Bristol-Myers Squibb Company, Q3 2020 Earnings Call, Nov 05, 2020
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Operator

Good day, and welcome to the Bristol-Myers Squibb 2020 Third Quarter Results Conference Call. Today's conference is being recorded. At this time, I would like to turn the conference over to Mr. Tim Power, Vice President, Investor Relations. Please go ahead, sir.

Timothy Power

Thanks, Kevin, and good morning, everyone. Thanks for joining us this morning for our third quarter 2020 earnings call.

Joining me this morning with prepared remarks are Giovanni Caforio, our Board Chair and Chief Executive Officer; and David Elkins, our Chief Financial Officer. And also participating in today's call are Chris Boerner, our Chief Commercialization Officer; Nadim Ahmed, President, Hematology; and Samit Hirawat, our Chief Medical Officer and Head of Global Drug Development. As you note, we've posted slides to bms.com that you can follow along with Giovanni and David's remarks.

And before we get going, I'll read our forward-looking statements. During this 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 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 those non-GAAP financial measures to the most comparable GAAP measures are available at bms.com.

With that, I'll hand over to Giovanni.

Giovanni Caforio

Thank you, Tim, and good morning, everyone. I hope that you and your families are safe and healthy. Q3 was a very strong quarter across the company, adding to great performance over the past year. I will go into more details about the quarter in a few moments, but recognizing that it has been almost a year since we established our new company, I would first like to give you my perspective on the company overall.

Turning to Slide 4. A year ago, we transformed our company with the goal of positioning us for growth in the near, medium and long term. I am very pleased with our ability to consistently deliver on that promise across multiple dimensions, starting with integration, where we continue to make great progress. The strength of our execution as a combined company is a testament to our successful integration so

far. The culture of our company is being shaped by our values, including a focus on innovation, collaboration and a great sense of urgency.

Our synergy capture is ahead of our original expectations. From a commercial perspective, we have driven strong performance from our in-line brands. We have launched 4 new medicines, including Inrebic, REBLOZYL, Zeposia and Onureg. We have entered the first-line lung cancer market with Opdivo and Yervoy.

In the past year, We've also delivered strongly on the potential of our pipeline, starting with immuno-oncology, where we have seen successful trials across both the metastatic and the adjuvant settings, which further supports the growth opportunity for Opdivo. Specifically, in adjuvant, Opdivo is well-positioned as a leading medicine with results in 4 different tumor types.

Beyond immuno-oncology, we are continuing to strengthen our presence in immunology with very encouraging data from a number of assets and programs. These include Phase III data for Zeposia in ulcerative colitis, the decision to move to registrational trials for cendakimab in eosinophilic esophagitis and Phase II data for our TYK2 inhibitor, deucravacitinib in psoriatic arthritis. Most importantly, we now have top line data from our first Phase III trial for deucravacitinib in psoriasis.

Let me take a moment to talk about deucravacitinib. Based on the top line data that we have seen so far, we are very encouraged with the potential for this asset to be the best oral option for patients with psoriasis, with potential broad applicability across multiple diseases, including psoriatic arthritis, lupus, ulcerative colitis and Crohn's disease.

And finally, we strengthened our IP position for Revlimid and Eliquis, delivered strong financial results and continue to invest in the future with a number of important business development transactions, including 2 early-stage assets through Forbius and Dragonfly as well as the announced acquisition of MyoKardia.

Now turning to Slide 5. Through the planned acquisition of MyoKardia, we're gaining mavacamten, a potential first-in-class medicine for the treatment of obstructive hypertrophic cardiomyopathy, which is a chronic heart disease with high morbidity and patient impact.

We believe mavacamten has multibillion-dollar potential with further potential value drivers from additional indications and the MyoKardia pipeline. We look forward to closing the transaction during Q4 and welcoming our new colleagues from MyoKardia to the Bristol-Myers Squibb team.

Turning to Slide 6. I am optimistic about the strategic position of our company and how we are well-positioned for growth and to navigate through the balanced cycle. Today, Bristol-Myers Squibb has significant strength and breadth in all 4 of our current therapeutic areas. Across oncology, hematology, immunology and CV, we have robust in-line businesses, exciting near-term launches as well as long-term pipeline opportunities.

Across all 4 areas, we are successfully building our portfolio of new medicines through a combination of short-term launches, the advancement of significant late-stage pipeline opportunities and disciplined business development.

To be more specific, Eliquis and Opdivo are assets with significant growth potential. We have 8 new medicines that are launching now or have the potential to launch over the next year. And most of these have important expansion opportunities beyond just their initial indication.

We have gained clear line of sight to our next set of registrational assets, with 7 in or close to registration development, including relatlimab, our 2 multiple myeloma CELMoDs, Iberdomide and CC-92480 as well as cendakimab and our Factor XIa inhibitor. And our early pipeline will continue to advance, with more than 20 assets with the potential to transition to full development over the next 3 years. Given the strength of our portfolio and pipeline, together with the talent of our people, we are focused on delivering on our full potential.

Within that context, let me turn briefly to the strength of the quarter on Slide 7. David will provide more details, but let me discuss a few highlights from my perspective.

First, we continue to execute very well in highly competitive markets, with sales increasing 6% compared to the same period last year on a pro forma basis. In addition, we are making good progress across our launches. And during the quarter, we have seen significant clinical progress, including multiple positive trials in I-O as well as the first Phase III trial for deucravacitinib.

Based on the strength of the business, we are increasing our EPS guidance for this year and continue to be very encouraged about the earnings growth opportunity asset as captured by our non-GAAP EPS guidance for next year, which we are reaffirming.

Before I hand it over to David, I want to reiterate that I'm more encouraged today than ever before about our future prospects. I can say with confidence that our company has never been stronger. Bristol-Myers Squibb is well-positioned to launch multiple new medicines, new indications and benefit more patients in the very short term.

And as we look to the future, our pipeline and financial flexibility, combined with the strength and critical mass we have built across all key areas, provide us with tremendous opportunity. I'm extremely optimistic about what is to come.

And with that, I'll hand it over to David.

David Elkins

Thank you, Giovanni. Hello, everyone, and thanks again for joining our call today. I'm very pleased by the execution of our teams, delivering very strong quarterly and year-to-date results, while operating in this global pandemic.

Let's turn to Slide 9 and discuss our top line performance. Third quarter and year-to-date revenues continue to reflect our strong execution, growing 6% versus prior year

on a pro forma basis. As you can see, a vast majority of our brands demonstrated robust growth.

Now let me provide additional commentary on the underlying performance of our key brands and new launches. Starting with Eliquis on Slide 10. Demand trends continue to be robust with double-digit TRx growth of 18% in the U.S. versus prior year. This demonstrates strong execution of our teams and best-in-class profile brand.

As we discussed previously, we accrue our liability related to the coverage gap as patients enter it, which affects our second half gross to net results. This is more pronounced this year as the size of the coverage gap per patient increased in 2020, and Medicare component is a larger component of our mix. This impact is in line with our expectations for Q3, and you should expect this to be a factor in the fourth quarter.

Internationally, sales remained strong with revenue growth of approximately $1 billion, growing 22% versus prior year. Eliquis continues to be the #1 NOAC in many key markets internationally, including Germany, France and the United Kingdom. Both in the U.S. and globally, we continue to see very strong outlook for Eliquis, resulting from the strength of its profile, enabling increasing share within a growing class.

Turning to Opdivo on Slide 11. In the U.S., the teams have been executing very well. We continue to see strong shares across key indications. We now have high single-digit share in first-line lung cancer with more patients benefiting from the approvals of -227 and -9LA. And you can see that the adoption of first-line lung is reflected in the acceleration of Yervoy.

What we are really encouraged by is return to sequential underlying growth for Opdivo. Underlying demand growth from Q2 to Q3 was approximately 2%. Sales grew 6% versus quarter 2, driven by growing underlying demand as well as the favorable customer buying patterns. We expect the impact to the buying patterns to reverse in the fourth quarter but sequential demand growth to continue, supporting our return to annual year-over-year growth for Opdivo in 2021.

Internationally, we've seen strong commercial execution across the board, with sales up 5% versus prior year. Sequentially, we saw a rebound to a stronger demand driven primarily by the European and Japanese markets as the markets continue to gain reimbursement for new indications and first-line RCC in melanoma.

While there continues to be some softness in new patient starts across tumors but most notably in melanoma, we generally saw good recovery of the impact of COVID in Q3. And we also look forward to bringing our Opdivo + Yervoy and limited chemotherapy to the first-line lung cancer patients in Europe this quarter.

As we look forward, we expect several additional near-term launches in 2021, including the potential for first-line gastric and several adjuvant indications such as esophageal and muscle invasive bladder cancer. And Opdivo + cabo in first-line RCC, for which we will grant a priority review, something that the teams have executed well, both commercially and clinically, which shows the continued promise

for Opdivo and Yervoy makes us even more confident in our expectations for the annual year-over-year growth in 2021.

Moving on to our in-line multiple myeloma portfolio on Slide 12. Revlimid and Pomalyst continue to perform very well with strong double-digit growth on a pro forma basis. Revlimid grew 10% primarily driven on increased treatment duration and Pomalyst grew 17%, driven by growth in earlier lines of treatment and increased treatment duration.

In U.S., we experienced some temporary softness due the new to brand share during COVID, which is now recovering. And this is being offset by better adherence and longer duration of therapy for existing patients.

Ex-U.S. performance sales for Revlimid increased 11%, while ex-U.S. per forma sales for Pomalyst increased 19%. This strong performance was driven by increased use of triple base therapies and treatment duration in major European markets. COVID had a minimal impact on ongoing patient treatments with a small impact observed in new patient starts. We are seeing strong signs of new patients returning to prior treatment patterns.

Now moving on to our recent launches on Slide 13. REBLOZYL has been off to a robust start with the approval of RS-positive MDS-associated anemia. Global sales in the quarter were $96 million, representing 75% sequential growth over quarter 2.

In the U.S., physician feedback remained positive as significant awareness of the brands, while still early, we continue to be pleased with the launch, including new patient uptake and patient retention on the product, where the majority of patients have adhered to their treatment.

As a reminder, a significant proportion of early uptick is driven by the initial bolus of patients waiting for a new treatment option. We remain very encouraged by the underlying demand for the product in patients with beta thalassemia as well as MDS-associated anemia.

Internationally, recent launches in Germany and Austria are going well although very early in the launch. We also received approval for beta thalassemia-associated anemia in Canada, and we look forward to launching the various markets globally in the course of 2021 as we receive reimbursement.

Turning to Zeposia. We're encouraged by what we are seeing through the first few months of Zeposia's launch. We are focused on driving demand and establishing Zeposia as the leading S1P modulator in multiple sclerosis.

We have secured strong commercial access, and our commercial teams are executing well. We're pleased with the physician receptivity and prescription initiation we've seen thus far.

Now moving on to our newest launch, Onureg, which has granted approval for first-line AML maintenance by the FDA on September 1. While very early in the launch, feedback from physicians have been promising. The message at Onureg as the first and only medicine to demonstrate overall survival in the maintenance setting with a

convenient oral route of administration is resonating well. This is a market that is largely underdeveloped as there were previously no FDA-approved options for patients in the maintenance setting after intensive chemotherapy.

And like many other medicines in the maintenance setting, it will take some time to educate prescribers about the use of new treatment for our patients. An MMA is under review in Europe, and we expect approval in 2021.

Now moving on to our balance sheet and capital allocation on Slide 14. We continue to generate significant amount of cash flow from operations in the third quarter. We ended the quarter in a strong liquidity position with approximately $22 billion in cash and marketable securities. That's after tax payments of approximately $1.7 billion for debt paydown and large cash payments, including tax payments associated with the gain on Otezla.

Our capital allocation priorities remain unchanged, delevering and achieving less than 1.5x debt-to-EBITDA ratio, which is now expected by the end of 2024. We continued our commitment to our dividend and investing in future innovation through business development.

To touch on our business development activities, as Giovanni discussed, we have not waived against our priorities. We have executed some important deals over the third quarter, including our acquisition of Forbius and license agreement with Dragonfly as well as our recently announced pending acquisition of MyoKardia. Each of these transactions is in line with our criteria for business development: strategically aligned, scientifically sound and financially attractive.

We will continue to be active in business development, searching for additional opportunities to further strengthen our growth profile for the company for the long term and creating value for our shareholders.

Now let's turn to guidance on Slide 15. Based on the strength of our results year-to-date, we are updating our full year 2020 outlook. We are narrowing our revenue range to between $41.5 billion and $42 billion based upon the strong performance year-to-date. And we do expect sales to be at the higher end of the range.

Turning to operating expenses. We expect total spend to be generally in line with our expectations. We do have some slight shifts in spend related to our MS&A and R&D lines. For MS&A, we decided to make additional onetime investment such as accelerating DTC advertising to support the business as we close out the year, and we now expect to spend approximately $6.9 billion. This is being offset by lower R&D expense, now expected to be approximately $9.2 billion.

At the same time, we remain very pleased with our synergy capture, which, as Giovanni mentioned, is tracking ahead of our original expectations. We now expect our tax rate to be approximately 16% for the full year. And taking all this together, we are increasing our full year adjusted EPS range to be between $6.25 and $6.35 per share.

Our revenue guidance takes into account [indiscernible], which continues to affect Eliquis in the fourth quarter, as I mentioned earlier, as well as continued competitive

dynamics associated with some of our established brands. Now as it relates to our 2021 guidance, we are reaffirming our non-GAAP EPS guidance of $7.15 to $7.45, which absorbs the dilution associated with the MyoKardia acquisition. We look forward to providing more color on 2021 during our fourth quarter call as we normally do.

Before we move to question-and-answer, I want to thank all of our teams around the world for delivering such outstanding results year-to-date. These results allow me to remain confident in the long-term outlook for the company.

I'll now turn the call back over to Tim and Giovanni for Q&A.

Timothy Power

Great. Thanks very much, David. Kevin, can we go to our first question, please?

Operator

[Operator Instructions] Our first question today comes from Chris Schott of JPMorgan.

Christopher Schott

Congrats on all the progress you've made this year. I guess just 2 here. Maybe first on the TYK2. Can you just elaborate a little bit more on the safety profile? I think there's still some lingering questions out there. Will we see any of maybe some of the JAK-like safety issues? I know you've talked a lot about that in the past.

But just to confirm, do you see any imbalance at all, small or not, on thrombotic events from the [indiscernible] study? And just help us a little bit in terms of the profile is shaping up like on the safety there.

And then my second question was on Opdivo. You're launching a number of adjuvant indications next year. Can you remind us on those, do you expect these will have fast uptake like we're seeing in some of the metastatic settings? Or are these indications that maybe take a little bit longer to build out over time?

Giovanni Caforio

Chris, thank you. I think I'll start off and then Chris, I'll pass on to you for Opdivo-related question. From a TYK2 perspective, first of all, we are very happy with what we've seen from the results perspective. It is the first of the 2 Phase III trials for TYK1 that has read out. And we have seen not only topical as well as clinical meaningfulness versus placebo, but also the superiority versus apremilast or Otezla in moderate to severe psoriasis.

From what we have seen before from the Phase II studies and we've talked about the safety profile, we continue to believe in that. There is a differentiated mechanism of action that we believe in. We do think that the TYK2 inhibition, which has a specific downstream effect on IL-12, IL-23 as well as interferon alpha has played out, and we continue to believe in that.

Of course, I can't go into the specifics of the data. They will be presented in the future in the macro meeting. But overall, we are very happy where we are, and I look forward to the very readout of the second Phase III in the first quarter of 2021. So hopefully, that answers your question, and let me pass it on to Chris to talk about Opdivo from here on.

Christopher Boerner

Sure. Thanks for the question, Chris. We do have a number of exciting opportunities in the adjuvant setting, and maybe I'll just highlight gastric and bladder, specifically. As we talked about a few months ago with respect to gastric cancer, we're excited about the opportunity coming out of CheckMate -577. This is a space where there's significant unmet need as very little in the way of systemic therapy that's used here. And as Samit has previously talked about, those patients who are getting neoadjuvant chemo radiotherapy, about 3/4 of those patients don't get a PAT CR. So really, there are no great options for those patients. And we've seen very good efficacy coming out of -577, with the doubling of DFS at a manageable safety profile. And there's relative clean air here from a competitive standpoint as we'll be the first I-O in the setting for a number of years.

With respect to bladder, again, happy with the results that we saw with -274. This is a space with about 6,000 to 7,000 treated patients in the U.S. Again, not a lot in the way of great systemic therapies here. And as we've said, we met the primary end point for Opdivo and very much look forward to launching in the space. And this is, again, another space where there's relative clean air. So we would expect a reasonably aggressive uptake in both of these indications.

Operator

The next question today comes from Seamus Fernandez of Guggenheim.

Seamus Fernandez

Congrats on the quarter and all the progress as well. Samit, my question is actually on the higher dose, the 12-milligram dose, that we're going to see next week in psoriatic arthritis. Can you just give us -- that's really where we've seen problems with other decks. Just trying to get your sense of what we should be looking for in those data. Obviously they're about to be presented, but I think that's something that investors are interested in.

And then incremental to that, as we think about the opportunity in areas like ulcerative colitis, you've really emphasized this IL-23, -12, -22 profile, is that really where your enthusiasm for the product is in ulcerative colitis in particular?

Samit Hirawat

Thank you, Seamus, for the question and quite appropriate, in fact. When you look at the POETYK 1 readout as we said in the press release, the dose used in the Phase III trial is the 6-milligram dose. And what you have in the abstract and the poster of the ACR for ulcerative colitis, as you mentioned, are both 6 and the 12 milligrams dose.

We do see a profile from a safety perspective of the 6-milligram dose as we talked about. Also in looking at the older Phase II study, generally very good in that dose, and that's the efficacy we have now seen in the Phase III study as well.

At the 12-milligram dose, we do see a dose response. But then you have to keep in mind as you very correctly said, the overall safety management results. So we'll continue to dig deeper into the data as we plan Phase III study in the ulcerative colitis space. But overall, we are very happy with the dose that we have tested in the Phase II study. And of course, as I said earlier, we look at it again, in the Phase III -- the second readout in the first quarter of next year as we move forward.

So that's -- I think, the differentiation that it's not just about efficacy. We have to balance the benefit risk. And that's why the 6-milligram dose is quite reasonable for us from a safety and efficacy combined benefit ratio. As it relates to the ulcerative colitis, the mechanism as we very well said, I think the differentiation, the oral administration, the convenience equipment, we've talked about ulcerative colitis with Zeposia already, and now we are looking towards readout in the future for the TYK2 program. And bringing that differentiated mechanism once again and hopefully, be able to show the efficacy and safety for patients with ulcerative colitis with TYK2 will be important. And yes, IL-12 and IL-23, in addition to mechanism, is going to play a big role both in ulcerative colitis and then in the future in Crohn's disease as well.

Operator

Your next question comes from Geoff Meacham of Bank of America.

Geoffrey Meacham

Great. Just had a couple, I think both of them for Chris. So when you look at the first-line lung trend for Opdivo, Chris, you guys have gained some share, I think, 5% or so in the U.S., but I don't see much of a trend break this quarter. Was there already reasonable share in first-line lung before the label expansion? And maybe just help us to what's been the feedback from the ground so far?

And the second one on REBLOZYL, the sequential trends have been really strong. I know obviously it's early. But what can you say about the distribution between MDS and beta thal and maybe just the cadence of uptick between the 2 indications?

Christopher Boerner

Maybe I'll start, and then I'll turn it over to Nadim to address the second part of your question. So with respect to Opdivo, let me just first give you the dynamics for the quarter. So obviously happy with the sequential growth that we saw for the quarter. On that, in the U.S., is a function of favorable demand, and I'll talk about first-line lung, specifically in a second.

We also, as David had noted, saw some inventory build. This was partially offset by the impact that we've seen with the decline in I-O eligibility that we've been discussing previously. That's mainly in the second-line thoracic indications. And that still is a drag on Opdivo currently.

That said, we're happy to see that we've got sequential growth for the quarter, and that was, in part, a function of first-line lung. And with respect to first-line lung, we're very happy with what we're seeing with the launches so far in the U.S. The uptake continues to increase steadily.

As we noted earlier, the market share is currently in the high single digits. The execution here continues to be very good. So for example, we have a leading share of voice in first-line lung.

And importantly, at this stage of the launch, we're seeing a nice steady growth in the number of new trials week-over-week. So overall, we're happy with the uptake that we've seen. We -- as we discussed previously that this was going to be a different set of launches just given the entrenched dynamics from a competitive standpoint in first-line lung, but we continue to be very pleased with the team's performance here. So maybe I'll turn it over to Nadim for the second part of your question.

Nadim Ahmed

Great. Thanks, Geoff, for your question. So regarding the REBLOZYL launch, maybe I'll just make a couple of points. So as David said, very pleased with the launch so far, high demand, very good brand awareness. Field team is doing really well.

And if you remember, we had always said that the predominant use, at least in the U.S., would be MDS, and it's playing out exactly that same way. So today, the majority use in the U.S. is on MDS patients. And the interesting thing is we've seen a little bit of a halo effect on beta thal, but we've seen a little bit more uptake with beta thal since the MDS launch, but the predominant use is still MDS.

Now globally, as we launch across the world, there will be different regions where you see a different prevalence profile, beta thalassemia, where it's higher, for example, in Asia, the Mediterranean. But today in the U.S., just the predominant use is still MDS, exactly as we had anticipated. Thanks for your question.

Operator

The next question comes from Terence Flynn of Goldman Sachs.

Terence Flynn

I was just wondering first, on Opdivo for neoadjuvant lung. If you can give us any update on the regulatory path and when you might know more there and if you're confident that you could get approval on the PCR endpoint alone.

And then the second question, you mentioned that the synergies are tracking ahead of your expectations. I guess just trying to understand how much of the spend is synergies, and how much is kind of from a COVID environment? And so how much of that should we expect to carry forward into 2021?

Samit Hirawat

Thank you, Terence, for the question. Samit here. As Chris mentioned earlier, there is still obviously a much required need for new medicines in patients with early

disease to be able to get into a complete response because that may signal for the long-term benefit for these patients.

Now of course, this is not a validated regulatory endpoint as you very well said. So what we are looking forward to now, of course, continuing our dialogue with the regulatory agency, especially with the FDA, as we also continue to follow these patients for the first data for event-free survival as well. So we will obviously keep you posted in the future as we make progress.

At the current time, we continue our dialogue and continue with the patient follow-up to generate more data. I don't think we can give a clear guidance today in terms of approvability based on the endpoint. And for synergies, I think David or...

David Elkins

Yes. I can. Thanks for the question. Look, we've been very pleased with our ability to capture synergies so far this year, and we're really encouraged to see that our synergy capture is actually tracking ahead of our original expectations for this year. So we'll provide further insight to that on our expectations of the overall synergy achievement after we close the year, but things are going very well.

Operator

The next question comes from Tim Anderson of Wolfe Research.

Timothy Anderson

I have a question on going back to TYK2. So I think most investors view the value proposition in psoriasis relative to Otezla being better efficacy. But we've wondered if better tolerability could also be a differentiator because with Otezla, there's GI side effects that require dose titration, and your drug doesn't require dose titration. At least in Phase II, there were no GI side effects. So when we see the full Phase III results, might we also see better tolerability is yet another area of differentiation beyond just oral dosing and beyond better efficacy?

Samit Hirawat

Thank you, Tim, for the question. As we said, if you look at the overall trial design for this one as well as for the next study to be followed, the good news is that there is a comparison not only versus placebo but also the comparison versus the Otezla. And so there will certainly be an opportunity to contrast and compare not only the efficacy, but also of the tolerability and safety as we talk about. And those are going to be very important from a patient perspective and physician perspective, from a convenience perspective. Certainly, these will have implications from a commercial perspective, and let me pass it on to Chris to comment on that.

Christopher Boerner

Yes. Thanks for the question, Tim. I mean, I think as we've said previously, we're excited with the opportunity that we have here based on the data that we see coming out of POETYK. I think we have a real opportunity to establish TYK as the frontline branded world of choice for these moderate to severe patients.

What I would say just to build on what Samit mentioned is that this is a market where in spite of new biologics coming into the space, dermatologists continue to believe in an ascending treatment algorithm. So they typically start with topical, they move to oral, then they go to injectables.

And it is also a market, as I think you point out, where patient preference drives choice. So you do see a very strong focus on safety concerns, needle phobia and issues here. And we think these dynamics really play to the profile that we have with TYK2, very strong efficacy in an oral formulation, a novel MOA and a favorable tolerability and safety profile. And so we think we've got real opportunity here to establish TYK as the leading oral in the space.

Operator

The next question comes from Andrew Baum of Citi.

Andrew Baum

Couple of questions, please. First on Otezla. As you think about marketing, is it positioned to displace Otezla as the oral agent of choice, given the efficacy tolerability? Or to what extent can you actually seek to slow or defer the initiation of therapy with biologics? And then second, perhaps you could just give us the market shares in non-small cell for -227, -9LA in the U.S. in the first-line setting.

Giovanni Caforio

Chris?

Christopher Boerner

Sure. Sure. Andrew, thanks for the question. With respect to Otezla and how we are looking at the TYK opportunity in psoriasis, I mean I think the way I answered the previous question is probably what I would go back to. We think based on these data that TYK has the opportunity to be the branded oral of choice for moderate-to-severe patients with large in this space.

And we think that's a reflection of the fact that this is a market where dermatologists typically are going to try to treat with less burdensome routes of administration. They're going to go for the activity that -- the best activity they can find.

However, safety is a prominent concern here. And so I think that we have the opportunity to displace existing therapy with respect to orals prebiologic. And we also believe that we have the opportunity to potentially provide more of an opportunity before patients move on to biologics.

And remember, this is a space where only about 15% of patients ultimately ever get to biologics, and that's in spite of a number of new biologics coming into the market. So we think we actually have an opportunity to do both.

As it relates to the first-line lung market share, as we said previously and as David mentioned, we have current first-line market share in the high single digits. The -227 regimen is mainly being used in the PD-L1 to -49 as expected. And then we're

seeing recent uptake of the -9LA regimen, and that's mainly in the PD-L1 less than 1 and PD-L1 negatives.

Operator

The next question comes from Luisa Hector of Berenberg.

Luisa Hector

I wonder now we have the ASH abstract, whether there's anything you'd like to point out from the various data sets you're presenting and any particular update from durability of response? And then ide-cel and liso-cel, any update you can give from the FDA review?

Samit Hirawat

Sure. Thank you. So let me start with ASH first, and then I'll go to the liso-cel, ide-cel. And then certainly, if Nadim wants to comment also that will be wonderful.

So for ASH perspective, over the last few years, certainly, both Celgene and [indiscernible] as well as the [indiscernible] had beta presence. And based on the data that has been presented in the past, so obviously these medicines have now moved on to late-stage development, and we are continuing to gather more data.

Having said that, there are a few abstracts that are very important that are being presented. So number one, the activity of liso-cel, the single therapy as well as in combination where the patients who received cardio [indiscernible], both in CLL, are quite important and interesting.

If you look at the overall response rate positivity as well as durability in these patients, that continue to evolve, especially as you think of the future where the population with CLL where patients with CLL have been treated with ibrutinib and venetoclax, there will be a need for subsequent therapy that will rescue them if the disease has a recurrence or relapse.

Another data set will be presented as you might have seen in the abstracts will be the triple combination of Iberdomide with daratumumab as well as dexamethasone and then valcade and dexamethasone. And those are evolutions in the data set, and we'll continue to see how that comes through, but certainly, response rates are going to be important as we look forward to moving Iberdomide into the earlier settings as these data will then start dictating how we proceed further.

So very happy with these. We'll continue to look deeper into it and next year will be from a CELMoDs perspective as we look to the completion of the trials for Iberdomide and then, of course, progressing other CELMoDs as you heard from Giovanni in his opening comments.

From liso-cel perspective, not much to share except for the fact that we've already communicated. We continue our dialogue with the regulatory agencies. We've had the inspection done for the facility in Washington. And as we have communicated earlier that we don't have any scheduled inspections for the second facility, which is one -- which is independent of the other facility.

For liso-cel, we do have a PDUFA date on 16th of November. For ide-cel, same thing, we are continuing our dialogue and that we have PDUFA date of March 27, 2021. That's where we are. I don't know, Nadim, if you want to add something or Giovanni?

Nadim Ahmed

No. I think you covered it well, Samit. Thanks.

Giovanni Caforio

The only thing I would add is -- this is Giovanni. The only thing I would add is just to close on what Samit mentioned with respect to liso-cel. As always obviously we will update you as our discussion with the regulatory authorities progress.

Operator

Next question comes from Dane Leone of Raymond James.

Dane Leone

Congratulations on all the progress. Just some quick ones for me. When do you think you would be able to disclose the actual pathologic complete response rate for the 816 study? And if that would still be a nondisclosure item for you until regulatory discussions are complete.

Could you at least give us how the study was powered on that endpoint, so we can make our own assumptions on how the chemo arm would perform and then how the combo arm probably would have performed to [indiscernible].

And then in terms of Iberdomide, do you have a longer time line now in terms of path to pivotal studies and when that could actually get to market? I think a lot of us in the clinical community as well are thinking about this as an offset to Revlimid and the patent expirations there. So any kind of longer-term insight you might be able -- given the development path to be super helpful.

Samit Hirawat

Thank you for the question. So let me start with the PCR part. So certainly, we're going to look for an opportunity for a tougher presentation of the data at a future medical meeting. That is not dependent on the regulatory aspects because it's an independent endpoint that can certainly be discussed. So we're looking to that.

I think the trial details, we have not shared the statistical analysis plan per se in terms of the assumptions made for the calculation at this time. So we'll not be able to share that. But certainly, there is a previous data that had been presented and published for chemotherapy leading to PCR responses so we can assume with that.

Now what differences will be important in terms of the delta between chemotherapy and then the combination of nivolumab? Those are the types of discussions we'll need to continue to have with the regulatory agency as to what becomes meaningful.

So as the dialogue evolves and once the decisions are made, we'll certainly communicate that with you.

From the Iberdomide perspective, the fourth-line cost study is already ongoing as we said. And as I've just mentioned previously, as the data continues to evolve and we'll have the data readout sometime next year, there will be a trigger point for us to discuss that single agent combination dexamethasone, discussions with the regulatory agencies to see if the data would suffice for the regulatory dialogue in the fourth-line plus setting.

And then as the data evolved for the doublet and the triplet in the earlier setting, when we launched the later line trials as well in the earlier settings. Nadim, do you want to add something to that?

Nadim Ahmed

Sure. I would just add a couple of points maybe. So thanks, Dane, for your question. The point that Samit had made, our plan had always been to move from the doublet to the triplet, which is, as you know, very important, especially in relapsed and newly diagnosed disease.

So having these data at ASH will be an important foundation on how we move the treatment up, from the late-line setting then to the early relapse setting and then ultimately, newly diagnosed setting since you had asked the question about Revlimid and impact in the future. So we have a very clear development plan.

As Samit says, of course, we have to pass all the clinical data as we go through but the starting point is the triplet data that we're seeing at ASH now. So we're excited about the opportunity moving forward. Thanks for your question.

Operator

The next question comes from David Risinger of Morgan Stanley.

David Risinger

Yes. So I have 2 questions, please. First, could you provide more color on what you need to discuss with the FDA on liso-cel? It seemed to me that discussion should be over by this point.

And a follow-on to that is, are there any issues with the recent manufacturing inspections? Or do you have confidence following those manufacturing inspections?

And then the second question is other BCMA ADCs have been associated with ocular tox in multiple myeloma. Do you expect a differentiated profile for your BCMA CC-99712? And when should we expect to see data?

Samit Hirawat

Thank you for the question. For liso-cel, as we mentioned earlier, as we disclosed in the past, FDA has informed the company that both our plants in Washington as well

as the one in Texas need to be inspected. They've been able to inspect our plants in Washington at the time but has not scheduled any inspection of the second plant.

As you know, as we are doing what they can to ensure that the staff are kept safe in this COVID pandemic. And because of the travel restrictions, we have to obviously honor their desire as to where they go and when they go.

As we've said in the past, that the conversations with the agencies are going well, and we look forward to seeing the -- hopefully, the approval at some point to be able to bring to the patients as soon as possible. We'll obviously let you know as soon as we get the decision.

We are not going to comment obviously specifically about the dialogue around inspections, et cetera. We're generally very happy with the dialogue that has been happening.

On this ADC front, for multiple myeloma, we are in the Phase I. It's early time to comment whether we'll be able to differentiate or not, but we absolutely are aware of the ocular toxicity. And certainly, we'll keep that in mind as we go along. We continue to evaluate the patients for that.

I think the first data we would see would be sometime late next year because we are still in the dose escalation phase. And so certainly, as soon as the data are mature enough to be presented, we'll be able to bring it to the medical conference and share that view.

Operator

Next question comes from Greg Gilbert of Truist.

Gregory Gilbert

Giovanni, you've made it very clear that cardiovascular is a core franchise for the company. On Factor XIa, what do you think you have to deliver in terms of clinical profile to enable that asset to add value in what will potentially be a generic environment? And then maybe more strategically, in cardiovascular, it looks like you have at one end of the spectrum, kind of a mass market, Eliquis and Factor XIa approach, and on the other hand, a more specialized approach with MyoKardia. So I assume your strategic vision in cardiovascular spans across that. But curious if you want to be more focused in one end or the other as you consider additional BD and cardiovascular.

And then a follow-up for David. How would you describe the LOE step-down for Revlimid in the coming years? And do you think The Street has that right, at least in general in terms of how it's being modeled? We obviously have imperfect information.

Giovanni Caforio

Thank you, Greg. Let me start, and then maybe I'll ask on -- specifically on cardiovascular and Factor XIa, Samit and Chris to add. And then maybe we'll cover your question about the Revlimid LOE.

So first of all, let me say, yes. To answer your question, cardiovascular is a strategic importance to us, and it has been consistently for the company. And when we look at what we've done with Eliquis, I'm really proud of our ability to develop differentiated assets and in cardiovascular, take a very different approach to establishing the value of those assets in the case of Eliquis through real or relevance as an example and maximize the value of all of the medicine.

And so whether you look at Eliquis, you look at mavacamten and a Factor XIa inhibitor, we feel really good about our ability to execute in cardiovascular and our commitment to cardiovascular.

I think the approaches are different between a broader asset like Eliquis or Factor XIa could be. In those cases, as you know, we made a choice to partner those assets because we want to be working with another company that together, enables us to have a broader reach into a primary care market and support the development of assets that require very large investments in the development of the asset across multiple indications.

I think when you look at mavacamten, it's much more by precision approach to cardiovascular, which fits really nicely with our R&D strategy. And actually, very consistent with the early pipeline we have in heart failure in cardiovascular. So I don't think it's necessarily, one approach versus the other. But it's really looking at cardiovascular as one of the areas where the unmet need continues to be really high.

The company has demonstrated ability to execute, which is excellent. And then we take a different approach depending on what an asset needs in order for its value to be maximized, and when we [at best] -- have the best capability. So as we think about it, and actually MyoKardia is really, really interesting asset because -- an acquisition because the precision approach is really consistent with the way we look at things. Let me just ask Samit, if he wants to add anything on Factor XIa, specifically in differentiation and our development strategy, and I will move to your question on Revlimid.

Samit Hirawat

Thank you, Giovanni. The one thing that I would also have on mavacamten to remember, patients with obstructive hypertrophic empathy, the ones that are symptomatic, the ones that we are talking about from a treatment perspective, also have [indiscernible], especially at fibrillation that they experienced. So Eliquis is used there as well, and many cardiologists are very well aware of need of Eliquis. And certainly in the future, when potentially might be available, would be very helpful for these patients.

Coming back again then on to the anticoagulation Factor XIa. I think certainly very happy that we are in that stage and the Eliquis, what we have done. The 2 things that are going to be important to remember is, number one, there are still bleeding risk. And patients don't necessarily get treated with both of the currently available treatments, and some patients are not even treated because of the bleeding risk.

The second unmet medical need is that patients cannot be treated on top of that background and late therapies for indications such as the secondary strokes. And that is a very high unmet medical need and patients will had a first stroke are at very high risk of experience, in the second stroke, maybe even 50% to 60% probability.

And therefore, what we're looking for in the Factor XIa development program as we look at the Phase II studies that are currently ongoing, is the -- is number one, the decrease in the bleeding probabilities. And second is the combined ability, where that background therapy of [indiscernible] in the secondary stroke prevention study that is currently ongoing in terms of its enrollment.

So those are the important aspect that will make us go into the Phase III development program once the data are available. Let me pass it on to David and to comment further on the Revlimid side.

David Elkins

Yes. Thanks, and Greg, thank you for the question. We made great progress this year on the IP front, both with Revlimid as well as Eliquis. And as you know, we settled with Dr. Reddy's. We have the settlement with [indiscernible], which just to remind you, remember, the macro agreement is a single-digit volume entry in 2022, which grows to about 1/3 by 2025. And we have some other sentiments, which aren't public with Dr. Reddy's and Alvogen.

But as you -- we clearly see it more as a slope, not as a cliff starting in 2022 with full generic entry coming in '26. And at the time we did the acquisition, all I'd say is that we took a more conservative view on Revlimid than the sell-side equity analyst did at that time. So with that said, we still believe Revlimid will add potential significant cash flow for the business over that period from '22 through '25.

Giovanni Caforio

Yes. Thank you, David. Let me just reiterate. I think specifically to your question, when we look at the period during which over time, the slope of Revlimid will take place between 2022 to -- sorry, 2022 to 2026.

First of all, I think it is playing out the way we had modeled it to be a slope, and it starts at a point where the overall performance of the brand has been really strong. And our view of IP and the strength of IP has been validated by the IPRs that were not granted and the 2 settlements that David mentioned.

At the same time, the strength of our business beyond Revlimid has continued to be really, really good. The progress we've made with the pipeline has given us real confidence in our ability as a company to continue to renew the portfolio.

So as I mentioned at the beginning, I feel really good about our ability to continue to perform very strongly as we renew our portfolio during the time in which over time, Revlimid will lose exclusivity. That's what we set up to do from the very beginning. And I think execution so far has been really strong, which makes me confident in our ability to continue to be successful during that time.

Operator

The next question comes from Matt Phipps of William Blair.

Matthew Phipps

Congrats on a nice quarter. Wondering if after the POETYK study, if you're going to look at moving this asset into a more mild patient setting, similar to the recent [indiscernible] study. And then also a second quick question on the Forbius acquisition. Just wondering if you could compare and contrast maybe moving a TGF-beta monoclonal antibody plus something like Opdivo versus a bispecific molecule like [indiscernible] alpha that you do for the [indiscernible] kind of combined with the PD-L1 antibody.

Samit Hirawat

Thank you for the questions, Matt. First of all, on the TYK2 aspect, so you know that we are very happy with the results from the POETYK 1 study. We also know that there is a broad program already underway where we have the evaluation ongoing in ulcerative colitis and lupus, SLE, as well as the inflammatory bowel disease. Mild psoriasis, we certainly have an eye on it. We obviously think about this as we evolve with the data on the psoriasis. We have to look at the overall efficacy and safety profile in the second study also readout, and that will dictate where we go next in terms of evaluation of deucravacitinib in psoriasis and other patients with liver psoriasis.

On the TGF-beta front, we are, of course, aware of the bispecific TGF-beta PD-1 that the competitors have. When we look at the data, the specificity of the inhibition caused by this particular entity is very important. And we certainly will look at the combination of our own pipeline, not only with nivolumab, but we also have relatlimab, as you know, in development. So we'll be looking at all those combinations as the Phase I study data evolves.

And we get to see what the dose and the schedule will be for dosing patients with oncologic indications and that will pave the way for the combination strategies looking forward. I think having the ability to give 2 drugs separately will give us more opportunities for combination strategies looking forward.

Operator

The last question today comes from Carter Gould of Barclays.

Carter L. Gould

Great. Congrats on the quarter. I guess, first, a competitor in the strategic space that was perceived to be most closely related to you with also an FC-mutated region discontinued their program recently. In the past, you've been relatively sort of balanced language incoming outlook for this program. Any change or updates on how you see there?

Any commentary on that discontinuation or differentiation that maybe The Street doesn't appreciate between those 2 programs?

And then maybe coming back to the CELMoDs again. Should we think about the Iberdomide decision sort of running independent to -92480? Or is there going to be a decision to be made at some point next year where you need to sort of pick a winner or [indiscernible]?

Samit Hirawat

Sure. Thank you, Carter. I think great questions. First of all, on the [indiscernible] side, we certainly have seen the announcement from the competitor from discontinuation of the program on the side. And we don't know the details and the structure of their molecule, et cetera.

But certainly, we have our own molecule, which is in Phase I study. We also have been looking at -- to see where we go with the combination, very early on, to define the path forward.

As the data evolves, we'll certainly update you and others in terms of where we go or what the fate of the program will be. But too early to say from our own perspective, the specificity of inert FC portion or an active FC portion. I think more still needs to be further investigated before a decisive decision can be made on that side. So more to follow on to in the future.

On the CELMoDs on Iberdomide side. As we said, both of our programs are in development. Iberdomide ran a little bit further because it started earlier. -480 is a very potent molecule. We shared the data of 50-plus percent of overall response rate with -480 plus dexamethasone in the late line setting. Both of those studies are in the development in the full time class setting.

But if you recall, the overall development of [it] in the past, Revlimid and pomalidomide how they were developed in the organization, how Revlimid then got set up in the upfront setting and pomalidomide became a preferred molecule for the second third-line patient population.

So we have to keep that in mind as we continue to evolve. And we also have the good position that we have a lot of data available from multiple perspective that we can actually investigate to see what is the mechanism, where these drugs will fit the best; what opportunities may be able to avail in terms of combination strategies with our own pipeline; looking at the platforms that we already have, not only with CELMoDs, but also from the T-cell engager from CAR-T cell therapy as well as the evolving ADC platform.

So those opportunities, because of the T-cells we have in our hand, can certainly be further investigated in a broadest way rather than limiting ourselves to a single CELMoD way. But let me ask Nadim to add anything if he wants to further elaborate on this. Thank you.

Nadim Ahmed

Sure. Thanks, Samit, and thanks, Carter, for your question. So I think right now, we're very pleased with the early data we're seeing for both. And as Samit said, we've done the same, Revlimid and Pomalyst in the past. So there are discrete

patient segments with very different clinical needs, where you could potentially see the coexistence of both CELMoDs.

So for example, the maintenance setting, a CELMoD more of a better tolerability profile. In relapse setting with high-risk disease, you could see a more potent CELMoD come through. So I think we're going to continue to look at the data that we're pleased with how both are progressing.

And then as Samit said, one of our key objectives is to come up with this multi-modality combination approach. So you can envisage a CELMoD plus BCMA through multiple lines of therapy as patients progress from newly diagnosed disease to late-stage disease.

And we've already seen the use of sequential treatment through the current CELMoDs, or even I should say, with Revlimid and Pomalyst. So we do think that the combination of BCMA and CELMoDs, across lines of therapies or different patient segments, could be really important, both clinically and commercially. So thanks for your question.

Giovanni Caforio

Thank you. Thank you, Nadim, and thanks to all of you for joining our call today. We have a lot to discuss, and I think that speaks to the breadth and depth of our business and importantly, of our pipeline.

So as we discussed, it's been a really active year and a very, very exciting first year for a new company. And I can say with confidence that Bristol-Myers Squibb today is in a really strong position with significant near-term launch opportunities and a substantial pipeline to address unmet needs of patients that will position us very strongly and very well for the future.

So thanks again for joining us. And as always, our team will be able to answer further questions you may have. Have a good day. Thanks, everyone.

Operator

Ladies and gentlemen, that concludes today's conference call. Thank you for your participation. You may now disconnect.