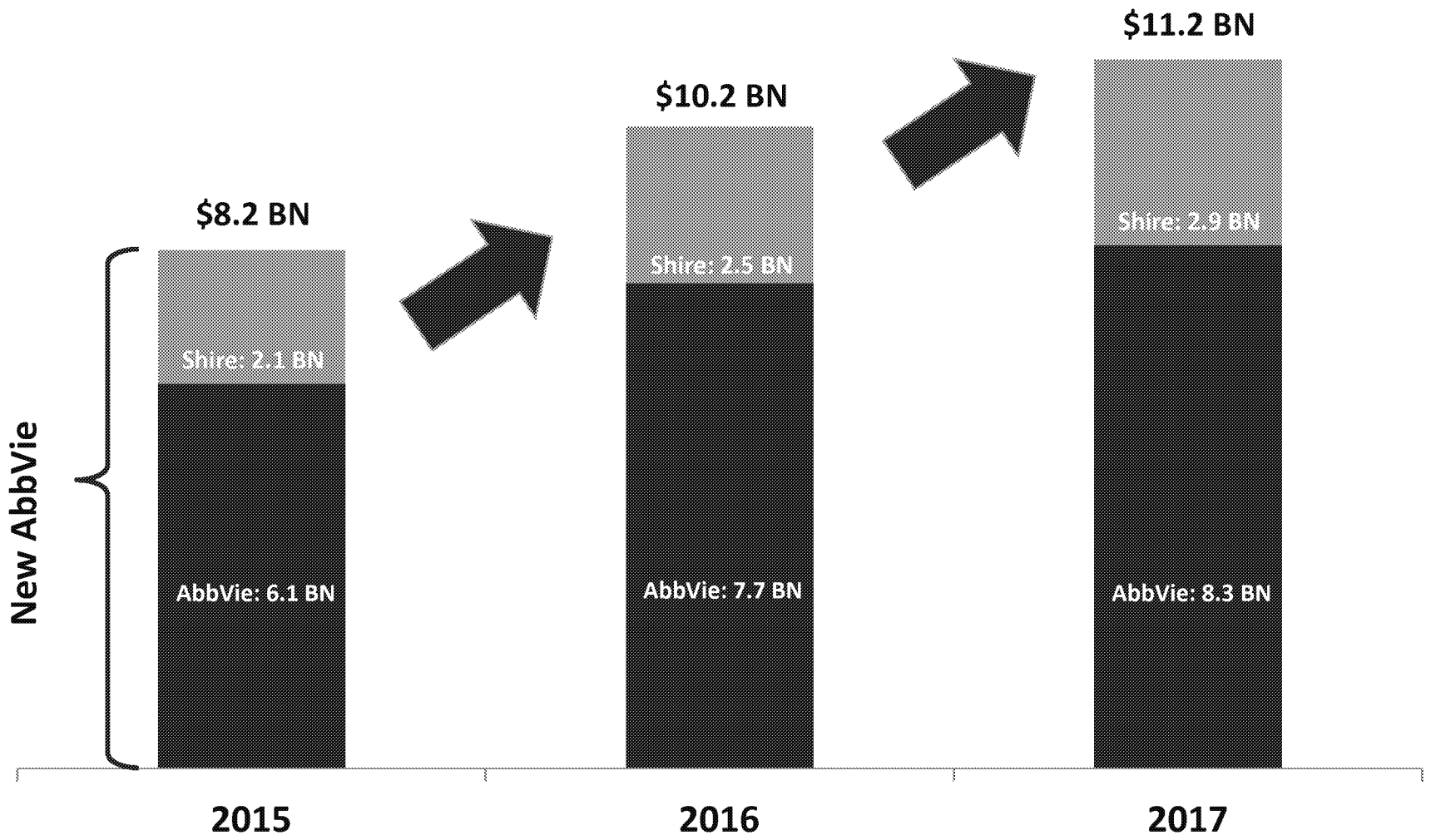
Pro-Forma Revenue Projections for New AbbVie



AbbVie 15

Expect Robust Cash Generation for M&A and Enhanced Return of Capital

Pro-Forma Operating Cash Flow Projections for New AbbVie



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Second price action on HUMIRA in 2016. Assume another 6.9% increase on July 1

	Incremental Net Sales $MM 2016	2017	2018	Assumption: Plans will continue to move toward more aggressive price protection contracts.
[redacted]	-	-	-	Currently at 10% NRPP, assume no fallthrough
	34	63	53	Currently at 15% RSS set 6/30/14. Assume 80% fallthrough.
	-	-	-	Assume no contract/impact
	13	25	25	Currently 5% RPP, assume 80% fallthrough.
	9	16	16	Currently 7% RPP, assume 80% fallthrough
All other Commercial	47	89	89	Blend of no PP, RPP, and non-RSS, assume 80% fallthrough
Total Commercial	-	-	-	
[redacted]	-	-	-	Currently at 12% NRPP, assume no fallthrough
	-	-	-	Currently at 7% NRPP, assume no fallthrough
	4	8	6	Currently no PP, assume 80% fallthrough
All other Medicare	14	27	23	Blend of no PP, RPP, and non-RSS, assume 80% fallthrough
Total Medicare	-	-	-	
[redacted]	7	18	14	Assume current rebate rate.
Non-Contracted	19	37	29	100% fallthrough
Channel Mix Shift	8	17	14	Assume current rebate rate.
WIPP/Rtns/Vchrs/SP Disc	-	-	-	Impact not calculated, immaterial
Medicaid/VA_DOD/Other	-	-	-	Assume no fallthrough.
Total	$155	$299	$270	

Scenario #1: 7/1/16 Price Action	$MM's 2016	2017	2018
Net Sales	155	299	270
Dist Margin	143	276	252
% Net Sls	92.6%	92.3%	93.5%
SG&A	-	-	-
% Net Sls	0.0%	0.0%	0.0%
Div Margin	143	276	252
% Net Sls	92.6%	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 increases.

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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.

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2014 November LBE Price Rollforward Summary

	Immuno
2014 October LBE vs. 2014 Update	(50.3)
HUMIRA - Revised Price Action (7.9% mid-Nov vs. late Dec)	31.6
Redacted – NR Product [redacted]	-
Reserve True-ups	-
All other items	-
Subtotal November LBE items	31.6
2014 November LBE vs. 2014 Update	(18.7)

Redacted – NR Product

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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)

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U.S. Viekira

Redacted – NR Product

Redacted – NR Product

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Redacted – NR Product

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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** 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**

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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

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Global Biosimilar Infliximab Pricing, Reimbursement & Market Uptake Report

As reported by Affiliates through Area surveys

Quarterly Report: July 2015

MAP GLOBAL MARKET ACCESS & PRICING
Global insights. Local value.

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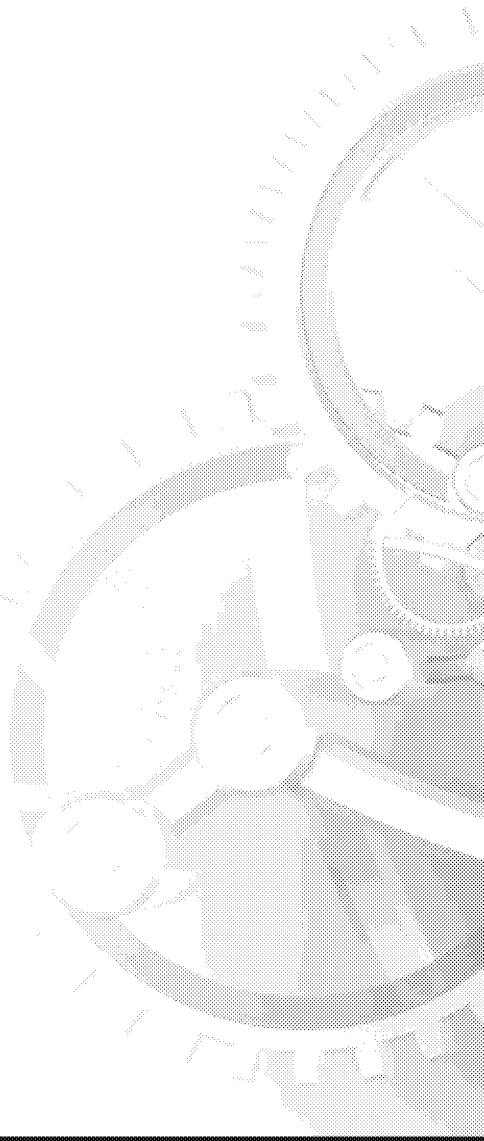


Executive Summary

Infliximab biosimilar availability

- Biosimilars IFX (Remsima &/or Inflectra) are priced, reimbursed and marketed in 36 countries globally
- New launches Q2: Austria, Ecuador, El Salvador, Panama

Pricing

- List price reductions vs. original Remicade price between 0%-46% (median: 25%)
- Net prices reported publically in tender markets range: 45-72% (median: 57%) vs original Remicade list price
- In tender markets with known net prices, 1st year IFX 5mg/kg drug cost is 30-60% lower than HUMIRA 80/40
- Originator competes on price in majority of markets, sometimes matching biosimilar price

Uptake & impact

- Uptake (& pricing) varies considerably across markets driven by market-specific factors including: procurement rules & incentives, competitor behavior and substitution rules
- ~10,000 pts treated w biosimilar IFX up to Apr '15, Korea, Norway & Germany together account for 62% of total volume
- IFX biosimilars captured 3% of total MS (15% IFX share) 1 year after launch on average
- IFX (originator + biosimilars) growth outperforms total market growth 22% vs 16% (+38%) after 1 yr of commercialization
- Active switching observed: Denmark, Finland, Germany, Latvia, Norway, Poland, Spain & UK

Key payer and payer-related events Q2 2015

- France: Reuters reported that Hôpitaux de Paris (AP-HP) June15-June16 tender was won by Hospira (Inflectra), after the company offered a 45% discount vs. Remicade list (51% vs pre-biosimilar Remicade list price). Existing Remicade patients will not be switched. AP-HP represents 12.5% of Remicade revenue in France.
- Denmark: After several month-by-month tenders, nat'l 1-year tender starting July15 was won by Orion (Remsima) @ 69% discount vs original Remicade list price
- Netherlands, Finland & Germany: Regulatory bodies issued statements concluding that patients could be actively switched safely from originator to biosimilar under supervision of the physician.
- Australia: HTA body (PBAC) has advised that biosimilar products would be suitable for automatic substitution where the data are supportive.
- Denmark: RADS (tender advisory committee) published guidance supporting NMS for Remicade patients
- Mexico: Remsima reimbursement approval is pending

Input data used for this report

Biosimilar patient volume & share:

- Where available, extracted from IMS or affiliate reported uptake data as collected and reported by Global Business Intelligence

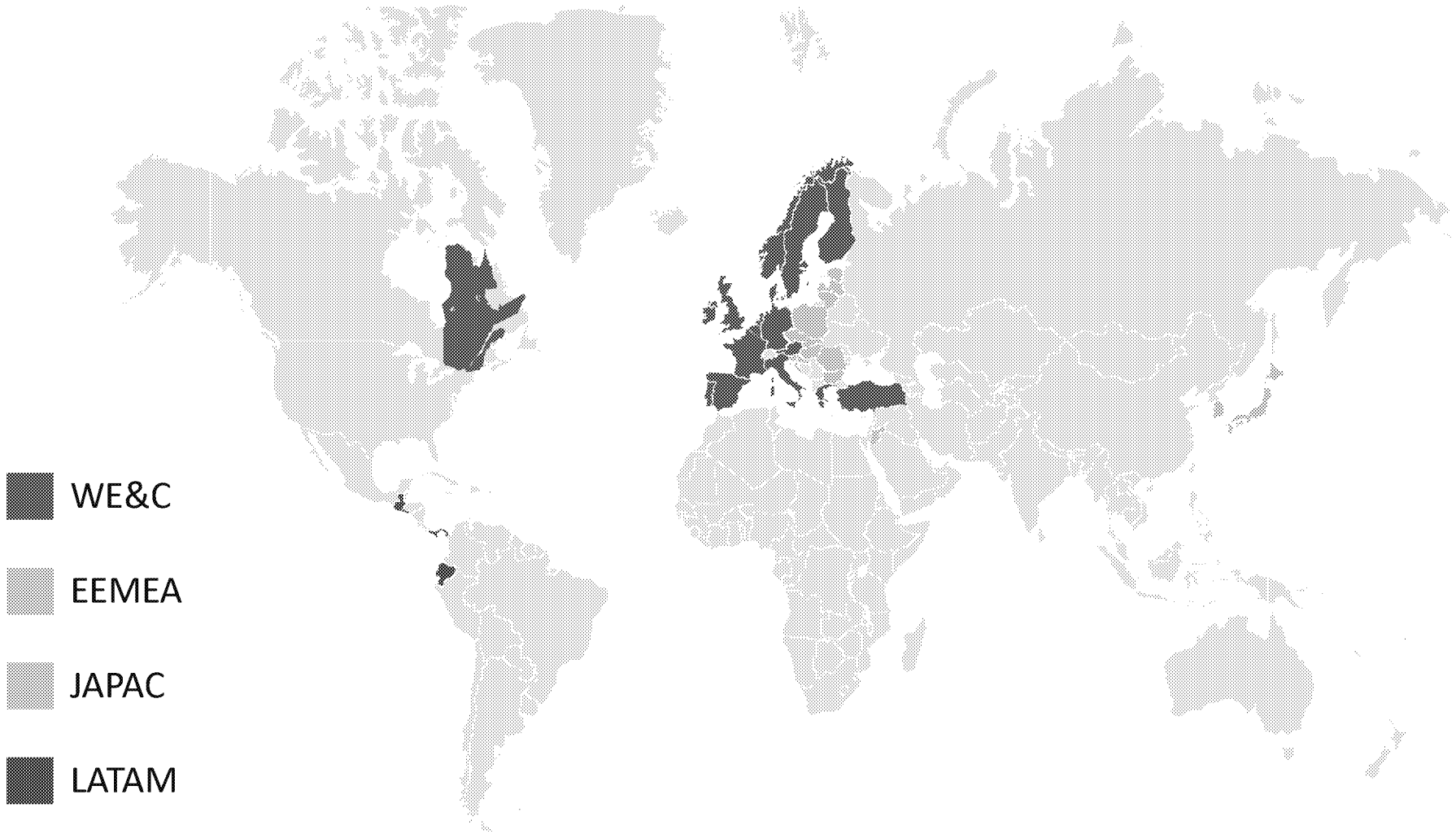
Reported prices:

- Prices are public list prices as of June '15 converted to US$ using average 2015 PLN exchange rates
- Discounting off the list price was excluded from the tracker with exception of national or regional tenders with publically disclosed discounts/rebates in: Denmark, Finland, France, Italy, Lithuania, Norway

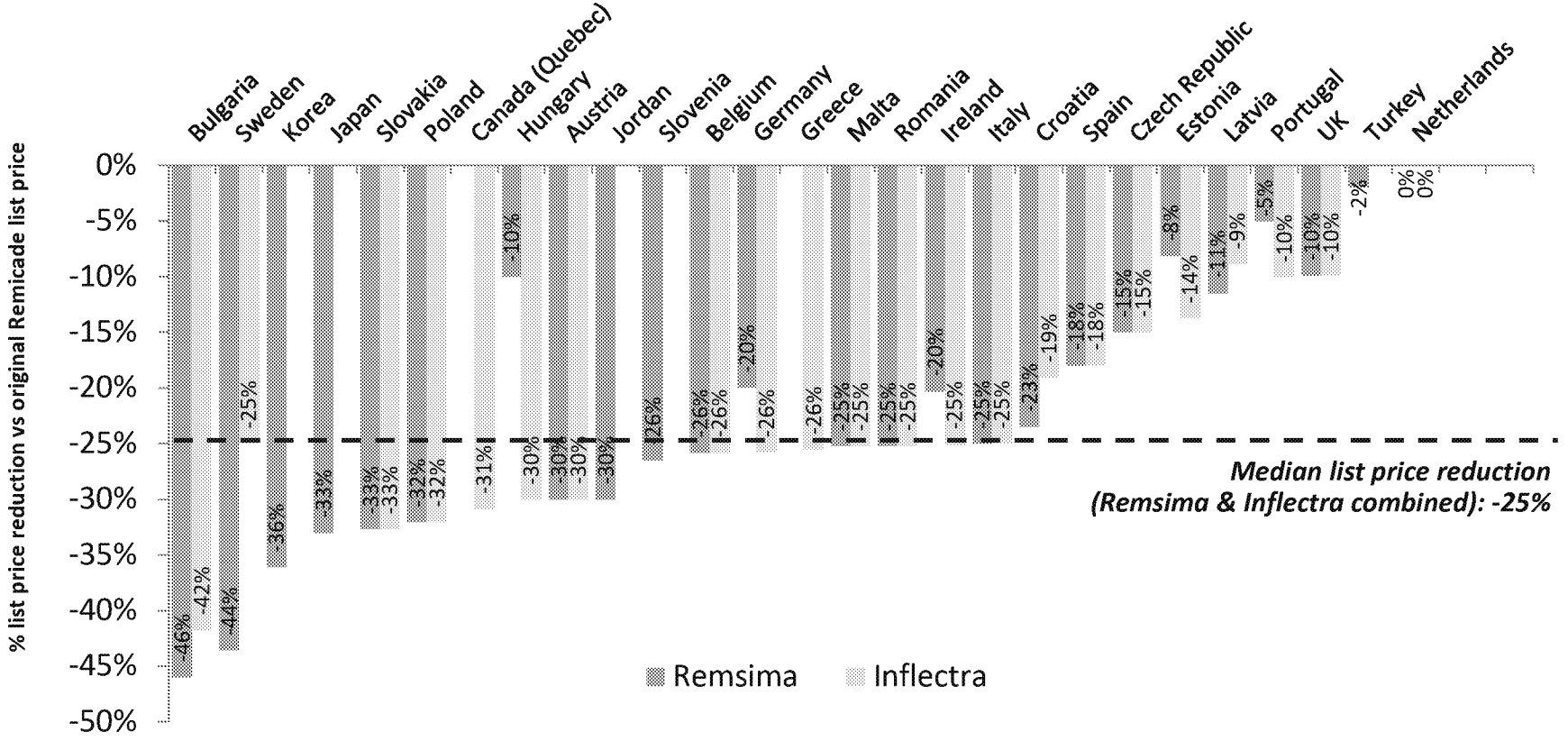
Calculations used for treatment cost comparison:

- 1st year cost of HUMIRA 80/40: 40mg unit price x 27
- 1st year cost of IFX 5mg/kg: lowest priced IFX 100mg unit x 4 (5mg/kg @60-80kg) x 8 infusions (week 0, 2, 6, then Q8W);

Infliximab [IFX] biosimilars (Remsima and/or Inflectra) are priced, reimbursed and marketed in 36 countries globally



Remsima and Inflectra **public list prices** are 0%-46% (median: 25%) lower than Remicade list prices prior to biosimilar availability



* Denmark, Finland, Lithuania and Norway: Prices reflect tender offers that were made public;
** Poland: Remicade price represents reimbursement limit

Despite biosimilar entry, HUMIRA is priced competitively compared to IFX in majority of markets based on list prices (excl further discounts)

All amounts expressed in US$ converted using PLN15 X-rates

	Lowest priced IFX 100mg	HUMIRA 40mg list price	Cost of 1st year Tx with lowest priced IFX[1]	Cost of 1st year Tx HUMIRA	Cost delta 1st year Tx with lowest priced IFX vs HUMIRA[2]
Austria	$510	$634	$16,332	$17,112	-5%
Belgium	$505	$617	$16,161	$16,656	-3%
Bulgaria	$467	$544	$14,937	$14,688	2%
Canada	$580	$661	$18,571	$17,839	4%
Croatia	$541	$588	$17,323	$15,876	16%
Czech Rep.	$486	$540	$15,557	$14,584	7%
Ecuador	$430	$570	$13,760	$15,390	-11%
Estonia	$539	$727	$17,247	$19,636	-12%
Germany	$726	$965	$23,242	$26,053	-11%
Greece	$433	$531	$13,841	$14,342	-3%
Hungary	$414	$532	$13,260	$14,362	-8%
Ireland	$671	$664	$21,486	$17,918	20%
Italy	$556	$694	$17,787	$18,725	-5%
Japan	$583	$503	$18,653	$13,578	37%

Calculations used for treatment cost comparison	
1. IFX 1st yr Tx cost	Assumed 5mg/kg dosing. IFX 100MG vial unit price x 4 (5mg/kg @60-80kg) x 8 infusions (week 0,2,6, then q8wks)
2. HUMIRA 1st yr Tx cost	Assumed 80/40 dosing. 40mg unit price x 27 syringes/pens

Despite biosimilar entry, HUMIRA is priced competitively compared to IFX in majority of markets based on list prices (excl further discounts)

All amounts expressed in US$ converted using PLN15 X-rates

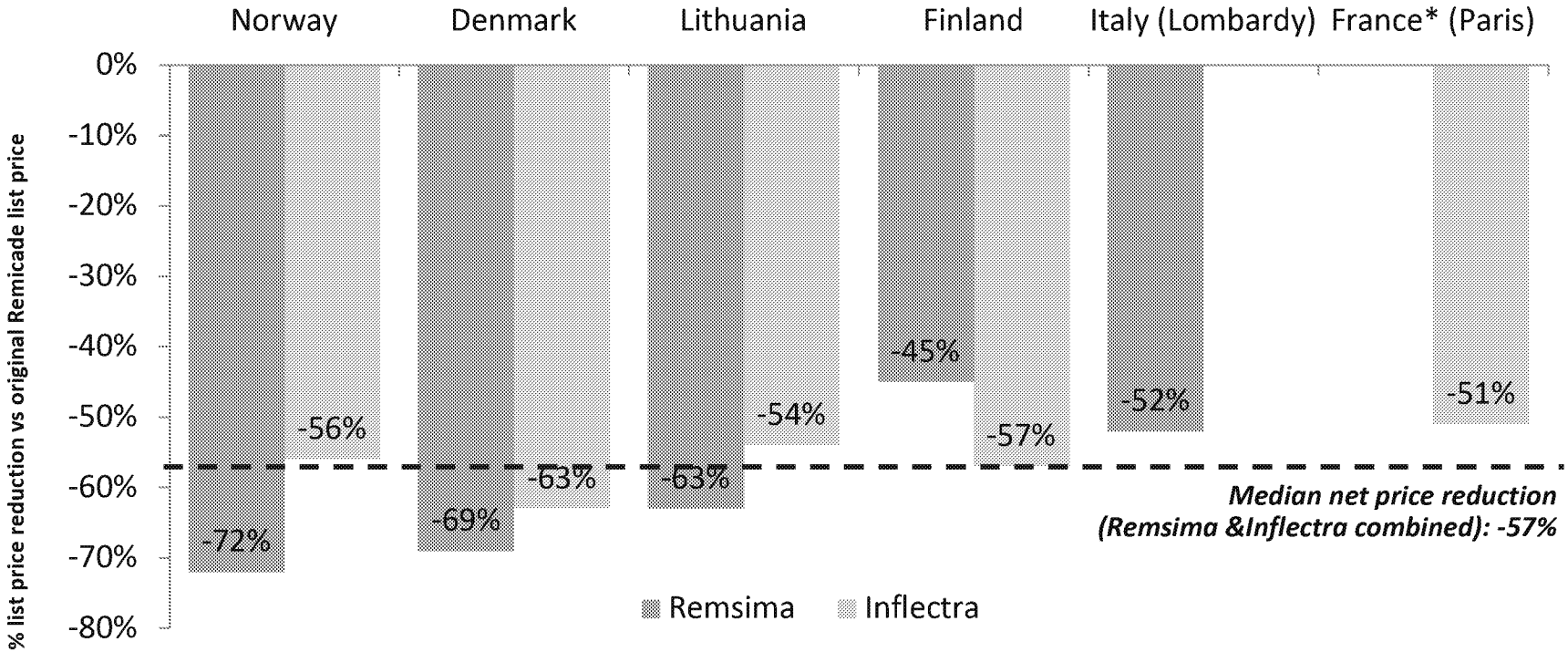
	Lowest priced IFX 100mg	HUMIRA 40mg list price	Cost of 1st year Tx with lowest priced IFX[1]	Cost of 1st year Tx HUMIRA	Cost delta 1st year Tx with lowest priced IFX vs HUMIRA[2]
Jordan	$346	$655	$11,084	$17,677	-37%
Korea	$362	$424	$11,579	$11,440	1%
Latvia	$441	$649	$14,126	$17,532	-19%
Malta	$594	$643	$18,994	$17,357	9%
Netherlands	$782	$695	$25,018	$18,760	33%
Poland*	$471	$601	$15,082	$16,234	-7%
Portugal	$639	$586	$20,463	$15,814	29%
Romania	$431	$508	$13,787	$13,708	1%
Slovakia	$490	$542	$15,668	$14,622	7%
Slovenia	$467	$542	$14,929	$14,622	2%
Spain	$571	$668	$18,275	$18,023	1%
Sweden	$435	$728	$13,927	$19,656	-29%
Turkey	$355	$363	$11,352	$9,804	16%
UK	$619	$577	$19,812	$15,580	27%

* Poland: price represents reimbursement limit

Calculations used for treatment cost comparison	
1. IFX 1st yr Tx cost	Assumed 5mg/kg dosing. IFX 100MG vial unit price x 4 (5mg/kg @60-80kg) x 8 infusions (week 0,2,6, then q8wks)
2. HUMIRA 1st yr Tx cost	Assumed 80/40 dosing. 40mg unit price x 27 syringes/pens

Where known, Remsima and Inflectra **net prices*** are 3%-72% (median: 57%) lower than Remicade's original list price

**** Net selling price are usually confidential. However, tender prices are often made public. Graph below is based public tender prices for IFX where available, and Remicade list prices prior to biosimilar entry***



*France: Reuters reported Hospira tender win in Parisian hospitals tender at 45% discount vs current Remicade list (=51% vs original list price). Potential discounts offered by Biogaran (Remsima) and MSD (Remicade) were not disclosed

* Denmark, Finland, Lithuania and Norway: Prices reflect tender offers that were made public;
** Poland: Remicade price represents reimbursement limit

1st year net drug acquisition costs are 32-62% lower for lowest priced IFX vs HUMIRA ASP in markets with known net selling prices

**** Net selling price are usually confidential. However, tender prices are often made public. Table below is based public tender prices for IFX where available and Average Selling Price (ASP) for HUMIRA***

	Lowest tender bid IFX 100mg	HUMIRA 40mg ASP	Cost of 1st year Tx with lowest priced IFX[1]	Cost of 1st year Tx HUMIRA	Cost delta 1st year Tx with lowest priced IFX vs HUMIRA[2]
Denmark	$227	$706	$7,272	$19,068	-62%
Finland	$244	$612	$7,813	$16,516	-53%
France* (Paris)	$310	$542	$9,929	$14,622	-32%
Italy (Lombardy)	$353	$439	$11,304	$15,394	-27%
Lithuania	$266	$464	$8,519	$12,518	-32%
Norway	$288	$567	$5,821	$15,313	-62%

*France: Reuters reported Hospira tender win in Parisian hospitals tender at 45% discount vs current Remicade list (51% vs original Remicade list price). Potential discounts offered by Biogaran (Remsima) and MSD (Remicade) were not disclosed

Calculations used for treatment cost comparison	
1. IFX 1st yr Tx cost	Assumed 5mg/kg dosing. IFX 100MG vial unit price x 4 (5mg/kg @60-80kg) x 8 infusions (week 0,2,6, then q8wks)
2. HUMIRA 1st yr Tx cost	Assumed 80/40 dosing. 40mg unit price x 27 syringes/pens

All amounts expressed in US$ converted using PLN15 X-rates

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ABBVIE LONG-TERM STRATEGY

Richard Gonzalez
Chairman and Chief Executive Officer

October 30, 2015

Broad U.S. Humira Patent Estate

Approved Indication	Rheumatoid Arthritis	Gastro Indications	Psoriasis	Psoriatic Arthritis	Ankylosing Spondylitis	Juvenile Idiopathic Arthritis	Hidradenitis Suppurativa
Composition of Matter	Expires Dec. 31, 2016						
Indication / Method of Treatment	**4 patents** Earliest Expiry: 2022	**6 patents** Earliest Expiry: 2022	**3 patents** Earliest Expiry: 2023	**4 patents** Earliest Expiry: 2023	**3 patents** Earliest Expiry: 2022	**1 patent** Expiry: 2030	**1 Patent** Expiry: 2031
Formulation	**14 Patents** Expire 2022 –2028						
Manufacturing	**24 patents** Expire 2027 – 2034						
Other (Device, Diagnostics, etc.)	**15 patents** Expire 2024–2032						

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Method of Treatment Patents

- Biosimilar companies must have the same route of administration, dosage form and strength as innovator
- AbbVie has patent protection covering all of the approved indications
- These patents reflect the development work of more than 100 clinical trials
- Treatment regimens differ across therapeutic areas

Indication	Humira Label	Patent Protection	Additional Detail
Rheumatoid Arthritis	40 mg every other week (Approved 2002)	✓	4 Patents; Earliest Expiry 2022
Psoriatic Arthritis	40 mg every other week (Approved 2005)	✓	4 Patents; Earliest Expiry 2023
Ankylosing Spondylitis	40 mg every other week (Approved 2006)	✓	3 Patents; Earliest Expiry 2022
Gastro Indications	160 mg / 80 mg / 40 mg every other week (Approved 2007-2012)	✓	6 Patents; Earliest Expiry 2022
Psoriasis	80 mg / 40 mg every other week (Approved 2008)	✓	3 Patents; Earliest Expiry 2023
Juvenile Idiopathic Arthritis	Patients 10 – 15 kg: 10 mg every other week Patients 15-30 kg: 20 mg every other week Patients ≥ 30 kg : 40 mg every other week (Approved 2008)	✓	1 Patent; Expiry 2030
Hidradenitis Suppurativa	160 mg / 80 mg / 40 mg every week (Approved 2015)	✓	1 Patent; Expiry 2031

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Litigation Process

- Litigation
  - The average time to trial of a patent action in courts hearing 10 or more patent cases was approximately 3.35 years(1)
  - Appeals to the Federal Circuit usually take about a year
- Total Litigation Timing: 4 to 5 years
- Would seek preliminary injunction against at-risk launch

1) Docket Navigator, Year in Review 2014 at 29

AbbVie 19

Message

From: [redacted]

Sent: 1/8/2016 10:03:00 AM

To: [redacted]@abbvie.com]

CC: [redacted]@abbvie.com]; [redacted]@abbvie.com]; [redacted]@abbvie.com]

Subject: 2016 Price Action Scenarios HUMIRA

Attachments: HUMIRA 2016 Price Scenarios.pdf

Hi [redacted]

Please see attached analysis on the value of accelerating the 2016 price actions.

Scenario 1 – Feb 9.9 and Sep 7.9 - $33MM
Scenario 1A – Feb 9.9 and Aug 7.9 - $22MM

The value of accelerating both price actions by 1 month is $55MM. ($33+$22).

Let me know if you have any questions.

Thanks,

[redacted]

abbvie

Dept. 0303/Bldg ABV1 - 4SE
1 North Waukegan Road
North Chicago, IL 60064
OFFICE [redacted]
EMAIL [redacted]

abbvie.com

From: [redacted]
Sent: Wednesday, April 6, 2016 7:16 PM
To: [redacted]
Subject: HUMIRA
Attachments: 4.6.16.docx

Sensitivity: Confidential

This is what I have put together so far – with your inputs. I would like to craft a few topline narrative points for consideration that pull a story together and will work on that tomorrow (i.e. in 2015, we made ~ $1B of a $14B product available at no cost, aggregated numbers around what we contributed charitably in the disease space over the last 3 years, etc…). Welcome your thoughts on that and the attached.

[redacted]

AbbVie 21


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HUMIRA:
US Pricing Analysis
September 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.

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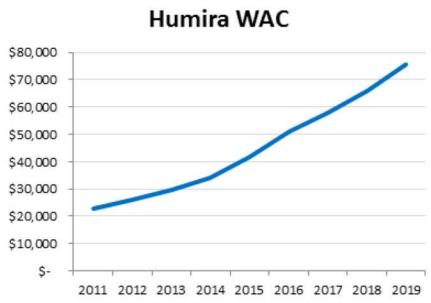
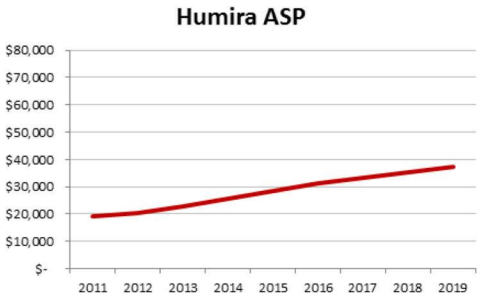
HUMIRA Pricing
Annual Price per Patient

- 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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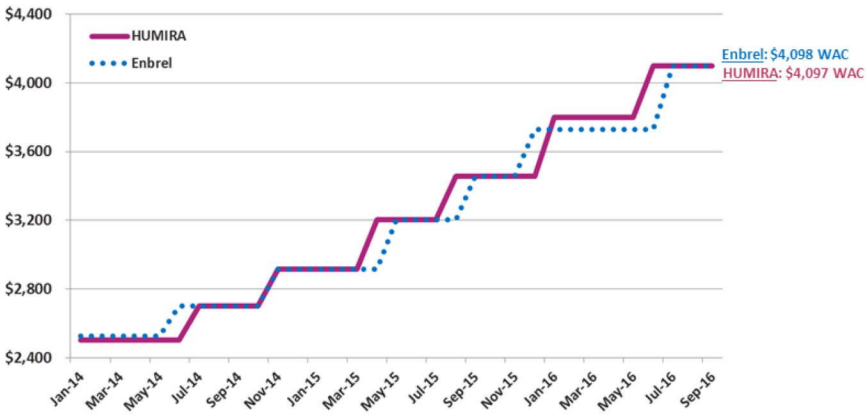
HUMIRA Pricing
WAC Price per NDC – HUMIRA and Enbrel



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

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HUMIRA PRICING OVERVIEW
Bill Chase
Executive Vice President, Chief Financial Officer
September 9, 2016

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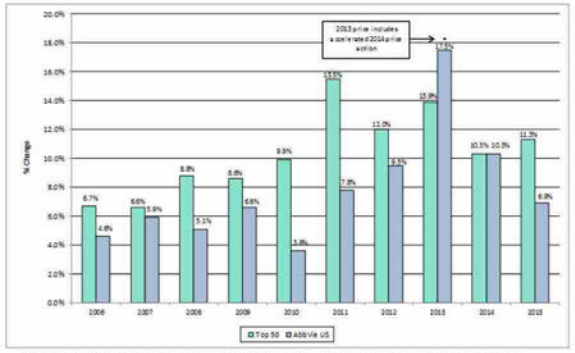
Since spinoff, price has contributed low single digit impact to sales growth. Average U.S. price actions are below the top 50 drug average.

	2013	2014	2015	2016 LBE
Total AbbVie Price Contribution	2.5%	3.4%	2.5%	3.4%



*2013 AbbVie US average rate of 17.5% includes the late December price actions. Excluding the December price actions AbbVie US is at 9.6%.
Top 50 price action % based on simple average WAC prices per Analysource.
Price Index / Price Actions do not take into account discounts paid to the government and private pay customers.

AbbVie 23

Humira has seen positive price in the U.S. and negative price overseas.

	2013	2014	2015	2016 LBE
Total Humira				
Price	5.9%	4.5%	5.8%	5.8%
Volume	9.5%	14.4%	13.3%	10.9%
Total Growth	15.4%	18.9%	19.1%	16.7%
U.S.				
Price	13.0%	9.5%	12.1%	9.9%
Volume	6.6%	15.1%	16.7%	14.8%
Total Growth	19.6%	24.6%	28.8%	24.7%
International				
Price	(0.4%)	(0.3%)	(1.1%)	(0.4%)
Volume	12.1%	13.6%	9.7%	5.1%
Total Growth	11.7%	13.3%	8.6%	4.7%

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Rheumatoid Arthritis Managed Care Pricing

	WAC Cost of Therapy
Enbrel	$53,271
Humira	53,262
Cimzia	50,897
Orencia	49,884
Simponi	45,734
Xeljanz	45,089
Actemra	43,252
Remicade	42,859

	Estimated Net Cost of Therapy
Cimzia	$50,897
Orencia	49,884
Xeljanz	45,089
Actemra	43,252
Enbrel	41,019
Humira	41,012
Simponi	40,475

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Psoriasis Managed Care Pricing

	WAC Cost of Therapy
Stelara 90mg	$88,402
Taltz	69,762
Enbrel	65,564
Cosentyx	65,033
Humira	57,359
Remicade	53,574
Stelara 45mg	44,201
Otezla	31,878

	Estimated Net Cost of Therapy
Stelara 90mg	$78,236
Taltz	69,762
Cosentyx	65,033
Enbrel	50,484
Humira	44,166
Stelara 45mg	39,118
Otezla	31,878

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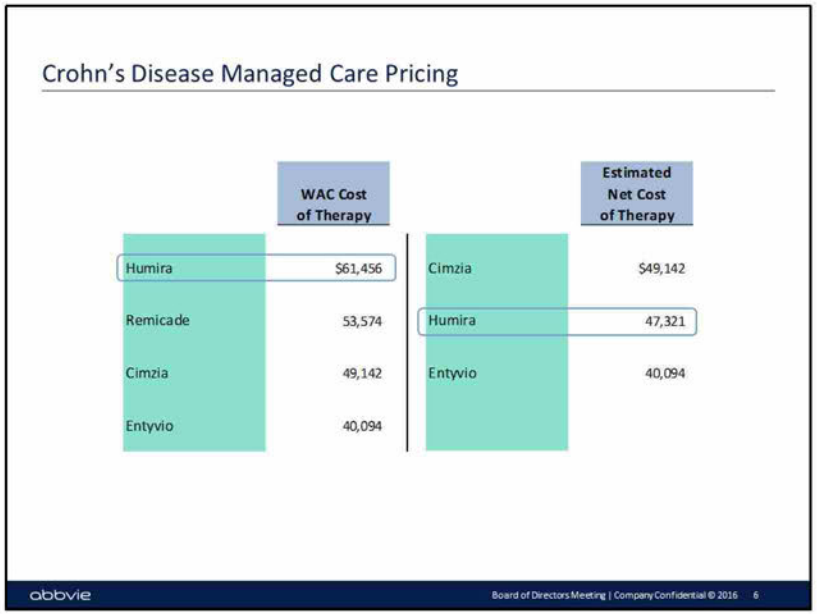
Crohn's Disease Managed Care Pricing
WAC Cost of Therapy
Humira $61,456
Remicade 53,574
Cimzia 49,142
Entyvio 40,094
Estimated Net Cost of Therapy
Cimzia $49,142
Humira 47,321
Entyvio 40,094
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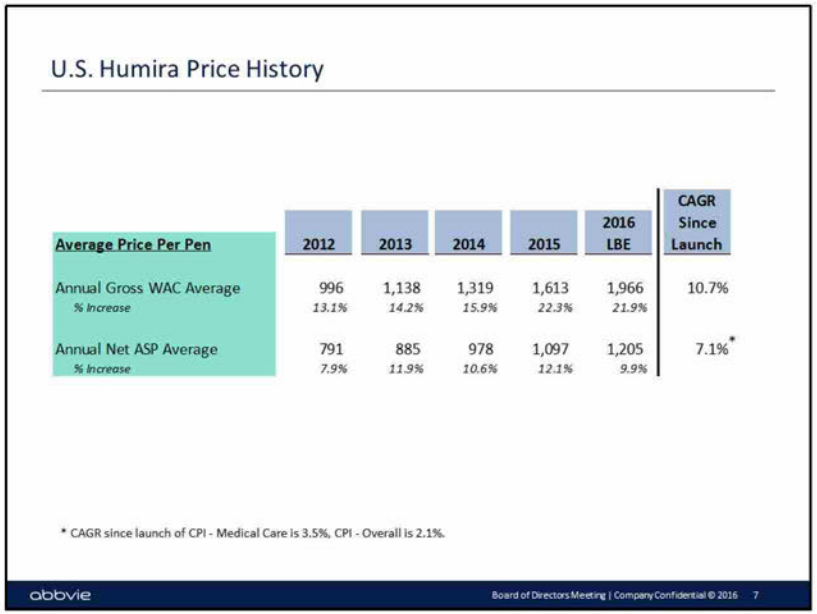
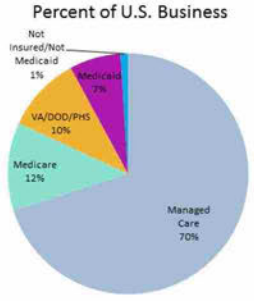


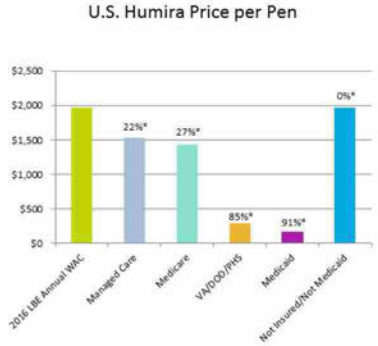
U.S. Humira Price History

Average Price Per Pen	2012	2013	2014	2015	2016 LBE	CAGR Since Launch
Annual Gross WAC Average	996	1,138	1,319	1,613	1,966	10.7%
% Increase	*13.1%*	*14.2%*	*15.9%*	*22.3%*	*21.9%*	
Annual Net ASP Average	791	885	978	1,097	1,205	7.1%*
% Increase	*7.9%*	*11.9%*	*10.6%*	*12.1%*	*9.9%*	

* CAGR since launch of CPI - Medical Care is 3.5%, CPI - Overall is 2.1%.

U.S. Humira price varies dramatically by channel.





* Percent discount to WAC

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U.S. patients have broad access to Humira regardless of financial condition.

Channel	% of U.S. Business	Access Program
Managed Care	**70%**	• 93% of patients are enrolled in the HUMIRA Co-Pay program. Co-Pay assistance varies based on insurance benefit design and can reduce patient out of pocket costs to as low as $5/month. • Annual patient benefit is up to $12,000/year.
Medicare Part D	**12%**	• 27% discount, cost per pen $1,431. • US Government prohibits the use of direct Co-Pay assistance for Medicare. • Majority of HUMIRA patients have employer retiree benefits or qualify for low income subsidies. Remainder subject to co-insurance and the doughnut hole (up to $4,600/year). • Medicare patients can apply for financial assistance from charitable foundations.
VA/DoD/PHS	**10%**	• 85% discount, cost per pen $291. VA out of pocket $10/month. TriCare out of pocket $24/month.
Medicaid	**7%**	• 91% discount, cost per pen $170. Medicaid enables patients to access medicine for free or less than $5/pen.
Not Insured/ Not Medicaid	**1%**	• AbbVie Patient Assistance Foundation provides Humira and other AbbVie medications at no cost to eligible patients in need but facing financial difficulty. Approx. 81,000 patients are provided no charge medicine per year.
Overall	**100%**	

AbbVie 23

The 2016 LRP forecasts reduced price increases on Humira.

	2016 LBE	2017	2018	2019	2020
Total Humira					
Price	5.8%	4.0%	3.3%	1.3%	2.4%
Volume	10.9%	8.9%	5.3%	0.9%	1.9%
Total Growth	16.7%	12.9%	8.6%	2.2%	4.3%
U.S.					
Price	9.9%	7.7%	6.8%	4.7%	4.9%
Volume	14.8%	10.2%	5.1%	2.6%	2.7%
Total Growth	24.7%	17.9%	11.9%	7.3%	7.6%
International					
Price	(0.4%)	(2.6%)	(3.8%)	(6.3%)	(4.2%)
Volume	5.1%	6.7%	5.8%	(2.6%)	0.0%
Total Growth	4.7%	4.1%	2.0%	(8.9%)	(4.2%)

Memo: Figures exclude impact of exchange.

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There are important differences between Humira and products recently spotlighted in the media:

- Humira is not a generic product, and is supported by a robust research and development effort.
  - It enjoys the broadest indication portfolio in the market, with two significant expansions in recent years.
  - Since spinoff, over $1BN of R&D funding has been invested in Humira.
- The auto-immune market is extremely competitive with product offerings priced similarly or higher than Humira.
- Volume growth has been a significant factor in Humira performance since spin-off.

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AbbVie 23

imbruvica
(ibrutinib) 140mg capsules

Janssen Recommendation 2017 FTEs and OOPs

October 26, 2016

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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**	

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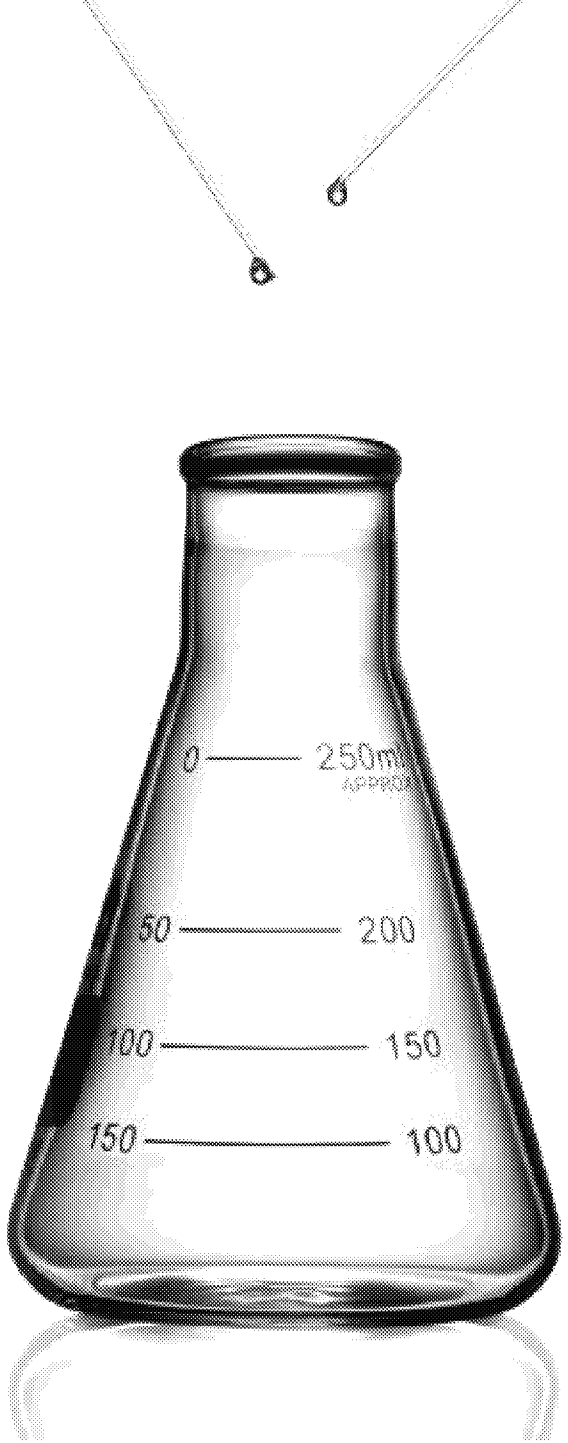
2017 LRP

Global Commercial Assumptions

12.16.2016



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2017 LRP Assumptions Meeting
AbbVie 25

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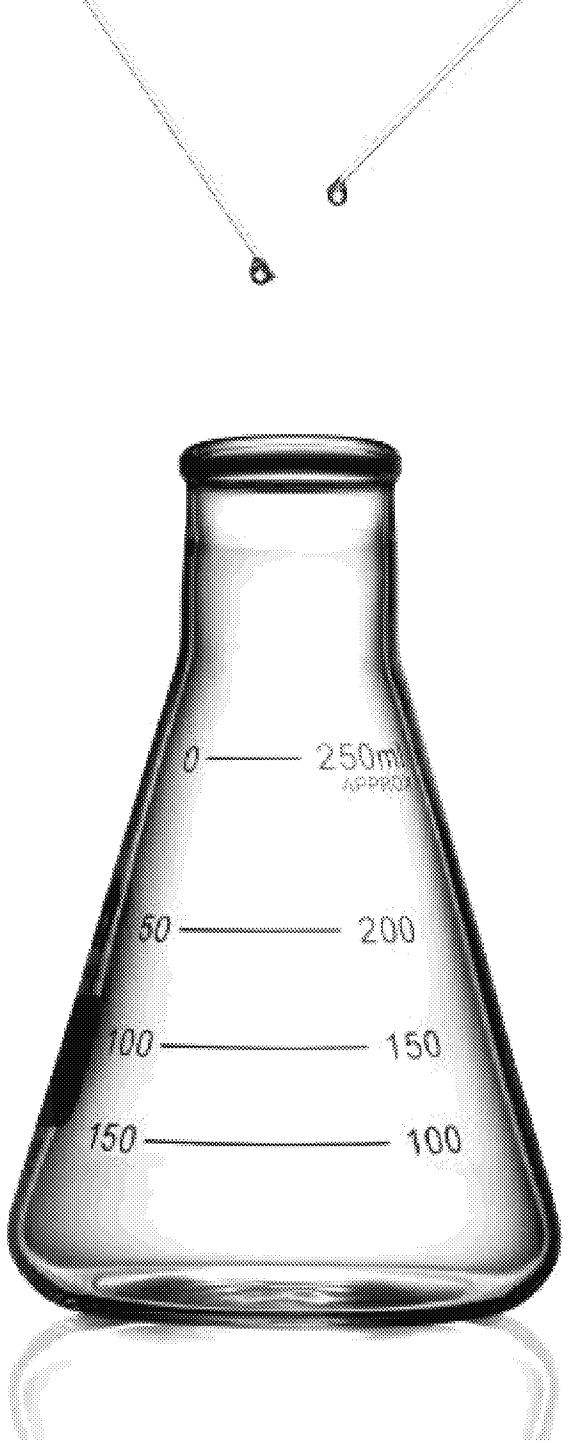
2017 LRP

Key Pipeline Product Assumptions



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Pipeline Assumptions Overview

- Changes in pipeline composition (entries & exits)
- Changes pipeline risk (PTRS updates)
- Changes in development timelines
- Changes in TPP/TPC, forecast assumptions, etc.

Pipeline Product Assumptions

2017 LRP Pipeline Composition (NME/indication exits & entrants) vs 2016 LRP

Assumed Exits **Entrants***

Redacted – NR Product

* Does not include new NME's launching outside of LRP window

Pipeline Product Assumptions

2017 LRP vs 2016 LRP Probability of Technical & Regulatory Success (PTRS)

Change Drivers

- Phase Advancement
- Reg Alignment (removed timeline risk)
- Placeholder → Explicit Assessment
- Other

Change in 2025 risk-adj revenue if applied to '16 LRP forecasts: +$688 (net for portfolio)

TA	Molecule	Project	LRP	Total	Change Driver	Detailed Rationale	"Impact"
Oncology							
Neuroscienc							
Virology							
Immunology							
Immunology							
Metabolic							
Metabolic							
Oncology							
Oncology							
Oncology							
Oncology							
Neuroscienc							

Redacted – NR Product

Full list in appendix. Current table excludes ABBV-8E12 and CF combo (minor favorable changes)

On-Market & Late-Stage Timing Changes

Program
[redacted]

Redacted – NR Product

Full list in appendix. Current table excludes early-stage and/or low impact programs (based on 2016 LRP revenue)

Stemcentrx Treatment in LRP

Redacted – NR Product

* St

Pipeline Product Assumptions

Approach to determine material changes

Only “significant” changes will be incorporated into the LRP

The following events trigger an evaluation of forecasts / P&Ls:

- Clinical trial data for AbbVie or competitor products
- Epidemiology database changes
- Changes in market access & pricing landscape
- Changes in regulatory agency position (e.g. label language)
- SG&A landscape in therapeutic areas where resource infrastructure exists

Discuss in meeting to obtain alignment for definition of a “significant” change:

- A guideline for relative impact a single “significant” change
- Guideline for the combination of several small changes

Product Profile / Product Claim changes vs. 2016 LRP

Asset / Indication	Proposed Change
[redacted]	**Redacted – NR Product**

RovaT / Stemcentrx TPP/TPC changes described on previous slide

Pipeline Product Assumptions

PTRS / Timing changes between now and April CFO review

- Several projects have data read-outs or milestones projected before April 2017 that may lead to PTRS re-assessments:

Asset / Indication	Milestone / Timing	Prob	2025 Rev* (MM)
[redacted]	Redacted – NR Product		

- In addition, Asset Development Teams continuously manage development timelines in light of data read-outs, available resources and regulatory requirements

- Change management process will continue to use the monthly heat map (HM) meetings to review / approve updates to timing or PTRS

* 2025 risk-adj revenue from 2016 LRP provided for perspective

Late-Stage Pipeline:

2017 data read-outs after April CFO review of Commercial Pipeline LRP

Asset / Indication	Key data availability / Timing	Prob	2025 Rev* (MM)
[redacted]	Redacted – NR Product		

* 2025 risk-adj revenue from 2016 LRP provided for perspective

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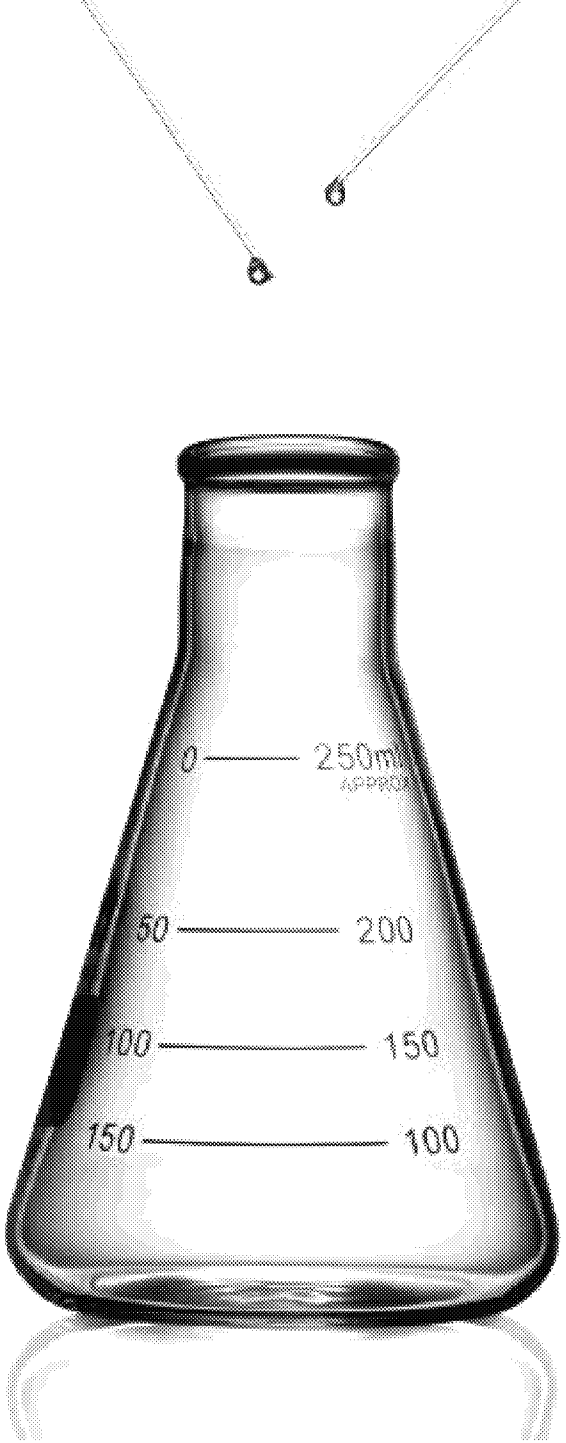
2017 LRP

Key On-Market Product Assumptions



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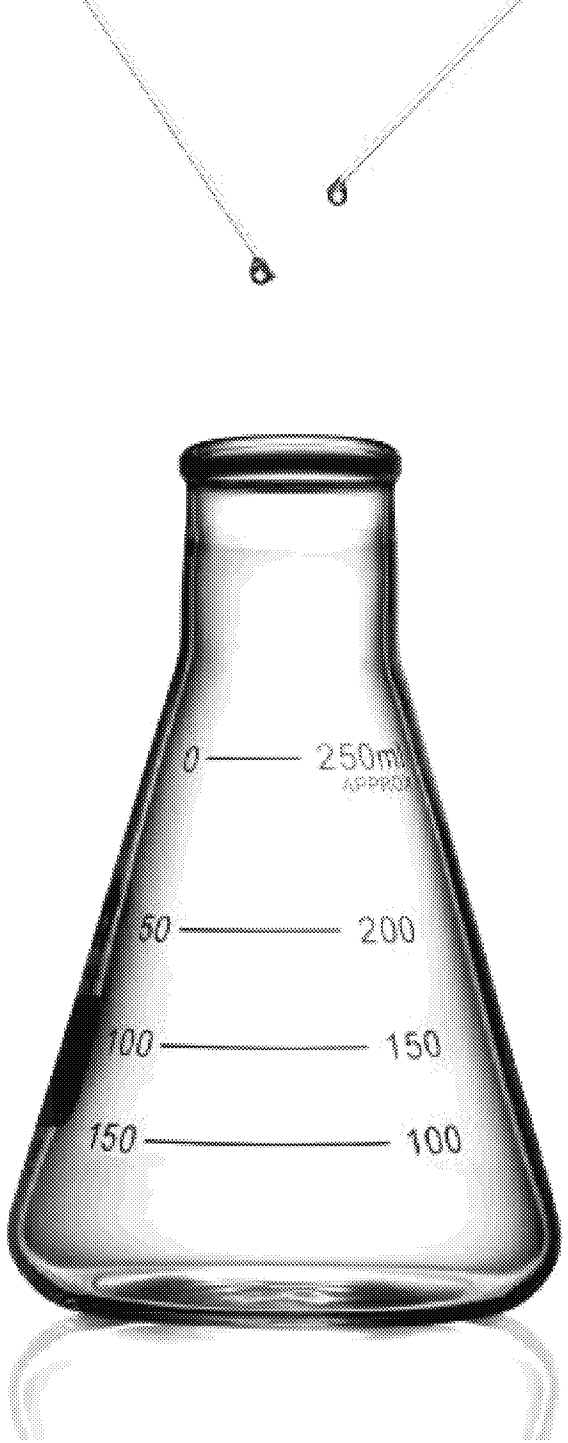
2017 LRP

Key On-Market Product Assumptions
US



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U.S. Commercial On Market Products

WAC Pricing Assumptions

2017 LRP vs. 2016 LRP Price Actions

	2017 LRP				Variances vs 2016 LRP		
	2017		2018 - 2026		2017	2018-2026	
HUMIRA	9.9%	Jan	18-21: 6.9%	Jan	-7.9%	-6.9%	a.
			22-23: 6.9%	Jan		0.0%	
			24+: 0.0%	Jan		0.0%	
AndroGel	Redacted – NR Product						
Creon							
Synthroid							
Lupron (all)							
Kaletra							
Zinbryta							
Venclexta							
Elagolix							
ABT 414							
Veliparib							
Rova-T							
ABT 494							
Risankizumab							

a. HUMIRA - In the 2016 LRP, 2018 - 2021 included two 6.9% price actions (March/Sept), but incremental rebates were added to negate any second price action benefit due to price protection/CPI for 2019 - 2021.

b. Redacted – NR Product Rova-T Redacted – NR Product

MBO and ACP Redacted – NR Product

Redacted – NR Product [redacted]

All December actions are assumed to be late December.

U.S. Commercial On Market Products

HUMIRA LOE and WAC pricing assumptions

LOE: The proposal is to build the base LRP as highlighted below with two alternates being modeled for an earlier interchangeable introduction and an earlier date for LOE + interchangeable. Given the competitive dynamics, Biosimilar discount to HUMIRA net price is recommended to be a progressive increasing % post LOE.

		2017 LRP		
	2016 LRP	Base	Alternate 1	Alternate 2
LOE Assumptions:				
LOE (Full Extrapolation)	2022	2022	2022	2021
# of Biosimilars@LOE	*11*	*11*	*11*	*11*
Single-source Interchangeability	none	2024	2022	2022
# of Interchangeable Day 1	*n/a*	*1*	*1*	*1*
Multi-source Interchangeability	none	2025	2023	2023
# of Interchangeable	*n/a*	*4*	*4*	*4*
Biosim Net Price	(30%)/(75%) of Humira Net Price	Starting at (65%) of Humira Net Price and progressively increasing over the LRP (eg. 2%/year)		

NOTE: Progressive biosimilar discount to net HUMIRA price would be modeled at 65% upon LOE and continue to erode further across the LRP based on biosimilar competition and/or interchangeable events

WAC Price Increases: The proposal is to build the base LRP as highlighted below with one additional sensitivity being run. Only one action/year is being recommended.

		2017 LRP	
	2016 LRP	Base	Sensitivity
Price Actions (annual):			
2017	9.9% (Jan)/7.9%(Jul)	9.9% (Jan)	9.9% (Jan)
2018-LOE	6.9% (Mar/Sept)	6.9% (Jan)	9.9% (Jan)
Post LOE	6.9% (Sept)	6.9% (Jan)	6.9% (Jan)
Post Interchangeability	n/a	0.0%	0.0%

U.S. Commercial On Market Products

Other Key Assumptions

Immunology

- HUMIRA
  - Alignment on launch timing of Citrate Free (not included in 2017 LRP or 2016 LRP)
- [redacted]
- [redacted]

HCV

- Redacted – NR Product

Neuroscience

- [redacted]
- Redacted – NR Product

U.S. Commercial On Market Products

Other Key Assumptions

Oncology

- Venclexta

Redacted – NR Product

- Rova T
  - Redacted – NR Product

- Veliparib
  - Redacted – NR Product

- ABT-414
  - Redacted – NR Product

U.S. Commercial On Market Products

Other Key Assumptions

Metabolics / Endo/ GI Care / ACP / MBO

- Androgel
  - Redacted – NR Product
- CREON
  - Redacted – NR Product
  - [illegible]
- MBO
  - Redacted – NR Product
- Elagolix
  - [illegible]
  - Redacted – NR Product

U.S. Commercial On Market Products

MBO Product Playbook Executive Summary

[redacted]

U.S. Commercial On Market Products
MBO Product Playbook

Divest | Withdraw NDA | Seek partner

FYI No decision needed

Product	'17 Plan Sales	5yr Cum. Sales	Strategy	Notes
[redacted]				

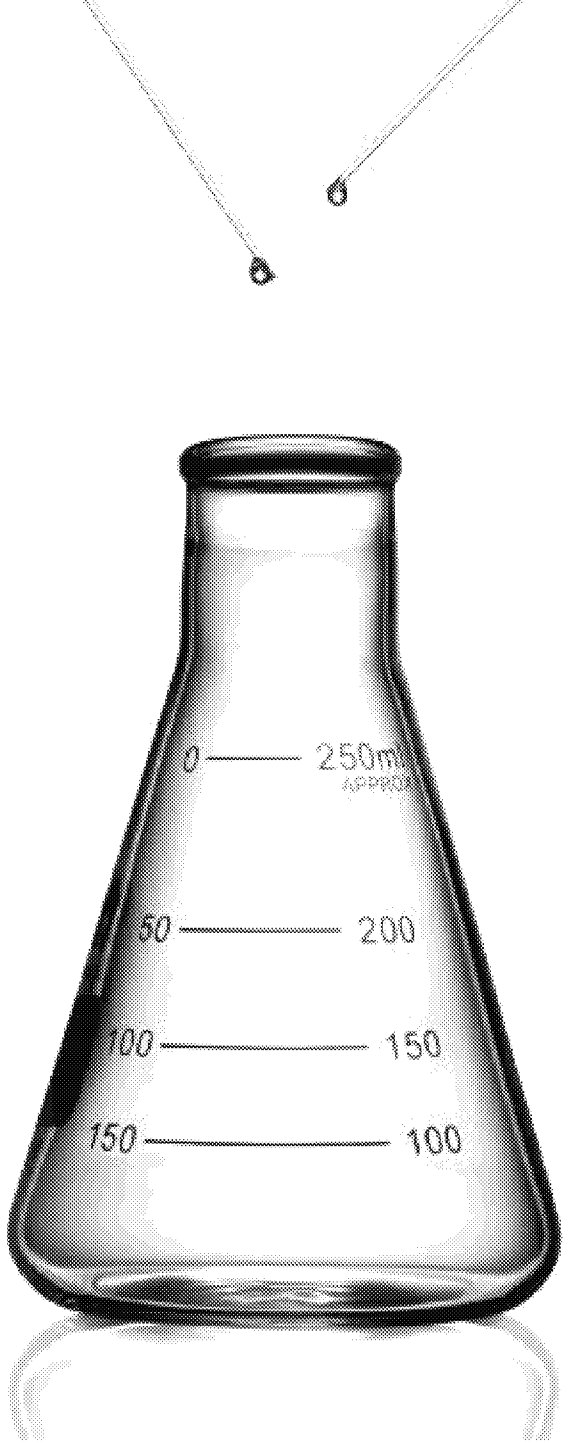
Redacted – NR Product

AbbVie 25

abbvie

2017 LRP

Key On-Market Product Assumptions International



AbbVie 25

Key On-Market Product Assumptions

OUS HUMIRA Key Biosimilars Assumptions

HUMIRA OUS Key Biosimilar Assumptions

	2016	2017
LOE Date	Q4 2018*	Q4 2018*
Interchangeability	N**	N**
Indication Extrapolation	Y	Y
Non-Medical Switch of Stable Patient	N	Depending on Market Archetype

* Represents most international markets

** Except in regulatory mandated countries

Base Case Scenario:

- Biofrontier is a market access lead initiative to understand potential biosimilar erosion impacts in key markets [including non-medical switch assumptions in some markets based on competitive dynamics] and develop strategies to limit the biosimilar erosion impact
- Propose the Base Case reflects the Biofrontier insights for each respective market, which could include non-medical switch
- Provide analysis to show the impact of non-medical switch vs. the Prior LRP

Downside Scenario:

- Affiliates to provide Bear scenario of potential worse case

Key On-Market Product Assumptions

OUS HCV Key Biosimilars Assumptions

Redacted – NR Product

abbvie

Appendix

AbbVie 25

Key Pipeline Product Assumptions

[redacted]

- Immunology strategic priorities include optimizing [redacted]
- Portfolio of indications funded in 2017 Plan

- In PsA, CD and UC
  - [redacted]
  - [redacted]
- 2017 LRP forecast will include full spectrum of approved indications for each asset, and reflect the differentiating TPPs, and targeted co-positioning

Pipeline Product Assumptions

2017 LRP vs 2016 LRP Probability of Technical & Regulatory Success (PTRS)

Change Drivers

- Phase Advancement
- Reg Alignment (removed timeline risk)
- Placeholder → Explicit Assessment
- Other

Change in 2025 risk-adj revenue if applied to '16 LRP forecasts: +$688 (net)

TA	Molecule	Project	LRP	Total	Change Driver	Detailed Rationale	"Impact"
Oncology	[redacted]						
Neuroscience							
Neuroscience							
Virology							
Immunology							
Immunology							
Metabolic							
Metabolic							
Oncology							
Oncology							
Oncology							
Oncology							
Neuroscience							
Neuroscience							
Neuroscience							
Respiratory							

Redacted – NR Product

Overall Probability of Launch for Ph 2 & Ph 3 NME Projects (proposed for 2017 LRP)

Ph 3

Oncology Ph 3 Ind Ave
Veliparib NSCLC sq
Veliparib NSCLC non-sq
Veliparib BRCA Breast
Veliparib Ovarian
Veliparib TNBC

Immunology Ph 3 Ind Ave
ABT-494 RA
Risankizumab Pso
Risankizumab UC

All TAs Ph 3 Ind Ave
Elagolix Endo
Elagolix Fibroids
Atrasentan DN

Antiviral Ph 3 Ind Ave
HCV Next Gen Japan
HCV Next Gen China

Redacted – NR Product

Notes- Industry historical technical success rates from KMR, 2006-15 & 2011-15
- Prob launch increase / decrease / new project vs 2016 LRP
- HCV Next Gen pending submission for regulatory review

* US
** ExUS

Overall Probability of Launch for Preclin & Ph 1 NME Projects (proposed for 2017 LRP)

Ph 1

Oncology Ph 1 Ind Ave
RovaT 1L SCLC Induct
ABBV-399 NSCLC combo
SC-002 Cancer
SC-003 Cancer
SC-006 Cancer
ABBV-838 MM 3L+ combo
Veliparib SCLC
ABBV-838 MM 4L+ mono
ABBV-399 NSCLC mono
ABBV-181 Cancer
ABBV-428 Cancer
ABBV-927 Cancer
ABBV-075 Cancer
ABBV-085 Cancer

Immunology Ph 1 Ind Ave
ABBV-323 CD
ABBV-599 RA
ABBV-553 Pso

Neuroscience Ph 1 Ind Ave
ABBV-951 Adv PD
ABT-555 MS
ABT-555 SCI

All TAs Ph 1 Ind Ave
CF Combo

Redacted – NR Product

Notes- Industry historical technical success rates from KMR, 2006-15 & 2011-15
- Prob launch increase / decrease / new project vs 2016 LRP
- *italic* denotes placeholder prob launch

* US
** ExUS

Overall Probability of Launch for On Market Asset Projects (proposed for 2017 LRP)

Oncology

Venclexta CLL 17p & RR CLL
Venclexta CLL 1L comorbid
Venclexta AML +LoDAC
Venclexta MCL
Venclexta AML +aza
Empliciti MM 1L
Venclexta CLL 1L fit
Venclexta AML +LoDAC (accel)
Venclexta AML +aza (accel)
Venclexta MM rel (+Vel)
Venclexta MDS
Venclexta DLBCL
Venclexta iNHL

Redacted – NR Product

Immunology

HUMIRA Nail Ps	80%* / 90%**
HUMIRA Japan HS	81%
HUMIRA Japan PG	64%
HUMIRA Japan GPP	64%

Assumed Exits

HUMIRA High-Ind Dose IBD (Halo.)
HUMIRA China CD
HUMIRA CD Endo Impr Mod-Severe

Note - Prob launch increase / decrease / new project vs 2016 LRP

* US
** ExUS

Summary of Timing Changes with 2016 LRP 2025 Risk-Adj Revenue Context

Program	Project	2016	2017	Change	2016 LRP Risk Adj 2025 Rev	Comments for Delays
Risankizumab						
Duodopa						
ABBV-951						
Venetoclax						
Veliparib						
Veliparib						
Veliparib						
HCV Next Gen						
HCV Next Gen						
HCV 1st Gen						
ABBV-8E12						
ABBV-8E12						
ABBV-085						
ABBV-323						
ABT-494						
ABT-555						
ABBV-927						
ABBV-428						
Empliciti						
Atrasentan						

Redacted – NR Product

First Launch Date

(occurs in US unless otherwise noted)

- No significant change (+ 3 months) relative to 2016 LRP
- >1Q month acceleration relative to 2016 LRP
- >1Q month delay relative to 2016 LRP
- New in 2017 LRP
- 2016 LRP Launch Date

Program	Project	2017 Q1 Q2 Q3 Q4	2018 Q1 Q2 Q3 Q4	2019 Q1 Q2 Q3 Q4	2020 Q1 Q2 Q3 Q4	2021 Q1 Q2 Q3 Q4	2022 Q1 Q2 Q3 Q4	2023 Q1 Q2 Q3 Q4	2024 Q1 Q2 Q3 Q4	2025 Q1 Q2 Q3 Q4	2026 Q1 Q2 Q3 Q4	2027+
Venetoclax												
Venetoclax												
Venetoclax												
Venetoclax												
Venetoclax												
Venetoclax												
Venetoclax												
Venetoclax												
Venetoclax												
Venetoclax												
Venetoclax												
Veliparib												
Veliparib												
Veliparib												
Veliparib												
Veliparib												
Veliparib												
Veliparib												
Empliciti												
Rova-T												
Rova-T												
Rova-T												
Rova-T												
Navitoclax												
ABT-414												
ABT-414												

Redacted – NR Product

First Launch Date
(occurs in US unless otherwise noted)

No significant change (+ 3 months) relative to 2016 LRP
>1Q month acceleration relative to 2016 LRP
>1Q month delay relative to 2016 LRP
New in 2017 LRP
2016 LRP Launch Date

Program	Project	2017 Q1 Q2 Q3 Q4	2018 Q1 Q2 Q3 Q4	2019 Q1 Q2 Q3 Q4	2020 Q1 Q2 Q3 Q4	2021 Q1 Q2 Q3 Q4	2022 Q1 Q2 Q3 Q4	2023 Q1 Q2 Q3 Q4	2024 Q1 Q2 Q3 Q4	2025 Q1 Q2 Q3 Q4	2026 Q1 Q2 Q3 Q4	2027+
ABBV-075												
ABBV-399												
ABBV-399												
ABBV-085												
ABBV-838												
ABBV-838												
ABBV-368												
ABBV-428												
ABBV-621												
ABBV-927												
Risankizumab												
Risankizumab												
Risankizumab												
Risankizumab												
ABT-494												
ABT-494												
ABT-494												
ABT-494												
ABT-494												
ABT-494												
ABT-981												
ABBV-323												
ABBV-553												
ABBV-599												
ALX-0061												

Redacted – NR Product

First Launch Date
(occurs in US unless otherwise noted)

No significant change (+ 3 months) relative to 2016 LRP
>1Q month acceleration relative to 2016 LRP
>1Q month delay relative to 2016 LRP
New in 2017 LRP
2016 LRP Launch Date

Program	Project	2017 Q1 Q2 Q3 Q4	2018 Q1 Q2 Q3 Q4	2019 Q1 Q2 Q3 Q4	2020 Q1 Q2 Q3 Q4	2021 Q1 Q2 Q3 Q4	2022 Q1 Q2 Q3 Q4	2023 Q1 Q2 Q3 Q4	2024 Q1 Q2 Q3 Q4	2025 Q1 Q2 Q3 Q4	2026 Q1 Q2 Q3 Q4	2027+
HUMIRA	Nail Psoriasis	▲										
HUMIRA	Generalized Pustular Psoriasis – Japan		▲									
HUMIRA	Japan Hidradenitis Suppurativa			▲								
HUMIRA	Pyoderma Gangrenosum Japan				▲							
HUMIRA	China CD				▲							
ABT-555												
ABBV-8E12												
ABBV-8E12												
ABBV-951												
Duodopa												
HCV Next Gen												
HCV Next Gen												
HCV Next Gen												
HCV 1st Gen												
Atrasentan												
Elagolix												
Elagolix												
ABBV-GLPG												
Triple Combo												

Redacted – NR Product

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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BlueMatrix
Applied intelligence™

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.

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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

AbbVie 27

Message

From: [redacted]

Sent: 10/8/2018 5:34:00 PM
To: [redacted]
CC: [redacted]
Subject: RE: Humira 15-Day Price Action Key Plus/Minus
Attachments: Reval Slide 10.8.18.pptx

See attached

From: [redacted]
Sent: Monday, October 8, 2018 4:26 PM
To: [redacted]
Cc: [redacted]
Subject: RE: Humira 15-Day Price Action Key Plus/Minus

[redacted] several key points to maximize revaluation at wholesale:

- Price action effective date on a Monday (either 1/7/19 or 1/14/19) enables full recapture of ABC's Monday order – this revaluation value is worth ~ $17MM. ABC orders product on Mondays -- if new price is not effective at the time of ABC placing their order (on Monday), this value is lost to Abbvie.
- Also need to weigh the sellouts that occur from wholesale to pharmacy. Each day during the week Abbvie delays, the more product that is sold out the door at wholesale – and the lower the amount of inventory available at wholesale for revaluation capture (as will sit @ pharmacy).

Call me @ 5, thanks.

From: [redacted]
Sent: Monday, October 8, 2018 4:13 PM
To: [redacted]
Cc: [redacted]
Subject: RE: Humira 15-Day Price Action Key Plus/Minus

There are two components. The first is the change in net sales without reval change. The second is the reval change.

The initial downside of a 15 day delay (January 15th) is approx. ($54MM) before reval change. This includes an estimated reval of $70MM (in Plan). There is no change in reval per Greg with a Jan. 15 date.

If we were to delay 14 days (Monday, Jan 14th), the downside is ($47MM) before reval change and the reval benefit would be $17MM, so the total net sales downside would be $34MM.

[redacted]

abbvie

ABV1/Dept. 0303
1 North Waukegan Road
North Chicago, IL 60064
OFFICE [redacted]

EMAIL [redacted]

abbvie.com

From: [redacted]
Sent: Monday, October 08, 2018 2:41 PM
To: [redacted]
Cc: [redacted]
Subject: Humira 15-Day Price Action Key Plus/Minus

[redacted]

Are you closed to calculating the 15 day delay on the Price action for Humira?

Thanks

[redacted]

abbvie

Dept 309, Bldg. ABV1-5SE
26525 North Riverwoods Blvd.
Mettawa, IL 60045
OFFICE [redacted]
CELL
EMAIL
abbvie.com

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U.S. HUMIRA

Executive Performance
October LBE
As of 10/11/18

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HUMIRA Citrate Free

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Executive Summary – data through 9/28

Overall Launch

- **Overall CiF transition:** 7.3% of total HUMIRA volume has now transitioned to Citrate-free
- **New vs. Existing patient transition:** 15.4% of new patients and 4.2% of existing patients transitioned to CiF (as of 9/21)
- **Adult launch (post Aug 20, 2018) performance:** 4,552 CiF TRx's were prescribed during wk. of 9/28, above the base case (50% @ Y1) forecast
- **Citrate-free Transition by SKU:**
  - 6% of the 40mg Pen and 9% of the 40mg PFS are now Citrate-free
  - 28-40% of adult starter kits are CiF within 4 weeks of launch

Pediatric Launch

- **Pediatric CiF transition:** ~71% of Ped. NDC volume has now transitioned to Citrate-free, while ~40% of total Ped. Patient redemptions are estimated to be transitioned (through copay claims, as of 9/21)
- **New vs. Existing patient transition:** 74% of new and 37% of existing pediatric patients transitioned to CiF (as of 9/21)
- **Citrate-free Transition by SKU:**
  - 68% of the 20mg PFS and 76% of the 10mg PFS are now Citrate-free
  - 89-96% of pediatric starter kits are CiF

Operations Summary

- **PAP patient requests (Reactive ONLY):** ~24% of Ped. Shipments are CiF, and 4.1% of the Adult shipments are CiF
- **US CiF Complaint Monitoring summary:** 218 MAI complaints to-date, 9 PFS complaints through 9/28/2018

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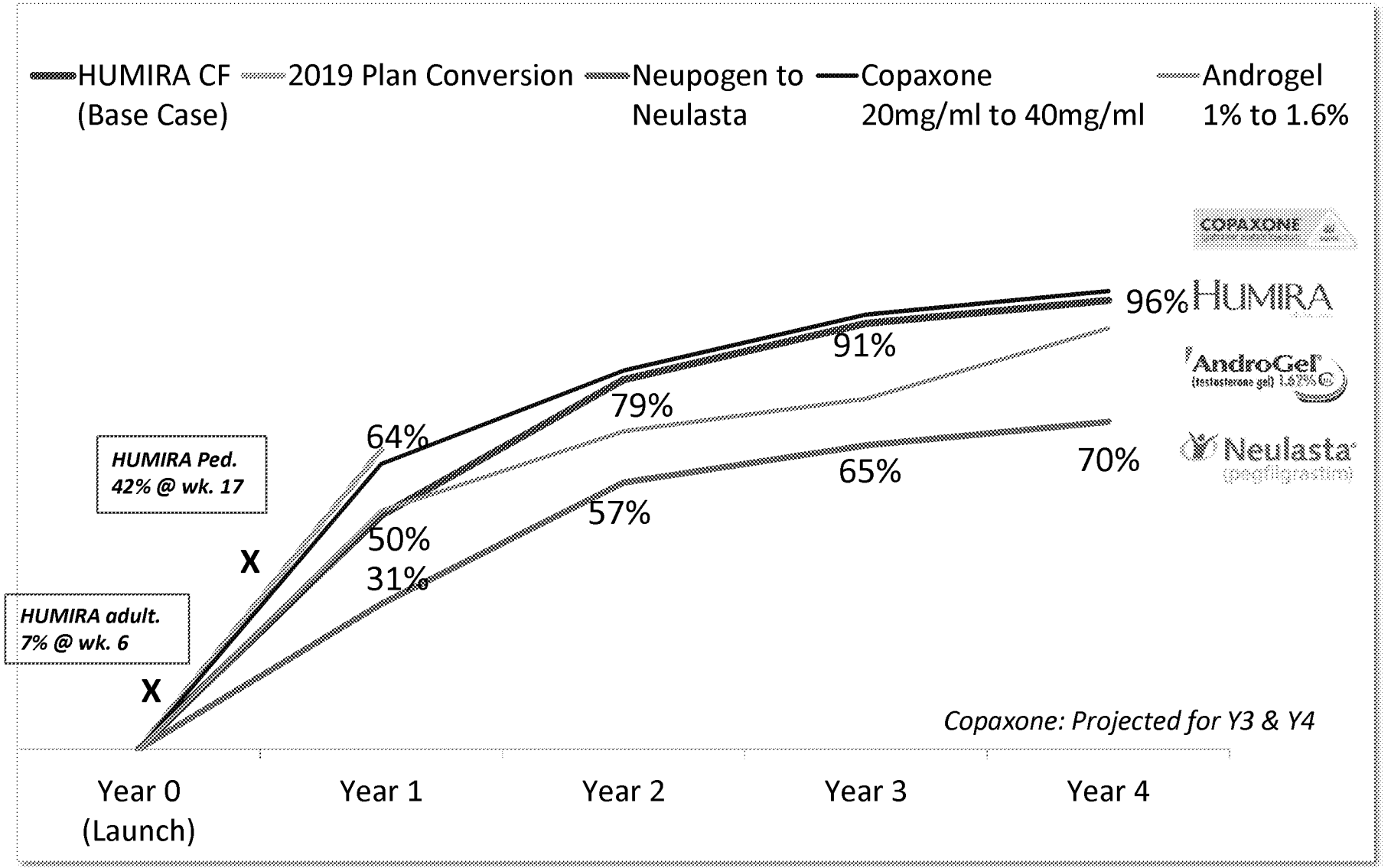
HUMIRA Pediatric transition @ week 10 vs. Analogs



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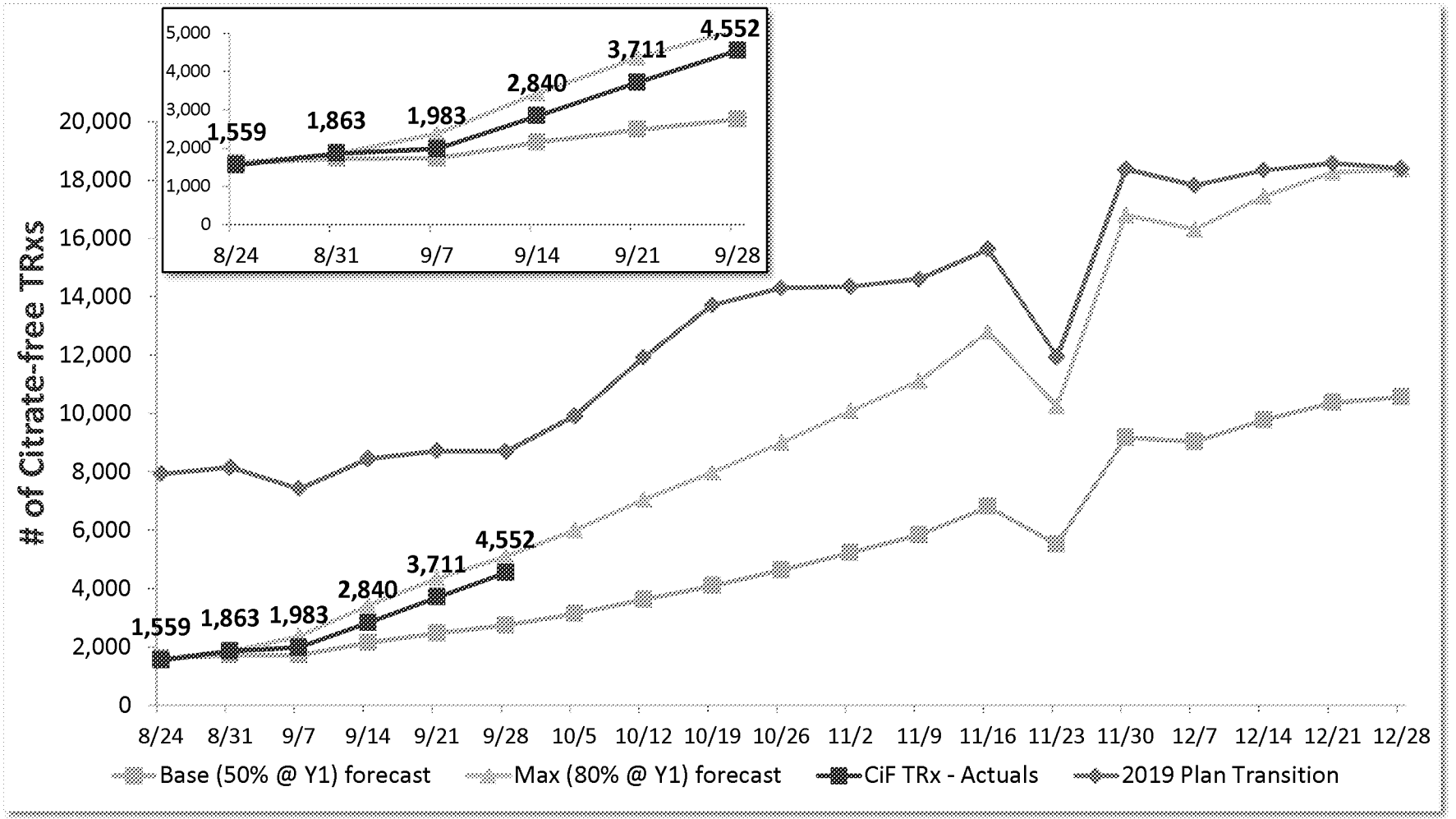
Adult launch (post Aug 20, 2018) performance:

Week-ending 09/28/2018

4,552 CiF TRx's were prescribed during wk. of 9/28, well above the base case forecast

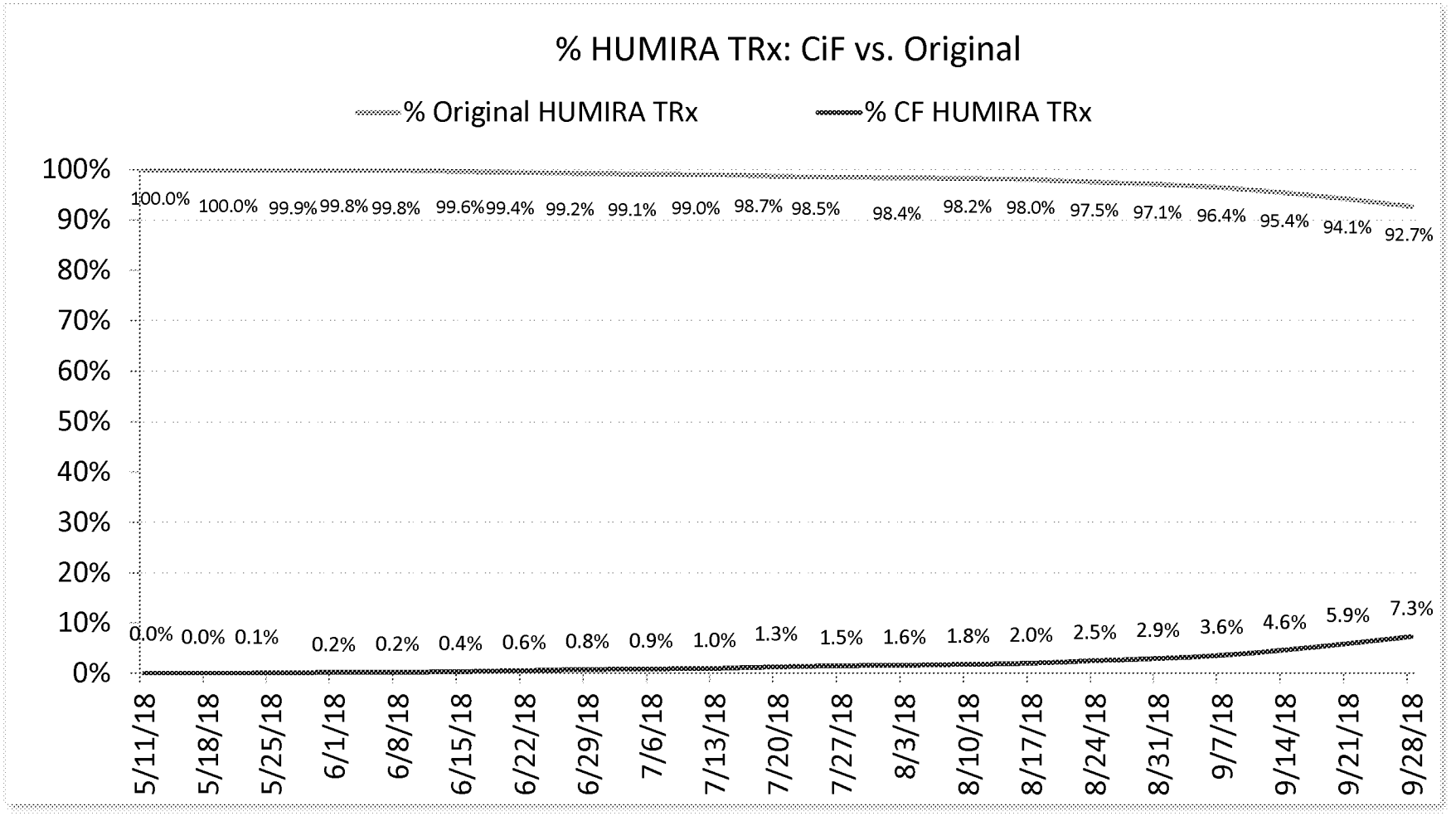
Weekly HUMIRA CiF TRx



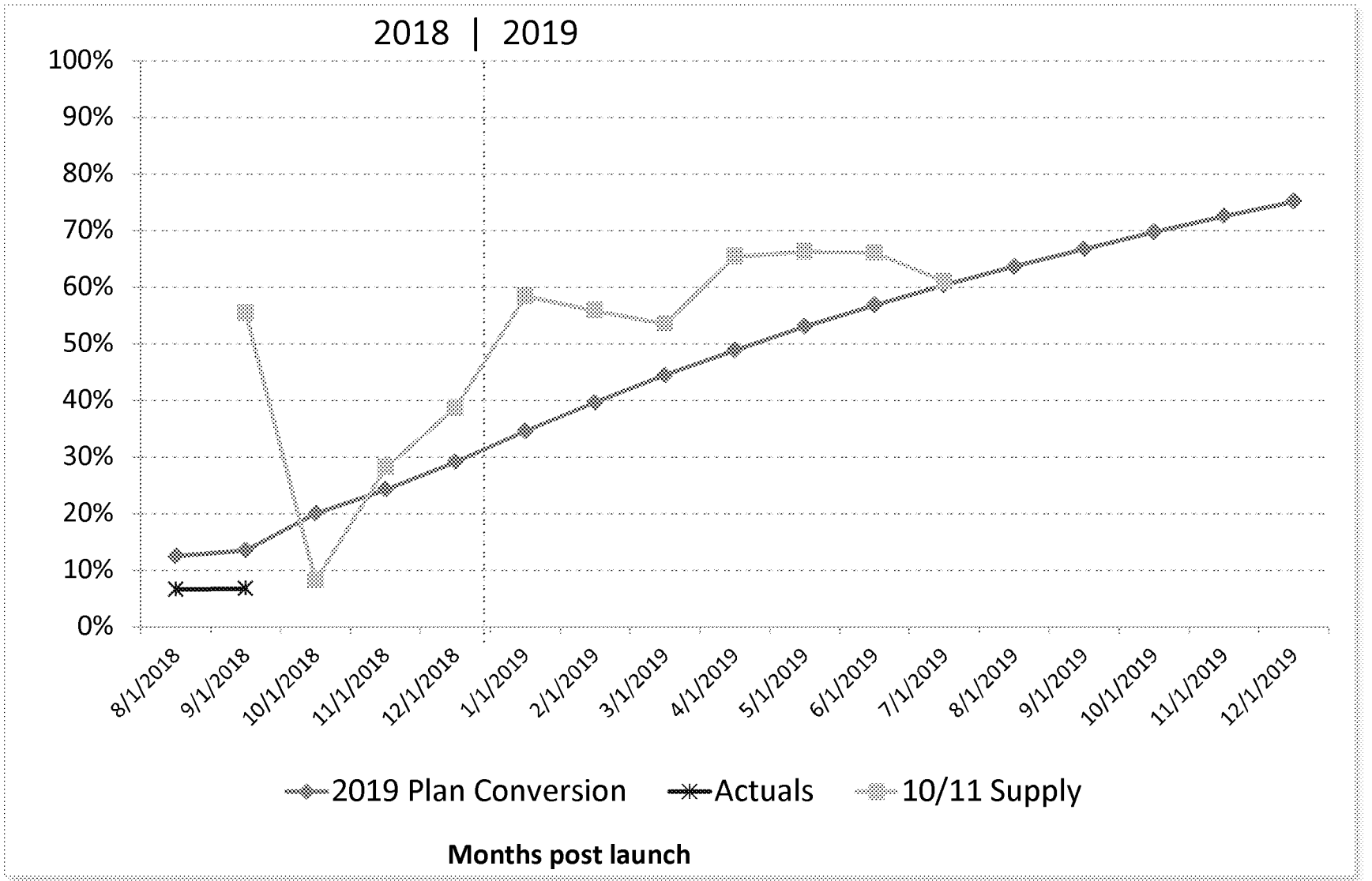
Overall CiF transition:
7.3% of total HUMIRA volume has now transitioned to Citrate-free

Week-ending 09/28/2018

All NDCs



CiF Transition
Plan scenario vs. S&OP Demand Scenario - Monthly



* Assumes professional implemented 8/2018 and specialty pharmacy discount effective 1/1/19

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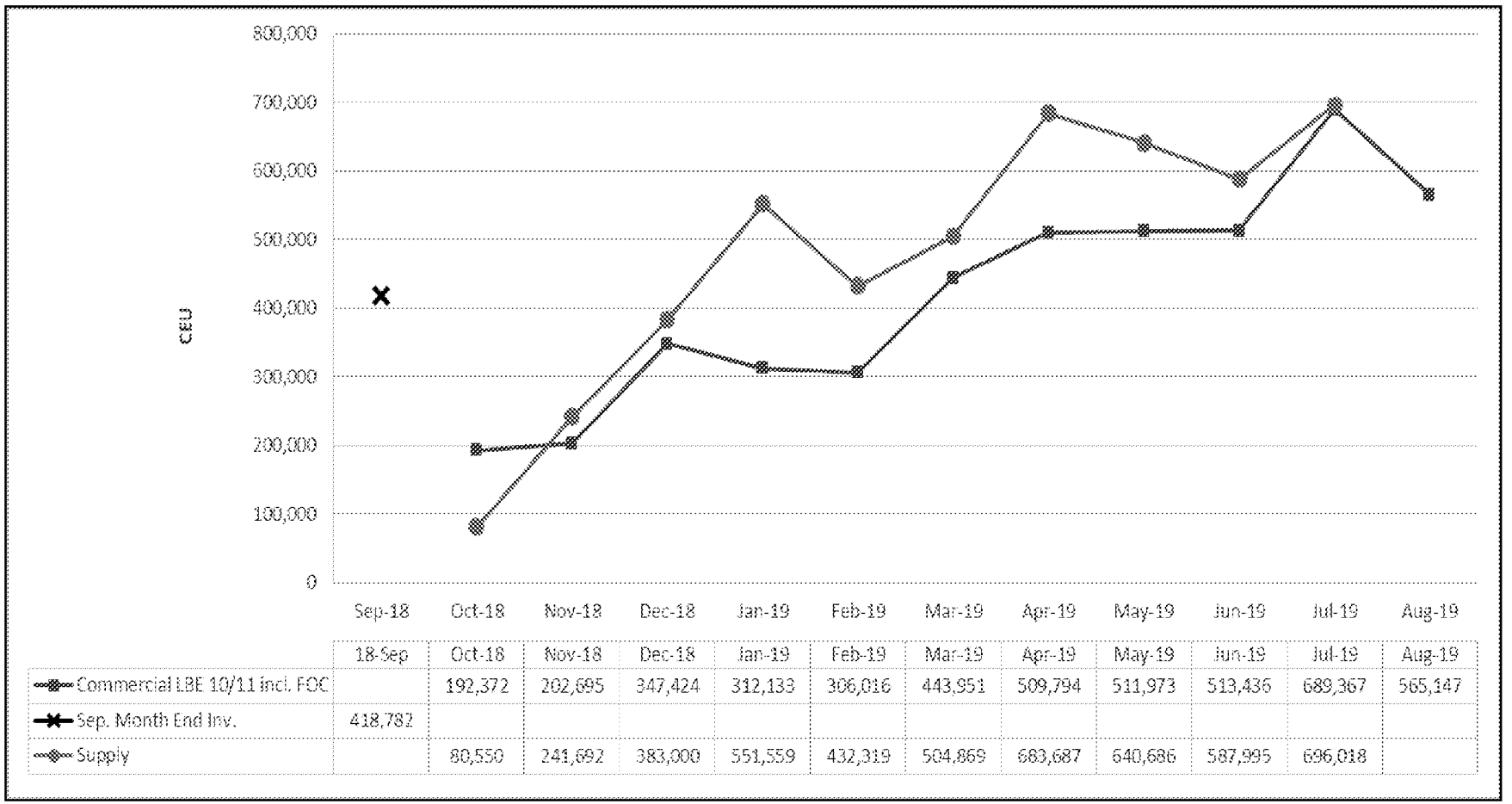
Demand vs. Supply

Demand provided Oct. 11



	18-Sep	Oct-18	Nov-18	Dec-18	Jan-19	Feb-19	Mar-19	Apr-19	May-19	Jun-19	Jul-19	Aug-19
Commercial LBE 10/11 incl. FOC		192,372	202,695	347,424	312,133	306,016	443,951	509,794	511,973	513,436	689,367	565,147
Sep. Month End Inv.	418,782											
Supply		80,550	241,692	383,000	551,559	432,319	504,869	683,687	640,686	587,995	696,018	

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IMBRUVICA Affordability Impact Analysis

Out of Pocket Cost Impact on Fulfillment of IMBRUVICA

October 2018

[redacted], *Mystic Seaport*
A retired art teacher and world traveler, Jane finds painting watercolors healing as she lives through multiple myeloma.

COMMERCIAL EXCELLENCE | INSIGHTS INNOVATION IMPACT

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Janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

COST EXPOSURE & ABANDONMENT SUMMARY

Cost Exposure

- Medicare STD patients are exposed to the highest costs, with over 70% of claims $250+
- Patients tend to experience higher costs earlier in the calendar year, mostly due to deductibles and coverage gap for Medicare patients, and high deductibles and max OOP for Commercial patients
- The proportion of high cost claims has increased year over year
- Medicare patient foundational support reduced by half beginning in mid-2016

Abandonment

- Abandonment rates *within each cost bucket* are relatively steady year over year
- However, more patients are facing higher costs year over year, resulting in overall abandonment rate increases, e.g., 16%-point increase from 2015 (9%) to 2017 (25%) for Medicare patients
- Overall, Medicare STD abandonment is higher than in Commercial (15% vs 9%); however, cost sensitivity within each OOP cohort is lower for Medicare patients than Commercial, up to ~$500 OOP level

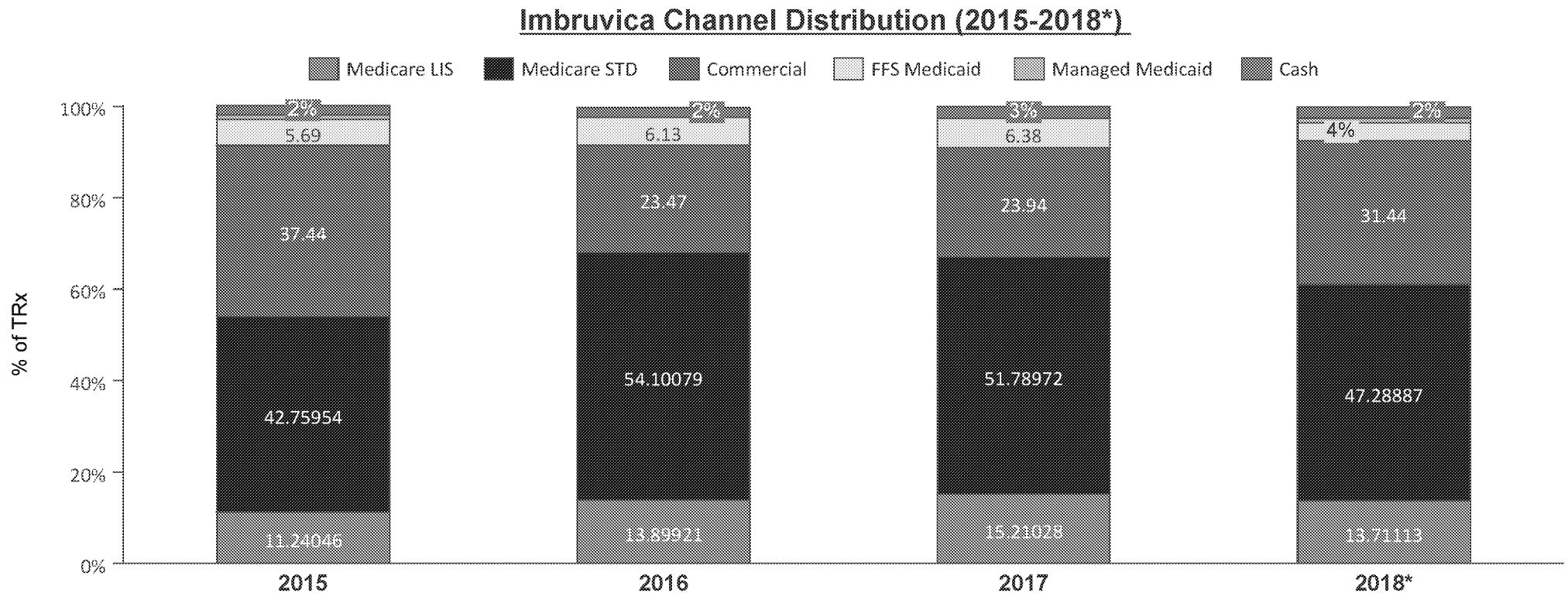
Follow-up: New Patients

- Compared to all patients, new patients face higher cost exposure, have less foundational support, and are more cost-sensitive, and are therefore a more at-risk patient population

Imbruvica patient overall abandonment has grown over time because of a shift toward higher out-of-pocket costs

The Medicare STD and Medicare LIS channels together account for over 60% of Imbruvica TRx volume, followed by Commercial

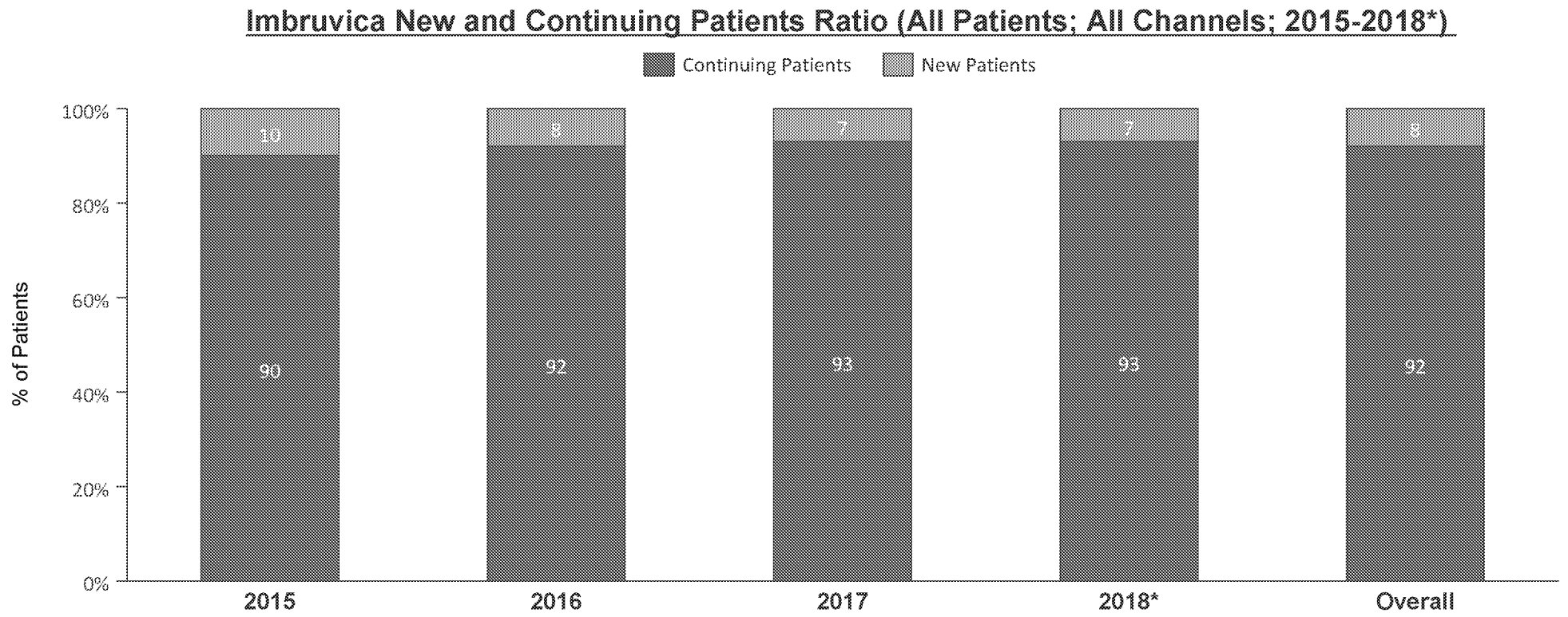
- Our analyses will focus on a subset of Medicare D standard (STD) and low-income subsidy (LIS) patients
  - Eligibility requirements needed to identify patients' Medicare status result in a restricted, but more accurate sample



*2018 only contains data from January-June

Source: IQVIA SP Data; IQVIA Access Strategy Consulting analysis

On average, ~8% of Imbruvica's patient population consists of new-to-brand patients for a given month



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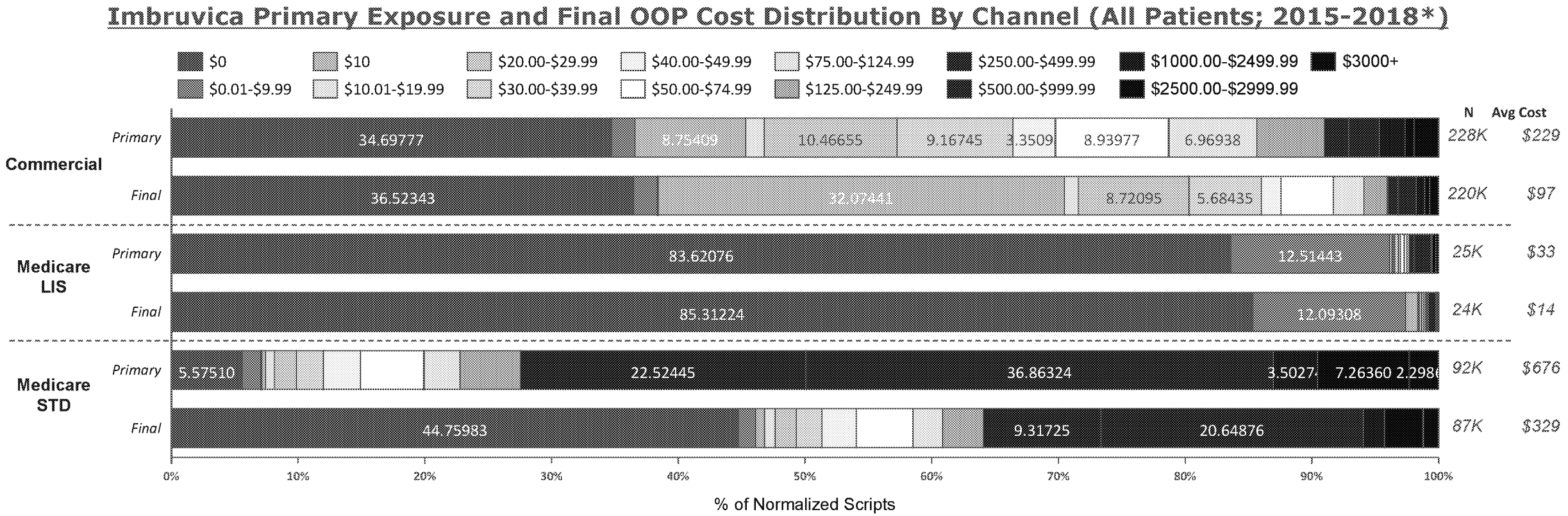
Medicare Standard patients face the highest costs as a result of deductibles, coinsurance, and coverage gap; 1/3 of Commercial and Medicare claims are bought down by copay assistance of some kind

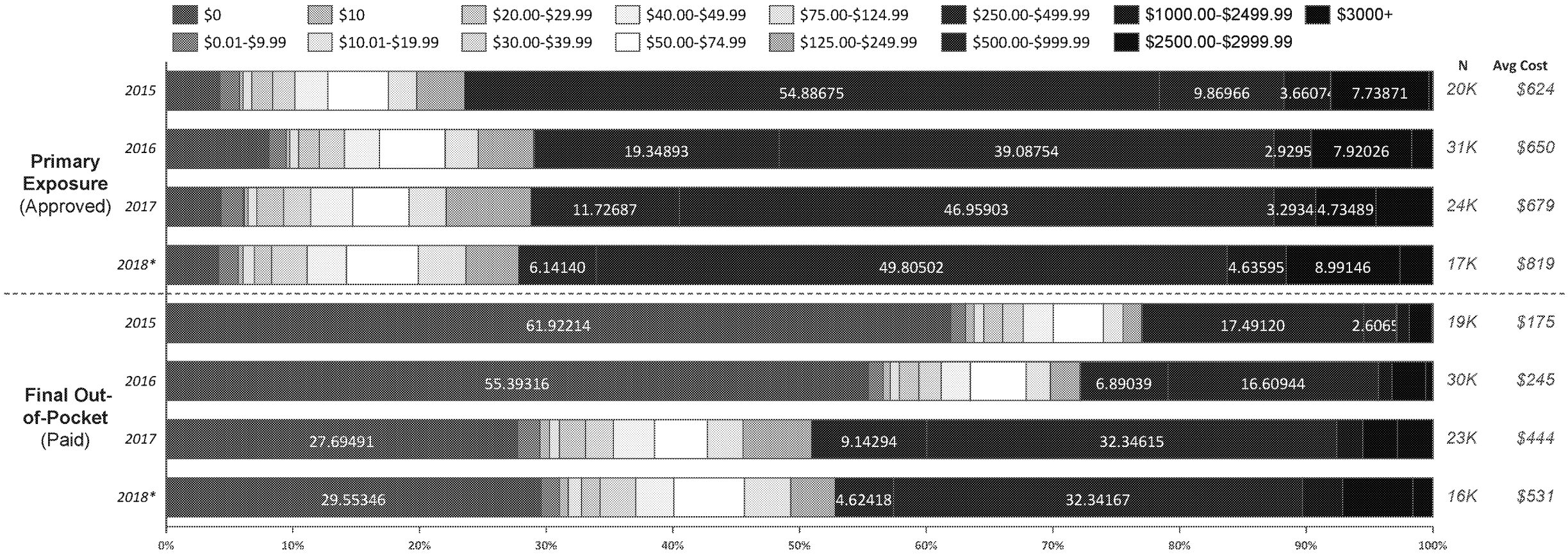
- Low-income subsidy (LIS) patients generally pay no more than $8.35 in copayment for their prescription drugs



Medicare patient cost distribution has shifted slightly upward year-o year, likely due to a combination of price increases and benefit design changes

- A 50% reduction in $0 out-of-pocket cost claims starting in 2017 coincides with a decline in foundational assistance

Imbruvica Primary Exposure and Final OOP Cost Distribution By Year (Medicare STD; All Patients; 2015-2018*)



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.

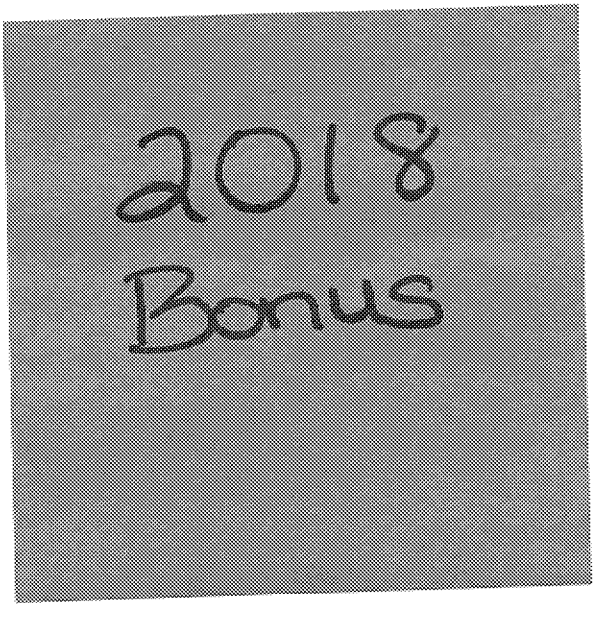
Sincerely,

Matthew Williams
Vice President, State Government Affairs
AbbVie

[2] Non-GAAP; excluding specified items

Rick Gonzalez

		Performance Grading	
Goals:	Weighting	Achievement	Score
Income Before Taxes	20%	100.0%	20.0%
Financial Goals	60%	99.50%	59.7%
Research and Development	20%	100.00%	20.0%
	100%		
		Total Goal Score	99.70%



Gonzalez, Rick - Chairman of the Board and Chief Executive Officer, Grade 40

Goal Name	Goal Description	Progress Against Goal
Achieve 2018 Plan Income Before Taxes of $13.0 BN.* (20%)	*Excludes specified items. Subject to appropriate adjustment due to unplanned one-time significant events such as acquisitions, government enforcement actions and external collaborations.	ACHIEVED – Income Before Taxes: Nov LBE $13.3BN @ Plan Exchange rates
Achieve other 2018 Plan financial goals as described.* (80%)	Achieve AbbVie Sales of $31.5 BN.* Achieve AbbVie Operating Margin of $14.0 BN.* Achieve Humira Sales of $20.1 BN.* Achieve Return on Assets of 20.9%.* *Excludes specified items. Subject to appropriate adjustment due to unplanned one-time significant events such as acquisitions, government enforcement actions and external collaborations.	ACHIEVED - AbbVie Sales: Nov LBE $32.3BN @ Plan Exchange rates ACHIEVED - AbbVie Operating Margin: Nov LBE $14.4BN @ Plan Exchange rates MOSTLY ACHIEVED - Humira Sales: Nov LBE $19.7BN @ Plan Exchange rates (98.0%) ACHIEVED - Return on Assets: Nov LBE 23.5% (estimate)
Research and Development (20%)	REDACTED: Non-Responsive	REDACTED: Non-Responsive