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Bristol-Myers Squibb Company (BMY) CEO Giovanni Caforio on Q3 2019 Results - Earnings Call Transcript

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Q3: 10-31-19 Earnings Summary

Press Release

EPS of $1.17 beats by $0.10 | Revenue of $6.01B (5.55% Y/Y) beats by $114.51M

Earning Call Audio

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Bristol-Myers Squibb Company (NYSE:BMY) Q3 2019 Earnings Conference Call October 31, 2019 8:30 AM ET

Company Participants

John Elicker - Senior Vice President, Public Affairs & Investor Relations

Giovanni Caforio - Chairman & Chief Executive Officer

Charlie Bancroft - Chief Financial Officer

Chris Boerner - Chief Commercialization Officer

Samit Hirawat - Chief Medical Officer & Head of Drug Development

Conference Call Participants

Terence Flynn - Goldman Sachs

Geoff Meacham - Bank of America

Chris Schott - JPMorgan

Tim Anderson - Wolfe Research

Seamus Fernandez - Guggenheim

Steve Scala - Cowen

Umer Raffat - Evercore

David Risinger - Morgan Stanley

Navin Jacob - UBS

Operator

Good day, everyone, and welcome to the Bristol-Myers Squibb 2019 Third Quarter Results Conference Call. Today's conference is being recorded.

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

John Elicker

Thanks, Augusta, and good morning, everybody. We're here to discuss our Q3 earnings results. With me we have Giovanni Caforio, our Chairman and Chief Executive Officer; Charlie Bancroft, our Chief Financial Officer, who'll both have prepared remarks; Chris Boerner, Chief Commercialization Officer; and Dr. Samit Hirawat, Chief Medical Officer and Head of Drug Development will be here for Q&A as well.

I'll handle the legal requirements first. During the call, we'll make statements about the company's future plans and prospects that constitute forward-looking statements. Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors including those discussed in the company's SEC filings.

These forward-looking statements represent our estimates as of today and should not be relied upon as representing our estimates as of any future date. We specifically disclaim any obligation to update forward-looking statements even if our estimates change.

We'll also focus our comments on our non-GAAP financial measures which are adjusted to exclude certain specified items. Reconciliations of these financial measures to the most comparable GAAP measures are available at our website. Giovanni?

Giovanni Caforio

Thank you, John, and good morning, everyone. I'm pleased to speak with you today about another great quarter in which we had strong operating performance, reported significant new data for our oncology franchise, and made important progress to close the pending acquisition of Celgene and integrate the two companies.

Let me start with our oncology franchise and the recent results we announced for our lung cancer program. I believe we have an opportunity to play an important role in first-line lung cancer. We now have a second trial demonstrating an overall survival benefit for the combination of Opdivo+ low-dose Yervoy in first-line lung cancer population, regardless of PD-L1 status or histology.

With the results of both CheckMate-9LA and 227 coupled with the strength of our commercial capability, I feel good about our ability to maximize the opportunity we see in the first-line lung cancer market.

Let me quickly recap the findings from our two recent lung cancer studies. With CheckMate-227 we've learned that dual I-O offers a unique potential for long-term survival in first-line lung cancer. Physicians have told us that the depth and durability of response is important. And we saw a clear contribution of parts when comparing Opdivo+Yervoy to Opdivo monotherapy in PD-L1 expressors. We also saw that Opdivo+Yervoy has better overall survival outcomes than the PD-1 chemo combination in PD-L1 negative patients.

As we described at ESMO in September, it is our view that the Dual I-O regimen will play a role in the treatment of first-line lung cancer and this is supported by the feedback we have received from physicians. We also know that due to rapidly progressing disease some first-line lung cancer patients need chemotherapy.

A key question for the CheckMate-9LA study was to determine whether a limited amount of chemo two cycles would be enough to stabilize the disease for those patients and manage the early part of the curve, allowing for the potential durability of effect of Dual I-O.

We are pleased with the positive interim analysis from CheckMate-9LA which demonstrated a meaningful overall survival benefit from our I-O combination concomitant with a limited course of chemo. We expect to report this data at an upcoming medical meeting likely in 2020. We also look forward to sharing the findings with health authorities soon.

At ESMO we also presented important data that explored new approaches in difficult-to-treat tumors and reinforced the benefit of the Opdivo+Yervoy arrangement. In addition to our first-line lung cancer data, we presented Opdivo+Yervoy five-year overall survival data metastatic melanoma. We also presented important data for other types of tumors including prostate, cervical, and esophageal cancers.

We continue to see opportunities to broaden the use of our I-O medicines to benefit more patients. And the breadth of data presented at ESMO is a good indication of our progress. I'm looking forward to future data readouts in our I-O development program, including adjuvant beginning next year. As John mentioned, Samit Hirawat is here with us today. He can share his perspective on the full portfolio as well as his priorities for the development organization during the Q&A.

Now, let me turn to the third quarter results. We continued to deliver strong results, driven by excellent commercial execution across our portfolio. Our teams have done a great job in a very competitive market for Opdivo and we're able to maintain strong market shares in key indications to-date. Eliquis continues to show significant growth, with potential for expansion moving forward. The Eliquis profile is strengthening globally, as the product is already established as the global standard of care. This quarter at ECC, we presented the largest real-world data set of French atrial fibrillation patients, which confirmed Eliquis' best-in-class profile. Charlie will provide more color on our performance in the quarter and the potential opportunities that we see ahead.

Turning to our transaction with Celgene, I am pleased with the significant progress we've made to bring together two leading innovation companies, united by a shared focus on transforming patient lives through science. While the transaction has been pending, Celgene has continued to deliver on their business priorities. And today, they announced strong results for the third quarter.

During the quarter, Celgene made significant progress on the late-stage pipeline. The FDA approved Inrebic or Fedratinib as the first new treatment in nearly a decade for patients with myelofibrosis. We were also encouraged to see the success of Celgene's CC-486 study in acute myeloid leukemia patients looking for a maintenance option. I am very proud of the people at Bristol-Myers Squibb and Celgene. Both teams delivered terrific quarters and at the same time made meaningful progress towards closing the transaction and planning for integration.

Importantly, we are on track to realize the expected $2.5 billion in run rate cost synergies by 2022. During the third quarter, we achieved two key milestones in the process to close the transaction. We received approval from the European Commission in July. In August, we announced an agreement between Celgene and Amgen to divest OTEZLA for $13.4 billion in cash, following the close of our acquisition of Celgene. FTC clearance is the remaining regulatory milestone to complete the Celgene transaction. We continue to expect to complete the combination of Bristol-Myers Squibb and Celgene before the end of 2019.

In the meantime, we are focused on building the organization structure of the new company, with the goal of delivering on the promise of this combination for our patients, our employees and our shareholders. Following the announcement of my future leadership team in June, we announced internally the next layer of management in September. These leaders are now working on preparing for integration, to ensure that we hit the ground running on day one.

To conclude my remarks, I'd like to reiterate, how pleased I am with our continued strong performance. I'm encouraged by the results we announced in our first-line lung program, by enforcing the benefit of the Opdivo plus low-dose Yervoy arrangement and the potential opportunity to provide new treatment options to patients.

As we move closer to completing the Celgene transaction, I'm even more excited about the potential of the combined company. Both businesses are performing well, the pipeline is progressing and we have seen significant clinical and regulatory progress. I am looking forward to more news at ASH. Commercially, we're on track to support multiple future launch opportunities and I'm confident we are ready for the integration in our ability to execute as a combined company.

With that, I'll hand it over to Charlie.

Charlie Bancroft

Thanks, Giovanni, and good morning, everyone. We had another good quarter with important pipeline developments, strong product performance and continued progress towards closing the Celgene acquisition.

Let's start with I-O performance. Our U.S. commercial team continues to execute very well, maintaining strong share in key indications. As expected, we continue to see the size of the eligible pool of second-line lung patients declined during the quarter. This trend has been in line with our projections and we continue to expect it to level off towards the end of this year.

In the first-line RCC space, we continue to perform well, where Opdivo+Yervoy remains a standard of care in intermediate and poor risk patients. As we've described in the past, TKI, I-O combinations are expanding the use of I-O, mainly at the expense of TKI monotherapy.

However, as we mentioned in Q2, there has been some attrition of new patient share for Opdivo+Yervoy. This combined with the unfavorable inventory movement affected U.S. sales for Yervoy during the quarter.

Also remember that Yervoy is more sensitive than Opdivo to variability in first-line RCC demand because the dose schedule is front-loaded. Internationally, we continue to see good I-O performance in launches such as renal and adjuvant melanoma with the second-line lung patient pool declining more slowly than in the U.S. as we expected.

Turning now to Eliquis. Our commercial teams globally continue to execute very well by leveraging the differentiated profile of Eliquis establishing Eliquis as the global standard of care. In the U.S. we delivered 23% revenue growth in the quarter. This was driven by significant demand generation with scrips growing 30% compared to the same time last year.

As expected, we saw increased gross to net from the donut hole impacting revenues during the quarter. As in prior years, we expect to see a significant impact from the donut hole again in Q4.

Internationally, we also saw a strong growth as Eliquis is now the number one oral anticoagulant in multiple countries outside the U.S. while continuing to build momentum to overtake Warfarin in countries such as France.

During the quarter, we saw continued stable demand for Sprycel in the U.S. So the inventory levels have normalized compared to a significant work down that occurred in Q3 last year.

Regarding some key line items in the P&L during the quarter. Other income and expense benefited mainly from licensing fees in the quarter as well as higher royalties. Our tax rate was favorably impacted by one-time items in the quarter, which we anticipated in our full year tax rate guidance of approximately 16%.

Based on the performance of the business, we've updated our non-GAAP EPS guidance today for BMS on a standalone basis. For the combined company as Giovanni has noted, we have significant opportunities ahead. So we won't be in a position to provide guidance for the combined company until some point after the deal closes.

Let me remind you about some of the mechanics of the pro forma P&L, starting with gross margin. This will continue to be primarily dependent on the product mix of the combined company. Eliquis for example will remain a headwind compared to the other products in the portfolio.

Regarding OpEx, it will be important to add back Celgene's stock-based compensation to the non-GAAP OpEx of the combined company consistent with the BMS practice. We also expect roughly one-third of the $2.5 billion of synergies to be realized next year.

OI&E for the combined company will include interest expense from existing debt from both companies including the $19 billion of acquisition-related debt we raised earlier this year at an average rate of 3.5%. After the close, the share count will increase by the number of shares outstanding for Celgene at close, as well as the dilution from stock-based compensation, partially offset by the ASR. When we look at the P&L of the combined company, we are very encouraged by the accretion and earnings power of the company moving forward.

Regarding capital allocation, we see significant cash flow generation for the combined company and we plan to continue to employ a balanced approach to capital allocation. We initially projected in excess of $45 billion of free cash flow over the first three years for the new company. So free cash flow will be slightly lower due to the absence of operating cash flow from OTEZLA. This doesn't include the $13.4 billion, we expect to receive on a pre-tax basis from the sale to Amgen.

The substantial cash flow generation will allow us to delever, increase the dividend, fund the ASR and invest in innovation. Reducing debt and delevering -- excuse me and delivering on our commitment to achieve gross debt-to-EBITDA at less than 1.5 times in 2023 is central to maintaining strong investment-grade credit ratings. The proceeds from OTEZLA will be prioritized to reduce near-term debt and avoid excess initial leverage.

We remain committed to the dividend as evidenced by our 10-year track record of continual dividend increases. And as we've previously mentioned, we've modeled annual increases in our proforma financials. We've increased our ASR from $5 billion to $7 billion, and we expect to execute the ASR after close. We will continue to be active in the business development in the near-term focusing on early-stage and smaller deals while we reduce debt and rebuild balance sheet flexibility.

To close, we've had very good operating performance during the quarter. And with strong business momentum for both companies, we are well positioned to embark on our next chapter as a combined company following the close.

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

John Elicker

Thanks, Charlie. And Augustus, we can got to the Q&A session now. And just as a reminder in addition to Giovanni and Charlie both Chris and Samit are here to answer any questions you might have. Augustus?

Question-And-Answer Session

Operator

Thank you, sir. [Operator Instructions] Our first question will come from Terence Flynn with Goldman Sachs.

Terence Flynn

Thanks for taking my question. Just wondering, if it's reasonable to assume that the CheckMate-9LA data are stronger than the -227 data across both PD-L1 and PD-L1 negative patients given the trial unblinded on an interim analysis? And then wondering, if the plan is to file these data separately than 227? And then the second question, I had just relates to Opdivo for 2020. Last quarter, I think you said you're expecting some pressure next year. Just given the third quarter trends and the recent clinical data any updated thoughts you can share there on the outlook for growth? Thank you.

Giovanni Caforio

Thank you. So, obviously as you know we're not going to comment on interaction with regulatory authorities or our regulatory strategy. As we did mention, we are planning obviously on sharing data from 9LA with health authorities around the world. Samit will give you a perspective on the results and the data and Chris will comment on Opdivo performance.

Samit Hirawat

Thank you, Giovanni. And just to reiterate, I think what Giovanni had already said in the beginning that we are truly happy with the results of 9LA and putting into perspective the two positive trials certainly bodes well for the combination of nivolumab plus ipilimumab.

I think it's going to be very important to then look at the data when we are able to present it at future medical meeting to understand the outcome for patients in terms of the efficacy, when we combine two cycles of chemotherapy right upfront in combination with nivolumab as well as low-dose ipilimumab in terms of safety management and overall outcome and how the curve might be impacted. And if the early part of the curve can then be carried through to the rest of the curve.

We obviously cannot compare and convey what the results are in terms of the comparison of 9LA versus 227. We can't comment on the biostatistical analysis plan itself. And as Giovanni said, we will not comment at this time about our regulatory strategy of filing. But let me pass it on to Charlie – to Chris for more comments.

Chris Boerner

Yeah. Thanks Terence. We're obviously from a commercial standpoint very pleased with the data that we saw in the front-line lung cancer over the last few weeks. Looking for – and we're also very much looking forward to the regulatory discussions that will take place and ultimately being able to commercialize in first-line lung. Given the competitive dynamics in the U.S. and the timing of those regulatory interactions, though we do still see Opdivo under pressure in 2020. However, as we've said consistently, the trajectory of growth beyond 2020 is going to be dependent upon new indications. And based on the data readouts, we've seen thus far and the continued very strong execution of our commercial teams, we feel pretty good about returning to growth in 2021.

Now the shape of that growth will continue to be a function of additional data readouts in the metastatic setting. Those include 9ER in first-line renal CheckMate-648 in first-line esophageal and first-line gastric cancer from CheckMate-649. All of those will read out in 2020. And then, we also expect to see adjuvant programs to begin to read out in 2020-2021. And those as you know include bladder melanoma gastric and neoadjuvant lung cancer.

John Elicker

Thank you, Terrence. Can we go to the question please, Augustus.

Operator

Certainly. We'll go next to Geoff Meacham with Bank of America.

Geoff Meacham

Just had a couple of – thanks for the question, guys. On the renal market, I just want to get a sense for what you guys are seeing first-line versus second-line trends just given the competitive dynamic during the quarter? And then just a follow-up on a prior comment from Chris just earlier, I know you guys have already offered a perspective on what to expect for 2020 I-O trends. But with the early interim look for 9LA and the 227 refiling, is it reasonable to assume a tick up let's say in the second half of 2020 as the first-line lung data are digested and rolled out in the marketplace? Thank you.

Chris Boerner

Yeah. So thanks Geoff. Let me just start with renal. Obviously we had competitive impact from I-O and TKI in the earlier part of this year, post the launch of those regimens in the first half of the year.

However, what I would say is in first-line renal today, as we look at our on label population, our shares holding around 30% to 35% that's been relatively consistent frankly over the last number of months. The competitive share that we've seen I-O TKI take has mainly been coming as was mentioned earlier from TKI monotherapy. And we've actually seen growth in the I-O class share in first-line renal as a result of that. But as I said our shares holding in the 30% to 35% range and that's been stable really over the last number of months.

With respect to second line our share, in second line is roughly 36%. We do see that decline in the eligible pool in second line as a result of first-line dynamics. But I think there's one thing to keep in mind in renal that's different from, for example, lung cancer at

least as of to date and that is in the renal cell market while you see a decline. And eligibly in second line you also see Opdivo plus Yervoy playing a role in the first-line setting. And, obviously, at least right now that's not the case in non-small cell lung cancer.

And then in respect to 2020 and 20 -- and growth for Opdivo beyond 2020, I think I would just refer back to the answer I gave to Terence's question. I think that we're going to have to see how the dynamics play out with respect to the timing of regulatory interactions. But I think right now, we still do see Opdivo under pressure for 2020. But as we get beyond 2020 and certainly into 2021 metastatic and adjuvant programs will read out and we very much continue to see Opdivo as a growth brand.

John Elicker

Thanks, Geoff. Augusta, can we go to the next question please.

Operator

Yes, sir. That will come from Chris Schott with JPMorgan.

Chris Schott

Great. Thanks very much. Just coming back to Opdivo Yervoy in first-line lung, I realize you can't talk about the 9LA data at this point. But just maybe a bigger picture question. As you think about the role of chemo induction followed by dual I-O as compared to just Opdivo Yervoy alone strategy.

At this point is there -- do you see one of those profiles really standing out relative to the other in terms of what's going to be optimal treatment profile for those agents in front-line lung? Just want to get just more, kind of, qualitative sense of is one really looking at like the front-runner versus the other?

My second question was on leverage. I know there's been a few moving pieces over the course of this year with the OTEZLA sale et cetera, and you get the longer term leverage targets. But can you just talk about your expected leverage and debt profile as we look at

2020? Should we -- turning my hands on how quickly your balance sheet is going to be back at a point where we can think about the company looking to deploy capital again? Thanks so much.

Chris Boerner

Chris, maybe I'll take the first question and then I can turn it over to Charlie for your second question. The way we think about 9LA, frankly is very much in the context of 227. And as you recall from the conversation we had at ESMO, we see first-line lung cancer still as a market with significant unmet need.

For example, the majority of patients treated with standard I-O plus chemotherapy are going to relapse within a year. And based on the conversations that we had with the physicians going into ESMO and certainly since ESMO, they see a few things.

First, there's considerable need for additional options given the unmet need in first-line lung cancer. And second, they see opportunity for dual I-O therapy. They're impressed with the tail of the overall survival curve that they saw from 227, the complete response rates and importantly the duration of those responses they view is very compelling. And they see 227 is providing an important option with a manageable safety profile for patients who don't need or want chemotherapy.

What 9LA does and the way we think about it is for patients who do require chemotherapy. The question really is whether a limited amount of chemotherapy in this case two cycles adds value to dual I-O therapy. Obviously we just got the top line data. We haven't gone through all the specifics, so we can't comment on that.

However, what we can say is, we're very pleased that we have a second trial demonstrating an overall survival benefit for the combination of Opdivo and low dose Yervoy. And remember this was a study that was regardless of PD-L1 status or histology.

And we do believe that 9LA and 227 coupled with the strength of our commercial organization gives us a real opportunity in first-line lung cancer and one that we can capitalize and we very much look forward to the opportunity to do so.

And so with that, maybe I'll turn it over to Charlie.

Charlie Bancroft

Yeah. Thanks Chris for your question. As I talked about in my comments and we've talked about in the overall deal dynamics deleveraging and getting back our balance sheet flexibility is really important, although, as we've continued to mention during early stage deal is already included in our cash flow analysis. But let me just kind of walk you through the math.

We have already taken out $19 billion in loans as you know. We've talked about that. Celgene has $20 billion in debt outstanding of 6. So at the end of 2019, we'll have as a combined company $45 billion in debt, which is significantly less than we originally considered given the OTEZLA sale and cash flow generation. As we exit 2020, we expect to be about 2.5 times debt-to-EBITDA leverage.

John Elicker

Thanks for the questions, Chris. Augusta, can we go to next one please?

Operator

That will come from Tim Anderson with Wolfe Research.

Tim Anderson

Thank you. Staying with Opdivo. It's been my assumption, I think it is most analysts on the Street that Opdivo will remain in the second spot in the I-O space in terms of the league tables among competitors. Are you confident that Opdivo will remain the second biggest brand in that space over time?

I look at a company like Roche for example. They've been knocking out trials consistently and you're really seeing an uptick in that program. And I'm wondering if you're confident that you can remain in the number two spot.

Second question, going back to 9LA, do you think that you have to show a PFS benefit not only an OS benefit, which you've talked about, but a PFS benefit as well for that trial to be commercially meaningful?

Giovanni Caforio

Thank you Tim. Let me just start and then I'll ask Chris to comment further. So, let me just say that we feel very good about where we are with Opdivo. The performance in the marketplace is quite strong. We've demonstrated our ability to maximize every opportunity we get.

Now as I said, we have a real opportunity to play a role in first-line lung cancer with a differentiated regimen. It's the third time that we have an overall survival advantage for Opdivo plus Yervoy in the front-line setting in an important disease. That gives us confidence that as we think about the rest of our metastatic program that are really important studies that read out in the next 12 to 24 months. And then as we've said in the past, the next wave of growth for I-O in the adjuvant setting, I think Opdivo is very, very well positioned to compete there. Chris?

Chris Boerner

Yeah. So what I would say is that I mean I think Giovanni has really highlighted kind of how we think about Opdivo overall. And I think the only thing I would add to that is remember we have 19 separate indications. We continue to have an important and leading market share in the vast majority of indications in which we're promoting.

So we feel pretty good about where Opdivo sits today as well as the growth opportunities in light of the -- not only results that we've seen in lung cancer, but also the opportunities that we have with additional data readouts into the metastatic setting as well as in the adjuvant setting.

With respect to your question regarding 9LA and whether or not there's a specific target that we would have to hit with respect to the data that we see there to be competitive. Look, if you look across the range of studies that I've read out in first-line lung cancer not only from our studies, but also from Merck and Roche, and you look at all of the data that's read out across those studies, you see a fairly broad range in terms of the hazard ratios for OS, the hazard ratios for PFS as well as response rates and durability of response and that variability increases as you start looking within specific subsets.

So we don't actually see a specific hurdle rate that we're going to have to overcome. What we think about in this market is really what physicians have played back to us. There's significant need in spite of all of those data readouts in first-line lung cancer. There is a role for dual I-O therapy to play in the setting based on the strength of the data that was presented with 227 and we are very much excited about the opportunity that 9LA play.

As I mentioned earlier, 227 is for those patients who may not require chemotherapy. 9LA has a really important role to potentially pay for those patients who do. And given that along with the strength of our commercial and medical organizations, we're excited about the opportunity we have.

Samit Hirawat

And Chris, just -- this is Samit. And just to add a couple more points that 9LA if you remember, the primary endpoint in the trial is overall survival. Secondary endpoint does include PFS, response rate, duration of response, safety, et cetera.

Second point is that, we started the study at the end of 2017 and the enrollment in 9LA finished only in the early part of this year. So from a follow-up perspective the duration is relatively short and so this data continue to evolve and mature.

And as Chris has said earlier, we just saw the top line data at this time. And as more data is available and we dig deeper into it, we'll be able to comment more as we present the data some time next year.

John Elicker

Thanks for the questions, Tim. Can we take the next one please, Augusta.

Operator

Thank you. The next question will come from Seamus Fernandez with Guggenheim.

Seamus Fernandez

Thanks for the question. So one question just on from an investment perspective. As you think about the 9LA results, can you guys talk to us about the strategy going forward? Do you see more opportunities to invest behind triple regimens on a go-forward basis? Are there other tumor types beyond lung cancer, where you would see a similar type strategy worth investing behind or perhaps even see an opportunity to invest behind this combination in the adjuvant setting? Or should we think about it more as a dual I-O/I-O strategy similar to the trials that you started recently, competitively in the stage three setting?

The second question is as we think about the opportunity Chris, across IBD and also some of the other inflammatory conditions, you're sort of exiting psoriasis because of the OTEZLA transaction. Can you just help us understand a little bit more the efforts that you're going through to kind of prepare to rebuild your presence not just in psoriasis but also in the IBD space as you think about ozanimod and the TYK2 assets coming on in 2020, 2021. Thanks.

Samit Hirawat

Thank you for the question. Let me just take it from the two questions that you've asked in terms of the nivo and also with the -- with chemotherapy. You will see that we have trials ongoing in the Phase III setting CheckMate-648 in the esophageal cancer and bladder cancer nivo-ipi and chemo and versus standard of care chemotherapy in gastric cancer mesothelioma hepatocellular carcinoma.

All these data will continue to evolve in 2020, 2021 time frame. And then of course, we'll continue to look for additional opportunities where we can develop this combination going forward. We are quite confident because now that we are using in many of these trials in low-dose ipilimumab, we'll be able to manage safety as well and also the experience of the physicians will continue to grow.

On your second question regarding the psoriasis space related to OTEZLA divestiture versus what we are doing in that space, we certainly are looking forward to quite excitedly to our TYK2 inhibitor. TYK2 as you know is differentiated from the JAK inhibitors which are not specific and through the inhibition of its activation domain has multiple downstream effects which leads to many of the side effects that we see.

The TYK2 inhibitor that we have which is BMS-165 was very specifically designed to target the pseudokinase domain. What it does is that it interrupts the signaling of the IL-23, IL-12 and Type II interferon pathways. And therefore it's quite specific in terms of its efficacy as well as safety not causing the neutropenias or the dystrophy that have been seen.

So we're looking towards the readout of the Phase III studies that are currently ongoing towards the end of 2020 and early 2021 as well as other indications where the Phase II studies are ongoing in psoriatic arthritis as well as in IBD. You already mentioned the Phase III program with ozanimod well in IBD. So we're looking forward to seeing that data as well towards 2020 end. But let me just pass on to Chris to add additional comment.

Chris Boerner

Yes. Let me just add a few things from a commercial standpoint. Obviously, the TYK program is very exciting. The initial indication as you know will be in psoriasis. That's a very large opportunity as you're aware, prevalence for psoriasis in the U.S. EU5 and Japan is on the order of 2.3 million patients. This is a big opportunity. And based on the data that we've seen coming out of the Phase II with a 75% response rate with the PASI 75 score, we think that TYK is going to play an important role for those patients who are looking for a biologic like efficacy but with the safety and convenience of an oral.

And obviously, that's just the first opportunity that we have with TYK. IBD is a very large market, roughly $17 billion worldwide. There are about 1.5 million patients diagnosed with this disease. And as we've discussed previously, the vast majority of those still are not ultimately treated with systemic therapies because the lack of really efficacious and safe products.

The way we look at this from a commercial standpoint in terms of building it out number one, we're building out obviously the ozanimod team working with our Celgene colleagues today. Obviously, there's an initial focus on MS, but we do have an eye towards the broader IBD opportunity. And remember, BMS has a history in immunology. So we know this space well and that's something that we'll obviously as we become a combined company bring to there. So I'm actually quite confident that we'll be in a position to capitalize on these opportunities.

John Elicker

Thanks, Seamus. Can we take the next question please.

Operator

That will come from Steve Scala with Cowen.

Steve Scala

Thank you so much. Charlie, did you provide the key aspects of the combined P&L, because you think consensus is too high? I'm curious, why you did it now versus in the past or upon closing. Second, the raised full year EPS guidance implies Q4 will be down between 6% and 17%. That's striking because it's been a very good year. Why will Q4 EPS be down so precipitously? And then if I might quick for Sumit. You said, 9LA follow-up was relatively short. KEYNOTE-189 hit with a median of 10 to 11 months, should we assume something similar for 9LA? Thank you.

Charlie Bancroft

Yes. Thanks, Steve. So in regard to just giving some perspective on the combined P&L. There has been some analysts who weren't modeling, particularly as we think about stock-based compensation in particular. So we wanted to get to be a little bit more specific, how we're going to handle it in addition to how we think about the share count. So I think that's fair. In regard to the fourth quarter, there's a number of things at play. If you think of the sales related to the business as we've talked about before we sold the UPSA business in July. The ELIQUIS donut hole continues to get slightly larger, as we think about the fourth quarter. And we've talked about -- we've already talked on this call a little bit of the Opdivo flattening in -- as we got into the third and fourth quarter. That coupled with -- historically we always have more OpEx in the business as we -- in the fourth quarter.

Samit Hirawat

And in terms of the question around 9LA. Of course, we will not compare this trial at this time to any other including KEYNOTE-189. And we obviously cannot compare, how the results will be presented in terms of the comparison to what we have seen with

KEYNOTE-189 at this time.

John Elicker

Thanks, Steve. Can we take the next question please.

Operator

That will come from Umer Raffat with Evercore.

Umer Raffat

Hi. Thanks so much for taking my question and I appreciate you bearing with me on this two questions. First, there's been confusion in the marketplace on your ongoing ELIQUIS patent litigation, specifically as it relates to whether the salt forms are appropriately tied in the written description of the patent or not. My question is given that there is MI on the chemical structure, isn't it fairly straightforward for a regular chemist to be able to make a salt form of ELIQUIS? And secondly, I want to touch up on the LAG-3 trial readout in melanoma for second half 2020. I realize this topic doesn't come up very much on the calls. My question is, I know there's a randomized Phase II and a Phase III component of this trial, has there been a readout of the randomized Phase II internally? And is there anything we can learn from that? Thank you very much.

Giovanni Caforio

Thanks, Umer. Let me just answer your question on the ELIQUIS pattern first. So a couple of things. First of all we feel very good about the IP position for ELIQUIS. You may remember there were about two dozen challenges to the IP of ELIQUIS over 20 generic companies have already settled with us and I think that speaks to the strength of our IP position. They are a small number of generic companies that are continuing to challenge the patent. There has been some news regarding the fact that there was an out of order witness that testified in the last couple of days. That was really a scheduling issue the trial really starts today. And I can just say we feel very good about the fact that we have a strong patent estate for ELIQUIS. Samit on...

Samit Hirawat

Thank you, Giovanni. In terms of the LAG-3 trial as you know it is a trial looking at a combination of LAG-3 plus nivolumab versus nivolumab in the first-line metastatic setting for melanoma. It's a seamless Phase II/III study. So we have not seen the data. The trial continues to enroll patients in the study. And as you already pointed out our data will be available towards the end of 2020. So we'll be able to communicate at that time.

John Elicker

Thanks, Umer. Can we take the next question Augusta please.

Operator

That will come from David Risinger with Morgan Stanley.

David Risinger

Yes. Thanks very much. So, I have a question about future trials. So 9LA was triple therapy including two cycles of chemo, but we had understood that Bristol was looking at chemo priming or sequential therapy with Opdivo and Yervoy following chemo.

So could you remind us do you have any registrational trials that we should be watching in the future with chemo priming or sequential therapy? And then second, with respect to Opdivo's outlook for 2020, could you just please provide some color on how we should think about the momentum in the U.S. relative to ex-U.S.? Thanks very much.

Giovanni Caforio

Thank you for the question. Maybe, I can take the first one in terms of the future trials and how we think about I-O and the chemo and sequencing. At the current time, we don't have trials that are looking at the sequencing of chemotherapy followed by I-O or I-O followed by chemotherapy, as such.

But certainly it's an idea that we may explore in the future with the new trials that we will be planning and looking at. And second and third generation I-O compounds yet to be developed in the future, but there are no registration trials that we have at this time that we're looking to this sequencing.

Chris Boerner

And, David, let me just comment on the Opdivo question. So with respect to U.S. versus ex-U.S, we continue to see opportunities to grow the business outside of the U.S. and that's based really on a couple of things. First, the strength of our business across our core tumors, renal melanoma and second line non-small cell lung cancer, as well as the timing of access in a number of countries ex-U.S.

The U.S. is under pressure as we mentioned previously. And really, that's a function of primarily competitive dynamics across lung cancer, as well as, two other indications head, neck and small cell. And let me describe what that looks like.

So, in all three of those cases, it's really a function of the decline in the eligible population in later lines where we have the bulk of our business today. We talked at length about the situation in second-line lung cancer with approvals of I-O agents in first-line, continuing to decrease the eligible pool in second line. That same dynamic has played out, or is playing out, in head and neck with competitor approvals earlier this year in first-line and in small cell with Roche's recent approval in a first-line setting.

What I will note across all three of those, however, is that we continue to maintain a leading share in second line, albeit, within a declining eligible pool and are stable -- and our shares in head and neck and small cell in second and third line, in both of those indications we expect to be stable in next year. Again, it's a function of the declining eligible pool in those markets.

John Elicker

Thanks, Dave. And Augusta, so I guess, it looks like we only have one more question in the queue.

Operator

Yes. And that final question will come from Navin Jacob with UBS.

Navin Jacob

Hi, thanks so much for taking my question. Just on CheckMate 816 in the adjuvant lung study. I think the PCR endpoint is expected in the first half of 2020. I think you recently added Opdivo plus chemo arm in addition to Yervoy plus Opdivo arm. We just wanted to clarify if the time line is still first half 2020? And just wondering what we could learn from that as it relates to your adjuvant lung study. And if you could remind us when the adjuvant long study reads out please.

Samit Hirawat

Sure. I will take on that question. So thank you for that. Look certainly the nivo-ipi versus nivo plus chemo versus chemo are the three arms that are being investigated in that study.

As you know at this time, we have a PCR endpoint, but from a regulatory perspective that is certainly something that we need to continue to discuss with the health authorities and how we will then be able to take that forward in terms of utilizing that data for the adjuvant setting and how we will utilize that data in terms of making future decisions. Adjuvant study as such also is a separate study looking at CheckMate 427 which is nivo versus observation and then there are other studies in the early stage lung cancer.

So at this time I think our only communication to you would be that the data does become available for PCR in 2020 and we'll continue to focus as we go forward in terms of looking at the data for the adjuvant trial from 816 as well.

Giovanni Caforio

Thank you, Samit, and thanks, everyone. So, in closing, let me just reiterate this is an exciting time for Bristol-Myers Squibb. We delivered another strong quarter demonstrating our ability to execute on commercial priorities, advance our pipeline while we work to close the Celgene acquisition and plan for integration.

I'm excited about the promise of our future and the opportunities we have ahead of us to help even more patients prevail over serious diseases. Thanks everyone for participating in the call and have a good day.

Operator

That does conclude today's conference. Thank you all for your participation. You may now disconnect.