Drug Pricing Investigation

Celgene and Bristol Myers Squibb—*Revlimid*

Selected Investigation Documents

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

Bristol Myers Squibb-Celgene Selected Documents

Document #	Citation	Short Description
BMS-Celgene 1	CELG_HCOR_000049208	March 1, 2014 Emails
BMS-Celgene 2	CELG_HCOR_000047564, at Slide 5	March 2014 Presentation Excerpt
BMS-Celgene 3	CELG_HCOR_000042262, at Slide 13	March 2016 Presentation Excerpt
BMS-Celgene 4	CELG_HCOR_000023827, at Slide 13	April 2017 Presentation Excerpt
BMS-Celgene 5	CELG_HCOR_000042295, at Slide 22	July 2013 Presentation Excerpt
BMS-Celgene 6	CELG_HCOR_000042295, at Slide 18	June 2013 Presentation Excerpt
BMS-Celgene 7	CELG_HCOR_000042295, at Slide 23	June 2013 Presentation Excerpt
BMS-Celgene 8	CELG_HCOR_000027347, at Slide 3	October 2018 Presentation Excerpt
BMS-Celgene 9	CELG_HCOR_000027347, at Slide 8	October 2018 Presentation Excerpt
BMS-Celgene 10	CELG_HCOR_000027347, at Slide 9	October 2018 Presentation Excerpt
BMS-Celgene 11	Exhibit 68(b) to Mylan's Response to Defendant Celgene's Statement of Material Facts, *Mylan Pharmaceuticals Inc. v. Celgene Corporation*	Litigation Exhibit
BMS-Celgene 12	CELG_HCOR_000047526, at Slide 8	February 2014 Presentation Excerpt
BMS-Celgene 13	CELG_HCOR_000051076 and Attachment	May 2016 Email, and Attached Memorandum
BMS-Celgene 14	CELG_HCOR_000000135, at Slide 5	November 2016 Presentation Excerpt
BMS-Celgene 15	CELG_HCOR_000026237	April 26-27, 2018 Emails
BMS-Celgene 16	CELG_HCOR_000042225, Slide 22.	2016 Presentation Excerpt
BMS-Celgene 17	CELG_HCOR_000042767	February 20, 2018 Emails

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

Hi [redacted]

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

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

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

Thanks [redacted] Hope you have a great weekend.

Mark

BMS-Celgene Document 1

1Q and 2Q2014 U.S. Pricing Actions

Corporate Market Access Committee Meeting
March 5, 2014

BMS-Celgene Document 2

2014 US MM Pricing Strategy - Revlimid

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

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

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

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Celgene

March /Q2 2016
U.S. Pricing Actions

[AutoDate]

Abraxane for Injectable Suspension

Revlimid (lenalidomide) capsules

Pomalyst (pomalidomide) capsules

ISTODAX (romidepsin) for injection

Otezla (apremilast) 30mg tablets

BMS-Celgene Document 3

Revlimid (lenalidomide)

Financial Impact

- A 6.80% price increase on 03/10/16 and 3.00% 09/01/16 yields $137.4M in incremental net sales in 2016 and $79.8M in incremental net sales first half 2017 versus Budget
  - 2016 Budget assumes 3% price increase on 4/1/16 and 10/1/16

Total Incremental Net Sales (in $M)

	2016	1H2017	Total Net Incremental Sales
Revlimid – All Strengths	**$137.4**	**$79.8**	**$217.2**

- *Based on demand assumption in Budget. March LE demand will change these numbers accordingly.*

Celgene

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Welcome!

BMS-Celgene Document 4

BMS-Celgene Document 4

U.S. Multiple Myeloma LRP Highlights

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

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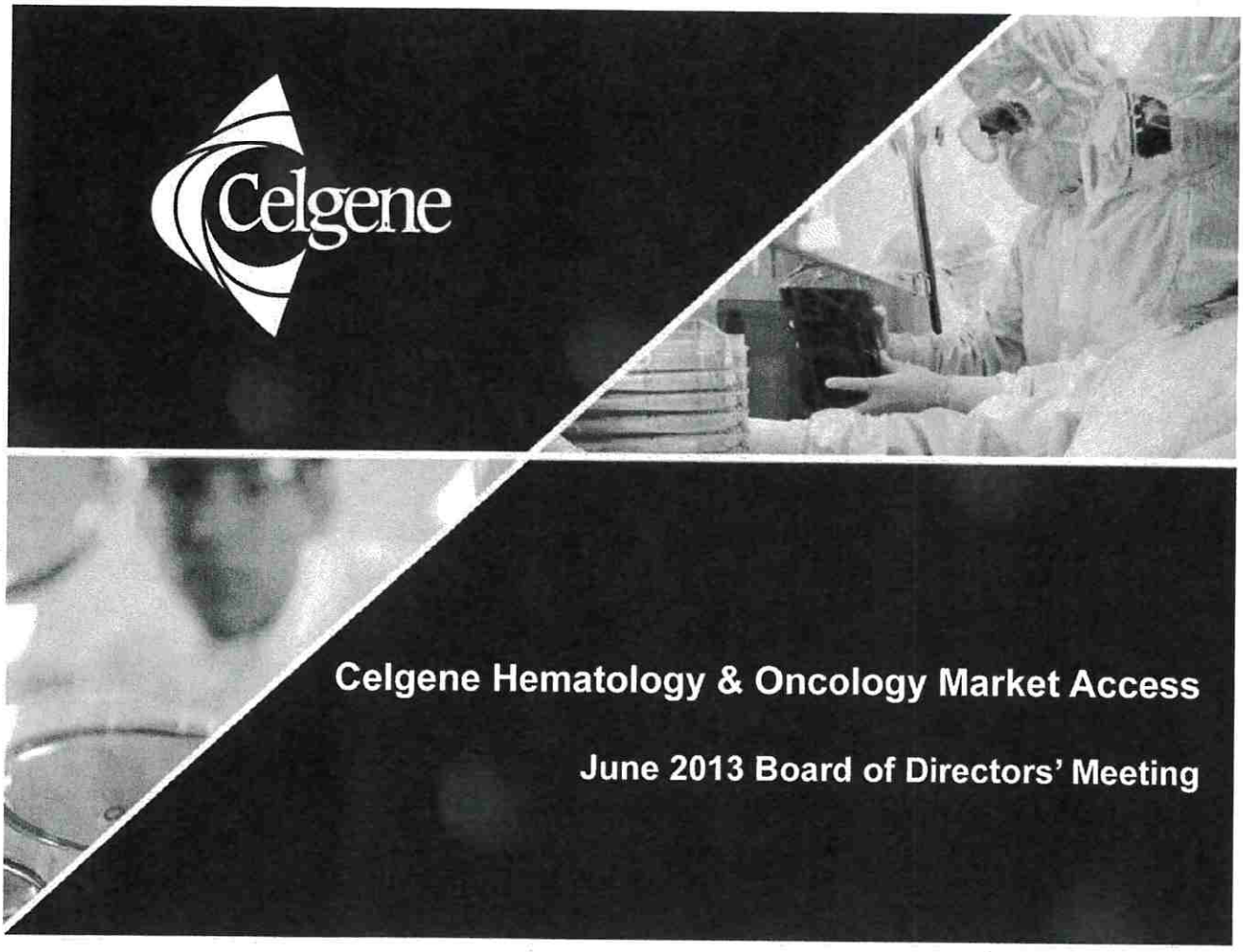

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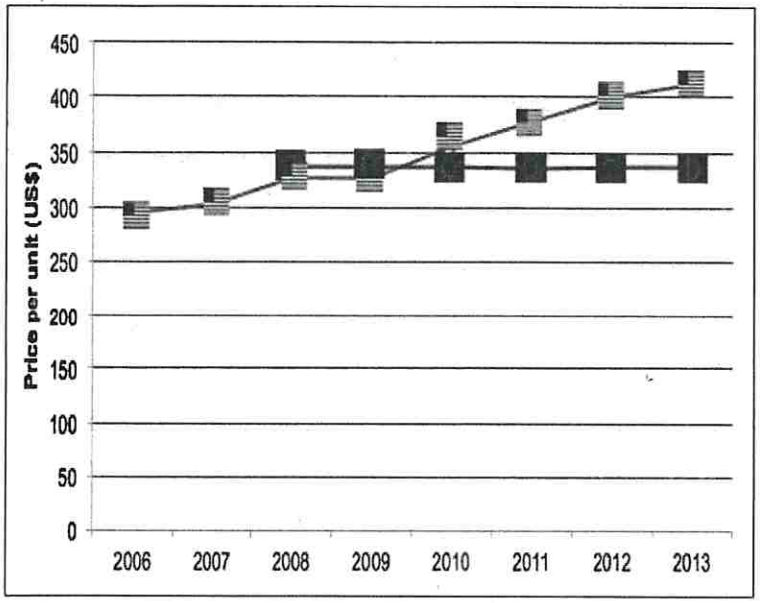
In aggregate - across this timeframe (2006-~2012) the EU price of REVLIMID has been sustained

REVLIMID Historical Price Evolution



***EU Revlimid Price 33% > than US at Launch**

*Source: Portfolio Review 2011

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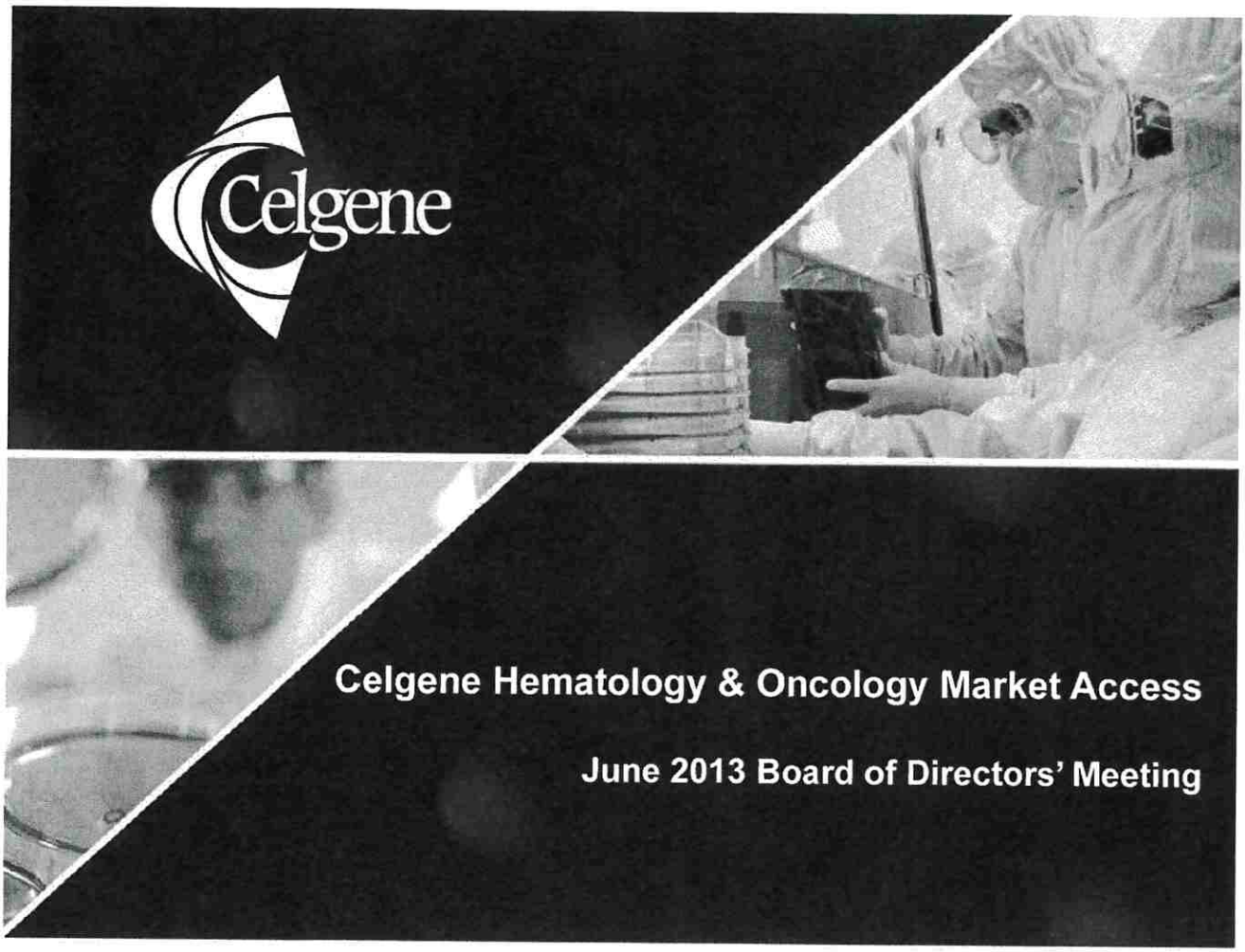

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Key to REVLIMID success in international (EU) markets; negotiated local market access solutions

Treatment charged up to Cycle 25 — Free of charge after cycle 26

Upfront 50% discount for the 2first cycle free + fixed rebate on national budget impact

Upfront 25% rebate on first 4 cycles + additional rebates every 4 cycles

Average rebate calculated from a staggered rebate scheme linked to national budget impact growth

= Optimal and customized management of price vs. budget impact for payers

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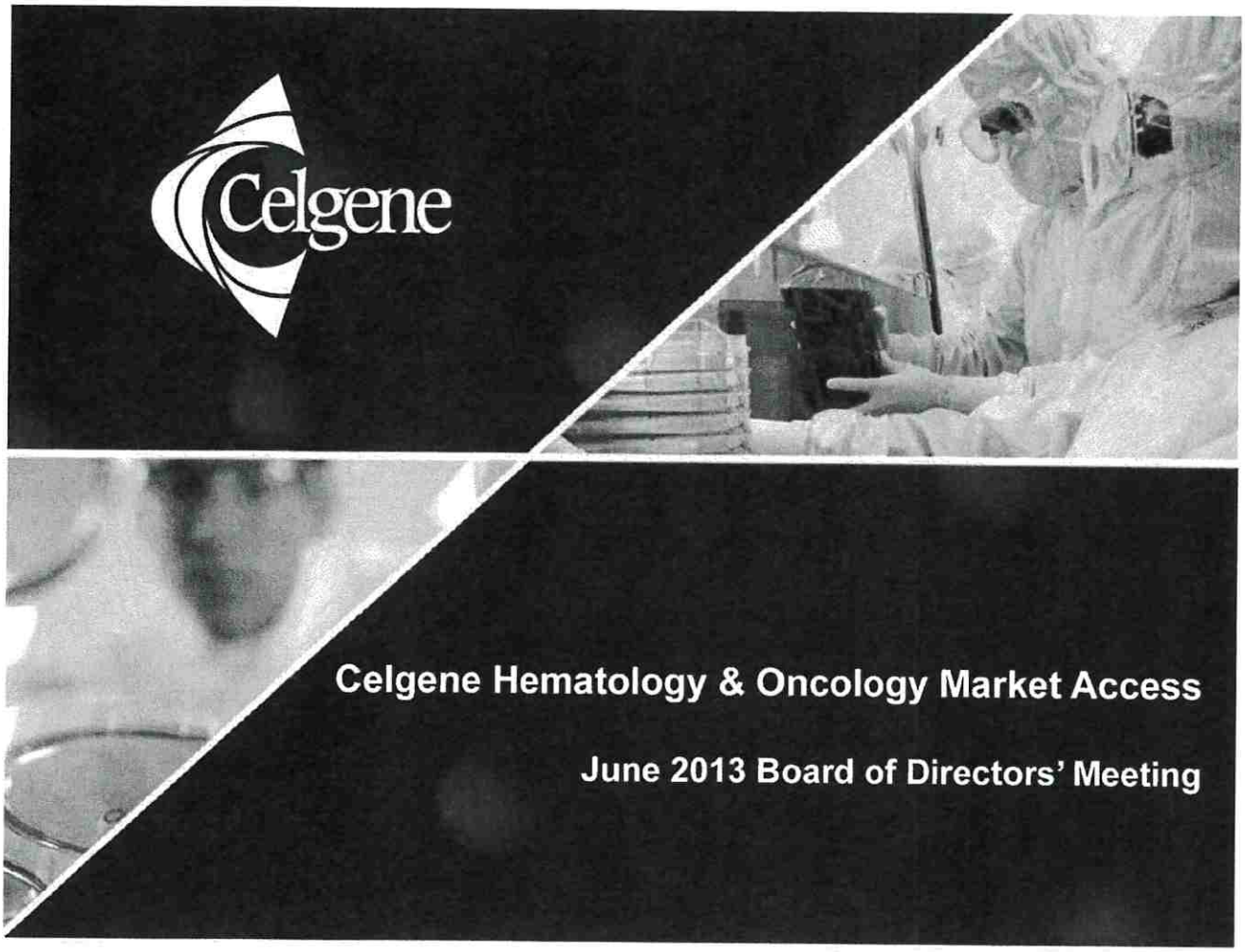

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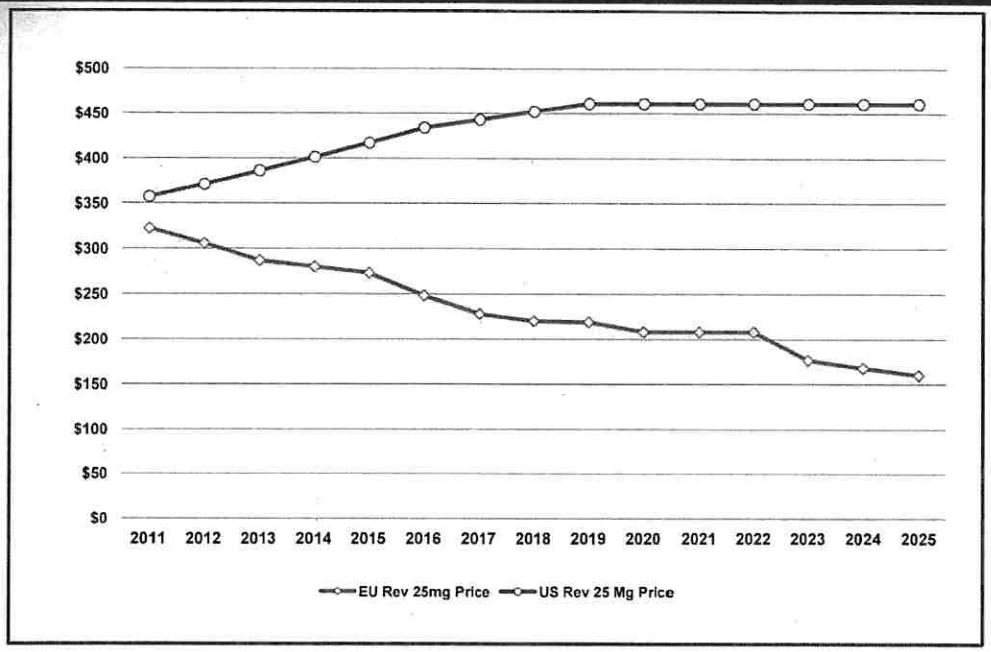
Current long-range REVLIMID price evolution forecast



US modest price increases each year through 2018 independent of volume
EU price decline driven by volume growth from multiple label expansions

*Source: Portfolio Review 2011

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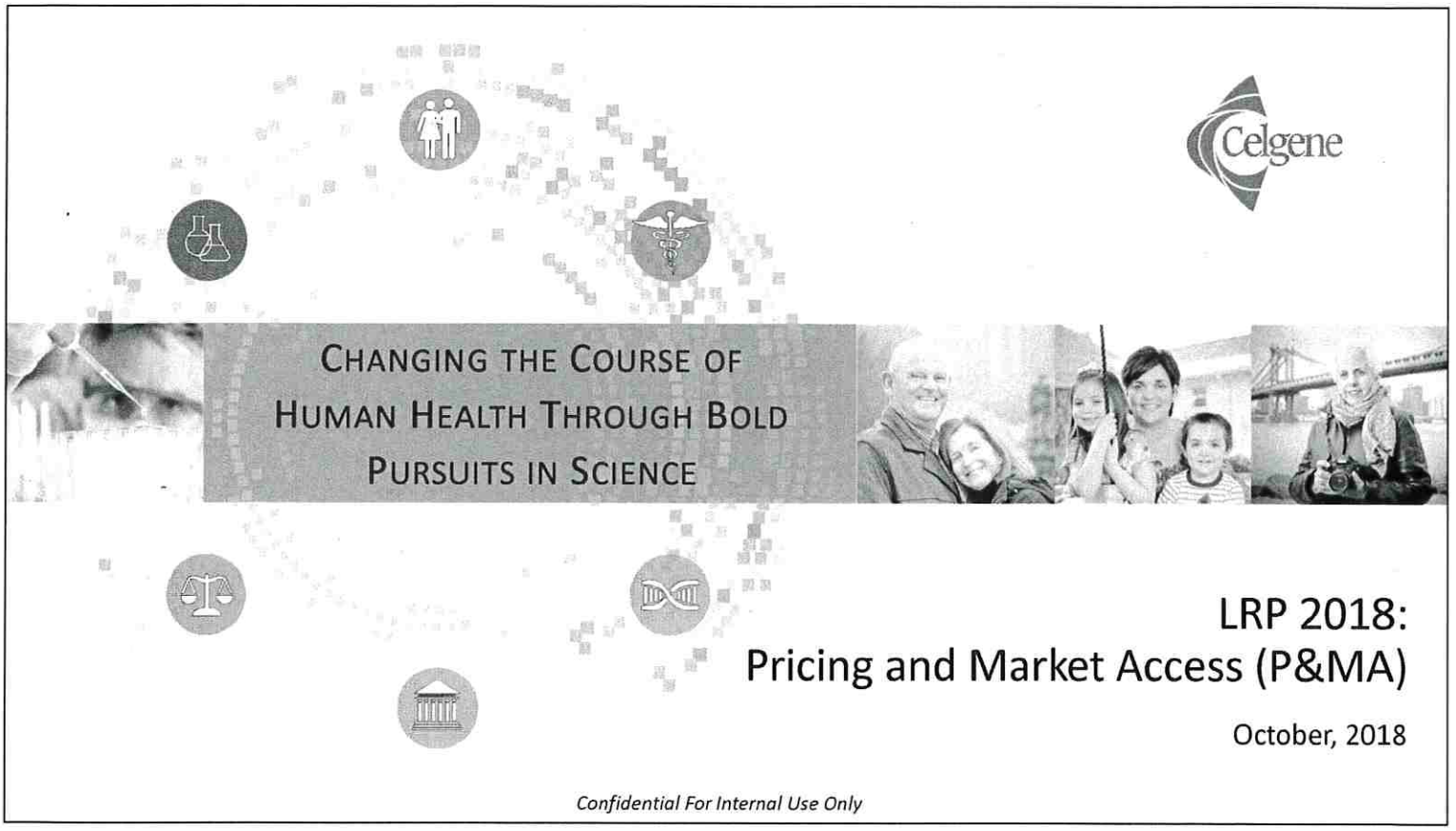

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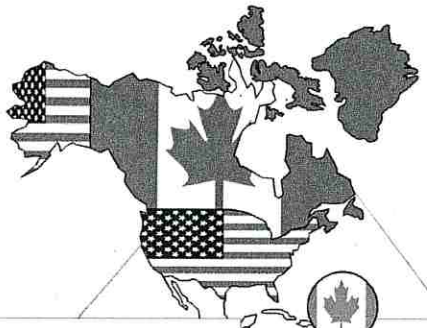
Celgene's key markets have historically been favorable toward pricing and market access for innovative products

RECENT PAST: PMA Environment



Manageable **P&MA environment for Celgene**

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

Unique access dynamics and budget pressures by country

Highly favorable **environment with free-market pricing**

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

Generally favorable coverage in oncology

Generally favorable **access environment, particularly in the private sector**

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

Generally favorable **product pricing informed by rigid methodologies**

Broad reimbursement for approved therapies

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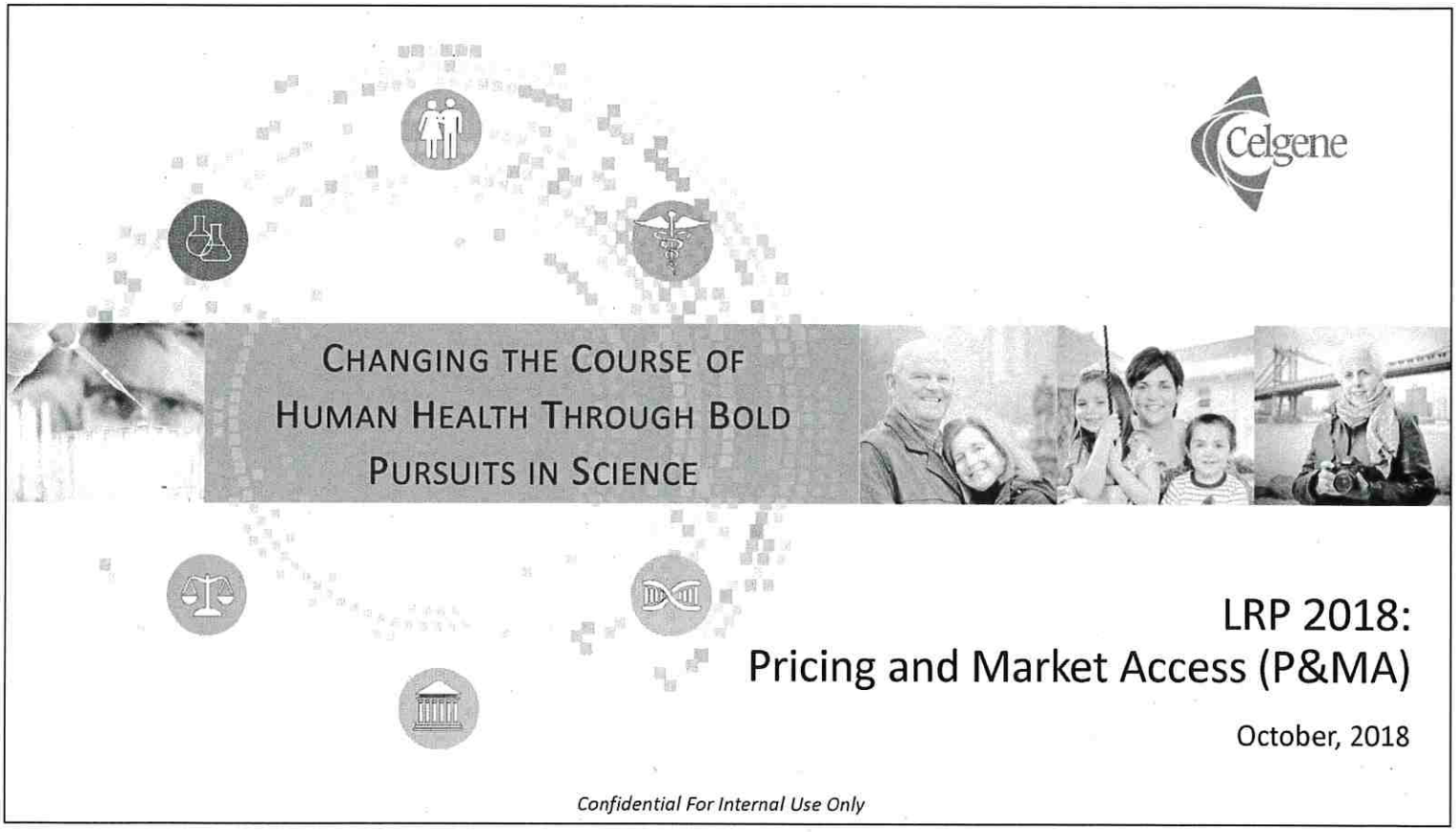

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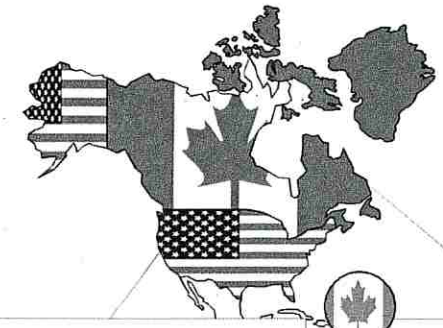
In this environment, payers are continually raising the bar for biopharmaceuticals to demonstrate the value of their products

PRESENT AND FUTURE: P&MA Environment



Growing rigor **in clinical assessments and price negotiations**

Potential for EU-wide clinical HTA assessments

Emergence of cross-country pricing negotiations and transparency

Continued pricing, access, and budget pressure and price referencing

Increased scrutiny **on pricing practices**

Greater expectation to demonstrate "value"

Growing influence of HTA-like frameworks (i.e. ICER)

Growing patient cost-sharing and affordability concerns

Continued reform **to control healthcare costs**

U.S. may be removed from price comparison country list

Biopharma required to report all confidential rebates, discounts, etc.

Potential for parallel regulatory and HTA reviews, possibly improving time to access

Focus on reducing **overall healthcare spend due to ageing population**

Initiatives to reduce drug spend include more frequent repricing, Price Maintenance Premium reform and HTA implementation

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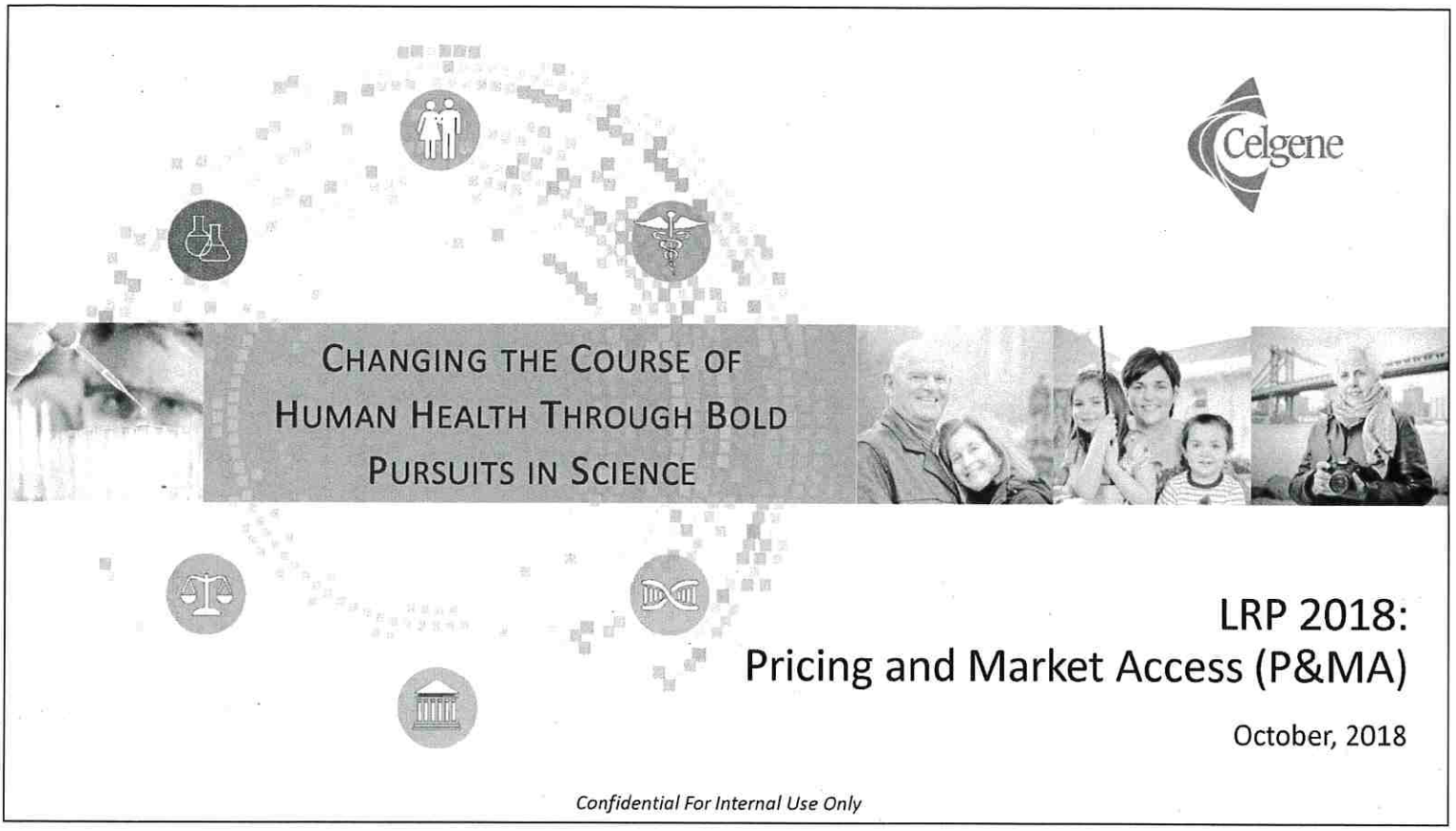

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To achieve P&MA success, we will continue active engagement with payers, policymakers and other key stakeholders

ADVOCACY & ENGAGEMENT

How do we win?

Communicate Value and Shape the External Environment

Key Strategies

- **Collaborate** with policy makers, payers and advocacy organizations to improve **patient access and affordability** (US)
- **Continue to be transparent** in our approach to pricing and **actively communicate the value** of Celgene innovation to patients, the healthcare system, and society
- **Protect** free-market competition-based **pricing** for Medicare and commercial insurance (US)
- **Engage** in policy advocacy discussions around **cross-border negotiations** and **price transparency*** (ex-US)
- **Partner with healthcare systems and payers** on unmet needs, system priorities and budget sustainability
- **Challenge perception** that innovative medicines pose a threat to **sustainability** of health systems
- **Shape health technology assessment** globally, including value assessment entities in U.S. (e.g., ICER)
- **Support** policies that accelerate the uptake of **value-based agreements** and **innovative** payment and access **models**

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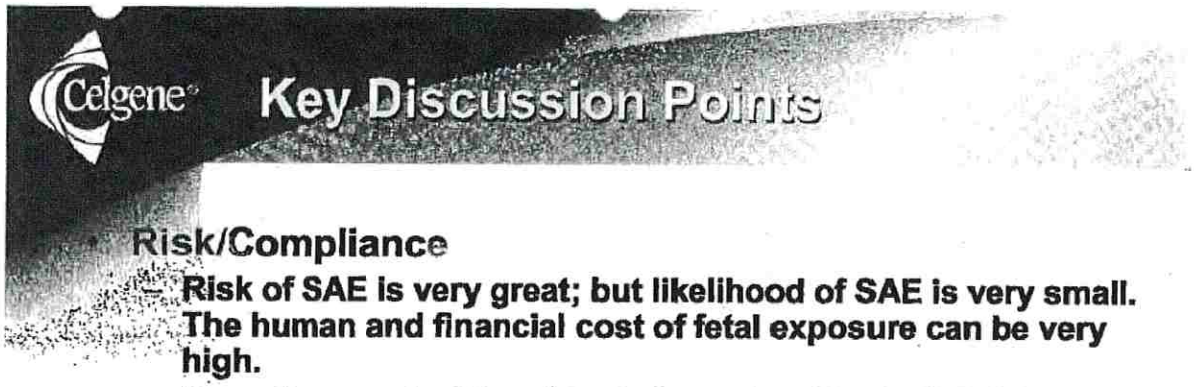
* Engagement as part of EFPIA's European Markets Committee and EFPIA Pricing & Reimbursement Working Group


Celgene
Key Discussion Points
Risk/Compliance
– Risk of SAE is very great; but likelihood of SAE is very small. The human and financial cost of fetal exposure can be very high.
– Compliance: significant deviation rate with retail distribution.
Prevention of generic encroachment
– Key assumption is that generic would be held to same standards as Thalomid, including all points in a RiskMAP.
– It would be a hurdle for generic companies if specialty pharmacy is included in RiskMAP and PI and there is a requirement for counseling by specialty pharmacy
– It is more difficult for generic companies to access Thalomid to conduct bioequivalence testing through specialty pharmacy

Multiple Myeloma Strategy Day

Pre-read Summary

February 14, 2014

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IP/Exclusivity Assumptions

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

*Up to 5 year PTE (Patent Term Extension)

** Pending inclusion of Pom/dex combination in label

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

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

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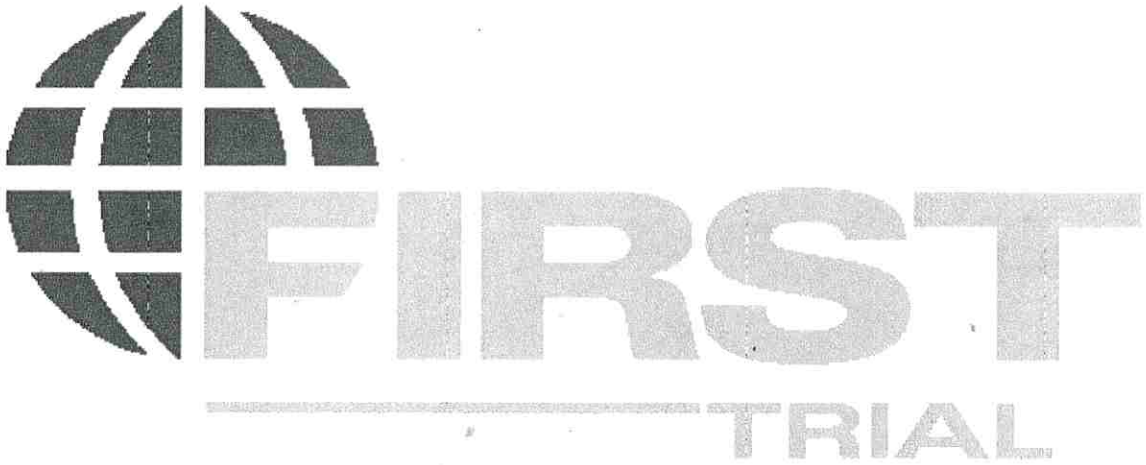

Frontline **I**nvestigation of **R**evlimid vs. **S**tandard **T**halidomide

Strategic Rationale

April 2009

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Document Purpose

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

Background

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

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

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

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

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

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

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

Description of the FIRST TRIAL

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

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

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Strategic Considerations

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

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

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

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

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

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

Registration Opportunity

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

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

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

Market Access

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

Current Clinical Profile

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

Phase III Newly Diagnosed Multiple Myeloma Clinical Trials

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

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

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The FIRST trial will:

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

Key Opinion Leaders / Institutions

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

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

Financial Opportunity

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

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

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

Summary

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

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

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Celgene
US Rev/Pom Proposed Value Based Pricing Strategy
November 7, 2016
1
Confidential - For Celgene Internal Use Only

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Revlimid Proposed Pricing Based On 3 Year Window of Innovation

	2017					2018					2019				
	1Q	2Q	3Q	4Q	Total	1Q	2Q	3Q	4Q	Total	1Q	2Q	3Q	4Q	Total
Planned	3.00%	0.00%	3.00%	0.00%	6.09%	3.00%	0.00%	3.00%	0.00%	6.09%	3.00%	0.00%	3.00%	0.00%	6.09%
Recommended	8.00%	0.00%	1.75%	0.00%	9.89%	0.00%	3.00%	0.00%	6.80%	10.00%	0.00%	4.00%	0.00%	5.50%	9.72%
Incremental Net Sales	$ 52	$ 56	$ 43	$ 43	$ 194	$ 7	$ 51	$ 8	$ 116	$ 182	$ 65	$ 139	$ 91	$ 195	$ 490

1Q2017 POLLUX Dara + Rd vs Rd L2

1Q2017 Rev SCT-M

2Q2018 SWOG0777 RVd vs Rd TNE

4Q2018 ELOQUENT-1 RVd vs Rd TNE

4Q2018 RELEVANCE RD + ritux. Vs ritux + chemo

4Q2018 AUGMENT RD + ritux. Vs ritux + placebo

2Q2019 TOURMALINE-2 Ixa + Rd TNE

4Q2019 ROBUST RD + R-CHOP21

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From: Wim Souverijns
Sent: Friday, April 27, 2018 3:30 AM
To: Richard Bagger; Ian Davies
Cc: Jim Kilgallon; Nadim Ahmed
Subject: Re: Corporate Market Access Committee Meeting - Friday, April 27, 2018 at 8:30am EDT

H Rich,

Won't be able to dial in, but I got a question regarding the US price increase.

Has the US team ran an analysis in how far the price increase for Rev/Pom drives an increase of free goods which would offset the benefit of the price increase? The sooner in the year patients cannot afford Revlimid & we provide free goods, the bigger the negative impact. There should be a point where the benefit of a price increase hits a break-even point with the loss due to an increase in free goods. Would be good to see where that break-even point is.

Thanks a lot!

Cheers
wim

Wim Souverijns, PhD
CVP Global Marketing Hematology & Oncology
Celgene Corporation

Celgene
86 Morris Avenue
Summit 07091
New Jersey

Cel [redacted]
E-mail [redacted]

From: Rich Bagger <[redacted]>
Date: Thursday, April 26, 2018 at 20:54
To: Christine Loggins <[redacted]>, Gerald Masoudi <[redacted]>, Gregory Oakes <[redacted]>, Ian Davies <[redacted]>, Lee Heeson <[redacted]>, Mark Alles <[redacted]>, Martin Gilligan <[redacted]>, Nadim Ahmed <[redacted]>, Peter Kellogg <[redacted]>, Terrie Curran <[redacted]>, Thomas Felton <[redacted]>, Tuomo Patsi <[redacted]>, Wim Souverijns <[redacted]>, "Ji (Jeff) Zheng" <[redacted]>, Greg Chesmore <[redacted]>, Lisa Nelson <[redacted]>
Subject: Corporate Market Access Committee Meeting - Friday, April 27, 2018 at 8:30am EDT

Colleagues:

Attached and pasted below is the agenda for tomorrow's CMAC meeting. The pre-reads for the two agenda items are also attached.

Rich

Corporate Market Access Committee Meeting
April 27, 2018 – 8:30 am (EDT)
Summit - H230
AGENDA

US Dial: 1-866-243-1342
Intl. Dial: 1-224-357-2810
Passcode: 3580769

Time	Agenda Item	Decision or Update
8:30 – 9:00am	U.S. Access and Reimbursement Policy Developments	Update
9:00 – 9:20am	Proposed U.S. Pricing Actions	Decision

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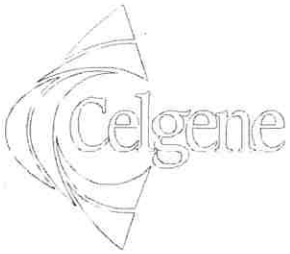

2016 Corporate Affairs and Market Access Goals

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

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

From: Nadim Ahmed
Sent: Tuesday, February 20, 2018 7:56 AM
To: [redacted]
Cc: [redacted]
Subject: Re: janssen request

Dear Both,

Happy to have the discussion.

Our decision should be based on benefit to Celgene and strategic fit. Development capacity or lack thereof for Janssen is their issue to deal with.

Best regards,

Nadim

Sent from my iPhone

On Feb 19, 2018, at 9:07 PM, [redacted] wrote:

> Fully agree with your assessment, [redacted]. Anything we can do to hamper their development would help.
>
> Cheers
> [redacted]
>
> On 19 Feb 2018, at 15:42, [redacted] wrote:
>
> > Hi, as you know, Janssen has requested a discount on Revlimid for their Dara+RVd vs RVd trial in Europe. We in turn are interested in getting free dara for our pipeline trials. I'd like to share my thoughts on this and get your input as well. I would recommend that we do not provide Janssen any discount unless we feel there is a higher strategic need to collaborate from your perspective. Rationale being:
> >
> > - They are the biggest threat to our Revlimid and Pomalyst business (non-imid combos, maintenance)
> > - They are a future threat to our BCMA car-t and bispecific.
> > - Making them spend a lot more on their trials puts financial constraints on their ability to simultaneously fund lots of trials (dara, car-t, bi-specific BCMA) like they did with dara
> > - If we provide a 30% discount (based on WAC), the amount they are requesting exceeds our request in value by ~$100MM+. (I don't have exact quantities or duration so this is an rough estimate.) At full WAC, they would pay ~$190-

200MM (annual) for Revlimid. That would pay for any dara at WAC price for any quantities we would need.

- The MRD data [redacted] would want from the study adds some value but in discussing with [redacted], he heard back from them and the actual data available to have turns out not to be significant enough to offset.
- The other value we could get is the rights to the data but, it will be 2022 by the time they get a label expansion. Plus we don't need to promote DRVd, assuming we will have RVd in our label and will be promoting that. Thus this too is of minimal value.
- Data on Isatuximab from Sanofi is expected end of this year. As they pose less of a threat, and [redacted] believe it is as good if not better than dara, I think we should see if we can partner more with Isa to help them compete against dara.

If you are available tomorrow morning, perhaps we can connect to discuss live. I'll send an outlook.

[redacted]
Celgene Corporation
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Summit, NJ 07901
office:
email: [redacted]