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CORPORATE PARTICIPANTS

Charles A. Bancroft *Bristol-Myers Squibb Company - Executive VP of Global Business Operations & CFO*

Christopher S. Boerner *Bristol-Myers Squibb Company - Executive VP & Chief Commercial Officer*

Giovanni Caforio *Bristol-Myers Squibb Company - Chairman of the Board & CEO*

John E. Elicker *Bristol-Myers Squibb Company - SVP of Corporate Affairs & IR*

Thomas J. Lynch *Bristol-Myers Squibb Company - Executive VP of R&D & Chief Scientific Officer*

CONFERENCE CALL PARTICIPANTS

Alex Arfaei *BMO Capital Markets Equity Research - Pharmaceuticals Analyst*

Christopher Thomas Schott *JP Morgan Chase & Co, Research Division - Senior Analyst*

David Reed Risinger *Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst*

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

Jason Matthew Gerberry *BofA Merrill Lynch, Research Division - MD in US Equity Research*

Matthew Christopher Phipps *William Blair & Company L.L.C., Research Division - Analyst*

Seamus Christopher Fernandez *Leerink Partners LLC, Research Division - Former MD, Major Pharmaceuticals and Biotechnology*

Stephen Michael Scala *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

Timothy Minton Anderson *Wolfe Research, LLC - MD of Equity Research*

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

Vamil Kishore Divan *Crédit Suisse AG, Research Division - Senior Analyst*

PRESENTATION

Operator

Good day, and welcome to the Bristol-Myers Squibb 2018 Fourth Quarter Results Conference Call. Today's conference is being recorded.

At this time, I would like to turn the conference over to Mr. John Elicker, Senior Vice President, Public Affairs and Investor Relations. Please go ahead, sir.

John E. Elicker - *Bristol-Myers Squibb Company - SVP of Corporate Affairs & IR*

Thank you, Greg, and good morning, everyone, and thanks for joining the call today. We do have a lot to discuss, including the quarter, our full year results, 2019 outlook as well as some additional perspectives on our announced acquisition of Celgene. We will be using a slide deck today, so we did e-mail it to you about 15 minutes ago. The slides are also available on our website.

Joining me today with prepared remarks are Giovanni Caforio, our Chairman and CEO; Charlie Bancroft, our CFO; and Chris Boerner, our Chief Commercial Officer. Tom Lynch is our Chief Scientific Officer, will also be here for Q&A. You'll see on Slides 2 and 3 of today's presentation our legal disclosures.

And with that, on Slide 4, I will turn it over to Giovanni.

Giovanni Caforio - *Bristol-Myers Squibb Company - Chairman of the Board & CEO*

Thank you, John, and good morning, everyone. I am proud to speak to you today about excellent results in 2018 and the exciting outlook for the company in '19 and beyond. As John said, let's start on Slide 4. Today, we will cover our 2018 financial results, the planned Celgene acquisition and how we are thinking about this in terms of the financials of the acquisition and the value we are creating for shareholders.

Before we start, I'd like to address today's announcement on our FDA application for CheckMate -227 in high-TMB non-small cell lung cancer patients. As you saw in our press release, we have decided to voluntarily withdraw the application. This is because following recent discussions with the FDA, we believe it is important to further characterize the interaction between the 2 biomarkers of TMB and PD-L1 in these patients in order to understand their relevance to overall survival in this setting. To do this, we will need data from Part 1a of CheckMate -227 that will not be available during the review period for this application. I would like to emphasize that we continue to believe that TMB is scientifically important, and we look forward to continuing to advance our research in this area.

Turning now to Slide 5 and our 2018 results. I could not be prouder of our very strong performance for the quarter, which wraps up a very good year for the company. This was driven by excellent commercial execution on our priority brands and disciplined expense management that has driven improvement in our operating margin.

Commercial execution was strong across the portfolio with significant growth, driven by our 2 key franchises of OPDIVO and ELIQUIS. Our I-O franchise performed well throughout the year in highly competitive markets, and we have consistently demonstrated very strong launch capabilities.

During 2018, we saw very significant growth coming from adjuvant melanoma and first-line RCC in the U.S. And we are now working through the launch process in Europe, having received approval for first-line RCC in that market. Charlie will talk more about OPDIVO a little later, and I will tell you that based on the strong momentum in the '18 business, we expect to see growth for OPDIVO in the U.S. and internationally in 2019.

Turning to ELIQUIS. We continue to see robust trends with ELIQUIS as the established #1 NOAC globally and the #1 OAC in the U.S. As I've said before, we see considerable room for the market to expand with continued increased adoption based on the superior profile in atrial fibrillation that has made it a leader to date. ELIQUIS will continue to be a strong growth franchise for our company in 2019.

In addition to strong commercial performance, we exercised disciplined expense management across our P&L, supporting significant earnings per share growth of 32%. Our focus on prioritizing investment in the most important opportunities will continue as we look to the planned integration of our company with Celgene. Our 2018 results and the approach that guided them provide a solid foundation for future success. You'll see today that we have provided additional line item guidance that shows expectation of sales growth in '19.

As I look back at our company's performance, I'm pleased not just with our results from last year but over the past several years. As I've said many times, I believe a key part of our success has been our ability to execute very well against a consistent strategy. Let me remind you of the key features of our strategy and explain why acquiring Celgene fits so well within that framework.

Looking at Slide 6. This is a slide you are very familiar with because it's the strategy we've been executing for over 10 years. Central to our strategy is bringing together the best of biotech, namely innovation and agility, with the best of pharma, the resources and scale to create a leading biopharma company. As I've said, this strategy has enabled us to be very successful over many years and has delivered strong performance. And I'd like to take a few minutes to explain what I mean by that.

Now to Slide 7. An important component of our strategy has been to ensure that we are constantly operating ahead of the curve. We took a very focused approach to creating the company we are today with an unwavering focus on science and innovation. We exited primary care and focused on specialty care and unmet medical needs. We designed the strategy to externally source innovation to build our priority therapeutic areas. Importantly, the actions we've taken have led to innovations that have helped transform diseases like atrial fibrillation, lung cancer, melanoma and RCC and resulted in strong earnings growth. The innovation cycle that led to ELIQUIS, OPDIVO and YERVOY has delivered for patients and, at the same time, has also delivered financially. We believe that now is the right time to move to the next exciting chapter of our company with the acquisition of Celgene. It allows us to become an even stronger company for the long term, bringing breadth to our business while remaining focused in key therapeutic areas that we know very well.

Slide 8 is a slide you've seen before, when we announced the acquisition of Celgene in early January. It provides an overview of how I am thinking about the combined company we will create, and I would like to call out the highlights. We will create a top 5 immunoscience and inflammation franchise with ORENCIA and Otezla and 2 near-term product launches. We will have the #1 oncology franchise with leadership in hematology and a pipeline that would sustain that leadership for the long term, along with a growing solid tumor franchise with OPDIVO and YERVOY. We are doubling our Phase I and II pipeline for many more possible new medicines, and we will gain platforms and capabilities important for scientific leadership in the future. None of these would be possible without the people of BMS and Celgene. We are creating a science leader, a leading scientific and innovation-based company that we believe will be a destination for talent moving forward.

Moving on to Slide 9. I want to explain how I view this transaction from a financial perspective. As I've described to many of you over the past weeks, we see an opportunity to create value for shareholders from day 1. Let me walk you through these key points. I believe the combined company provides value to shareholders through a robust and complementary marketed medicines portfolio, the near-term launch of 6 new medicines, the doubling of our pipeline assets and the opportunities for synergies. The strong cash flow of the 2 companies would allow us to delever our balance sheet and strengthen our credit profile within 2 to 3 years, enabling a stronger balance sheet and increased flexibility. As we modeled the combined company, I see sales and earnings growth now through 2025. Overall, I believe that the combination of Bristol-Myers Squibb and Celgene will create a company that will be well positioned for the second half of the next decade, better than each company alone.

Now let me turn it over to Charlie to walk you through our financials in more detail.

Charles A. Bancroft - *Bristol-Myers Squibb Company - Executive VP of Global Business Operations & CFO*

Thank you, Giovanni, and good morning, everyone. Let's turn to Slide 10. We believe this transaction will bring significant financial benefits to shareholders of both companies with 3 defined sources of value. First is the value from the in-line portfolio of marketed products. This includes Revlimid, which I know many of you have questions that I'll try to address in upcoming slides. The second source of value are the cost synergies of approximately $2.5 billion that can only be achieved by combining the operations of these 2 great companies. These 2 sources in total are substantial when you consider the transaction in aggregate. Lastly, we see significant opportunity in the Celgene pipeline, which includes 5 Phase III assets, which are positioned to launch in the next 12 to 24 months, and a significant number of assets that are in Phase I and II that will bolster our existing pipeline in oncology and I&I as well as complementary platforms such as cell therapy and protein homeostasis.

Turning to Slide 11. When you look at the combined company on a pro forma basis, we see a stronger, more diversified set of opportunities that will enable us to drive growth both on top and bottom line through 2025. We see complementarity in the combined portfolio with near-term growth, driven mainly by the Celgene assets, and subsequent growth, driven mainly by BMS assets, particularly from I-O. This speaks to the strength of our in-line businesses, the short-term growth potential from launches of new medicines together with life cycle opportunities from our I-O portfolio and a stronger late-stage pipeline. The combination results in a much more balanced company better positioned for the latter end of the next decade.

As we move to Slide 12, the combined company will generate substantial cash flow that will allow us to reduce debt to quickly delever our balance sheet and strengthen our credit profile. While always subject to board approval, we have modeled continued dividend increases as well. So when I step back and think about the broad financial benefits of this transaction, I see a definitive path for value creation, a company that has significant growth potential over multiple periods and, in a few years, a reset balance sheet that allows us to complement our stronger internal R&D efforts with the continued sourcing of external innovation from business development.

Quickly on Slide 13. We've outlined a few assumptions in our models with respect to Revlimid and how we accounted for the pipeline assets. From an accounting perspective, we will include the Celgene stock-based compensation in our non-GAAP P&L.

Now let me spend a minute discussing how we think about Revlimid and the outlook of our I-O franchise since I know many of you had questions on each of those. Turning to Revlimid on Slide 14. It's important to know that we performed extensive due diligence on the Revlimid IP situation, both independently and as part of the diligence process with Celgene. We also had the opportunity to review confidentially the Celgene Natco settlement and its impact on various litigation outcomes. With that in mind, we considered 2 bookend scenarios for Revlimid, one in which there

is an early at-risk launch and another that is reflective of sell-side consensus representing gradual erosion starting in 2022. We believe both of these scenarios have a very low probability.

In between these bookends are several other litigation outcomes or potential settlements that could play out, and in our view, each are likely to have somewhat comparable implications on the Revlimid revenues in the near term. Our analysis assumes a more conservative approach than sell-side consensus and results in lower sales between 2022 and 2026. Through any of these scenarios, we see the combined company generating significant cash flows that will enable us to delever while delivering returns for our shareholders.

Now moving beyond Revlimid and the combination with Celgene, let me turn to Page 15 and our I-O business going forward. As we think about the combined business, we continue to see OPDIVO as a key growth pillar, so let me take a few minutes to lay out the opportunities ahead of us. We've demonstrated excellent launch execution and have driven growth through a broad set of new indications. Two launches that exemplify this high level of performance are adjuvant melanoma and first-line RCC in the U.S. Even with today's announcement, we still see OPDIVO growing in the U.S. this year as our teams are well resourced to drive performance across key indications. As we think about our ex U.S. business, while the dynamics are a bit different, we see growth there given the new launches in adjuvant melanoma and first-line renal.

Turning to the long-term growth outlook for I-O, as I mentioned, for all clinical stage opportunities with risk-adjusted revenue potential. Given the breadth of opportunities, you can see on this slide we see significant growth potential for OPDIVO, with the growth trajectory predetermined by the cadence of new indications. Naturally, for 2020, the growth outlook will depend on the data we see this year in lung and in other tumors.

Now I'm going to hand it over to Chris, who will share his view on the 6 Phase III assets that will be launching over the next few years. Chris?

Christopher S. Boerner - *Bristol-Myers Squibb Company - Executive VP & Chief Commercial Officer*

Thanks, Charlie. Turning to Slide 16. You've seen this slide before. It shows how the combination of BMS and Celgene will create an exciting, industry-leading late-stage pipeline, including 6 near-term launch opportunities with more than $15 billion in non-risk-adjusted revenue potential. Three of these products are substantially de-risked because the pivotal data are known or regulatory filings are well advanced, and the majority of these products are either first or best-in-class, providing a meaningful opportunity to help patients across a number of disease areas.

To put this potential set of launches into context, I want to provide you with some background as to why we are excited by them and why they give us the basis for sustained leadership in key therapeutic areas moving forward. In I&I, we will be moving from being 2 companies, each with a single product, to one I&I franchise delivering ORENCIA and Otezla right away with the potential of adding ozanimod and TYK2 in the near future. And in hematology, we see 4 assets that form the first step to building on the current capabilities that Celgene brings with its Revlimid business today to establishing sustained leadership in this space. We view these near-term launches as exciting opportunities and key drivers of value in the combined company, and I'd like to take a few minutes to walk through these 6 upcoming launches in more detail.

Let me start with luspatercept on Slide 17, a very exciting compound from our perspective, which is a potential first-in-class erythroid maturation agent to address chronic anemias. As you may know, chronic anemias present a serious unmet medical need across various indications, and luspatercept is a compelling new mechanism for treating these patients. The data presented at ASH have demonstrated that luspatercept provides very good efficacy in MDS patients that have failed EPO as well as beta thalassemia. These are populations with very few treatment options today, beyond often chronic blood transfusions, and these data are expected to be filed with the FDA soon.

Beyond these indications, important life cycle management trials are already underway, including a in a much larger first-line MDS population, where luspatercept will be tested head-to-head versus EPO. Finally, based on the mechanism, we believe there is potential for this medicine in other indications involving ineffective erythropoiesis.

Turning to Slide 18. Fedratinib is a second important near-term launch. This asset has potential to establish a position for the company in myelofibrosis, most likely in the population of patients that are intolerant to or refractory to Jakafi. As you can see on the slide, many patients are either not well controlled or resistant to Jakafi. For these patients, there are limited treatment options. Fedratinib has demonstrated strong efficacy in these

patients, including splenic volume reduction and improvement in symptoms. As you know, Celgene has already confirmed that the NDA for fedratinib has been recently submitted to the FDA.

On Slide 19, the CAR-T platform for Celgene has built -- that Celgene has built is an important and differentiated capability driving value for the combined company. We view CAR-T as a very exciting opportunity for our oncology franchise given the unprecedented efficacy data that has been demonstrated with this modality.

In order to unlock the commercial potential of this platform, we believe there are a number of conditions necessary, and we feel good that we will satisfy them. First, the specific products need to be differentiated, and I'll explain in a moment what we see as the advantages of liso-cel and bb2121.

Second, we need to have an access and reimbursement infrastructure that is appropriate for this modality. With that in mind, we feel that we have a leading capability in value and access at BMS, particularly within the oncology space, and this capability will be critical in shaping and navigating access for these platforms.

Third, we need to see these products being used by more physicians to benefit more patients. This will require the right products from a safety perspective and leveraging Celgene's leading capabilities in hematology commercialization.

And finally, we need to move these products beyond the current very late line settings where they are used today to earlier lines of treatment, and we see that there are already trials underway to make this happen. Taken together, the capabilities of the combined company will be prime to commercialize these differentiated products successfully. With that in mind, let me discuss how we see the positioning of the 2 lead CAR-T assets.

Turning to Slide 20. Liso-cel is a CAR-T asset, which has the potential to be the best-in-class anti-CD19 CAR-T for B-cell malignancies. We believe this product will be differentiated in the marketplace with efficacy at least as good, if not better, in KYMRIAH and YESCARTA in heavily pretreated DLBCL. Importantly, the rate of cytokine release syndrome are far lower for liso-cel compared to the currently marketed CAR-Ts. We believe this safety advantage is differentiated and potentially enables an expansion in both the treating physician base and the patients considered eligible for CAR-T therapy. Liso-cel is currently in development for earlier lines of DLBCL as well as for potential use in ALL and CLL.

Now looking at Slide 21. bb2121 also has the potential for transformative efficacy as a first-in-class and best-in-class BCMA CAR-T for the treatment of refractory multiple myeloma. Looking at the efficacy data on the left side of the slide and acknowledging that this data set is from a small study, it's clear that the depth and rate of response with this technology against this target is compelling compared to current treatments. With patients in this setting historically having very few realistic treatment options, we believe these data are very exciting, and we are looking forward to a potential filing early next year.

As I also mentioned and you can see on the right side, trials are already underway to move into earlier lines of treatment. We see this as a very important potential option for multiple myeloma patients, a market that Celgene knows very well.

I'll move to I&I on Slide 22 with ozanimod, a therapy that has the potential to play an important role in 2 very large markets. Ozanimod's initial indication will be in relapsing and remitting MS as the first selective S1P. Here, it has the potential to play a role as a safer option than either GILENYA or Tecfidera, the 2 leading currently marketed world therapies. We expect that the resubmission is on track for later this quarter, as Celgene has said, with the potential for a launch next year.

Beyond MS, ozanimod is also being developed in inflammatory bowel disease, an even more commercially interesting market given the treatment options at launch will likely include biologics and JAK inhibitors. Based on the Phase II data so far, we see this mechanism as having potential in IBD, and the Phase III trials are already underway. Commercially, ozanimod could have a competitive advantage with the potential to offer an effective option for patients seeking an oral therapy that doesn't come with the safety concerns of a JAK inhibitor.

I'll now turn to TYK2 on Slide 23, an important agent that has demonstrated biologic-like efficacy in psoriasis, with upside potential to address multiple autoimmune diseases. Here, you see the data published in The New England Journal in September. The data are strong, and Phase III trials for psoriasis are ongoing, with proof-of-concept studies underway in Crohn's and lupus. We are planning additional Phase II trials that will allow

us to determine future registrational programs. In the meantime, we believe we have a very compelling opportunity in psoriasis as we believe the existing dermatology capabilities that Celgene has established with Otezla will be beneficial in ensuring a successful launch of TYK2 in this market following completion of Phase III trials.

Stepping back, I'm very enthusiastic about the breadth of launch opportunities we expect as a combined company. Our commercial organization has clearly demonstrated that we can launch very effectively. And together with the assets, capabilities and talent that Celgene brings to the table, we are well positioned to deliver some very exciting opportunities for the combined company.

With that, I'll turn it back to Giovanni.

Giovanni Caforio - *Bristol-Myers Squibb Company - Chairman of the Board & CEO*

Thank you, Chris. Now turning to Slide 24. As I look at what we are creating for the short and long term, for 2025 and beyond, I feel really good. We've discussed in detail why the transaction makes financial sense. We talked about 6 near-term launches, and as you know, we're also strengthening our early-stage pipeline and platforms. This is a transaction that allows us to stay ahead of the curve and provide value for the long term.

When I look ahead to the future, I feel very good about the position of the company. We will have a younger portfolio of marketed medicines, providing a more balanced payer mix, supporting a strong reimbursement position for our medicines. This, in access and reimbursement environment that we believe will continue to evolve over the coming years. Our early pipeline will have matured, giving us a diversified portfolio of late-stage assets, providing the next set of registration opportunities. We'll have a strong balance sheet with continued flexibility to invest in innovation. We will be in a strong position with a broad portfolio and deep pipeline and significant financial flexibility. I'm confident in the company we are building and the opportunities ahead.

Now I'll turn it back to John to start with the Q&A.

John E. Elicker - *Bristol-Myers Squibb Company - SVP of Corporate Affairs & IR*

Thanks, Giovanni. Greg, I think we're ready to go to the Q&A session with Giovanni, Charlie and Chris as well as Tom here for Q&A as well. So Greg?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) We'll now take our first question from Alex Arfaei of BMO Capital Markets.

Alex Arfaei - *BMO Capital Markets Equity Research - Pharmaceuticals Analyst*

First question for Giovanni or Charlie. As you mentioned, the combined company with Celgene should generate significant cash flows. I appreciate the general comments you made about the dividend increase. But as you look at some of your payers and your current payout ratio, would you be able to, I guess, provide additional color? Would the payout ratio that you would expect for the combined company given the earnings accretion be similar to what you have right now? And as a follow-up, could you comment on your OPDIVO life cycle planning? Specifically, what's the development -- or what's the latest on the development of subcutaneous OPDIVO with your collaboration with Halozyme? And could that be used to extend the OPDIVO patent life beyond 2028?

Charles A. Bancroft - *Bristol-Myers Squibb Company - Executive VP of Global Business Operations & CFO*

Yes, thanks, Alex. This is Charlie. In regard to your first part of your question, as I mentioned in my comments, we have modeled dividend increases throughout the planning period, always subject to board approval, of course. I don't want to comment on the payout ratio at this particular time because, as you know, we don't do it based on any one particular year. We look at it over the longer term. But needless to say, we did model increases.

Thomas J. Lynch - *Bristol-Myers Squibb Company - Executive VP of R&D & Chief Scientific Officer*

Thank you, Alex. Regarding the product formulation, from an R&D standpoint, we think it's very important to be able to create products that can be used in a variety of settings. And our relationship with Halozyme, as you pointed out, we think offers a very important opportunity for OPDIVO, OPDIVO-YERVOY and up to 6 to 8 additional I-O targets to be looked at in formulations that can be given subcutaneously. We think in many markets around the world and in many places in the United States, the ability to give a subcutaneous treatment with an I-O agent, or an I-O combination even, offers a very distinct advantage. So we think that there's a lot of promise there. The implications of that on the IP, I think we're going to have to defer that to see how that topic evolves with time.

Operator

We'll now take our next question from Seamus Fernandez of Guggenheim.

Seamus Christopher Fernandez - *Leerink Partners LLC, Research Division - Former MD, Major Pharmaceuticals and Biotechnology*

So just 2 quick ones. The first one, in the past, Tom, you've given us information with regard to whether or not interim looks have been passed, in particular, trials. I think we have passed that in Part 1a. So Part 2 for OPDIVO plus chemo, we know, is ongoing, is expected to finish midyear this year. Can you just tell us whether or not the interim look has been passed or not at this point? And then the second question, can you guys give us a little bit of a better sense as we think about products like bb21 and liso-cel? One of the key feedback areas that we get is the challenges that hospitals are facing when delivering CAR-T therapy and the issue around hospitalization and the costs associated with it. So it's not profitable today for hospitals to be able to do this. In fact, they're losing quite a bit of money. Just wondering how you guys see that dynamic evolving as you seek to launch both of these products in the next couple of years, assuming the Celgene acquisition closes.

Giovanni Caforio - *Bristol-Myers Squibb Company - Chairman of the Board & CEO*

Yes. Seamus, thank you. This is Giovanni. I'll start and then I'll ask Chris to comment on the CAR-T question you had. There is no news with respect to the rest of our first-line lung cancer program. We're not commenting on interim analysis.

Christopher S. Boerner - *Bristol-Myers Squibb Company - Executive VP & Chief Commercial Officer*

Yes. So thanks for the question, Seamus. Let me talk a little bit about how we see CAR-T evolving and the important role that the 2 agents we talked about will play in terms of potentially expanding the opportunity for CAR-Ts generally. You're absolutely correct that existing CAR-T therapies have struggled a bit, both with respect to logistics in the hospital as well as with respect to access in large part because of the profile of these drugs. As you know, existing CAR-Ts are administered in the hospital setting. Today, patients must remain in the hospital, often in the ICU, for treatment as well as monitoring. And one of the things that we find really exciting about -- particularly an asset like liso-cel is that with no significant Grade 3, 4 toxicities, with a CRS rate that's significantly lower than both KYMRIAH and YESCARTA, around 1%, patients could potentially be monitored in the outpatient setting. And that actually bridges to your question about access. Because these patients have had to be managed in the inpatient setting, the cost associated with CAR-T therapy has been very substantial, above and beyond the list price of the drug. You've seen some improvements in the access and reimbursement for these agents over time. About 2/3 of commercial patients -- payers are now -- have put in place policies that cover these therapies. That said, anything you could do to potentially move these agents into an outpatient setting would do a number of things.

It would bring the overall cost of these therapies down. It would increase the value of these assets. And importantly, as I mentioned in the prepared remarks, it would be an opportunity to expand the physician base who are using these agents outside of large academic centers to potentially community centers and then ultimately expand the patient pool considered eligible for these therapies. And that's a potentially important opportunity that we see with the differentiated profile, particularly of liso-cel.

Operator

We can now take our next question from Tim Anderson of Wolfe Research.

Timothy Minton Anderson - *Wolfe Research, LLC - MD of Equity Research*

A couple of questions. I realize this will be a difficult question to answer, but many have wondered if Bristol is buying Celgene as an attempt by you to prevent another company from potentially acquiring Bristol. So my simple question here is, whether this played any role whatsoever in your decision to acquire Celgene. The second question. You sit in front of 3 set of results in non-small cell lung with OPDIVO: Part 1, Part 2 and 9LA. Can you tell us which one of those you have the greatest confidence in and which ones you have the least confidence in? My guess is you would probably rank order those: Part 2 as being most likely to hit, 9LA would probably be beneath that, and then Part 1 is probably at the bottom. If you only hit Part 2, would you be willing to say that OPDIVO will grow in 2020?

Giovanni Caforio - *Bristol-Myers Squibb Company - Chairman of the Board & CEO*

Tim, thank you. Let me just try to address both questions. To your first question, I hope that through many of the discussions we've had since the announcement and clearly today, we've been able to communicate a strong strategic rationale of the combination and the value it generates for shareholders and patients. So I -- my answer is, we are creating a great company with complementary franchises or marketed products an opportunity to launch 6 new products in the next 24 months and doubling the size of our early pipeline in therapeutic areas we know well. We're really excited about the strategic and financial value of the transaction. With respect to your second question, my perspective is that, as we've said many times, we have multiple opportunities to play a role in lung cancer. I think we need to see the data readout to understand the data. And as you mentioned, Study 1a, Part 2 and 9LA are all important components of our lung cancer program. We've communicated before our expectations with respect to the timing of those programs, and there is really no change there. But more importantly, as Charlie mentioned, when we think about the OPDIVO business, this is a growing franchise. And you've seen on one of the slides we presented today, the breadth of opportunities that we have over the next few years with over 20 registrational trials ongoing. There are clearly a number of opportunities in lung cancer this year. We have an exciting and very broad adjuvant program to drive growth in the medium and the long term. And I would say that with any franchise, the growth expectations in the short term depend on the data readouts that are coming in the next few months, and that's true for us as well. But my confidence is that this is a growing franchise with multiple opportunities for growth, and this is what we've modeled as we thought about the total company.

Operator

We can now take our next question from Chris Schott of JPMorgan.

Christopher Thomas Schott - *JP Morgan Chase & Co, Research Division - Senior Analyst*

I guess my first question was just going back to Slide 11 and that pro forma look at the company. I guess investors are trying to get their hands on the growth of the non-Revlimid portion of the pro forma company. Is there any color you can provide as we look out to 2025, what percent of that pro forma company sales and net income is coming from the non-Revlimid business if we just kind of think about the growth of that piece of the business separate from Revlimid? My second question was then coming back to the Revlimid assumptions. I think you mentioned that Revlimid was modeled more conservatively relative to consensus. Is there any more color you can give on those assumptions? Specifically, how much of a delta versus the Street are you thinking about? And is that delta particularly pronounced in certain years over the planning period relative to the other years in that planning period?

Thomas J. Lynch - *Bristol-Myers Squibb Company - Executive VP of R&D & Chief Scientific Officer*

All right. Chris, thanks for your questions. I think that we probably can't give you more -- too much more color on. I think as it relates to 2025, in particular, regarding your question on the split between Revlimid and non-Revlimid, we don't go that far out as we talked about in the past. So I think what you will see in the proxy, you will see the split between the 2 companies' sales, and you can get sort of a baseline there. As it relates to how we think about specifically Revlimid versus consensus, again, I think this is more -- we did multiple scenarios. And I mentioned, we did the bookend. There's a number of scenarios in between. There's a number of things that still have to play out, both at the District Court level and at the patent office level. So for us to give -- to declare that at this point, I think is premature.

Giovanni Caforio - *Bristol-Myers Squibb Company - Chairman of the Board & CEO*

What's important to me, Chris, is that if you look at this slide and if you think about the way we think about the company between now and 2025, we have -- rapidly growing business is driven by many of our in-line franchises, the opportunity to launch 6 products in the next 2 years and a pipeline that will continue to advance and will generate incremental launch opportunities between now and 2025. And then when I think about 2025, we will have not only a business that will have grown, but also we will have a much more diversified company, a significantly higher number of opportunities across multiple diseases to drive the growth of the company in the second half of the decade. So I think beyond the contribution on individual components, the breadth of growth opportunities across different parts of this growth period is what's really complementary and exciting about the new company.

Operator

We'll now take our next question from Jason Gerberry of Bank of America.

Jason Matthew Gerberry - *BofA Merrill Lynch, Research Division - MD in US Equity Research*

I guess first question is just for Tom. Just thinking about the upcoming readouts at the ASCO GU. I'm curious, it seems like the advantage of OPDIVO-YERVOY in frontline renal really is the longer-term follow-up survival data versus competitors who likely have immature OS data. So just kind of curious, you guys have a longer-term follow-up study. It's about 30 months of follow-up, but it was about 25 months of follow-up at ESMO 2017. So just kind of curious why this upcoming follow-up isn't longer-term follow-up and what that suggests regarding the durability of the OPDIVO-YERVOY benefit beyond 30 months. And then my second question is just regarding Revlimid. Have the parties -- have you guys and Celgene pre-agreed already on what would be acceptable settlement terms with some of the outstanding generic challengers? Just sort of curious how you guys navigate some of the upcoming legal update.

Thomas J. Lynch - *Bristol-Myers Squibb Company - Executive VP of R&D & Chief Scientific Officer*

So Jason, thank you for your question about renal cell. So a couple of things about renal cell. First, we are extremely happy that OPDIVO-YERVOY has become the standard of care in many settings in the United States. And we're also very happy that just recently, we received our full approval in Europe as well. So we look at that as a great endorsement of the value this combination provides. We look forward to updating survival as we always do with the most reads in database lock, and we continue to update that data. When I think about this combination, as you point out, I think about something which could be distinguished, and again, we haven't seen all the data from our competitors yet, but could be distinguished on durability of response. And I think that's one of the most important things to keep in mind that durability of response can play a very important role. And so we look forward to seeing that data emerge and the comparative datasets emerge over time. But also, remember that one of the other key things is, we also believe that there may be a role for TKIs with IO. And we have our study 9ER, which we'll be reading out with cabo and OPDIVO as well. Looking at that -- that's a little bit later in the time frame later this year. But we look forward to being able to play a role both in -- across a spectrum of patients with renal cell carcinoma.

Charles A. Bancroft - *Bristol-Myers Squibb Company - Executive VP of Global Business Operations & CFO*

Yes. I would just -- on the Revlimid settlement with generic filers. I think it would be inappropriate to talk about how we are thinking about that other than -- or Celgene, in particular. I would say that we do have consultant sort of perspective or overview with the process with Celgene and their generic filers.

Operator

We'll now take our next question from Umer Raffat of Evercore ISI.

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

So I wanted to focus on lung cancer for a minute and maybe -- just so I understand the regulatory status exactly on what's happening. It seems to me that once the overall survival data in the TMB-lows, the hazard ratio was about the same as the hazard ratio in TMB-highs. Maybe FDA was no longer comfortable with TMB to begin with. Is that a fair way to think about it? And perhaps is that why there is sort of now more and more focus on the PD-L1 positive cohort specifically? And on that note, I recall, the expectation for overall survival data in PD-L1 positives of -227 was by late '18, early '19. And I saw that it's now obviously pushed out and 9LA is pushed out a little bit as well. So I'm just trying to understand the broader dynamic here and also to understand how FDA is looking at TMB and whether TMB is ever happening or not from their perspective.

Giovanni Caforio - *Bristol-Myers Squibb Company - Chairman of the Board & CEO*

Yes. Umer, let me just start and then I'll ask Tom obviously to answer your question in more detail. First of all, as Tom will describe, the issue that is important really is the interaction between various biomarkers. I think we've been very clear since October that this was a complex file. You've mentioned that the overall survival data we disclosed in October with respect to low-TMB patients and, obviously, we've been in discussions with the FDA on this application. Tom will give you his perspective about that. If you look broader at our lung cancer program, nothing has really changed with respect to the importance of Study 1A, Part 2 and 9LA. We've always said these are event-driven trials and the timing is impacted by the evolution of events, but we continue to look forward to seeing the results of the study. It is a broad program and we will see the data. We believe that based on that program, we have a real opportunity to play a role in lung cancer. And as I said earlier, that's part of a much broader set of opportunities for OPDIVO. Tom?

Thomas J. Lynch - *Bristol-Myers Squibb Company - Executive VP of R&D & Chief Scientific Officer*

Thank you, Giovanni. And Umer, I think just to give you a little bit more emphasis there. I mean, obviously, I don't know what the FDA is thinking. I can tell you what I'm thinking about TMB, and I feel that TMB will continue to be important. I think the broad genomic profiling will continue to be important in the way we approach patients with cancer. I just think it's early days in trying to understand that. I think if you look at the totality of data, data from us, data that was just published last week from Memorial and from Merck, data from Roche, data from AstraZeneca, whether you're looking at blood, whether you're looking at tumor, what you see consistently is TMB is a marker for response often for PFS, and we don't yet have evidence or data that's as confirmatory around survival. Much of that I would argue is around the way the studies have been designed, data collection. And I think it remains a very important part of how we move forward. I want to make one important comment about -227. As you know, we believe it's very important to understand this interplay of the various different biomarkers of PD-L1 and of TMB and how they may work together. We know that TMB predicts for PFS benefit in patients who are high-TMB with OPDIVO-YERVOY compared to chemotherapy. But as you've mentioned, we also found evidence that the survival trends were very similar whether you were TMB-high or TMB-low. And to really further understand what that means and to be able to give guidance to treating physicians, I think you really do need to see the totality in survival data, which will be available hopefully, reasonably shortly with -- when 1a comes out. One comment just to finish on the timing of data release. As you know, these are inherently event-driven phenomena. And it's very difficult to be able to predict with exact precision when the events will occur that will trigger the ability to read out. And again, both these studies are slightly prolonged. But again, we have to wait for the events to occur. And as soon as they occur, we will analyze the data.

Operator

We can now take our next question from Matt Phipps of William Blair.

Matthew Christopher Phipps - *William Blair & Company L.L.C., Research Division - Analyst*

A follow-up to Umer's question. Tom, do you think the subsequent usage of PD-1 in the second line from patients that were high-TMB might influence that survival where those chemo patients ended up maybe doing really well in second-line PD-1 and therefore kind of confounded the OS results, in particular? Subsequently, if Part 1a is positive for the PD-L1 positive patients, do you really consider pursuing TMB? Or would you consider looking at a pan-tumor high-TMB type of indication similar to MSI-high if you're really confident in this biomarker?

Thomas J. Lynch - *Bristol-Myers Squibb Company - Executive VP of R&D & Chief Scientific Officer*

So two questions, [William]. So Matt, thank you. A couple of question -- a couple of answers. First is, I do think that PD-1 treatment in second-line makes a big difference and provides great benefit for patients. We've shown that and have read it in the area in second-line lung cancer. So I do believe that, that can obscure the ability to look at potential survival differences. I think you also remember that the group of patients who are most likely to develop the most impressive responses are those patients who are high-TMB. So -- and I think that's true in second-line as well as we showed with Study -026. So I think that's really important. The second part of your question regarding if a1 is positive, how will we approach that from a regulatory standpoint. Giovanni made that really clear earlier when he said you really have to see what -- where the data takes us. So we have to look at the data, see what the data shows us. As you know, we have not seen survival data from Part 1 of the study. So we need to be able to look at that to be able to determine what's the best way to determine the patients who get the most benefit and importantly, the largest group of patients that we can benefit as well in this setting. So again, really hard to comment on what the regulatory path would be until we see these datasets. I think as Giovanni said, we've got the 3 important datasets maturing in the next 3 to 12 months. And we're going to need to look at the group of them to be able to make the most important strategic decisions from a regulatory standpoint.

Operator

Our next question comes from Steve Scala of Cowen.

Stephen Michael Scala - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

What are the dynamics that led to essentially flat OPDIVO sales quarter-over-quarter? And related to that, the Bristol business has good momentum, but the 2019 EPS guidance suggests mid-single-digit growth ex Celgene and growth was further lowered by the Q4 beat. So maybe you could talk about that dynamic. And then secondly, would you like to call out any design differences between the OPDIVO chemo arm of CheckMate -227 and KEYNOTE-189 that might influence the results? For instance, Roche notes greater chemo dose intensity in IMpower132 relative to KEYNOTE-189 among other differences.

Giovanni Caforio - *Bristol-Myers Squibb Company - Chairman of the Board & CEO*

Chris, why don't you start with the performance of OPDIVO?

Christopher S. Boerner - *Bristol-Myers Squibb Company - Executive VP & Chief Commercial Officer*

Yes. Thanks, Steve. Thanks for the question. So overall, sales for OPDIVO were quite strong ending the year. While we grew sales outside of the U.S., as you point out, net sales were relatively flat in the U.S. Q3 to Q4. There were a couple of unique factors that affected the quarter. First, we had an inventory build in the government channel in Q3 that had to be worked down in Q4. And second, we had slightly higher sales in THS and Medicaid,

which had a modest impact on gross to net. Those two things notwithstanding, we did actually see demand growth of about 3% for the quarter. It was just offset by these other factors. But if you step back from the quarter, we actually ended 2018 very much in line with expectations. In the U.S., second-line lung shares is holding around 30%. We continue to see the percentage of IL eligible patients decrease, but that's very much in line with what we expected and where we expected to be at the end of the year. We're holding leading shares in first-line metastatic melanoma as well as in second-line renal cell. And as we look forward, we still see growth opportunities, albeit more modest in the U.S. coming from adjuvant melanoma as well as first-line renal cell. You'll recall that we drove rapid uptake in the U.S. in these indications in 2018. We still, however, see opportunities to continue to grow in first-line renal, particularly in intermediate and poor-risk patients. We've got a great story to tell there in terms of the strength of our OS and, as Tom mentioned on the previous call, the durability of the data that we're seeing there. And we'll also benefit from full year sales in adjuvant melanoma in the U.S. And of course, outside of the U.S., we're still very much in the early stages of the launch of both of those indications. So if you add it up, we see a good opportunity for growth in 2019 and good momentum globally coming out of '18.

Charles A. Bancroft - *Bristol-Myers Squibb Company - Executive VP of Global Business Operations & CFO*

Yes. Steve, just a couple of things and maybe to remind you of one -- I would call a maybe one-off item related to our 2019 guidance. So we announced in December the sale of our book-to-business that we expect to close in April of 2019. That has about $480 million of full year sales in 2018, and we already indicated that's up $0.04 dilutive to us on an 2019 basis. We also announced our pension de-risking back in November of last year. And that shows up in other income, but that's also $0.05 dilutive to us in 2019. And then we've talked about before that the Sanofi alliance income ended in 2018.

Christopher S. Boerner - *Bristol-Myers Squibb Company - Executive VP & Chief Commercial Officer*

And Steve, just to answer quickly your question about -227 versus 189. Except for the obvious difference which you would note about histology as being different that -227 was [a little more common] and 189 was in nonsquamous. And except for the fact that the 189 control arm performed particularly less well than some of the other control arms that we've been seeing from both our studies and competitors' trials, I think it's really difficult to make those comparisons. I think we have to really see -- until we see what our data from -227 look like both from Part 1 and Part 2 of those trials and to see how they emerge.

Operator

Our next question comes from Vamil Divan of Crédit Suisse.

Vamil Kishore Divan - *Crédit Suisse AG, Research Division - Senior Analyst*

So maybe one around Celgene and then one other one. So just on the Celgene deal, obviously, stock was trading quite a discount before the deal was announced. I think the market has not been as bullish from the late (inaudible) as you are. So maybe if you -- in just under 3 weeks, you've been having a discussion with investors, what do you think investors are most missing about these pipeline assets? And what should we be getting more excited about? Appreciate the detail on the call, but any further intel would be helpful. And then changing gears to Eliquis. So we from Johnson & Johnson relative to sales growth, a little late this quarter. And obviously, there's a lot of volume growth in that class, but just wondering about the pricing side of that equation. So can you just comment on the discount that you're seeing? And maybe the impact of the donut hole had enough product this quarter. And how are you thinking about the donut hole impact next year given you'll be responsible for a greater percentage of the sales, covering more of the sales there?

Giovanni Caforio - *Bristol-Myers Squibb Company - Chairman of the Board & CEO*

Yes. Thank you, Vamil. This is Giovanni. Let me just start answering your question. So first of all, let me say that we've just reviewed in some detail with you some of the key drivers of value of the acquisition of Celgene and specifically with respect to the value of the pipeline assets. If you think about that, and as we've said in the past, do we see none risk-adjusted sales at peak for the 6 assets we discussed today at least $15 billion in sales.

And we are having really good discussions with investors about the strength of the combined company, the key value drivers, the opportunity for growth that these assets provide and then obviously the strengthening of the rest of the pipeline.

Thomas J. Lynch - *Bristol-Myers Squibb Company - Executive VP of R&D & Chief Scientific Officer*

And, Vamil, just to add from an R&D standpoint, I just want to share. It's obviously very hard for you or for anyone to model the particular value of a pipeline asset that's very early. But I can tell you the enthusiasm that our group at BMS has had when we look at the depth and strength of what Celgene has in their pipeline, particularly around the concept of protein homeostasis. Chris mentioned earlier the incredible technology that's been developed in cell therapies that will make a difference. And overall, when I look at this company, I see a company that's done for myeloma what we have done for renal cell and melanoma. They've absolutely transformed the disease by understanding the biology and by developing treatments which exploit the fundamental biologic differences. And so there, I think you see a lot of similarities between these 2 companies.

Christopher S. Boerner - *Bristol-Myers Squibb Company - Executive VP & Chief Commercial Officer*

Chris here. Let me touch on Eliquis. So a few points, Vamil, and thanks for the question. So first, we're still very bullish on the business with Eliquis, both in the U.S. and ex U.S. We grew sales in the fourth quarter of 27%. Without TRx, volume was up 36%. In the U.S., we've extended our leadership position as the #1 OAC across all specialties of indications. And we still have room to grow in the U.S. Outside of the U.S., we've seen strength in a number of key markets, notably the U.K. and France. And in fact, in France, we became the #1 OAC in the fourth quarter. So the base business and the fundamentals look really good across-the-board. We did see an impact on higher rebates in the U.S. in the fourth quarter. In Q3, rebates were around $185 million. They increased to $278 million in the fourth quarter. There were 2 things really driving that. There was a onetime true-up of $36 million. But as you point out, we do have a higher volume of patients running through Part D channels. And those are highly discounted channels. As we take those dynamics and look forward, I think there are a few dynamics that you need to take into account with Eliquis. First, the donut hole rebate is increasing from 50% to 70%. That's going to put pressure on that price. Second, we had a differentiated profile. And as a result of that, we've strengthened our access position in Part D. That is going to lead to higher gross-to-nets over time. And then importantly, we have significantly increased the volume going to Eliquis. We did that in 2018 based on the strength of the business. We had every expectation to believe that we'll continue to grow this business in 2019, and that will drive more volume through highly discounted segments. And thus, increasing gross-to-net. What I will say is in spite of these drags on net price, our expectation is that we'll continue to grow net sales. And that's a result of having a differentiated product; good underlying strength in the business in the U.S. and ex U.S.; and frankly, the quality of the commercial execution that we've seen on this brand.

Operator

We can now take our next question from Geoff Meacham of Barclays.

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

I just have a few. On Revlimid, I think investors are struggling with the erosion curve beginning in 2022 in the pro forma model and then the pricing environment longer term. So I guess the question is how much value is given for 2121 in earlier lines of therapy, say, first or second-line myeloma where Revlimid has pretty meaningful share? And then on the first-line lung application, does it make sense to wait even longer, say, for Part 2 of -227 or even 9LA to ensure a broader label? I'm just -- I guess I'm struggling with how you balance speed-to-market and sort of data differentiation in I-O versus science behind TMB versus PD-1 better.

Giovanni Caforio - *Bristol-Myers Squibb Company - Chairman of the Board & CEO*

Thanks, Vamil, let me -- sorry, Geoff. Let me answer your first question. So as we've discussed, bb2121 and other assets, our current forecast includes the lead indication. In that case, obviously, we see significant potential for further expansion into other lines of therapy.

Thomas J. Lynch - *Bristol-Myers Squibb Company - Executive VP of R&D & Chief Scientific Officer*

And Geoff, just to comment on the first-line lung application. Obviously, we want the -- speed-to-market is important. I think you're right or -- in bringing up a very good point that we want to see what the data shows us. And that will determine how we proceed from a regulatory standpoint. And I just want to emphasize that Part 1a, Part 2 and 9LA are 3 distinct separate studies. Maybe that we get a very strong signal from one of them that allows us to proceed with a regulatory filing. So I think we'll have to take that and call out the data as you point out.

Operator

Our last question comes from David Risinger of Morgan Stanley.

David Reed Risinger - *Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst*

My first question is just a follow-up on Eliquis, and thank you for the color. I think the comment was that you expect growth going forward, but i believe the Street expects substantial growth going forward. So could you just provide some level of color on the outlook for growth relative to the growth that you reported in the fourth quarter for Eliquis? And then second, pivoting to novel I-O pipeline candidate that was mentioned earlier in the call, could you just discuss if there are any key readouts to watch in 2019?

Giovanni Caforio - *Bristol-Myers Squibb Company - Chairman of the Board & CEO*

David, thank you. This is Giovanni. So let me just start. As Chris said earlier, we are very bullish on Eliquis. Performance is strong around the world and particularly in the U.S., there is strong momentum in the brand. It's one of the key growth drivers for the company. So let me just reiterate, we are very bullish on the prospects of -- for the asset. And Tom, on data readouts?

Thomas J. Lynch - *Bristol-Myers Squibb Company - Executive VP of R&D & Chief Scientific Officer*

And Dave, a couple of things on data readouts. First, when you think about what we have in the established products, looking at OPDIVO-YERVOY, we've talked in detail about lung cancer. We do know that we've got a data reading out this year in hepatoma and possibly some data in (inaudible) head, neck later in the year. You specifically asked about novel compound, so -- and I think that's an area of great excitement from our standpoint. First, we hope to have some data later this year with our [ligands] compound to get a better sense of how this unique molecule that approaches the concept of lymphocyte exhaustion might be able to play a role in cancer. The second is you'll see more evolution of data with our combination between OPDIVO and Nektar as the year progresses. We're very excited about the potential for this combination to be able to improve outcome and provide a unique therapeutic opportunity for patients. And then again, CTLA-4 is a really, really important compound and has important target. And so the 2 compounds that we're excited about are the Probody that we're doing with CytomX as well as the nonfucosylated formulation, both of which are moving through Phase I this year. In fact, this year, we hope to advance the product compound close, which should be the Probody of the nonfucosylated formulation. So again, combining those 2 technologies looks particularly exciting. So a number of important early signals, I would say, from some of our novel I-O agents. And then of course, we talked earlier, and you saw the slide, Slide 15 in the deck, which looks at the timing of some of the established readouts, which we look forward to in the next 12 to 24 months.

John E. Elicker - *Bristol-Myers Squibb Company - SVP of Corporate Affairs & IR*

I'll turn it over to Giovanni for some closing comments.

Giovanni Caforio - *Bristol-Myers Squibb Company - Chairman of the Board & CEO*

Thank you, John. And thanks, everyone.

So as we close, let me just reiterate, this was a very good quarter, which capped a really great year. Our performance is driven by strong commercial execution with good momentum in the business going into '19. We've made important progress in our pipeline, and we have demonstrated disciplined management of our P&L. And this will create strong foundation as we enter into 2019. This will be an exciting next chapter for our company as we plan on the integration of Celgene, and I'm confident we are creating value for BMS's shareholders. I'm excited about the prospects we had -- we have as a leading scientific company, and I want to thank everyone for participating in the call. Thank you.

John E. Elicker - *Bristol-Myers Squibb Company - SVP of Corporate Affairs & IR*

Greg, I think that concludes our call.

Operator

That concludes today's conference call. Thank you for your participation. You may now disconnect.
