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EDITED TRANSCRIPT

INCY.OQ - Q2 2020 Incyte Corp Earnings Call

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OVERVIEW:

Co. reported 2Q20 YoverY total revenue growth of 30%.

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PRESENTATION

Operator

Hello, and welcome to the Incyte Second Quarter 2020 Financial Results Conference Call and Webcast. (Operator Instructions) As a reminder, this conference is being recorded.

It's now my pleasure to turn the call over to Mike Booth, Head of Investor Relations at Incyte. Please go ahead.

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Michael Booth - *Incyte Corporation - Divisional VP of IR & Corporate Social Responsibility*

Thank you, Kevin. Good morning, and welcome to Incyte's Second Quarter 2020 Earnings Call -- Earnings Conference Call and Webcast. The slides used today are available for download on the Investors section of incyte.com. I'm joined on the call today by Hervé, Barry, Steven and Christiana, who will deliver our prepared remarks, and by Dash, who will join us for the Q&A session. (Operator Instructions)

Before we begin, I'd like to remind you that some of the statements made during the call today are forward-looking statements, including statements regarding our expectations for 2020 guidance, the commercialization of our products and the development plans and expectations for the compounds in our pipeline as well as the development plans of our collaboration partners. These forward-looking statements are subject to a number of risks and uncertainties that may cause our actual results to differ materially, including those described in our 10-Q for the quarter ended March 31, 2020, and from time to time in our other SEC documents.

In addition, I would like to caution everyone that the COVID-19 pandemic is an evolving situation. And it is still relatively early to be able to assess the full effect of governmental, business and social actions and policies and overall economic conditions on our business. Accordingly, it is important to keep in mind that our statements on this webcast speak as of today.

We'll now begin the call with Hervé.

Hervé Hoppenot - *Incyte Corporation - Chairman, President & CEO*

Thank you, Mike, and good morning, everyone. In the second quarter, we continued to execute well across the various facets of our business, driving strong revenue growth, achieving success in regulatory actions and in key clinical programs, while further improving our sound financial position. Jakafi grew 16% year-over-year to reach $474 million in the second quarter. Jakavi and Olumiant royalties also grew nicely, up 16% and 35%, respectively. And I'm also pleased to be able to report 6 sources of product and royalty revenues for the first time with the approvals of Pemazyre and Tabrecta. Total product and royalty revenues were $593 million for the quarter, up 16% year-over-year.

We announced 2 product approvals since we reported Q1, including Tabrecta, which is licensed to Novartis. And just recently, we received our first approval for Monjuvi in collaboration with MorphoSys. Monjuvi is the first FDA-approved therapy for the second-line treatment of adults with DLBCL, and we believe it has the potential to transform the treatment of patients with relapsed or refractory disease. We also announced the positive results of REACH3, which is the largest randomized clinical trial ever conducted in steroid-refractory chronic GVHD patients. At EHA, we presented encouraging proof-of-concept data from our ruxolitinib plus parsaclisib trial as well as updated 2-year data from the L-MIND trial, which confirms durability of responses to tafasitamab. Our financial position is also very strong with $1.6 billion in cash and equivalents at the end of the quarter.

Slide 5 shows our ongoing revenue momentum over the last several years, and we expect recent new approval to add further to our top line. During the remainder of this year, we expect to maintain the momentum of Jakafi in MPN and look to drive additional growth in GVHD. Furthermore, we are focusing on executing successful launches of both Monjuvi and Pemazyre, and we expect Tabrecta royalties to increase following the approvals and subsequent launches by Novartis in both the U.S. and Japan. Before the end of 2020, we plan to submit the NDA for ruxolitinib cream seeking approval in atopic dermatitis, and we also expect to initiate the pivotal program of ruxolitinib plus parsaclisib in patients with myelofibrosis.

Before I hand off to Barry, I felt it important to provide an overview of COVID-19 impact on our business. On the revenue and supply side, we have not seen any material impact to-date. And on the regulatory front, there has not been any impact on key timelines. With regards to clinical development, there has been no change to key late-stage programs since we reported Q1. While the original shutdowns due to COVID-19 affected certain studies, the impact has been largely transient, and we remain on track with key timelines. For example, while new patient recruitment in our vitiligo study has experienced a slowdown early in the quarter, recruitment has since rebounded to pre-pandemic levels. Therefore, we continue to expect results in 2021.

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In summary, since the beginning of 2020, we have announced 3 product approvals and announced positive results from 2 separate pivotal programs, REACH3 and TRuE-AD. These achievements, on top of strong commercial performance and excellent progress in clinical development are important parts of this transformational year for Incyte.

I will now pass the call over to Barry.

Barry P. Flannelly - *Incyte Corporation - Executive VP & GM of North America*

Thank you, Hervé, and good morning. Jakafi sales increased 16% year-over-year. We continue to see robust demand across all 3 indications and the number of patients on therapy continues to grow. In April and May, new patient starts were negatively impacted due to regional shutdowns related to COVID-19. However, since June -- since early June, we have seen a rebound in new patient starts. Despite the challenges of the pandemic, I am proud of our team for their efforts to continue providing the level of service and responsiveness that our customers have been accustomed to over the years. We have expanded our multi-channel engagements, and our field representatives are continuing, are conducting multiple virtual and digital programs with our customers.

Turning to Slide 9. We have been successful in identifying the appropriate patients, and there are already more than 100 patients on therapy. We have not had any unexpected reimbursement issues, and patient refill rates are encouraging. We have maintained a good depth of prescribers in both academic and community settings, and we are proud to be able to provide these physicians with a much needed therapy to help their patients. We're also excited about the approval of Monjuvi, the first FDA-approved second-line treatment for adults with diffuse large B-cell lymphoma. Monjuvi is an important non-chemotherapeutic option that has a convincing clinical profile as reflected in the clinical data included in the U.S. prescribing information.

With compelling response rates and a long duration of response while avoiding many of the toxicities associated with other forms of treatment, Monjuvi represents a significant opportunity to transform the standard of care for patients with relapsed/refractory diffuse large B-cell lymphoma. Our commercial and medical teams are fully staffed with joint Incyte MorphoSys team of approximately 150 full-time equivalents. We have identified 11,000 potential prescribers which -- of which approximately 80% are also Jakafi prescribers, (technical difficulty). We expect broad market access for Monjuvi and already have patient assistance programs in place. While the challenges presented by COVID-19 pandemic are not ideal for new patient launches, we believe Monjuvi's strong clinical profile, the significant unmet need in relapsed/refractory diffuse large B-cell lymphoma, and our company's combined expertise leave us very well positioned for a successful launch.

With that, I'll now turn the call over to Steven.

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

Thank you, Barry, and good morning, everyone. Recently, we announced the success of our REACH3 trial evaluating ruxolitinib versus best available therapy in patients with steroid-refractory chronic graft-versus-host disease. This was the largest randomized trial ever conducted in this patient population and the positive data reinforce the importance of JAK inhibition in the treatment of graft-versus-host disease. Ruxolitinib met its primary endpoint of superior overall response rate at month 6 and achieved statistically significant and clinically meaningful improvements in both key secondary endpoints, the modified Lee chronic graft-versus-host disease symptom scale and failure-free survival. The safety profile of ruxolitinib was consistent with previously reported studies of ruxolitinib in graft-versus-host disease. Following these results, we expect to submit the data from REACH3 for presentation at an upcoming medical Congress, and we are preparing the supplemental NDA submission to the FDA.

Turning to our LIMBER development program on Slide 13. As part of our life cycle management, we have multiple strategies ongoing, including the development of a once-daily formulation of ruxolitinib, combinations with ruxolitinib and potentially new targets, and we are making progress on all fronts. The most advanced combination within LIMBER is our ruxolitinib plus parsaclisib program, and we recently presented positive proof-of-concept data, which showed the additional benefit obtained from adding 5 milligrams of daily parsaclisib to ruxolitinib in myelofibrosis patients with an inadequate response to ruxolitinib monotherapy. Importantly, the addition of parsaclisib was well-tolerated and treatment-emergent adverse events common to PI3 kinase delta inhibitors were infrequent with the addition of parsaclisib. These results warrant further study of the

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combination, and we have plan to initiate ruxolitinib plus parsaclisib trials in both first-line myelofibrosis patients and in MF patients with a suboptimal response to ruxolitinib monotherapy.

Turning to Slide 14. In June, at the European Hematology Association, we presented updated 2-year data from the L-MIND study of tafasitamab in combination with lenalidomide. These data were consistent with prior presentations. The overall response rate in this data set was 59% and 41% of patients achieved a complete response. The median duration of response for complete and partial responders collectively was 34.6 months, driven by the median duration of response for complete responders, which has not yet been reached. We hope and expect that the data from the L-MIND are only the beginning for tafasitamab. Working with MorphoSys, we believe that we have multiple near-term opportunities in diffuse large B-cell lymphomas and other non-Hodgkin's lymphomas as shown in the summary slide.

Later this year, we expect to have initial results from our first-line diffuse large B-cell lymphoma trial, First-MIND. Based on results from the study, we expect to select the appropriate combination, either tafasitamab plus R-CHOP or tafasitamab plus lenalidomide plus R-CHOP, and move forward into a pivotal first-line diffuse large B-cell lymphoma trial in 2021. We also expect to initiate a proof-of-concept study evaluating tafasitamab plus parsaclisib in non-Hodgkin lymphoma before the end of this year.

Turning now to our development programs in inflammation and autoimmunity. As Hervé mentioned upfront, our development timelines for ruxolitinib cream remain on track as we continue to collect long-term safety data from our 2 pivotal atopic dermatitis studies and plan to submit the NDA at the end of 2020. The Phase III vitiligo trials are now recruiting very well, and new patient enrollment has rebounded since a dip at the beginning of the second quarter. We remain on track for results in 2021.

We have made significant progress within our key development programs thus far in 2020. We have announced 3 product approvals this year and have presented positive data from multiple programs. We continue to expect to have data in-house from the ongoing pharmacology studies of once-a-day ruxolitinib in 2020. While a transient COVID-related delay means the external presentation of these data won't be until next year, these data are not on the critical path, and we are still on track for an sNDA submission seeking approval of once-a-day ruxolitinib in 2021. We also have decided to discontinue development of our PIM inhibitor and its combination trial with ruxolitinib. Lastly, a reminder of the various COVID trials that are underway, including studies of both ruxolitinib and baricitinib.

With that, I'd like to turn the call over to Christiana for the financial update.

Christiana Stamoulis - *Incyte Corporation - Executive VP & CFO*

Thank you, Steven, and good morning, everyone. The financial update this morning will include GAAP and non-GAAP numbers. For a full reconciliation of GAAP to non-GAAP, please refer to Slides 25 and 27 in the backup section of the deck and to the press release we issued this morning.

Moving to our results for the second quarter. Revenue growth continued to be strong, with total product and royalty revenues of $593 million, representing an increase of 16% over the second quarter of 2019. This is comprised of net product revenues of $474 million for Jakafi, $23 million for Iclusig and $4 million for Pemazyre. Royalties from Novartis of $66 million for Jakavi and $1 million for Tabrecta and royalties from Lilly of $26 million for Olumiant. We recorded revenue growth across both the products commercialized by Incyte and those commercialized by our partners, with the exception of Iclusig, where we recorded a 7% decline in revenues as a result of some stocking that we experienced in the first quarter of the year due to the COVID-19 pandemic.

Total revenues increased 30% over the prior year quarter driven by both the increase in product and royalty revenues as well as $95 million of milestone revenue related to the approvals of Tabrecta and Pemazyre. Total cost and expenses for the quarter of $400 million on a non-GAAP basis represent an increase of 5% over the prior year quarter, well below the growth rate in product and royalty revenues. Ongoing R&D expense for the quarter was $250 million on a non-GAAP basis, representing a 6% increase from the prior year quarter. This increase was primarily due to our 55% share of the global and U.S.-specific development costs for tafasitamab, the clinical trials of ruxolitinib as a potential therapy for COVID-19 and other pipeline programs progressing to later stages of development.

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SG&A expense for the quarter was $104 million on a non-GAAP basis, representing a 12% increase over the prior year quarter. This increase was primarily due to an increase in commercialization efforts related to Jakafi and Pemazyre and preparation for the potential commercialization of ruxolitinib cream. Collaboration loss for the quarter was $13 million, which represents our 50% share of the U.S. net commercialization loss for Monjuvi. Our financial position continues to be strong as we ended the quarter with $1.6 billion in cash and marketable securities. The decrease from $2.1 billion at 2019 year-end reflects the upfront payment and stock purchase related to the MorphoSys collaboration, partially offset by the cash flow generated during the first half of 2020.

Moving on to our guidance for 2020, we are reiterating our revenue and expense guidance for the year. While there continue to be uncertainties associated with COVID-19, including risk of a broader resurgence, we believe these are captured in the ranges provided. As a reminder, the R&D guidance excludes the $805 million upfront consideration related to our collaboration with MorphoSys. Finally, at this early stage of their launches, we are not providing guidance on Pemazyre sales or on our collaboration net profit or loss resulting from the commercialization activities for Monjuvi in the U.S.

Operator, that concludes our prepared remarks. Please give your instructions and open the call for Q&A.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question today is coming from Vikram Purohit from Morgan Stanley.

Vikram Purohit - *Morgan Stanley, Research Division - Equity Analyst*

So I had 2 questions on the LIMBER program. First, I just wanted to see if you could talk a bit more about what you saw in the initial PIM plus RUX data that led you to the decision to discontinue that facet of the LIMBER program? And then, secondly, for the RUX plus PI3K combination studies, you're looking to start in the first-line and the refractory setting. I just wanted to see if you could talk a bit more about what those studies would look like from a design perspective and how you're thinking about what the initial bar for success there is going to be.

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

Vikram, it's Steven. Thanks for your question. In terms of the PIM RUX program, as far as we know, we were the sort of last PIM inhibitor left standing across R&D programs. And it's largely due to on- target effects in terms of the liver and transaminitis. And we weren't able to get the PIM dose much above 80 milligrams. And then if you look at that tolerability profile in combination with some of the efficacy we've seen, although interesting and pre-clinically very interesting, it wasn't a program that we felt had high chance of success going forward. So for those 2 reasons, both tolerability in terms of liver and reaching adequate efficacy bars.

Turning to the RUX delta program, as we alluded to in our remarks, this is our lead program. We've shown our internal proof-of-concept data. We explored various dosing and schedule regimens. And clearly, there's a delta effect. If you go back to the biology, PI3-kinase delta as a pathway is upregulated in myelofibrosis, with preclinical data that makes sense. And in terms of the clinical effect we've seen although very strictly defined in our proof-of-concept that patients had to have been on 6 months of RUX and a stable dose for a couple of months. Even with that, we saw increased spleen response as well as symptom responses. So we're initiating 2 studies, a suboptimal responder RUX study, as we've spoken about for people who've been on at least 3 months and they're not having an adequate RUX response as well as a first line study. In terms of the endpoints, you're going to have to wait for the ClinTrials.gov listings to go up when we start these studies before we make those public. They should be relatively obvious for the first-line study and then the suboptimal responder study that will go up on that particular listing.

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Operator

Our next question today is coming from Cory Kasimov from JPMorgan.

Cory William Kasimov - *JPMorgan Chase & Co, Research Division - Senior Biotechnology Analyst*

Wanted to ask you around GVHD. And can you just kind of describe next steps and timelines we should be thinking about on -- for the chronic GVHD opportunity and expanding the label for the syndication? And would you expect more -- I know you're not going to market to, but would you expect more spontaneous use in this setting, even ahead of approval, given the promising REACH3 data and the unmet need that's out there?

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

So Cory, I'll start off and then the second part of your question, Barry, will take. I assume you're alluding to the REACH3 study that we have recently press released the outcomes. It's an outstanding outcome for patients and for us in terms of hitting both the primary, very strictly defined overall response rate endpoint at month 6, plus failure-free survival and the PRO, the patient-reported outcome, in terms of the modified Lee symptom score. So a great outcome for that. Obviously, we will -- we filed REACH2 as well now. Now we'll be going ahead with filing REACH3 as a supplemental NDA as soon as we can in terms of getting it into the label. Just -- I don't know if you were talking also about steroid naïve chronic graft-versus-host disease. That work with itacitinib continues this year in terms of dose exploration. We're looking at various doses and schedules plus the steroid effect there before initiating further work with itacitinib there. So across the entire spectrum of graft-versus-host disease, we're still very active, both with filing and then with itacitinib in steroid naïve. In terms of your question, well, Barry?

Barry P. Flannelly - *Incyte Corporation - Executive VP & GM of North America*

Cory, yes, in terms of spontaneous use in chronic GVHD, obviously, we know that there's already some use in chronic GVHD with Jakafi. And I think because we only released sort of the top line results from REACH3, not until there's a full presentation or publication will the awareness increase. At that time, some additional spontaneous use may occur. But we'll have to wait and see.

Cory William Kasimov - *JPMorgan Chase & Co, Research Division - Senior Biotechnology Analyst*

Okay. And Barry, did you see any major impact from COVID on the GVHD front to your transplants that were presumably taking place?

Barry P. Flannelly - *Incyte Corporation - Executive VP & GM of North America*

Well, we certainly saw a decrease in new patients. So as you know, Cory, new patient starts really represents a relatively small part of the total number of patients that are on Jakafi. So we do know that bone marrow transplants were delayed. We saw a decrease, perhaps, in April and May. And we know that patients that need a bone marrow transplant have to come back when they're feeling more safe and when their disease requires it. So as more bone marrow transplants go up, then GVHD will go up.

Operator

Our next question today is coming from Brian Abrahams from RBC Capital Markets.

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

Maybe a follow-up question also for Barry. Can you talk about any shifts in growth patterns that you saw with Jakafi maybe across the other 2 indications due to corona? I guess I'm curious if there's any inventory impact that you're seeing or any patient level stockpiling, changes in compliance

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or persistence? And then would you expect to see any changes now with the pandemic rebounding in July and August to the overall patterns of Jakafi use?

Barry P. Flannelly - *Incyte Corporation - Executive VP & GM of North America*

Sure, Brian. Well, I don't think that the percentage of patients who are taking Jakafi for PV GVHD and myelofibrosis has really changed at all due to COVID. Now we do know, as I said, particularly in certain regions, you can imagine East Coast, particularly New York and New Jersey, you saw new patient starts for each of these indications go down. In June and now in July, we have seen week after week small increases in new patient starts, but new patient starts are relatively small in each given quarter and each given month anyway. But we have seen week after week starting in June new patient starts coming back. So again, we haven't really seen any movement in 1 area versus another in terms of total amount of bottles sold.

Operator

Our next question is coming from Salveen Richter from Goldman Sachs.

Salveen Jaswal Richter - *Goldman Sachs Group, Inc., Research Division - VP*

So as we look towards proof-of-concept data from the oral PD-L1 inhibitor later this year, can you help frame expectations on the type of data we'll see? And what level of activity you're looking for to move forward?

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

Salveen, it's Steven. Thanks for the question. So in terms of our oral PD-L1 program, we've been progressing well, and we're in this phase now where the second half of this year from our clinical program we'll be able to present translational data from the actual clinical specimens to show, directionally, the right degree of PD-L1 inhibition, T cell changes that we want, et cetera, that are supportive of continuing the program. Substantive clinical data, in its entirety, will be more likely next year. But all the data we have in hand, and that we are presenting in the second half of this year at the appropriate meeting, are supportive of continuing.

Operator

Our next question today is coming from Evan Seigerman from Crédit Suisse.

Evan David Seigerman - *Crédit Suisse AG, Research Division - VP & Senior Equity Research Analyst*

Congrats on a really great week with strong results today and the approval of Monjuvi late last Friday. So just on Pemazyre in the tumor-agnostic setting, can you just remind us of the status of this program? I can't remember if you mentioned it earlier. Is it also delayed as with the bladder trial? And then any color on the penetration into the eligible patient population in cholangiocarcinoma following the launch earlier this year?

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

Evan, Steven, thanks. So in terms of your question, actually, the tumor-agnostic program has not been affected by COVID much at all. It's enrolling extremely well, probably speaking to an extreme unmet need there. So it's across various fusions in terms of the molecular biology as well as rearrangements as well as testing if there's any activity in amplifications as well. So there are different buckets we fill up that are histology agnostic, and that's progressing well. You spoke a little bit about the bladder program. The data we will be getting in the second half of the year will complete the continuous dosing experiment. But in terms of presenting the data, it will be next year. So that's the status of the bladder program. And then I'll turn it over to Barry.

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Barry P. Flannelly - *Incyte Corporation - Executive VP & GM of North America*

Sure, Evan. So you talk about penetration. I think I said in my prepared remarks that there was over 100 patients treated already. And actually, we know that there's more -- most of those patients have come back for refills as well. So they're continuing. So the duration of therapy is something that we'll continue to follow. But even the $4 million that we reported in this quarter and the more than 100 patients on therapy right now is ahead of what we predicted internally.

Operator

Our next question is coming from Tazeen Ahmad from Bank of America.

Tazeen Ahmad - *BofA Merrill Lynch, Research Division - VP*

I just wanted to get a sense perhaps on how you're thinking about the first-MIND study. Is there a particular combination of the 2 that you're looking at that you would prefer as it relates to specifically lenalidomide? Is it somewhat of a priority to potentially avoid having that in the combo, given its side effect profile and its toxicity, or I'd like to hear your thoughts of how that might impact some patients' desire to be on therapy?

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

Yes. It's Steven. Thanks for your question. If you look at first-line diffuse B-cell lymphoma, standard of care remains R-CHOP with approximately a 40%, 50% care rate -- cure rates. Many have tried to beat that and hasn't been easy historically in the past to do that. So it's really about upfront efficacy and improving the cure rate. That's what you have to achieve to beat that bar. So -- and a little bit maybe in terms of sacrificing tolerability because it's about cure upfront. So we'll see. The safety data, as we said on the call yesterday, will be key, looking at either tafasitamab alone, plus the R-CHOP regimen or tafasitamab plus len plus the R-CHOP regimen. If the safety ends up and we'll get the data by the end of this year, being is mostly a wash, and there's no increased tox that's worrying from the doublet with R-CHOP, that may be the way we end up going because it's about getting to the efficacy bar. As the MorphoSys CMO said with us on the call yesterday, this is still subject to getting that data in-house and then regulatory discussion on the appropriate endpoint. So those are the caveats there. But I just want to reiterate. You have to win on efficacy here. You have to improve the cure rate in diffuse large B-cell lymphoma upfront.

Tazeen Ahmad - *BofA Merrill Lynch, Research Division - VP*

Appreciate that. Just maybe a follow-up. What percent of this population would be older patients, given that they might be potentially more prone to side effects?

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

In terms of the epidemiology on age, we'll have to get back to you. I'm not sure what percent if you're asking is above 65. I'll have to find that out for you, sorry.

Operator

Our next question today is coming from Marc Frahm from Cowen and Company.

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Marc Alan Frahm - *Cowen and Company, LLC, Research Division - Director*

Barry, just to follow-up on your comments about the Pemazyre launch and kind of the success relative to your internal expectations. I guess, what learnings have you had on kind of a virtual launch about things that are working, maybe some things that aren't working and how are those going to get applied to the launch of tafasitamab?

Barry P. Flannelly - *Incyte Corporation - Executive VP & GM of North America*

Yes, Marc. I think we learned a lot, actually. And I think we -- despite this pandemic, we learned things that really work that we'll keep doing. Virtual programs, virtual visits, virtual speaker programs, virtual advisory boards, all of these things work. For Pemazyre, we really targeted the physicians that we wanted to target ahead of time that we know are GI docs that specialize in cholangiocarcinoma, liver cancer and so forth. And we were able to reach them virtually through our representatives. And then, of course, before that, our medical affairs people had relationships with these docs and our oncology clinical nurse educators helped them manage the dosing and side effects. And they were each able to reach out to them. What we also learned about Pemazyre about a new launch during this time period and I think it relates to Monjuvi very much is that docs want to hear about new launches and how to use drugs. Particularly, Pemazyre is being used for -- first approved drug for a patient population that's never had anything that was really effective before. And in terms of Monjuvi, the first drug approved for second-line diffuse large B-cell lymphoma. They want to hear about these new options for their patients who desperately need new therapies.

Marc Alan Frahm - *Cowen and Company, LLC, Research Division - Director*

Okay. And then just on the initial demand you're seeing, is that all in cholangiocarcinoma? Are you already seeing some off-label use either in that -- the tumor-agnostic indication or even maybe people who can't tolerate the available inhibitor in the bladder cancer?

Barry P. Flannelly - *Incyte Corporation - Executive VP & GM of North America*

Yes. To the best of our knowledge, Marc, it's really all in cholangiocarcinoma for patients that have FGFR rearrangements and fusions.

Operator

Our next question today is coming from Alethia Young from Cantor Fitzgerald.

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

Congrats on all the progress. I just wanted to ask you a question on the CITADEL program, and now that you have the combination data. It looks interesting, kind of wanted to talk about your kind of focus on monotherapy there. And then can you just kind of talk a little bit about kind of continued investment for AD heading into the upcoming launch for the RUX cream? Thanks.

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

So Alethia, I'll start off. It's Steven, on your first question related to the CITADEL program. So all the studies have enrolled really well, follicular, mantle cell and marginal zone. We presented data at various points along the route for all 3 histologies. We have in the range of the high activity we wanted as well as the durability of response that we wanted. So, we will get that in-house, and we will proceed with appropriate regulatory filings for monotherapy in the different parts of the world where it's relevant. They are all likely to be under accelerated approval or conditional marketing authorizations. And we'll need, as you allude to, confirmatory programs, and those are likely to be in combination, the designs of which still need further refinement and discussion with regulators but they're likely to include combinations with CD20 or even CD19 antibodies, given that we are treating lymphomas. And then, I'll hand the question over about the investment related to the launch.

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Barry P. Flannelly - *Incyte Corporation - Executive VP & GM of North America*

Yes. So Alethia, I guess you were asking about the continuing investment in AD related to the launch. Obviously, it's AD and vitiligo because we anticipate vitiligo could be relatively soon after we get approval for atopic dermatitis. But I think Hervé said multiple times that we're building a separate business unit for dermatology or autoimmune diseases. So we already have on board, a good part of our medical affairs team, our market access team. We're building out the commercial organization. So that's our continuing investment. And obviously, we're really getting ready because we believe that RUX cream could really transform the treatment of atopic dermatitis in the United States.

Hervé Hoppenot - *Incyte Corporation - Chairman, President & CEO*

Regarding just -- so that's for the U.S., where the situation is very clear. Regarding the rest of the world, in Europe, we are looking at a scenario where, in fact, vitiligo could be the first indication that we would be submitting. So the timing for Europe is slightly different from what we have in the U.S., like more than slightly. It can be a few months behind. And we are still looking at the best commercial deployment there. And frankly, we want to have -- take our time. And I know some of you are asking what is the model that we'll be following in Europe, and we are really going through a level of diligence that requires more time, and we'll be able to communicate how we are going to commercialize in Europe probably early next year.

Operator

Our next question today is coming from Mara Goldstein from Mizuho.

Mara Goldstein - *Mizuho Securities USA LLC, Research Division - MD of Equity Research Department*

I had a question just on retifanlimab and the status of where you are from a clinical trial perspective? And which data from the POD1UM program are we likely to see initially? And then, secondarily, is there an update on the Jakafi COVID-19 program for CRS?

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

Yes. In terms of retifanlimab, our IV PD-1 inhibitor, the niche programs have, again, all enrolled incredibly well. Squamous cell anal carcinoma, MSI-high endometrial and the Merkel cell program, we intend to submit data from Merkel and anal cell carcinoma at a medical meeting second half of this year. And that's when that data will be public. In terms of RUX in COVID-19, just a reminder. There are 2 programs. There's 1 in conjunction with Novartis globally called RUXCOVID. Those -- that's in patients that are pre mechanical ventilation, but have evidence of cytokine storm and is looking at RUX 5 milligrams twice daily, plus standard of care versus standard of care. It's in 400 patients. The primary endpoint for that study was the proportion of patients who die, develop respiratory failure or require ICU care by day 29. And that's progressing well. And obviously, we hope to have data, a complete study with an endpoint and report out before the end of the year.

The second study we are running ourselves largely in the United States is the ventilator study. So it's again adults with COVID-19 associated respiratory failure who are on ventilation. It has 2 dosage arms in terms of RUX, a 5-milligram BID arm and a 15-milligram BID arm, both with standard of care versus standard of care. And that is tracking a little bit behind in terms of enrollment, largely because there's less ventilation than there was with people who are trying to avoid that. So again, we hope to have data before the end of the year, but it's hard to tell you exactly when at the moment. The N on that study, just to remind you, was a little larger. So that was 500 patients because there's 3 arms. And the primary endpoint was a very clean one, was overall survival due to any cause through day 29. So that's the status of those studies.

Operator

Our next question is coming from Jay Olson from Oppenheimer.

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Jay Olson - *Oppenheimer & Co. Inc., Research Division - Executive Director & Senior Analyst*

Congrats on the progress. I wanted to follow-up on the LIMBER program where you've tightened up the focus a little by discontinuing RUX plus PIM and you're moving RUX plus parsa into pivotal trials. But you still have quite a few shots on goal. So I was wondering which of those are you most excited about with the highest probability of success and the greatest clinical differentiation?

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

Yes, Jay, it's Steven. So it's an extremely important program to us for all the obvious reasons. Plus we have a lot of scientific ownership of the myeloproliferative neoplasm space, just even beyond ruxolitinib, they're diseases we feel very passionately about. Just to remind you, the LIMBER program has 3 pillars to it. The first one is the formulation work, which we spoke about in our prepared remarks. And the once-daily formulation work is going well, and we intend to file that sNDA next year. And we believe that is important in itself and also potentially from a convenience point of view. And it may lend itself down the pike to us doing fixed-dose combinations with other once-daily mechanisms.

In terms of the second arm, which are ways to either enhance efficacy in a particular disease setting or safety or both, those programs, the lead one is the RUX plus parsaclisib program. Again, we spoke about in the prepared remarks. We feel we have internal proof-of-concept data, and we're initiating both the suboptimal responder to RUX study as well as the first-line myelofibrosis study this year. The other programs that are really important to us are our resurrected BET inhibitor program, so we're doing monotherapy work this year, just to prove safety at the dose we've chosen. And then we'll very quickly go to combination to work there. And we'll see where that leads us. Again, that could be potentially in a second-line setting as well as in a first-line setting.

And then, very importantly, although on the surface, looks like a tolerability play in terms of the ALK2 inhibitor, and the hepcidin mechanism in improving anemia, either due to the underlying disease, myelofibrosis or due to the effect of a JAK inhibitor, not only if that works, should it improve the anemia, but then it will also allow patients to stay on RUX longer and should improve efficacy as well. So that is in, again, monotherapy safety now and should also go to combination, hopefully, by the end of this year. And then the third pillar, which for obvious reasons, we speak less about, but is all around discovery efforts run out of Dash's shop looking at other ways, other new targets, epigenetic targets or other ways that we may be interested in even in PVR itself. And those will obviously be announced if and when they get to the clinic. So that's the entirety of the program.

Operator

Our next question is coming from Tyler Van Buren from Piper Sandler.

Tyler Martin Van Buren - *Piper Sandler & Co., Research Division - Principal & Senior Biotech Analyst*

Great to see the quarterly results, especially in light of the ongoing pandemic. I had a question on the Jakafi product revenue guidance, which was reiterated and seems very conservative. You mentioned that new patient starts have rebounded in June. You have a growing pool of total patients and robust demand in all three indications. Yet the midpoint of the guidance assumes relatively flat quarter-over-quarter growth on an absolute basis. And if you look at the top end of the guidance, it's still lower year-over-year growth rates or a deceleration in the second half. So is this just factoring in the ongoing uncertainty due to the pandemic? Or are there any potential year-over-year pressures that the guidance is factoring that we should also consider?

Christiana Stamoulis - *Incyte Corporation - Executive VP & CFO*

Tyler, you are absolutely right. If you look at Jakafi in the first half of the year, we grew 19% when you compare to the first half of 2019, with the growth primarily coming -- over 70% of this growth coming from volume, from demand. So if you were to look at this, you would think that at this point in the year we would be, if anything, bringing up the low end of the guidance. The low end of the guidance implies a flat Q3 and Q4 to Q2. So given the significant uncertainty that remains around COVID-19, the risk for a broader resurgence, we felt that this year it's appropriate to keep

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the guidance to where we had set it to keep a broader guidance at this point in the year to be able to address any potential impact that we may see from a resurgence in COVID-19.

Operator

Our next question today is coming from Josh Schimmer from Evercore ISI.

Joshua Elliott Schimmer - *Evercore ISI Institutional Equities, Research Division - Senior MD & Equity Analyst*

Was positive REACH3 data reflected in your long-term guidance for $3 billion peak sales of Jakafi? And are you considering expanding your dermatology portfolio to further complement ruxolitinib cream? And if so, what might that look like?

Hervé Hoppenot - *Incyte Corporation - Chairman, President & CEO*

Hervé here, I'll take it. So obviously, the REACH3 results are very positive. And it's -- I won't say more than expected, but it's certainly a very good study. You will have the opportunity to see the results when they are published. And the question of what does it mean in term of long-term guidance came up when we saw the results. So I think your question is totally appropriate. We have said in the past, $2.5 billion to $3 billion for Jakafi. You can see where this year is going. So we are sort of ahead of the curve, if you look at it from that standpoint. What we also looked at is political uncertainty and the fact that in the U.S., there are a number of questions still open related to the health care system in general and reimbursement of products. So I think the best way to think about it is probably to see how this is evolving. Also see the data that we have in REACH3 publicly, and then it will give us with both of them an opportunity to look again at the long-term guidance if we need, and that's again, something that would be after the end of this year.

The second question is dermatology. So you know we are very excited. I must say, over the past few months, we have had a number of advisory board and sessions of feedback with dermatologists in the U.S. and in Europe on the profile of RUX cream. And that has made us evolve our expectation from that franchise. Because what we are hearing from them is that there are no other product that is providing that level of efficacy that you saw in TRuE-AD and, obviously, the lack of systemic exposure and the level of safety that you can expect from a topical. So it's not really -- in the category of the other topical product, it is a product that has the potential to be transformative. So we are looking at it now with a new eye in term of how big it could be. We still have the vitiligo study that is, as Steven was describing, moving very quickly. So it gives us a potential submission in 2020 for AD, approval in 2021, submission in vitiligo and then approval in vitiligo. So there is already a sort of a cycle of new product that is coming for the next 2 years. And we are obviously looking at other products that could be complementing the franchise. Internally, we have programs ongoing with our own group of products that have potentially an immunomodulating potential, so that could apply to many indications. And we are also looking at external opportunities for what would be good science applied to dermatology that could be complementing the portfolio. So there is literally a new division of Incyte that is being built now that will be starting with RUX cream, and I think could have a very important potential over the next 5 years to add to the growth that we have in cancer and oncology and hematology.

Operator

Our next question today is coming from Ren Benjamin from JMP Securities.

Reni John Benjamin - *JMP Securities LLC, Research Division - MD & Equity Research Analyst*

Congrats on the quarter. Can we talk a little bit about the patent extension strategies? I see that once-daily can definitely seems to make sense and can extend, obviously, your patents there. But how do we think about these combinations that are being evaluated, particularly in the LIMBER studies? Do they ultimately have to be developed as once-daily formulations as well to continue to extend the patents?

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Hervé Hoppenot - *Incyte Corporation - Chairman, President & CEO*

The patent itself from RUX, I would not comment on that. So what is, obviously, part of our plan is to improve over ruxolitinib from the clinical and the patient benefit standpoint, and to do it in a way that will help us extend the life of our franchise in MF and PV and potentially in GVHD. So the QD is very important for two reasons, is that by itself, it has a longer patent than we have with twice a day. And it is also a way to do combination with other once-a-day products that we have in our portfolio. And when you think of 2 oral products being once a day, then you're obviously looking at the possibility of doing fixed-dose combination. And if the product you are combining with has a patent life that goes beyond the patent of Jakafi, ruxolitinib itself, it's obviously increasing the exclusivity that you have on this fixed-dose combination. So you can think of ALK and parsaclisib and BET as potential partners for ruxolitinib that we are testing in the clinic, first, to establish the superiority from the clinical standpoint, and then that could give us an opportunity to develop fixed dose combination, if possible, that would be certainly helping maintain the leadership that we have in the field of MF, PV and GVHD. So that's really the way we are looking at it.

Reni John Benjamin - *JMP Securities LLC, Research Division - MD & Equity Research Analyst*

Got it. And then just as a quick follow-up with Monjuvi. Can you just remind us the gross to net assumptions that we should be factoring?

Barry P. Flannelly - *Incyte Corporation - Executive VP & GM of North America*

Well, this is Barry. So we didn't really comment on the gross to net assumptions. We talked about the price -- the average monthly price. And obviously, we're working on that together with our partners. Some, obviously, discounts are required through government programs, through CMS and so forth. But we really haven't said what the gross to net will be. We'll have to see as we go forward.

Operator

Our next question today is coming from Aydin Huseynov from The Benchmark Company.

Aydin Huseynov - *The Benchmark Company, LLC, Research Division - Senior Equity Analyst for Biotechnology*

I have one on Monjuvi. So given this is a combinational agent and given that REVLIMID is already expensive drug, I think, more than $20,000. Do you expect any payor resistance or impediments, especially in budget conscious EU pay environments such as NICE and French authorities?

Barry P. Flannelly - *Incyte Corporation - Executive VP & GM of North America*

So I'll take the first part of the question, address the United States and Hervé can address outside the United States. So we think the combination of this injectable and oral drug together is priced appropriately for the benefit that the regimen provides. If you look to other analogs, for example, particularly in multiple myeloma, injectable drugs that are combined with REVLIMID are approximately the same price per month per year, and others are actually priced higher. If you compare it to CAR-T therapies, obviously, there are many different complications there, but obviously, that's in the same sort of price range per patient. And Hervé?

Hervé Hoppenot - *Incyte Corporation - Chairman, President & CEO*

Just to comment on the EU. The cycle of patent expiration for lenalidomide is different in the EU. There are generics already available in a number of countries already today. And when we look at the approval -- timing for approval and reimbursement timing for Monjuvi or tafasitamab in Europe, in fact, it is almost coincidental that it is when lenalidomide is going generic in many of the large countries. So what we anticipate is to be negotiating the price as we have to do in all of these countries in Europe at the time where the cost of lenalidomide will be going down very drastically. So it should be -- it's a little bit by chance, but it should be a good timing to be able to have a reasonable good price for tafasitamab in Europe.

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Aydin Huseynov - *The Benchmark Company, LLC, Research Division - Senior Equity Analyst for Biotechnology*

Appreciate it. And I have one follow-up regarding Jakafi. So how would you compare the performance of Jakafi versus Jakavi in Europe? Because both showed 16% growth, but Jakavi actual sales only grew 9%. And just was curious what's the MF growth in Jakafi -- Jakafi indications MF growth?

Hervé Hoppenot - *Incyte Corporation - Chairman, President & CEO*

The comment on Jakavi in Europe versus Jakafi in the U.S., I think what we have seen since the launch is sort of a classical curve where, obviously, the volumes are higher, the prices are lower in -- outside of the U.S. That's sort of a general statement on all of these products. And Novartis has done an excellent job to ensure that Jakavi became standard of care in MF and PV. The GVHD launch has not been yet done in Europe. GVHD, the decision was to submit together REACH2 and REACH3. So there are 2 large -- largest ever pivotal studies that would be used for the submission in Europe and outside of the U.S., in fact, in general, that will be used together. The reason to do that is related to pricing because every new indication is leading to price reduction. So the decision was made by Novartis to do it together. And now that we know the results of REACH3 are fantastic, it is certainly a very good decision. So we will see the GVHD expansion happen later than what we have seen in the U.S. But overall, I must say the growth ex U.S. and U.S. has been, first, exceeding expectations for both sides and has been very parallel in term of how MF and PV have been evolving. So it's a story of good partnerships that, frankly, now for 10 years has been working very well.

Operator

Our next question is coming from George Farmer from BMO Capital Markets.

George Farmer - *BMO Capital Markets Equity Research - Analyst*

Can you hear me?

Hervé Hoppenot - *Incyte Corporation - Chairman, President & CEO*

Yes, we can.

George Farmer - *BMO Capital Markets Equity Research - Analyst*

Okay. Great. I'd like to talk more about your strategy with parsaclisib in RUX and in MF. And how do you see that combination fitting in kind of with other JAK inhibitors?

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

It's Steven. So again, just to reiterate, the program, as we're setting it up. So there will be 2 studies. The first-line study would be in RUX plus parsa versus RUX. So if it ends up down the pike being successful, then that particular combination would become the standard of care there. In terms of the suboptimal responder study, that is for patients who've been on at least 3 months of ruxolitinib at a stable dose, but are having a very carefully defined inadequate response in terms of spleen volume reduction and/or symptoms. And then you add on parsaclisib to that particular patient profile and looking for added benefit. The endpoint for that, as I said earlier, we will announce when the study goes live and will go up on ClinTrials.gov. But it's a very different patient segment because these are people who have had an inadequate response to ruxolitinib. If you play this out in your head, if the first-line study wins and is more efficacious, then there are less patients with inadequate responders down the pike. So, that's how you work out the patient flow through the various lines of therapy in myelofibrosis.

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George Farmer - *BMO Capital Markets Equity Research - Analyst*

Okay. Great. And then, Hervé, could you comment a little bit more on how we should think about launching RUX for atopic dermatitis in Europe in the meantime? And you had said that maybe you'd file for vitiligo or maybe launch ahead of -- with vitiligo ahead of AD. Can you just clarify that?

Hervé Hoppenot - *Incyte Corporation - Chairman, President & CEO*

Yes. I said that because there was a discussion on how the price will be impacted by the sequence of launch. And what we believe today -- and I'm not -- you never know what can happen. But at this point, what it looks like is that if we do a sequence of atopic derm followed by vitiligo, we will end up with reimbursement that will be very much lower than if we do vitiligo first. So that's what we are now thinking about. I was saying that because there were a lot of questions on the commercial model in Europe. And I think what seems to be emerging is that the launch in Europe may be delayed compared to the launch in the U.S., if we start with vitiligo.

Operator

Our next question today is coming from Stephen Willey from Stifel.

Stephen Douglas Willey - *Stifel, Nicolaus & Company, Incorporated, Research Division - Director*

Maybe for Steven. I guess your comments around endpoint selection in the inadequate RUX responders trial maybe implies like there's still some regulatory dialogue that's ongoing there. I think AbbVie just posted details around the Phase III Transform study in the relapsed/refractory setting, and it looks like they're using SVR35 as a primary. I guess, should we think about this as a surrogate of regulatory flexibility around the potential use of lower SVR thresholds?

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

Yes. I'm not going to satisfy you with my response because you'll have to wait for the outcome when we publish it. But we did see they published their endpoint at an SVR 35% decrease in the second line. That is the established endpoint that we established in the first line, as you well know, and that's no secret likely to be the endpoint in any further first-line studies at the moment. So you'll just have to wait to see what we -- we have completed our negotiations with regulators, and we're all set to go, but you'll have to wait until we put it up. Thanks.

Operator

Our next question is coming from Matt Phipps from William Blair.

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

An editorial associated with the recent Lancet publication on topical RUX and vitiligo, it does bring up the acne side effect of the potential limitation, given a lot of exposure to the face. So I was just wondering if there's any temporal nature of acne. Is it associated with similar exposure? Or was it more transient? And then does this -- do you guys think this has any potential commercial impact mainly on duration of therapy?

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

Yes. It's Steven. I'll comment a little bit. We haven't seen a temporal link per se in terms of the onset of some acne, nor has it been particularly problematic, so from the data we have thus far in the proof-of-concept study, that's the conclusion. Obviously, as we've been telling you, we're enrolling now 2 large Phase IIIs. It'll be north of 600 patients total with longer follow-up, and we'll see how that plays out. But it's just not something

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that -- other than the adverse event being reported, which is important for patients, that's particularly problematic in terms of long-term use thus far.

Operator

Our final question today is coming from Michael Schmidt from Guggenheim.

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

I had a question on your bispecific antibody program, MCLA-145. Maybe, Steven, just wondering what your level of excitement is for that asset. And based on what you've heard from other similar product candidates, it seems like there's some interest there. Just curious where you are and when we might see initial data from the study.

Steven H. Stein - *Incyte Corporation - Executive VP & Chief Medical Officer*

Yes. Thank you for mentioning our bispecific program. No, there -- it's a very interesting doublet from a biology point of view. It's 4-1BB or CD137 is the target coupled with PD-L1. So, 4-1BB has a long history in the past of other companies trying it on its own and ran into toxicity, particularly liver tox. So the coupling with PD-L1 was done as a delivery mechanism to take that 4-1BB to PD-L1 expressing areas. And the theory being would avoid the associated toxicity plus then get the enhanced efficacy either additive or synergy-wise. And the program is going well. We'll present data probably next year. We won't see data this year from it. But it continues to go well. There is a tremendous amount of interest from people who work in the field around it. And the sort of ball's in our hand, so to speak, to get to a safe dose and then progress it. But we're encouraged by what we've seen thus far and the program is enrolling pretty well. Thanks.

Operator

Thank you. We've reached the end of our question-and-answer session. I'd like to turn the floor back over to Mike for any further or closing comments.

Michael Booth - *Incyte Corporation - Divisional VP of IR & Corporate Social Responsibility*

So thank you all for taking the time to join us on the call today and for your questions. Of course, Christine and I will be available for the rest of the day for any follow-ups. But for now, we thank you again, and we'll close the call. Thank you, and goodbye.

Operator

Thank you. That does conclude today's teleconference and webcast. You may disconnect your lines at this time, and have a wonderful day. We thank you for your participation today.

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