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# EDITED TRANSCRIPT

CELG - Q4 2018 Celgene Corp Earnings Call

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**OVERVIEW:**

Co. reported 4Q18 total net product sales of over \$4b and adjusted diluted EPS of \$2.39. Expects 2020 revenue to be \$19-20b. and adjusted diluted EPS to be greater than \$12.50. And expects 2019 total revenue to be \$17.0-17.2b and adjusted diluted EPS to be \$10.60-10.80.



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### CORPORATE PARTICIPANTS

**David V. Elkins** *Celgene Corporation - Executive VP & CFO*

**Jay T. Backstrom** *Celgene Corporation - Chief Medical Officer*

**Jonathan Biller** *Celgene Corporation - Executive VP & General Counsel*

**Mark J. Alles** *Celgene Corporation - Chairman & CEO*

**Nadim Ahmed** *Celgene Corporation - President of Global Hematology & Oncology*

**Nina Goworek** *Celgene Corporation - Executive Director of IR*

**S. J. Rupert Vessey** *Celgene Corporation - President of Research & Early Development*

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### PRESENTATION

#### Operator

Good morning, and welcome to the Celgene Investor and Analyst Conference Call. I would like to remind you this call is being recorded.

I would now like to turn the call over to Nina Goworek, Executive Director of Investor Relations at Celgene.

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**Nina Goworek** - *Celgene Corporation - Executive Director of IR*

Thank you, Chelsea. Good morning, and welcome to our fourth quarter earnings conference call. The press release reporting our financial results, in addition to the presentation for today's webcast, can be accessed by going to the Investor Relations section of the corporate website at [celgene.com](http://celgene.com).



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Joining me on today's call are Mark Alles, our Chairman and Chief Executive Officer; David Elkins, our Chief Financial Officer; Nadim Ahmed, Global Head of our Hematology and Oncology franchise; Terrie Curran, Global Head of our Inflammation and Immunology franchise; and Dr. Jay Backstrom, our Chief Medical Officer. Also available for the Q&A portion of the call are Dr. Rupert Vessey, Global Head of our Research and Early Development Group; and Jonathan Biller, our General Counsel.

As a reminder, during today's call, we will be making forward-looking statements regarding our financial outlook in addition to regulatory and product development plan. These statements are subject to risks and uncertainties that may cause actual results to differ from those forecasted. A description of these risks can be found on our most recent 10-Q on file with the SEC. You will see on Slides 3 and 4 of today's presentation our legal disclosures. These statements speak only as of today's date, and we undertake no duty to update or revise them.

Reconciliation of the adjusted financial measures to the most comparable GAAP measures are available as part of the earnings release.

I would now like to turn the call over to Mark.

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### **Mark J. Alles** - *Celgene Corporation - Chairman & CEO*

Thank you, Nina, and thanks, everyone, for joining us this morning. We appreciate the opportunity to review the results from our very good fourth quarter and full year 2018 and the significant progress made advancing our early-, mid- and late-stage pipeline. Across our product portfolio and around the world, our operating performance was excellent, exceeding both top line and bottom line guidance. Compelling value propositions for patients, plus outstanding commercial execution, drove strong year-over-year growth for each of our flagship products, 4 of which exceeded \$1 billion in sales last year.

As we communicated earlier this month, this operating momentum supports our 2019 financial guidance of total revenue of \$17 billion to \$17.2 billion and adjusted diluted earnings per share of \$10.60 to \$10.80. We are also reaffirming our 2020 outlook of \$19 billion to \$20 billion revenue and greater than \$12.50 for adjusted diluted earnings per share. David, Terrie and Nadim will discuss our financial results, commercial performance and strategic progress later during the call.

Importantly, our multiyear investment to optimize the potential of our existing products and accelerate the development of several new medicines is delivering. In 2018 alone, we achieved 11 positive Phase III clinical trials spanning hematology, oncology, immunology and new products. At the end of 2018, our industry-leading blood cancer portfolio was featured at the American Society of Hematology meeting, introducing and highlighting additional data and compounds across multiple disease areas and technology platforms. Our 5 near-term launches remain on track, with U.S. approvals expected by the end of 2020. Dr. Jay Backstrom will provide a detailed update on ozanimod, fedratinib, luspatercept, liso-cel and bb2121 shortly.

Our next wave of innovation is well underway as Dr. Rupert Vessey's research and early development team continue to advance new programs and novel mechanisms directed at cancer and inflammatory diseases. In 2018, 7 new INDs were filed for innovative medicines discovered internally or in collaboration with one of our many partners.

For more than 15 years, our mission to become a preeminent company by discovering, developing and delivering the most innovative therapy for patients has driven us to constantly explore scientific frontiers and opportunities for sustainable long-term growth.

This is the lens by which we evaluate strategic alternatives and how we became very excited by the proposed combination of Celgene and Bristol-Myers Squibb. Fundamentally, we are 2 innovation-focused companies coming together to build an even stronger organization with virtually the same mission and purpose. As has been discussed, the strategic rationale for this transaction is clear and compelling: the combination of our highly complementary portfolios creates a world leader in the important specialty areas of oncology and inflammation and immunology. We believe the combined company will have even greater financial strength to further accelerate our research and development engine, continue to invest in external partnerships and to attract the most talented people in our industry.



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For Celgene shareholders, this cash and stock transaction recognizes and unlocks significant value by delivering immediate and substantial cash value and providing meaningful participation in the combined company's future growth. We are working together with our colleagues at Bristol-Myers Squibb to complete this transaction, which is expected in the third quarter of 2019.

We believe that Celgene's 2018 operational performance and significant clinical and regulatory progress sets us up very well to deliver on our ambitious 2019 goals. With 5 near-term product launches and many promising pipeline assets advancing, we are very optimistic about the potential for long-term growth as part of the new Bristol-Myers Squibb.

Thanks again for joining us today, and I'll now turn the call over to our Chief Financial Officer, David Elkins.

### **David V. Elkins** - Celgene Corporation - Executive VP & CFO

Thank you, Mark, and good morning, everyone.

As Mark mentioned, we are pleased to have exceeded our full year top line and bottom line guidance. 2018 operating results highlight the strength of Celgene's business across the portfolio. Revenues grew 16%, 18% year-over-year in the fourth quarter and full year, while adjusted diluted earnings per share also grew double digits year-over-year at 20% and 19% for the fourth quarter and full year, respectively.

We also continue to make significant investments in research and development, in particular on our late-stage pipeline, to ensure we are advancing our regulatory submissions and driving towards approvals. We expect double-digit growth on our top and bottom line to continue through 2019, and it's reflected in our guidance.

Now turning to Slide 10. Total net product sales grew 16% year-over-year, achieving over \$4 billion for the first time in Celgene's history, which is almost entirely driven by volume. Growth in our hematology and oncology franchise came primarily from volume gains across multiple brands and geographies. OTEZLA had a very strong quarter, mainly driven by volume increases as we continue to expand access and utilization and also benefited from additional stocking in the quarter. Nadim and Terrie will elaborate further on these drivers.

Turning to our full year 2018 top line performance. Net product sales grew about 18% to approximately \$15.3 billion, exceeding our guidance of approximately \$15.2 billion. Consistent with Q4, our full year 2018 net product sales was driven primarily by volume as price is only about 3% of our full year growth.

On Slide 12, adjusted diluted EPS increased approximately 20% year-over-year and 4% sequentially to \$2.39. The increase was primarily driven by strong top line growth, partially offset by increased expenses relating to the Juno acquisition as well as our investments in our late-stage pipeline. The net impact of these are reflected in the \$0.30 of operating improvement seen on the slide. Other income and expenses was negatively impacted by \$0.12 due to increased interest expense from a higher level of debt primarily related to the financing of the Juno acquisition. Lower share count had a favorable impact of \$0.25 to adjusted diluted EPS growth for the quarter, bringing adjusted diluted EPS to \$2.39.

Full year adjusted diluted earnings per share grew 19% year-over-year to \$8.87. This was driven by higher operating income of \$0.97 and the benefit of \$0.81 from lower share count, partially offset by higher interest expense and a slightly higher effective tax rate. Note, these outstanding results were achieved despite approximately \$0.50 dilution related to Juno post-acquisition costs.

Now turning to the key adjusted P&L line items on Slide 14. You'll see product gross margin was in line with our expectation at 96% for the fourth quarter and 96.4% for the full year. Product gross margin was slightly decreased versus prior year, primarily due to raw material charge incurred in the year.

R&D as a percentage of revenue increased to 23% in the fourth quarter and for the full year. The increase in R&D is primarily driven by the inclusion of Juno expenses. Excluding these expenses, R&D as a percentage of revenue decreased about 60 basis points versus prior year.



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SG&A expense was \$762 million for the fourth quarter and \$2.7 billion for the full year. SG&A expenses were primarily driven by Juno and prelaunch marketing expenses for our late-stage pipeline. The net result was about 70 basis point year-over-year decrease in our operating margin to 54.4% in the fourth quarter. This resulted in a 55.5% operating margin for the full year. Excluding the Juno-related expenses, operating margin improved 40 basis points for the full year, and we closed out 2018 with a slightly higher effective tax rate at 16.5%, which is mainly driven by U.S. Tax Reform.

Now on to capital allocation. In 2018, we continued our disciplined approach to capital allocation. Overall, we generate significant cash flow of about \$5.2 billion. We also invested 6 -- \$9.7 billion in the strategic acquisition of Juno and IMPACT and returned \$6.1 billion to our shareholders through stock repurchases. We ended the year with a strong cash balance of approximately \$6 billion in cash and marketable securities.

Now turning to our 2019 guidance. 2019 reflects continued strong double-digit top line and bottom line growth. Summarized, we expect total revenue to be \$17 billion to \$17.2 billion, growing at about 12% year-over-year using the midpoint of our guidance. We expect adjusted operating margin improvement while maintaining a high-level investment in R&D. Our adjusted effective tax rate is expected to be about 17%. As a result, our adjusted diluted EPS is expected to be \$10.60 and \$10.80, reflecting strong 21% growth year-over-year when using the midpoint.

Lastly, we expect to maintain our share count where we landed (sic) [ended] the fourth quarter with about 715 million shares.

Finally, as we've discussed and experienced in the past, we want to remind you that we expect the typical seasonality of our business in Q1 as well as the impact of the doughnut hole payments, which is exacerbated by the manufacturing's responsibility increasing from 50% to 70%. We expect Q1 as a percentage of full year revenue to be broadly in line with Q1 2018. As a result, you should expect Q1 adjusted diluted EPS to be broadly in line with Q4.

Thank you, and I'll now turn the call over to Nadim.

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### **Nadim Ahmed** - Celgene Corporation - President of Global Hematology & Oncology

Thank you, David, and good morning, everyone. The hematology and oncology franchise had another outstanding quarter, with net sales of approximately \$3.6 billion and 15% year-over-year growth. For the full year 2018, net sales revenue was approximately \$13.7 billion with 17% year-over-year growth. For REVLIMID, we met our full year 2018 guidance with approximately \$9.7 billion in revenue and 18% year-over-year growth. For POMALYST/IMNOVID, we also met our full year guidance of approximately \$2 billion in revenue and 26% year-over-year growth. REVLIMID and POMALYST/IMNOVID continue to drive our overall growth, with volume gains across brands and geographies.

In 2019, we also anticipate additional label expansions that will continue to drive near-term growth for our key in-line brands. For example, we have now submitted the sNDA and MAA for the chemotherapy-free R2 regimen in relapsed/refractory indolent lymphoma based on the positive AUGMENT trial. And we expect FDA approval in the second half of 2019.

Finally, we continue to progress our portfolio of novel assets, with ASH 2018 showcasing the significant advancement of our pipeline across a wide range of hematologic diseases. The data for luspatercept, a first-in-class erythroid maturation agent in MDS and beta-thalassemia, were a key highlight of ASH, with luspatercept demonstrating a significant impact on disease-related anemia across 2 distinct diseases.

There were also numerous oral presentations that demonstrated our progress with cellular therapy. We saw the first preliminary liso-cel data in CLL patients, demonstrating an approximately 45% complete response rate in patients with heavily pretreated relapsed/refractory disease.

In terms of our broad BCMA campaign, we completed recruitment in our pivotal KarMMa study for bb2121 and also saw encouraging data for bb21217 and JCARH125 in relapsed/refractory myeloma. We have also now submitted the NDA for fedratinib in myelofibrosis in the U.S. and expect approval by the end of 2019.

From a commercial perspective, our teams are now in full launch preparation mode for our key near-term launches.



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REVLIMID continued to deliver strong quarterly results, with 16% year-over-year growth. In the U.S., REVLIMID grew 17% year-over-year for the quarter as market share and treatment duration continue to increase. We continue to see strong underlying demand growth, with solid performance in the non-stem cell transplant and post-stem cell transplant maintenance settings. Outside of the U.S., REVLIMID net sales grew 15% year-over-year with 24% volume growth. This growth is a result of robust underlying demand in ex U.S. markets, driven by REVLIMID share in both frontline non-stem cell transplant and post-stem cell transplant patients.

Duration also continues to increase with the impact of REVLIMID-based triplet regimens. We also expect continued growth for REVLIMID in newly diagnosed multiple myeloma, with the addition of new triplet combination regimens, including REVLIMID, daratumumab, dexamethasone in the U.S. and also RVD outside of the U.S. based on expected European regulatory approval later this year. The expected FDA approval later this year for R2 in lymphoma will also provide a new growth driver for the brand.

Finally, we're awaiting the results of the REVLIMID ROBUST trial in first-line diffuse large B-cell lymphoma. This is an event-driven trial, and we continue to monitor the status of patients.

POMALYST/IMNOVID net sales for the quarter increased 28% year-over-year. In the U.S., POMALYST fourth quarter net sales grew 39% year-over-year, driven by the continued adoption of the triplet regimen of POMALYST, daratumumab and dexamethasone for relapsed/refractory myeloma. Outside of the U.S., POMALYST/IMNOVID revenue grew 9% year-over-year, with volume increasing by 17% despite competition from new entrants, which includes REVLIMID-based triplet regimen.

Similar to REVLIMID, we expect to see additional POMALYST share and duration gains through the use of newer triplet regimens. We are anticipating approval of the PVD triplet combination in relapsed/refractory myeloma later this year in Europe and Japan. PVD will provide another important triplet option for patients with relapsed/refractory myeloma.

ABRAXANE net sales for the fourth quarter increased by 7% year-over-year, and the brand surpassed the \$1 billion mark for the first time. In the U.S., we saw a 15% increase in net sales year-over-year. Outside of the U.S., ABRAXANE decreased slightly due to changes in distributor buying patterns. We look forward to the upcoming ABRAXANE data readout for the Phase III APACT adjuvant pancreatic cancer trial. This is an event-driven trial, and we continue to monitor the status of patients.

The upcoming ABRAXANE I/O combination approvals represent another near-term growth driver for the brand. The first ABRAXANE I/O combination regimen was approved in October 2018 in frontline metastatic squamous non-small cell lung cancer. And the PDUFA dates for the ABRAXANE I/O combination in metastatic triple-negative breast cancer and frontline metastatic non-squamous non-small cell lung cancer are set for March and September, respectively.

In summary, the hematology and oncology franchise had another robust quarter to finish 2018. Underlying demand is strong for our key in-line brands. We have multiple label expansions in 2019 to drive near-term growth, and our commercial teams are in full preparation mode for the launches of our key near-term novel assets.

Thank you, and I will now turn the call over to Terrie Curran.

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### **Terrie Curran** - Celgene Corporation - President of Global Inflammation & Immunology

Thank you, Nadim, and good morning, everyone. The inflammation and immunology franchise delivered a very strong fourth quarter and demonstrated outstanding growth in 2018. We exceeded our original revenue target and continue to drive strong demand across geographies.

A key growth catalyst has been the successful execution of our strategy to expand market access for appropriate post-topical prebiologic patients. We have secured biologic step pre-access for more than 85% of commercial patients in the U.S. and in key international markets, such as France, Germany and Japan. This expanded access footprint has increased the number of patients eligible for OTEZLA coverage and continues to be an important driver of worldwide growth.



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There is a robust life cycle development plan in place for OTEZLA. And in 2018, we advanced multiple programs that have the potential to add substantial value in the years ahead. In the second half of the year, we submitted the regulatory filing for the treatment of oral ulcers associated with Behçet's disease in both the U.S. and Japan and announced positive Phase III data in scalp psoriasis. We also initiated several Phase III and Phase IV trials in new and complementary patient populations and look forward to continuing to advance those efforts in 2019.

Moving on to our pipeline compounds. In 2018, we made significant progress on the U.S. and EU regulatory filings for ozanimod in relapsing MS and remain on track to submit in March 2019. We believe that ozanimod has the potential to be our best-in-class S1P receptor modulator, and we are currently building out the infrastructure necessary to ensure a world-class launch.

We continue to build the platform for ozanimod in IBD through our Phase III trial in ulcerative colitis, which will complete enrollment in the first half of 2019 and the initiation of a Phase III trial in Crohn's disease. My colleague, Dr. Jay Backstrom, will provide a more detailed update on ozanimod regulatory and clinical development activities later in the call.

In 2018, we also presented positive 52-week Phase II data for RP4046 (sic) [RPC4046] in eosinophilic esophagitis, a disease with high unmet need. We continue to advance our other new and late-stage pipeline assets and expect to complete the enrollment of the Phase II trial CC-220 in SLE in 2019.

Now diving deeper into 2019 OTEZLA performance. Q4 revenue was \$448 million, which represents 21% year-over-year growth. For the full year 2018, year-over-year growth was 26%, and we raised our revenue guidance of \$1.6 billion. These strong results have been driven by our outstanding team that has demonstrated an unwavering commitment to excellence and passion for improving outcomes for the patients we serve. In the almost 5 years since the launch of OTEZLA, we've experienced strong, sustained volume-based growth in our core indications, which is a tremendous accomplishment and a testament to the unmet need that existed for a treatment option like OTEZLA.

Despite increased competitive activity, OTEZLA continues to maintain new-to-brand leadership and healthy market share in the U.S. The newer entrants that have come into this space have primarily taken share away from existing biologic therapies, which we believe further supports our view that OTEZLA has a unique value proposition and is well positioned to deliver future growth.

Outside the U.S., we've also achieved dynamic market leadership in France and continue to have record-breaking success post-launch in Japan. As we look forward to what's to come in 2019, we will continue to maximize the OTEZLA opportunity for a focused strategic execution and the advancement of life cycle development activity.

While we are very pleased with our momentum heading into the year, in Q1, we expect to experience the typical demand softening in the psoriasis market, which, of course, has been factored into our 2019 guidance of approximately \$1.9 billion in sales.

In terms of upcoming regulatory submissions and approvals for OTEZLA, we expect to submit the filing in Behçet's disease to EMA in the first half of 2019 and anticipate approval in the U.S. and Japan in the second half of the year. Excellent progress is also being made on the sNDA for a scalp psoriasis label enhancement, which we plan to submit to the FDA in the second quarter of 2019.

Another important area of focus this year will be to enroll patients in our recently announced Phase III trial for pediatric and mild to moderate plaque psoriasis and Phase IIIb trial for moderate to severe genital psoriasis.

Our combined development activities for OTEZLA represent a potential revenue opportunity of more than \$500 million at peak for the brand. We're excited by the prospect of having a positive impact on the lives of these patients. Throughout these efforts, we remain focused on further expanding the post-topical prebiologic market opportunity for appropriate patients.

I'm extremely proud of what our team has accomplished in 2018 and look forward to another year of growth in 2019.

Thank you, and I'd now like to turn the call over to Dr. Jay Backstrom.



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### **Jay T. Backstrom** - Celgene Corporation - Chief Medical Officer

Thank you, Terrie, and good morning. The clinical and regulatory teams had a strong finish to 2018, and we are well positioned at the start of 2019 to advance our 5 near-term new therapies: fedratinib, ozanimod, luspatercept, liso-cel and bb2121 toward regulatory approval.

I would like to now provide you with an update on these 5 key programs, starting with ozanimod on Slide 25. As Terrie indicated, we continue to advance the ozanimod NDA that will be based on 2 randomized controlled Phase III studies, SUNBEAM and RADIANCE. As a reminder, both studies met their primary endpoint, demonstrating a significant reduction in the annualized relapse rate compared to beta interferon.

With respect to safety, ozanimod was generally well tolerated as reflected in the low incidence of serious adverse events. In addition, less than 5% of patients discontinued treatment due to adverse events. No patient experienced second-degree or higher AV block, and the rate of infection was comparable between treatment groups. Together, the efficacy and safety results support a favorable benefit/risk profile.

With respect to our submission date, Slide 26, we have successfully completed the additional nonclinical and clinical pharmacology study and plan to submit the relapsing multiple sclerosis applications in the U.S. and Europe in March, with an expected U.S. approval in the first half of 2020.

The ozanimod inflammatory bowel diseases program, including the Phase III clinical studies in ulcerative colitis, TRUE NORTH; and in Crohn's disease, YELLOWSTONE, also continues to advance. The enrollment for TRUE NORTH, which includes both an induction and maintenance phase, is nearing completion for enrollment. And we expect the last patient to be randomized by the end of the first half of this year, with top line results, including the maintenance phase, reporting out in mid-2020. The Phase III randomized trials in Crohn's disease are ongoing and actively recruiting.

Turning to fedratinib, our selective JAK2 inhibitor, on Slide 27. As we announced earlier this year, the fedratinib NDA for the myelofibrosis indication, which includes both JAKARTA, the Phase III randomized placebo-controlled study in ruxolitinib-naïve patients; and JAKARTA-2, the single-arm trial in patients who have failed or were intolerant to ruxolitinib, was submitted as planned. And we now look forward to advancing the fedratinib NDA through the regulatory review process with an expected U.S. approval by the end of 2019. We expect to submit the marketing authorization application to the EMA in the first half of this year.

The fedratinib clinical teams continue to execute on the development plan in myelofibrosis, including additional studies in patients that have failed or intolerant to ruxolitinib, FREEDOM and FREEDOM-2; and a Phase I/II combination study with luspatercept planned for later this year.

Luspatercept, on Slide 28, remains on target for U.S. and EU submissions in the first half of 2019 for both the MDS and beta-thalassemia indications with an expected U.S. approval in the first half of 2020. The BEYOND trial, a randomized Phase II study in non-transfusion-dependent beta-thalassemia, is expected to complete recruitment later this year. The COMMANDS study in ESA-naïve lower-risk MDS is open and ongoing. And we expect to have data available later this year from the Phase II myelofibrosis study that will help inform subsequent trials in myelofibrosis.

Now turning to our CAR T programs. Both liso-cel and bb2121 remain on target for expected 2020 approvals. For liso-cel, on Slide 29, we remain on track for submitting the BLA in the second half of 2019 with an expected U.S. approval in mid-2020. As we've previously mentioned, the BLA will include a robust data package containing substantial follow-up on the relapsed/refractory diffuse large B-cell lymphoma cohort, allowing further characterization of the duration of response and will include a safety database that will be approaching 300 treated patients by the time of our submission, a safety database that will be 2x to 3x that included in the initial submissions for the 2 approved CD19-directed CAR Ts.

In addition, we are advancing liso-cel to earlier lines of treatment, with the second-line studies TRANSFORM and PILOT in diffuse large B-cell lymphoma patients who are transplant eligible or non-transplant eligible, respectively.

As Nadim mentioned, the data presented at ASH from the Phase I TRANSCEND CLL study in patients with relapsed/refractory chronic lymphocytic leukemia who failed or were ineligible to receive a BTK inhibitor are very promising. And we are initiating a pivotal Phase II trial in this high unmet need population.



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Finally, for bb2121 on Slide 30, the enrollment for the pivotal KarMMa study in relapsed/refractory myeloma was completed in November. And we are well positioned pending follow-up to submit the BLA for this first-in-class BCMA-directed CAR T, leading to an expected U.S. approval in the second half of 2020. The clinical teams continue to implement the development plan designed to evaluate bb2121 in earlier lines of therapy, including KarMMa 3, a randomized Phase III study in relapsed/refractory multiple myeloma in patients who received at least 2 prior lines of therapy; and KarMMa 2, a Phase II study, which includes a high-risk cohort who have done one prior line of treatment. A Phase II study in newly diagnosed myeloma is under development.

In closing, our teams have made excellent progress in advancing our 5 near-term programs. With the NDA submitted for fedratinib, the ozanimod NDA planned for March, the BLA for luspatercept to follow and the pivotal studies for both CAR T programs fully accrued, we are well positioned to remain on track for expected U.S. approvals for all 5 of these innovative products by the end of 2020.

I will now turn the call back over to Mark.

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**Mark J. Alles** - *Celgene Corporation - Chairman & CEO*

Thank you, Jay, and thanks, David. Thanks, Terrie and Nadim. I also want to thank our colleagues around the world and across every function for another outstanding year. Really well done. Thanks so much.

2018 was an important year for Celgene, highlighted by strong operating performance and continued investment in the pipeline and people critical for our future. We are excited to accelerate and expand these opportunities by combining with Bristol-Myers Squibb later this year.

Before we open the call for questions, please note that while we look forward to answering any questions you may have about Celgene, we will refer certain questions pertaining to the acquisition of Celgene by Bristol-Myers Squibb to BMS.

Thank you. Chelsea, please open the call for questions.

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## QUESTIONS AND ANSWERS

### Operator

(Operator Instructions) And our first question will come from the line of Geoff Meacham with Barclays.

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**Geoffrey Christopher Meacham** - *Barclays Bank PLC, Research Division - MD & Senior Research Analyst*

Just had a few. On luspatercept, you guys had initial top line data in June of last year. So are there studies or analyses that you have yet to do? It just seems like it's a long time from data to filing when it was a pretty clean result. And the second one is on oral azacitidine. There hasn't been much discussion of this asset in the Bristol deal. What, if any, valuation consideration was given, is my question. You guys have had top line data, I think, on 2 studies, so I wasn't sure if little mention of this meant lower probability of success or how to interpret that.

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**Jay T. Backstrom** - *Celgene Corporation - Chief Medical Officer*

This is Jay. Let me start with luspatercept. This is a BLA that's going to include both MDS and beta-thalassemia. So we've been working on that, as you know, since we had the top line results. There are no additional analyses or anything else pending. We're really pushing on that. We're on track for what we declared earlier this year, which is we'll have this in by this half. And for oral azacitidine, 2 Phase III studies, those trials are still ongoing. The second trial, which is in maintenance for patients that have successfully got to a CR in AML, that's an event-driven study, and we're waiting for those results. Event rates sometimes slow down, that's happening here, so we're waiting to see what happens with that. And the low-risk MDS trial, that's a time-dependent one, and they should read out at or near the same time probably later this year.



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**Operator**

Our next question comes from the line of Brian Abrahams with RBC Capital Markets.

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**Brian Corey Abrahams** - *RBC Capital Markets, LLC, Research Division - Senior Analyst*

I was wondering if you could make any comments on ozanimod in terms of what your learnings have been from the additional nonclinical and clinical work that you've done there, how your interactions with the agency have been, whether you expect any delays in the -- either the filing or the review based on the recent shutdown.

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**Jay T. Backstrom** - *Celgene Corporation - Chief Medical Officer*

Yes. This is Jay. So from the learnings, it's really interesting, we were further characterizing one of the active metabolites, but our prediction going into that is given the selectivity, specificity, et cetera, that it would look similar, and in fact, that's exactly what we've seen. So that's really progressed well. We're on track, as I mentioned, to submit in March. We've had no delays to date with the issue that we had previously with the government shutdown. It's premature to say what will happen when folks say they won't shut down. But right now, it's full steam ahead, so we're really -- with good engagement with the FDA, we're looking forward to getting that to them for their review.

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**Operator**

And our next question comes from the line of Michael Yee with Jefferies.

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**Michael Jonathan Yee** - *Jefferies LLC, Research Division - Equity Analyst*

Question for Mark. The market seems to be a little bit nervous about the transaction. I guess I'm speaking from high level. Maybe you could just give some context to the market about how this all came about with Bristol, and more specifically, what gives you or what can you say to shareholders to give them comfort that this will complete and that nothing else would happen.

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**Mark J. Alles** - *Celgene Corporation - Chairman & CEO*

Michael, thank you for the question. We're extremely excited about this transaction. As we've said from the beginning and as my colleague, Giovanni Caforio, has said, we think this is the right transaction at exactly the right time. Both companies -- BMS reported late last week, we reported today -- have incredibly strong operating momentum. In fact, we come off of the best quarters separately and then collectively using pro forma in the history of both companies. For Celgene shareholders, it's quite clear how this unlocks and recognizes a lot of the value that the market has not assigned to us more recently. The notion that we would create a new company that would have very dramatic leadership in the high specialty areas of oncology, inflammation and immunology is, again, quite clear. I think of the separate companies, immunology, inflammation franchise is coming together, where together they become a top 5 franchise with lots of opportunity, including, as BMS has talked about more recently, the prospects for TYK2, which in Phase II looks fantastic and, of course, is moving into later-stage development. I think other aspects of the deal that are probably underappreciated is the scientific prowess of both companies and how, when they come together, we enhance our opportunity to accelerate research and development unlike, we think, either company alone could do. Obviously, that's the mother's milk for all of us. We've got to have innovation, new medicines coming through. And I think the combined scientific prowess is underestimated. I think on the cultural side, there's also an underestimation about how these companies come together in such a complementary way, where the mission, the purpose is quite unique, but at the same time, it overlaps beautifully. So I think this is a deal that investors weren't expecting. I think investors will get very comfortable with it over time, but we're really excited about it. We're moving along the continuum to close this transaction sooner rather than later. But of course, we all know that we've got to go through the regulatory steps, shareholder approval, et cetera. But I'm quite excited about it, Mike, and I appreciate the chance to talk about it today.



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### Operator

Our next question comes from the line of Phil Nadeau with Cowen and Company.

### Philip M. Nadeau - Cowen and Company, LLC, Research Division - MD and Senior Research Analyst

First, just on the Dr. Reddy's lawsuit. Could you give us an update on the time lines, both for the IPR and the lawsuit? There seems in particular to be some controversy about exactly when discovery is going to be done in the lawsuit.

### Jonathan Biller - Celgene Corporation - Executive VP & General Counsel

Sure, Phil. This is Jonathan Biller. The time line, it hasn't changed from really the way that we've been discussing it. Fact discovery has not closed yet. The expert phase will close sometime this quarter. Most recently, in that case as well as the other cases, you saw publicly that there was -- the judge moved this to mediation. So all of the cases are now moving to a mediation phase. We're in the process of scheduling that. There's been nothing scheduled on that front. And with respect to the IPRs, sometime later in February, and then in March, there's 3 IPRs from Dr. Reddy's. Those are initiation decisions, so what will be decided there, the TTAB will decide whether or not to initiate those cases. If they chose to do so, it would be about a year before we have a decision. And then on the Lotus/Alvogen, there are some additional IPR initiation decisions that will be made in March. And again, those are just on our method of treatment patents, MDS in the case of Dr. Reddy's and multiple myeloma in the case of Lotus. And so they're not -- they do not address all of our patents, in particular our polymorph patents. So even as those things play out, they're not dispositive to the case.

### Philip M. Nadeau - Cowen and Company, LLC, Research Division - MD and Senior Research Analyst

That's helpful. And then my follow-up is actually on liso-cel. Can you give us an update on the status of the manufacturing? In particular, is the commercial process ready? And do you need to do any manufacturing work prior to submission?

### Nadim Ahmed - Celgene Corporation - President of Global Hematology & Oncology

Yes. I think everything is on track from a manufacturing process, actually across all of our CAR T programs, both from the clinical trial perspective and the commercial perspective. So as I said earlier, both our commercial teams and our manufacturing teams are just getting ready for approval and launch now. So we feel very good about where we are.

### Operator

Our next question comes from the line of Umer Raffat with Evercore ISI.

### Umer Raffat - Evercore ISI Institutional Equities, Research Division - Senior MD & Senior Analyst of Equity Research

Nadim, perhaps the first one for you or perhaps Terrie. Can you remind us what percentage of REVLIMID sales are in first-line myeloma and then also in transplant maintenance? And I'm looking to understand that as a percentage of total REVLIMID protected by the 2022 and the 2024 exclusivities that are in place. And then, Mark, question for you. Should The Street expect additional REVLIMID settlements prior to the close of transaction? I know it's a hard question to answer, but would be curious about your thoughts and priority.



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### **Nadim Ahmed** - Celgene Corporation - President of Global Hematology & Oncology

Umer, thanks for the question. Nadim first. So we don't necessarily get specifically granular. But what I will say is that the majority of our shares -- of our share and use for REVLIMID, especially in the U.S., is in the frontline setting, both non-transplant and transplant settings. And that's where we're seeing continued growth in Europe also. So most of our use is coming from the frontline setting.

### **Mark J. Alles** - Celgene Corporation - Chairman & CEO

Umer, thanks for the question about IP. And we already have settled, so I think our view about settlements is under the right conditions. We've already demonstrated a willingness to settle. That's the Natco settlement that's in place. But it remains to be seen what those circumstances would be with additional filers. We're very confident in our patent estate. We've been at this for a very long time, and we continue to defend it in a very confident and straightforward way. As we've said many times and even presented more recently at ASH, as you'll recall, we think it is an unlikely scenario that there would be an at-launch risk prior to the time line that we've outlined, that is out to 2022. But we're engaged. We're working through the process. We stay confident in our position. And without doubt, under the right circumstances, we would be willing to engage in settlements.

### **Operator**

Our next question comes from the line of Salim Syed with Mizuho.

### **Salim Qader Syed** - Mizuho Securities USA LLC, Research Division - MD, Senior Biotechnology Analyst of Equity Research & Head of Biotechnology Research

Now just one on CAR T, just kind of long-term thinking here. So there's some discussion in the marketplace that an allo CAR T could be actually more efficacious than an auto because you are taking the cells from a healthy donor. So the debate here is not just about convenience but about efficacy. And I was wondering what Celgene has done to prepare for that, if you agree with that statement and what the company has done to prepare for that. And so when you do hand the company over to Bristol, what do they exactly get on the allo front?

### **S. J. Rupert Vessey** - Celgene Corporation - President of Research & Early Development

Salim, it's Rupert Vessey here. So allo CAR T is still a theoretical prospect, and there are a number of hurdles that need to be overcome in order to achieve that objective that would include extensive gene editing strategies so that both the CAR T itself is not detrimental to the patient and the patient's immune system does not attack the CAR T. So those are problems that need to be solved from a scientific point of view. There are also a number of manufacturing issues that need to be solved as well. On the auto CAR T side, obviously, we know that works very well, and we know that there are many manufacturing improvements that can be put in place over time that we will see that I think will close the gap between these different approaches. That doesn't mean, though, that we are not really well aware of the allo approach, and we have an allo strategy that we're putting in place, including some agreements that we already have that are in the public domain. So we're on top of that as well as it emerges.

### **Operator**

Our next question comes from the line of Ying Huang with Bank of America Merrill Lynch.

### **Ying Huang** - BofA Merrill Lynch, Research Division - Director in Equity Research

Just a couple of quick ones from me. First of all, can you talk about the ex U.S. versus the U.S. pricing contribution to the growth in the year of 2018? And what's your outlook for pricing overall for net product sales in 2019? And then secondly, on the KarMMa 3 trial, the protocol calls for a security against the triplet. Can you tell us whether it's a request from regulators or it's probably coming from your commercial consideration?



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**Jay T. Backstrom** - *Celgene Corporation - Chief Medical Officer*

Yes. This is Jay. I'll take the question on KarMMa 3. No, that design was a combination of what we thought would be a very good comparator to show the benefit of CAR T moving forward with the triplet. We certainly discussed it with the agencies, so there's agreement and consistency with that. But that was the design as we thought about moving forward.

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**David V. Elkins** - *Celgene Corporation - Executive VP & CFO*

Yes. Now on the question around price, as we talked about for the full year, price is around 3%. And that's the net impact of price increases in the U.S. being offset by price declines in rest of world.

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**Operator**

Our next question comes from the line of Ronny Gal with Bernstein.

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**Aaron Gal** - *Sanford C. Bernstein & Co., LLC., Research Division - Senior Research Analyst*

Two of them if you don't mind. First on luspatercept, if you can give us a bit of your feeling about what are the right benchmarks to think about when we think about luspatercept pricing given the safety. Is this more echogen or given durability of efficacy, more like the first-line drugs we are seeing in MDS today, or another benchmark? And the second question is about the timing of the CVR. You're progressing quite well on those programs, but if I look at the time line that Jay have given us today, it looks like you're going to have a 6 months window between the first potential approval and the time the CVR expires. And you kind of think about a typical review cycle by FDA, if there's a need for further answers, to be at least 6 months. But with immuno-oncology drugs, it might be faster. Can you just give us a little bit of your thinking about the safety margin you've built into those -- into the CVR to ensure that if there's some sort of extra questions by the FDA, we're not going to lose the value of that?

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**Nadim Ahmed** - *Celgene Corporation - President of Global Hematology & Oncology*

Thanks for your question. So obviously, we're early in the game when it comes to pricing for luspatercept. And I think what you can expect is we're going to make sure that the price matches the value proposition for the brand. So we're not going to talk about analogs today, but we'll continue to look at the data and make sure we price the value of luspatercept at launch.

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**Mark J. Alles** - *Celgene Corporation - Chairman & CEO*

Ronny, on the CVR, this is Mark. Thanks for the observations. And of course, many of the variables that you described you can imagine were a part of our thinking and discussions through the negotiation. I can just tell you, we're very confident and comfortable with the timing and the probability that we achieve the CVR. So thanks for that.

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**Operator**

Our next question comes from the line of Alethia Young with Cantor Fitzgerald.

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**Alethia Rene Young** - *Cantor Fitzgerald & Co., Research Division - Head of Healthcare Research*

Just 2 quick ones. One, Mark, I just wanted you to kind of -- or the team opine on just, do you think that there will more industry consolidation in the future? Obviously, you have a unique perspective in this question. Then for Terrie, just can you talk a little bit about -- with OTEZLA, the growth



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year-over-year has been very good. And I guess just break down for us maybe kind of where you're seeing this coming from. Is it indication? Or is it certain geographies? And where will the future growth come from?

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### **Mark J. Alles** - Celgene Corporation - Chairman & CEO

Alethia, it's Mark. I'll start with the broader macro question about consolidation. I really don't know. I think it's an interesting thing to think about in the context of Bristol and Celgene coming together. I think we've gone through these episodic windows where it makes sense or it doesn't make sense at a macro level. I think a lot of other companies have been in the media, through their earnings, talking about their strategic outlook. I think there is a very common theme, though. And that is that we have to search for innovation wherever it comes from, whether that's a small cap, mid-cap or, in some cases, which is how BMS and Celgene think about this, we see ourselves as innovators of the first order and are happy to come together. So this certainly makes sense for us. I think every other company has to decide for themselves what will make sense for them long term. But it's -- as I answered the question Michael asked me, this is clearly the right transaction at the right time for Bristol-Myers Squibb and Celgene.

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### **Terrie Curran** - Celgene Corporation - President of Global Inflammation & Immunology

Yes. Thanks for the question. It's Terrie. Regarding OTEZLA, we're very pleased with the momentum heading into 2019, and the growth is really coming from a number of places. Firstly, the U.S. is continuing to really perform exceptionally well. Our strategy has been, from the beginning of the launch, to really secure that positioning at first-line post-topical prebiologic. And that was why we kind of implemented the contracts to really secure that position so that 85% of our business is coming from patients that have just been on topical treatment. Importantly, the ex U.S. business now is really growing very quickly. It took us a little longer to get secure in this, I mean, outside of the U.S., and so core markets like Japan and France are performing exceptionally well. I think heading into 2019, I think the growth will continue to come from that prebiologic segment in the psoriasis market. Importantly, about 60% of patients in that segment remain untreated. So there remains a really -- a fairly large opportunity for us to continue to grow in that segment. And then we've got the life cycle opportunities, as I mentioned, that will also deliver growth into the future, so mild to moderate psoriasis, scalp psoriasis, Behçet's disease and genital psoriasis. Those additional either label-enhancing or additional indications will generate an additional \$500 million at peak. So it's really a great position heading into 2019 for OTEZLA.

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### **Operator**

Our next question comes from the line of Carter Gould with UBS.

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### **Carter Lewis Gould** - UBS Investment Bank, Research Division - Large Cap Biotech Analyst

Two from me. I guess first, just real quick, can you remind us again beyond sort of what the -- beyond the nonclinical bridging data and the PD data for ozanimod, any other kind of incrementally new information that will go into this filing versus the last one? And then just real quick on fedratinib, any indication from FDA if there will be an AdCom and/or do you expect one?

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### **Jay T. Backstrom** - Celgene Corporation - Chief Medical Officer

This is Jay. So let's start with ozanimod. I think the one other piece that's going in, which is substantial, as we've had another year of data to time to follow up for safety. So I think we're really putting in a very, very strong safety data package. Data looks really -- very, very consistent with what we've seen early. So I think that really strengthens it, so -- for ozanimod. And for fedratinib, we -- I think it's a classic drug that's known to the agency. We will learn during the review whether or not they'll invite us to an advisory. At this point, I would have to say what I'm predicting, but I think the application is fairly straightforward. So if we learn that later, we'll certainly let folks know.



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### Operator

And our next question comes from the line of John Newman with Canaccord.

### **John Lawrence Newman** - *Canaccord Genuity Limited, Research Division - Principal & Senior Healthcare Analyst*

Maybe a question for maybe Jay, Mark and Nadim all together. Wondered if you could give us an update on kind of the current status of debate at the FDA with respect to MRD negativity for multiple myeloma. And the reason I'm curious is because you've obviously got a very aggressive and efficient clinical program moving forward for bb2121. And I'm wondering if there's a chance that perhaps some of these later studies, like the newly diagnosed study, could kind of shift towards that MRD negativity endpoint over time.

### **Jay T. Backstrom** - *Celgene Corporation - Chief Medical Officer*

Yes. This is Jay. I mean, FDA is certainly interested in this, in the MRD negativity to be applied in clinical trials and are actually encouraging sponsors to come forward and find ways to include that. To me, if I look at it from the regulatory framework, the ultimate place that they'd want to take this is to be using that as a recognized endpoint that they could use to action. That requires a little bit of additional work. There's ongoing efforts, I think, across the industry to get data in front of FDA for that to occur. But I think you're spot on. I think as we look forward into particularly frontline trials, given the improvement that's been made with current available therapies, FDA is very interested in finding ways to get surrogate endpoints built into that such as MRD negative. So today, yes, we're including it into our trials. FDA is encouraging such action by sponsors to engage and discuss with them. So it's definitely something to watch.

### Operator

Our next question comes from the line of Michael Schmidt with Guggenheim Securities.

### **Michael Werner Schmidt** - *Guggenheim Securities, LLC, Research Division - Senior Analyst & Senior MD*

I had one around your CAR T program. So the question is, what growth have you done at this point around pricing and access for bb2121 and liso-cel? To what degree, for example, are you considering outcomes-based pricing strategies as opposed to using a traditional onetime payment options for those types of products? And then the second question would be on the market dynamics in multiple sclerosis. And I was just wondering how you see the market and opportunity for oral drugs like ozanimod to be potentially impacted by the increased use of infused drugs like OCREVUS.

### **Nadim Ahmed** - *Celgene Corporation - President of Global Hematology & Oncology*

Michael, I'll take the CAR T question first and then hand over to Terrie. So in terms of the access/reimbursement environment, we continue to work with both our government affairs team and our market access team to work with payers, both commercial and CMS, to look at a range of ways to make sure patients get access to these treatments. So in answer to your question, we're looking at the full range of spectrum of options, including innovative approaches as well. So that's very much on our radar. Thanks for your question.

### **Terrie Curran** - *Celgene Corporation - President of Global Inflammation & Immunology*

Yes. And just in terms of the MS market dynamics, I think what we see is a large market. It's a chronic market where there's a need for physicians to have a range of treatment options. I think if you look at the segmentation of the market and the movement towards oral, there is an opportunity for ozanimod in the market. Clearly, as Jay kind of talked to, the clinical data is very well differentiated, and we see a role for ozanimod in that kind of first-line switch segment of the market.



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### Operator

Our next question comes from the line of Dane Leone with Raymond James.

### **Dane Vincent Leone** - *Raymond James & Associates, Inc., Research Division - Research Analyst*

Just 2 for me on the cell therapy space. One, for bb2121 with the newly diagnosed plans in the second half, could you elaborate whether this would be as a lead into transplant or for those patients that would not qualify for transplant and whether there would be some sort of combination therapy with bb2121? And the second one is just, any general update on plans to develop JCARH125 this year?

### **Nadim Ahmed** - *Celgene Corporation - President of Global Hematology & Oncology*

Thanks for the question. So let me start with bb2121. And just again to emphasize, this is our first-in-class, best-in-class asset. And so we are accelerating it as rapidly as possible and building out a strong development program around it, which is what leads us to the frontline setting. So I think if you think about how Jay outlined the relapsed setting, we're looking at high-risk patient populations. And that's the approach we'll take in newly diagnosed multiple myeloma across both non-transplant- and transplant-eligible patient populations. So definitely interested in that space. And this Phase II study will allow us to determine early activity in high-risk patient populations, which will then allow us to build a rapid development program around the frontline setting. So you can see them as proof-of-concept studies. As for JCARH125, you saw the early data at ASH. So we continue to enroll patients, so we continue to have follow-up for both JCARH125 and bb21217. And we'll -- as the data emerge, we'll assess the clinical profiles and make those data available. Thanks for your question.

### Operator

And our last question will come from the line of Asthika Goonewardene with Bloomberg Intelligence.

### **Asthika Goonewardene** - *Bloomberg Intelligence - Senior Biotech Analyst*

Two quick ones and a slightly bigger-picture one from me. Can you give us an update on the expected completion of enrollment for YELLOWSTONE? And then to build on Umer's question, will the time line specifically with Dr. Reddy's litigation permit a settlement before the 3Q deal close? And for the big picture, we noticed a flurry of deal activities even after the Bristol-Myers deal -- after the Bristol-Myers bid. Could you maybe tell us a little bit more about what your overall strategy is with deals and future deals you plan on accomplishing before the Bristol deal close and if Bristol is getting involved in these -- in the decision-making process or not?

### **Mark J. Alles** - *Celgene Corporation - Chairman & CEO*

The deal question.

### **Jay T. Backstrom** - *Celgene Corporation - Chief Medical Officer*

Yes. So this is Jay. YELLOWSTONE is -- it's a program. We've got 2, induction and the maintenance in Crohn's, so those are all up and running, actively accruing. So we're continuing with that. So at this point, we won't be able to tell you the projected time lines, but we're actively moving and progressing that.

### **Jonathan Biller** - *Celgene Corporation - Executive VP & General Counsel*

Yes. So I'll just jump in on the time line with Dr. Reddy's. I mean, as you can appreciate, I'm sure every piece of litigation has its own cadence. And so there's nothing between now and closing that would prevent 2 parties reaching a settlement, but there's also nothing that would impact it the



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other way either. So just as Mark said earlier -- and this process, subsequent to the Natco settlement, we have -- everything's been as we've expected. There's been no surprises to us. These cases are moving along the way that we would have imagined, and we remain very confident in our position.

### **Mark J. Alles** - Celgene Corporation - Chairman & CEO

Just before I hand it off to David, the 3 deals that were referred to were deals with Kyn, Obsidian and Triphase that we signed through the month of January. These are extensions of our efforts to look at protein degradation, to look at controllable CAR T function and mitigating certain side effects. In the case of Triphase, this is classic Celgene where we look for novel mechanisms, new therapeutics. And in the case of Triphase, they have a molecular target that we think is important across a number of cancer cell lines, but it's very early. The upfront was \$40 million, and of course, we would love for this to pay out over time on success. David?

### **David V. Elkins** - Celgene Corporation - Executive VP & CFO

Yes. Thanks, Mark. And we remain open for business. We're going to continue to follow the science, continue working with our collaborators, and we'll do that in consultation with BMS as well. So for everyone out there, very much we remain open.

With that, as we close out this call, we want to thank you again for everyone's interest in Celgene. We also want to thank all the Celgene employees around the world for another excellent year of operating results and commercial execution while making significant progress on advancing our pipeline.

As we progress into 2019, we look forward to continuing our strong momentum, executing against all of our regulatory milestones and coming together with Bristol-Myers Squibb to create a leading and focused biopharmaceutical company.

Operator, you may now end the call.

### **Operator**

Thank you. Ladies and gentlemen, thank you for participating in today's conference. This concludes the program. You may all disconnect. Everyone, have a great day.

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