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PRESENTATION

Operator

Hello, and welcome to the Incyte Corp. Third Quarter 2020 Financial Results Conference Call. (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, sir.

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

Thank you, Kevin. Good morning, and welcome to Incyte's Third Quarter 2020 Earnings Conference Call and Webcast. The slides used today are available for download on the Investors section of incyte.com.

I am 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 our 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 June 30, 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 we may, therefore, be unable to assess the full effects 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 third quarter, we saw continued strong growth within our commercial business, and we progressed our clinical portfolio on both development and regulatory fronts. Commercial performance across the business was strong. Our product and royalty revenues grew 16% to $621 million driven by Jakafi as well as an increasing contribution from new product launches and from royalties.

Jakafi sales grew 13% year-over-year to reach $488 million with growth seen across all 3 indications. Jakavi and Olumiant royalties grew 17% and 32%, respectively, totaling nearly $100 million in revenues for the quarter. There is significant momentum in the first weeks of launch of Monjuvi in the U.S., and I am pleased to say that Pemazyre, which was launched at the end of April, has outperformed our initial expectations.

The application seeking approval of tafasitamab in relapsed or refractory DLBCL is under review in Europe and applications seeking approval for pemigatinib in cholangiocarcinoma are under review in both Europe and Japan.

It has been a busy quarter for baracitinib development updates. Exciting data were recently presented from the ongoing evaluation of baracitinib in patients with severe alopecia areata, and Lilly's development program in this indication includes 2 Phase III trials. If approved, baricitinib may be the first JAK inhibitor to be approved for alopecia areata, and in October, baricitinib became the first oral JAK inhibitor indicated for the treatment of moderate to severe atopic dermatitis following its approval by the European Commission. This represents a new potential source of revenue for Incyte, and with Lilly, we also announced positive data from the ACTT-2 trial of baricitinib in COVID-19.

From our I-O portfolio, positive results were presented from our trial evaluating retifanlimab in squamous cell anal carcinoma and from our dermatology portfolio, we shared positive preliminary efficacy and safety results for our oral JAK1 inhibitor, 54707 in hidradenitis suppurativa, HS. HS is a chronic skin condition caused by inflammation and infection of the sweat glands.

We also presented pooled results from the Phase III TRuE-AD program of ruxolitinib cream in atopic dermatitis. These results are indicative of why we are so excited by the potential of our dermatology portfolio and why we are establishing a new dermatology franchise for Incyte.

Incyte has deep expertise in immunology within our drug discovery team, and we have leveraged our cross-program knowledge of the JAK-STAT pathway to develop innovative medicines to treat autoimmune disorders. We are now developing science-based therapeutics for the medical dermatology community and have multiple first-in-class candidates that we believe can deliver important benefits to patients.

Our dedicated dermatology development group continues to execute with precision and speed, as evidenced by the rapid advancement of RUX cream in recent years, including the successful Phase III program in atopic dermatitis and the recent completion of recruitment into the pivotal vitiligo program.

We are also building our U.S. commercial organization. The expected acceleration of regulatory timelines through the use of the priority review voucher gives us added momentum here, and I'm very pleased to say that we have been able to recruit some exceptional talent as we continue to build our dermatology team.

I will end my introduction by reminding you of the tremendous progress we have made so far in 2020. We have announced multiple positive pipeline developments since the beginning of this year, as shown by the checkmarks on Slide 6.

And looking forward, we have 5 important updates to come over the next 2 months. We expect to submit the NDA for ruxolitinib cream at end of the year and to initiate the first Phase III trial in the LIMBER program.

Important translational data from '86550, our oral PD-L1 inhibitor is going to be presented at SITC next week, and we are also expecting a busy ASH conference in early December.

At ASH, our presentations will include an oral presentation of the REACH3 data from ruxolitinib in chronic GVHD, as well as a series of updates from the parsaclisib CITADEL program in several different non-Hodgkin lymphomas, and we also intend to host an investor call on Monday, 7th of December to provide our highlights from the conference.

I will now pass the call over to Barry for the commercial overview.

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

Thank you, Hervé, and good morning, everyone. In the first 9 months of 2020, Jakafi sales increased 17% versus the same period in 2019, and we continue to see good demand for Jakafi across all 3 indications. The continued strong performance in the year-to-date has enabled us to tighten our sales guidance for Jakafi to a new range of $1.91 billion to $1.94 billion.

On the right-hand side of the slide, you can see the evolution of a proportion of patients by indication. Myelofibrosis patients still represent the largest proportion of patients on Jakafi, but numbers of polycythemia vera, and GVHD patients on Jakafi are increasing and now comprise 33% and 13% of total patients, respectively.

Slide 10 provides additional color around new patient growth for Jakafi. The chart on the left shows that over 90% of total patients are ongoing patients from prior periods, and this pool of ongoing patients continues to grow quarter-over-quarter.

As we have previously disclosed, new patient starts were down significantly in Q2 this year, as we felt the effects of COVID-19 due to total patient visits being down. Following this transient decline in Q2, there was a partial rebound in new patient starts in Q3.

Turning now to the Monjuvi launch progress.

We are very pleased with the performance of Monjuvi generating $5 million in the first few weeks since launch in mid-August. With our colleagues at MorphoSys, the commercial and medical teams have been driving increased awareness of the benefits of Monjuvi, and we are now the market leaders in terms of share of voice. Field activity, participation in educational presentations and inclusion in the NCCN guidelines are all contributing to the increasing awareness of Monjuvi within the Heme/Onc community.

Feedback thus far has been very positive with physicians highlighting the importance of Monjuvi's depth and duration of response and its favorable safety profile.

We have built strong momentum for Monjuvi within both the academic and community settings with greater than 200 accounts having now ordered. We are seeing a sizable uptick by Heme/Oncs in the community, which now accounts for approximately 65% of total prescribers, a trend that we anticipated. Our market access teams have also made significant strides since launch, achieving nearly 90% formulary approvals in our top 30 accounts.

Turning to Pemazyre, which we launched in the second quarter. We have been very pleased with the rapid adoption of this new medicine, this novel medicine, with $8 million in sales generated in the third quarter.

Broad access to FGFR testing has contributed to this rapid patient adoption, and we have seen good uptake of Pemazyre nationally with over 200 patients treated since launch. The high refill rate also suggests that the appropriate patients are being identified via this testing as they continue on Pemazyre therapy.

I'll now turn the call over to Steven for our clinical updates.

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

Thanks, Barry, and good morning, everyone. I'll start with our ruxolitinib cream program. Initial data from the Phase III trials presented earlier this year at RAD showed that ruxolitinib cream resulted in significantly higher investigator global assessment treatment success and Eczema Area Severity Index 75 scores for RUX cream versus vehicle.

At EADV in October of this year, pooled analysis of the 2 Phase III trials were presented. These pooled results reinforce the efficacy profile of ruxolitinib cream as it relates to IGA-TS, EASI-75 and the rapid, substantial and sustained itch reduction in patients with atopic dermatitis.

Newly presented data at EADV showed that patients on ruxolitinib cream also experienced significantly better sleep quality, sleep depth and restoration. These results further highlight the potential for ruxolitinib cream to become an important treatment option for atopic dermatitis patients. We are on track to submit the NDA in atopic dermatitis at the end of this year, and intend to use our priority review voucher, which should accelerate the FDA decision.

The priority review voucher is expected to shorten the FDA review period by 4 months. Therefore, we could expect an FDA decision in June next year if all goes according to plan as opposed to October of 2021. Our Phase III program for vitiligo is now fully recruited, and we expect results in the first half of 2021. Given the accelerated timelines with the use of the priority review voucher, there is also the potential of an acceleration of the vitiligo program because an earlier decision on the atopic dermatitis NDA may allow for consequently, earlier submission of the sNDA for vitiligo.

Staying within our dermatology development group, we announced positive initial data for '54707, an oral JAK1 inhibitor in patients with moderate-to-severe hidradenitis suppurativa, which is a chronic skin condition where inflammation and infection near sweat glands can result in painful abscesses, sinus tracts and scarring on the skin. The Phase II trial evaluated 3 doses of '54707 versus placebo, each of which were taken daily for 8 weeks, followed by 30-day safety follow-up.

Preliminary efficacy was seen in the reduction in the number of abscess and inflammatory nodules termed the AN count, which with results seen as early as week 1, as well as reductions in skin pain. '54707 was well-tolerated, with no treatment discontinuations due to treatment-emergent adverse events, and we have already initiated a larger, 200-patient Phase IIb study.

We are excited by the global opportunities for tafasitamab, and Slide 17 reminds you of our broad development program, which covers several non-Hodgkin's lymphomas in both the first line and the relapsed or refractory settings. We have multiple pivotal trials in preparation across various indications, including first-line diffuse large B-cell lymphoma and in relapsed or refractory follicular lymphoma. We also expect to initiate our proof-of-concept trial, evaluating tafasitamab in combination with our PI3K-delta inhibitor parsaclisib for which the final protocol is in preparation.

Turning to our I-O portfolio. At ESMO in September this year, we presented Phase II results from POD1UM-202, evaluating retifanlimab in squamous cell anal carcinoma. The disease control rate of 49% and median duration of response of 9.5 months were well received, and we are opening a Phase III trial for retifanlimab in patients with squamous cell anal carcinoma.

Slide 18 also reminds you of the status of the other indications we are pursuing for retifanlimab as well as the important clinical translational data we'll be sharing from '86550, our oral PD-L1 inhibitor, which is to be presented at SITC next week.

The translational data are from actual clinical specimens taken during the ongoing trial, and we will be able to share with you the data showing, for example, the degree of PD-L1 inhibition and T-cell changes illustrative of immune modulation with '86550. We expect to provide more fulsome clinical safety and efficacy data from this ongoing trial during the next year, and we are also initiating a new Phase II trial in patients with treatment-naive PD-1 sensitive tumors as we continue to move forward with this important project.

I will end my section on our development projects addressing COVID-19. With Lilly, we recently announced positive results for baricitinib in the ACTT-2 trial in hospitalized COVID-19 patients. In combination with remdesivir, baricitinib reduced time to recovery, improved clinical outcomes and showed a numerical decrease in mortality compared to remdesivir alone. These results were most pronounced in patients receiving oxygen. Based on these data, Lilly has submitted baricitinib to the FDA for a potential Emergency Use Authorization and regulatory discussions remain ongoing.

For ruxolitinib, we recently completed enrollment of the RUXCOVID trial, and we expect top line results from this trial by the end of this year.

With that, I would 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 year reconciliation of GAAP to non GAAP, please refer to Slide 27 in the backup section of the deck and to the press release we issued this morning.

Moving to our results for the third quarter. Revenue growth continued to be strong, with total product and royalty revenues of $621 million, representing an increase of 16% over the third quarter of 2019. This reflects growth across both products commercialized by Incyte and those commercialized by our partners. Total product and royalty revenues for the quarter are comprised of net product revenues of $488 million for Jakafi, $26 million for Iclusig and $8 million for Pemazyre, royalties from Novartis of $68 million for Jakavi and $1 million for Tabrecta and royalties from Lilly of $29 million for Olumiant.

Total costs and expenses for the quarter of $559 million on a non-GAAP basis include $120 million related to the purchase of an FDA priority review voucher fully expensed under R&D, which we intend to use to accelerate the FDA review of ruxolitinib cream for the treatment of atopic dermatitis, and $21 million of upfront consideration and milestones related to our collaborative agreements. Excluding the impact of these expenses, our total costs and expenses increased 15% over the prior year quarter.

Ongoing R&D expense for the quarter was $268 million on a non-GAAP basis, representing a 7% 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 and the clinical trials of ruxolitinib as a potential therapy for COVID-19, and was partially offset by the timing of other development activities.

SG&A expense for the quarter was $106 million on a non-GAAP basis, representing an 18% increase over the prior year quarter. This increase was primarily due to an increase in commercialization efforts related to Jakafi and Pemazyre, the preparation for the potential commercialization of ruxolitinib cream and the timing of certain expenses.

Collaboration loss for the quarter was $15 million, which represents our 50% share of the U.S. net commercialization loss for Monjuvi. The total U.S. net commercialization loss of $30 million for Monjuvi is comprised of total net product revenues of $5 million and total operating expenses, including COGS and SG&A expenses, of $35 million. Our financial position continues to be strong as we ended the quarter with $1.7 billion in cash and marketable securities.

Moving on to our guidance for 2020. Based on the continued strong performance of Jakafi in the first 9 months of the year, we are tightening our Jakafi full year guidance to a range of $1.91 billion to $1.94 billion. This implies net Jakafi revenues of $489 million to $519 million for the fourth quarter of the year. This range reflects some uncertainty associated with the resurgence in COVID-19. We are reiterating our guidance for both R&D and SG&A. As a reminder, the R&D guidance excludes the $805 million upfront consideration related to our collaboration with MorphoSys and the $120 million of expense related to the purchase of the FDA priority review voucher.

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 Cory Kasimov from JPMorgan.

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

I guess I'll start with the obvious. Barry, can you just talk a little bit more about the real-world physician feedback, the field teams getting on Monjuvi since launch? Is there anything that you're particularly surprised or pleased by relative to your prevailing expectations in these admittedly very early days?

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

Sure, Cory. Thanks for the question. It's actually been very good. I participated in a number of advisory boards. Lots of our interactions now are virtual, of course. But I think most physicians, most hematologists would choose Monjuvi as being the preferred second line agent for most of their patients with diffuse large B-cell lymphoma. So we're very happy. We think our trends will continue to grow in the right direction. I think it's going as well as it could possibly go. And even with COVID, for example, sales representatives and medical representatives in the field have actually been able to communicate and get into their accounts and talk about the benefits that Monjuvi provides.

Operator

Next question is coming from Brian Abrahams from RBC.

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

Congrats on the continued progress. I was wondering if you could -- maybe there's a question for both Christiana and Barry. I was wondering if you could speak to the acquisition of the priority review voucher in atopic derm. And I guess how you were thinking about a potential return on investment in the context of what an initial launch trajectory could look like and the potential pricing strategy there?

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

This is Christiana. Thank you for the question. So on the priority review voucher, as Steven described, it provides us the potential to accelerate the overall timeline to market for RUX cream, both for AD and vitiligo. So for AD, it could shorten the FDA review period by 4 months, from 10 months to 6 months. And then if AD review is completed earlier than under the normal 10 month period, it gives us the possibility to subsequently submit vitiligo for review earlier than we could otherwise do.

So given the potential opportunity we see with the RUX cream in both AD and vitiligo, the unmet needs that we see in both indications, getting RUX cream to market earlier than we would otherwise could under the normal timelines, review timelines, it's something that we see very attractive and was easily supporting the investment we made in the PRV.

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

And just to add, I think we're completely ready to go as a new dermatology business unit. We're excited about the potential that RUX cream will offer to a whole range of patients with mild to moderate disease. And as far as pricing and launch trajectory, launch trajectory, we think is going to be very good. Pricing decisions haven't been made yet.

Operator

Next question is coming from Salveen Richter from Goldman Sachs.

Andrea R. Tan - *Goldman Sachs Group, Inc., Research Division - Research Analyst*

This is Andrea on for Salveen. Maybe another question on the new product launches. Could you speak to what you're seeing with Pemazyre? And any initial thoughts on what the drivers of momentum have been that have surpassed your expectations?

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

Sure, Andrea, thanks, Barry. The drivers of momentum are simply that this is the first targeted therapy available for patients with FGFR2 fusions or rearrangements. Really, these patients had nothing after second-line therapy. So testing has been easier than we expected, next-gen sequencing, identifying the right kinds of patients and getting the drug to them at the right time. Patients are not only accessing the drug, but they're staying on the drug, at least for the time being. Obviously, it's very early. But yes, we're quite pleased with the number of patients we have and the amount of patients that are coming back for refills.

Operator

The next question is coming from Evan Seigerman from Crédit Suisse.

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

Really congrats on the continued progress. So it's really clear that dermatology is a focus for you now. Can you provide some color as why you opted to invest and build your own dermatology franchise? I know there have been questions about whether or not you're going to do an in-house or partner out? And how large is this kind of commercial force expected to be? Then I have one follow-up there.

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

Maybe I'll take that. Hervé here. As you know, I mean, we have been sort of following the product. So the product led us into dermatology, where if you remember, we had studies in alopecia areata. In fact, that was the first study we did, and then we had studies in atopic derm and vitiligo. I think what changed our view from finding a partner and getting royalties for this is when we realized the profile of the product in atopic dermatitis is, in fact, very much superior to what you have available today. And the number of patients is potentially very large. And then we also realized it was probably over the past 2 years that the benefit we are providing in vitiligo is very unique. Vitiligo is not just a cosmetic issue. It's a life issue, and we can reverse for some patients, the disease that is hurting them.

So when we came to the quantification of what it meant, we saw this opportunity in the U.S. as being very meaningful for our goal of growth and diversification. So that's where we said we could potentially do it ourselves. We have a team we are putting in place. I think I described it in the past as 200 people, more or less, something of that size. And it's in good shape to being built now over the next 6 months with a priority voucher. And I think it's an opportunity for Incyte to have literally a new franchise. It's not changing our attention or taking our attention from cancer and immunology and hematology; it's literally a separate team.

So there will be 2 legs now that will be basically driving the growth of Incyte starting in 2021. One of them will be the, we call it, IAI, immunology, dermatology, and the other one will be cancer. And frankly, there is no real change in our investment or energy that we put behind our cancer hematology portfolio. It's just an addition to what we had before. Now for the rest of the world, we are still in a situation where we think we will have partnership for Asia and a large part of the world for the cream. And in Europe, we are looking at what makes the most sense.

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

And one quick follow up there. Beyond topical RUX, do you expect '54707 to be the next key asset in the franchise?

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

Yes. It's Steven. So as you saw, it's another JAK inhibitor we have in our portfolio. It's relatively JAK1 selective. We're developing it currently in hidradenitis suppurativa. We believe, based on research we've done, that there remains an unmet need there, that the available drugs aren't as effective as patients want them to be. And we're very encouraged by our early data, which I showed you in terms of abscess reduction and in skin pain relief. So it's an important entity to study with a compound that is clean for that indication. Beyond that, what we do with the compound still needs to be determined.

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

Yes, there are additional indications for RUX cream, we are also looking at. So the way we see it is that there is a developing portfolio that is evolving and at the same time, if you look at eczema and vitiligo, we have 2 very large opportunities that are just in front of us where we will have the first-in-class. We'll have the first JAK topical. And in the case of vitiligo, it will be the first medicine to be approved for these patients. So there are 2 very important short-term growth drivers, and then there is, obviously, other products that will be or other indications that will be coming subsequently.

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 some color on what data points we could expect from the CITADEL program at ASH?

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

Tazeen, it's Steven. I think you're asking for a little bit of color or granularity on the CITADEL program at ASH.

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

Yes.

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

As you can see, at a high level, the program continues to advance in terms of maturity of data. We have data being presented there in terms of an oral presentation in marginal zone lymphoma and then further presentations in terms of mantle cell and follicular lymphoma. And the mantle

actually is broken down into different presentations with prior BTK inhibitor and then the lack of prior BTK. In totality, the data continues, in our view, to be extremely encouraging. The response rates have been maintained over time, and they're independently reviewed response rates and then keeping with what they should be in those different entities. And then very encouragingly, the duration of responses held up and the progression-free survival as well. So we're encouraged by the totality of the data set. And this is exactly what we wanted. We wanted to have those response rates and now with further follow-up to be able to show that they're both durable and give you appreciable median progression-free survival. So we're on track to -- in the U.S. to submit an NDA, hopefully, in the second half of 2021. And that's where we are with that important program for delta in lymphomas.

Beyond that, delta has other indications we're pursuing. Obviously, in myelofibrosis in combination with ruxolitinib, we're starting our Phase IIIs as part of the LIMBER program. And then also just to mention in autoimmunity and inflammation, we're also studying it in autoimmune hemolytic anemia. It's a very comprehensive program for a very active compound in our view.

Operator

Our next question is coming from Michael Schmidt from Guggenheim.

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

I had one on Monjuvi. With the application now being under review also by European regulators, I was just wondering if you had any prior interactions with the EMA? And what your confidence level is in potential accelerated approval in Europe? There's been a few rejections recently of oncology products based on single-arm studies.

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

Yes. Michael, it's Steven. Thank you for your question. You know, you're correct and we've always prefaced European regulatory discussions on single-arm studies has been more difficult, as you just alluded to, some recent examples in areas where they've declined approvals in certain entities. For tafasitamab itself, as Hervé even said upfront, there -- and then Barry furthered by the real world experience, there's obviously a very strong data set, a very high complete response rate that median duration of response for the CRs continues to improve. In the update, the CRs was not even reached, but the median for the combined with PRs was 34 months.

So we think that represents a very appreciable efficacy combined with the safety profile that's tolerable. Obviously, our job is to convince European regulators of that, given the single-arm study and the real-world evidence we have from Re-MIND to say there's a discernible treatment effect that's appreciable and that we'd like you to approve it, given that. And we're in that process now. And all I can tell you is it's going well. I mean it's marching through the different Day 120, et cetera questions that we need to have, and we'll see how it goes with them. It's hard to give you any further color other than that.

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

Perfect. And then just on the first line -- the planned first-line DLBCL regulatory study. Looking at the abstract from First-MIND, it looks like both of the combinations look very safe. Is there anything else that you're looking for in the First-MIND study before completing your plans for the Phase III?

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

Thank you for pointing that out. So you're right. The abstract is live now for the safety component of First-MIND, which looks at tafa plus R-CHOP or tafa / LEN plus R-CHOP, and you're right, our interpretation is the same as yours that there's comparable safety for both. And we've already announced publicly that we're going ahead, thus, with the tafa / LEN / R-CHOP combination in the first-line study. And then we're just working out

the final details with regulators on size and those sort of things, endpoints, et cetera. But we'll be ready to go soon and obviously, a very important study not only to us, but to the community in terms of first-line diffuse B-cell lymphoma to try and improve the cure rates from R-CHOP.

Operator

Our next question is coming from Jay Olson from Oppenheimer.

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

I appreciate the comments on Pemazyre launch. It seems like it's outperforming your expectations. And I was wondering, I know you only promote it for cholangiocarcinoma, but are you seeing any spontaneous use in bladder cancer or other tumor types?

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

Not I'm aware of, Jay. We really haven't dug into it all that much. It seems that just about every patient that I'm aware of comes in is for cholangiocarcinoma. Occasionally, we'll get a request for an individual patient -- for an individual IND for some tumor type or another, but it's very rare.

Operator

Our next question is coming from Mara Goldstein.

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

Yes. Just a follow-up on that question. The announcement to discontinue the studies in bladder cancer, does that affect the studies that you're looking at for (technical difficulty)

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

Mara, it's Steven. Your question was breaking up a little bit, but I think you just wanted some view on our strategy in bladder cancer with our FGFR inhibitor. I think if you step back and you look at how bladder cancer, particularly metastatic bladder cancer is evolving with new data sets with checkpoint inhibitors, with EV from Seattle Genetics, clearly, there's a change now in the treatment paradigms and treatment course and line therapy in bladder cancer. And what we want to do is literally do that. We feel that in conjunction with our advisers that our current first-line study thus becomes irrelevant given how care standards are changing, and we obviously have stopped recruitment there. And we're re-looking at the bladder program in totality, looking at the biology, particularly just to give you some granular detail, given EV's effect in nectin expression bladder cancer, we want to ascertain whether FGFR3 on its own is a separate driver in this setting and if it is, how that will play with our FGFR inhibitors. And we're busy doing that preclinical work to understand the biology right now. This doesn't change our strategy for pemigatinib in the agnostic program, which is recruiting very well, nor in the myeloproliferative neoplasm 8p11. But we feel bladder is evolving enough that we need to step back and understand the biology there.

Operator

Next question is coming from George Farmer from BMO Capital Markets.

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

Nice to see the rebound in new patient starts with Jakafi after the slowdown due to COVID. Where do you see that going, going forward? And could you comment on your progress with Jakafi in chronic GVHD?

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

Sure, George. I'll take that. So new patient starts have actually -- especially within the last 2 weeks even, come back to almost pre COVID levels. So we're happy with that. If you recall in the first quarter, in fact, our new patient starts, we were extremely pleased with. And until COVID hit, we looked like we're going to have a very, very good year. So we're hoping to get back to that number of new patients on each of the indications. Of course, we're looking forward to the approval in steroid-refractory chronic GVHD sometime next year. And we really think that this is going to be a great benefit for patients. We know that there is the prevalent population in chronic GVHD is fairly high compared to the acute steroid-refractory GVHD patients. So we really believe that there's an opportunity for more growth there with the patient's longer duration of therapy when they're treated for chronic GVHD. So we're looking for that approval.

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

Yes. And thanks, Barry. It's Steven. Just to add a little bit. You saw the abstracts go live yesterday, and the REACH3 is an oral presentation at ASH. And again, now, a second study, a large study, randomized study in GVHD, that's positive. So it's a good achievement, obviously, for the drug and really important for patients. If you look at the totality of the data in the abstract, it's superior efficacy versus best available therapy with a higher response rate, longer failure-free survival and better symptom improvement. What's not in the abstract, but will be presented at the actual meeting is also best overall response at any time, just to try to give you comparative data to other agents. So it's an important oral presentation at ASH.

And as Barry said, our intent is to get the submission in as soon as possible given that.

Operator

Our next question is coming from Kenneth Atkins from Cowen

Kenneth Craig Atkins - *Cowen and Company, LLC, Research Division - Research Associate*

For your JAK1 inhibitor '707, what do you think you need to show in hidradenitis in the Phase IIb to have a compelling profile there versus standard of care?

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

Yes. Kenneth, it's Steven again. Thank you. So it's a disease as we were outlining in our formal presentation that has a lot of morbidity for patients, given this abscess formation in different skin folds in the body. Obviously, TNF inhibitors are licensed and used there with not the efficacy that I think patients fully want. So the idea was here to try -- given the biology in a relative JAK1 agent to try and get further improvements in abscess formation, sinus tract, et cetera. We use -- so you got to be really careful on what you do cross-trial comparisons here. So for this data set, we use what's called an AN count, and we believe that the best way to measure patient benefit here. But there are other endpoints that are used in other studies. So particularly for TNF, there's HiSCR that's used, which is a greater than 50% reduction in AN count, but no increase in new lesions. So it's a combination thereof in terms of the lesion improvement plus ways of measuring clinical benefit and morbidity on patients. And that's why it's a very stepwise development. We're now going to Phase IIb with a 200-patient study, and we're likely to then need a Phase III program to get it across the finish line. But we were told repeatedly by people in the area that there remains this unmet need here, and that's what we're going to try and address in the Phase IIb, that we have enough efficacy to get there in terms of AN count reduction.

Operator

Our next question is coming from Andrew Berens from SVB Leerink.

Gang Li - *SVB Leerink LLC, Research Division - Research Analyst*

This is Gang Li for Andy. Just a quick question regarding the topical Jakafi. So how do you see the opportunity in more severe atopic dermatitis patients once it's approved? Do you see that more in combination with other systemic treatments? Or as a monotherapy?

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

So thanks, Gang Li. So I think there's an absolute -- well, if you look at our studies TRuE-AD1 and TRuE-AD2, you see there's a high proportion of patients with moderate disease. So we think when we look across trials, we could have an opportunity there. But we really think it's going to be the best drug available for patients from steroids all the way up to biologics. So we think we have a clear opportunity there. If it's going to be used in the future with biologics like Dupixent, for example, we'll have to wait and see. Obviously, Dupixent is often used with topical steroids now because you have to have some local control for particular parts of the skin, their disease. So it could happen in the future, but that's certainly not our indication. We didn't study patients with severe disease, but we do believe that there's a wide range of patients who will absolutely benefit from RUX cream.

Operator

Next question is coming from Stephen Willey from Stifel.

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

Maybe one for Steven. I guess how should we just be thinking about the go-forward dosing strategy for parsaclisib and some of these B-cell malignancy subtypes? I know the ASH abstracts kind of highlight a little bit of a response rate delta between the weekly and daily dosing, which I think also appears to be a little bit tumor type and maybe line of therapy dependent. So should we expect that you're going to be pursuing kind of a different dosing strategy in some of these different subtypes? Or would you expect to have one that kind of covers the whole gamut of B cell malignancies?

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

No, it's a good question, and thank you for it because we did spend a little bit of time trying to work out the optimal dosing schedule to get the therapeutic ratio we wanted in terms of the efficacy and safety benefits that we wanted to weave. For the class, it's had a bit of a rocky run over the years, starting off with idelalisib early on. And particularly, people were concerned about longer-term toxicity and things like colitis. We knew from the get-go, the drug is incredibly active. So we wanted to work that out, and we spent some time doing it. So where we are now is where we think is the optimal way of doing it, and you'll see in the abstracts, the totality of the information. But we start off at a high dose, 20 milligrams daily for the first 8 weeks. And the idea there is to maximize efficacy. These patients, when they respond, they respond early and quickly. So the vast majority, if not all, of the responses happen in that time period.

And then we stepped back and we looked at after that weekly maintenance versus daily. And again, looked at both retention of efficacy then as well as safety. And it turns out that, that it's best for us is afterwards to switch to the daily dosing and not the weekly maintenance. So if you look at the totality of the data there, you retain efficacy, we're getting the durability of response in PFS we want. But we've also been able to tone down some of the toxicity with that regimen. So I think going forward, from a regulatory point of view, obviously, you're going to have to work with regulators around the world, yes. You'll be looking at 20 milligrams induction for 8 weeks, followed by the daily schedule thereafter.

Operator

Our next question today is coming from the line of Matthew Phipps.

Robert Andrew - *William Blair & Company L.L.C., Research Division - Research Analyst*

This is Rob Andrew on for Matt Phipps here. So maybe just on the early-stage programs with the BET and ALK2 inhibitors. Just getting started up here. Maybe what are the expectations with those programs given the monotherapy dosing? Are we clearly looking for a safety profile acceptable for Jakafi combinations? Or what are the expectations there?

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

It's Steven. Thank you for your questions. So I'll separate them out because BET has a slightly different history. So if you look at BET BRD, this is a compound we had in the clinic a few years ago, primarily targeting solid tumors and working on a slightly different hypothesis around MYC inhibition, and we were at multiples at the dose we were at now.

We were at 12 to 16 milligrams, whereas we are at 4 milligrams now. And what we saw there in that program a couple of years ago was on target toxicity in terms of thrombocytopenia as well as other some worrying toxicities. So we had put ourselves on a clinical hold at the time for that compound. And then what happened over the ensuing year with BET, as you saw the data from Constellation and CPI come forward, and we knew, by the way, the biology was relevant in myelofibrosis, and we think there is something to that data set, and there is clearly an effect from addition of BET therapy to ruxolitinib.

So we revitalized our own program there. We worked with the FDA to come to what we think is a safe starting dose to avert a lot of the toxicities, modeled off what we saw happen in an external world, and we've restarted the program. What we have to do is demonstrate monotherapy safety, which we're doing now with the BET, and we expect that to be the case given the dosing we're using and then quickly go to combination with ruxolitinib. So that's the story behind BET. In terms of ALK2, it is a very exciting program to us. We think the anemia seen in myeloproliferative neoplasms, particularly myelofibrosis, is mediated through the hepcidin pathway, building a little bit on the momelotinib data there, as well as the anemia seen with the use of JAK inhibitors.

So we're trying to ameliorate that anemia of the underlying disease, plus potentially the JAK-induced anemia so that you can maintain dosing. And in fact, as a corollary of that, actually increase efficacy as well because you can stay on the combination. So again, the idea is to get to ALK2 monotherapy safety pretty quickly and then start the combination very soon with both.

ALK2, in terms of its mechanism of action, may have utility in anemias across the board in terms of hepcidin inhibition. So that's something we're interested in. And then there are some entities where solid tumors may have underlying genetic mutations that may be amenable to this as well. So it's a very interesting program, a very interesting mechanism and we're going fast.

Yes. Just to add one more thing because I didn't, just -- we're also studying a rare disease, which is also mediated by the program FOP, which is a condition where you get premature bone formation in soft tissues, a lot of morbidity from it and sometimes early death as well. It's a rare entity. But again, it's something we're committed to doing as well. So we will have an FOP program as well with the ALK2 agent.

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 about dermatology. So given relatively high vehicle responses, 10% to 20%, so what would be your sales pitch to a dermatologist especially when we hypothetically compare RUX cream to other standards of care, not necessarily a vehicle?

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

Well, Aydin, this is Barry. First of all, I think that our response from the TRuE-AD1 studies and TRuE-AD2 studies are very good, and the difference -- the delta between the active drug and the vehicle is very good. And as compared to other therapies, well, oral therapies for -- that may be coming oral JAK inhibitors and may be coming for atopic dermatitis. Obviously, you're suppressing the entire immune system when you take an oral drug. So that doesn't seem to be the best way to go about it. We have a great JAK inhibitor that's topical that you can apply right on the area that's most effective. So we think that's an advantage for us. And as far as just some of the evolving data that might be coming from other topical JAK inhibitors, we've seen the data so far, we don't see any reason to be concerned about it, and there's still some questions about their dose response of those therapies.

So our sales pitch is, actually, we've had many interactions with dermatologists -- very positive interactions with dermatologists, and they feel very strongly that this is a drug that they've been looking for, RUX cream. So I think it will be a relatively straightforward approach. We'll talk about the science, and we'll talk about the benefit that it offers to patients who are really suffering from this autoimmune disease, atopic dermatitis.

Operator

Our next question today is coming from Vikram Purohit from Morgan Stanley.

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

So I had a follow-up question on real-world use for Monjuvi. So to the best of your knowledge, has there been much or any off-label use of Monjuvi in combination with another agent like bendamustine? Or has it so far primarily been in line with the labeled use in combination with lenalidomide?

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

Yes. So Vikram, I don't -- well, it depends on what you call off-label. Certainly, we've been used in a whole variety of places, relapsed/refractory, second line and plus. Obviously, we're studying the drug in combination with bendamustine in the future. So we'll have multiple other studies that will have a chance to see what different combinations, including parsaclisib that we'll try to study the drug with in the future. So we're excited about that. But I think that most hematologist-oncologists are most excited about what Steven was talking about before, about our complete response rate and how high that is and long duration of response that continues to get better. So the combination of LEN plus Monjuvi right now has both the efficacy and safety profile that most physicians who treat diffuse large B-cell lymphoma are looking for.

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

Okay. Understood. And as a follow-up, I had a question on the ASH abstract on the First-MIND safety data. So I believe that abstract mentions that we could see some initial efficacy data during the presentation at ASH. To the extent you can discuss it, could you characterize a little bit about what we could see there? And what we should make of it? And how we should interpret it when thinking about Monjuvi in the first line setting?

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

Yes. The entire intent of the abstract and presentation is safety, and that's what I'll point to. And just to be maybe a little bit repetitive on my earlier comments, given that the safety of the combination of TAFA / LEN / R-CHOP is very similar to TAFA / R-CHOP. Given that you have to -- aiming for

cure here and maximizing cure rates, it became automatic then that TAFA / LEN / R-CHOP was the way to go in terms of the first-line study. I think given the intent of safety, that's where you should focus on what the presentation will be about. And then obviously, we'll have to wait for a large first-line study to deliver here.

Operator

Our final question today is coming from Alethia Young from Cantor.

Li Watsek

This is Li on for Alethia. Maybe just one on your PD-1 program. How does your Phase II data that you presented at ESMO match up with standard care? And can you just remind us of your strategy in the PD-1 space since it's crowded. Are you looking at indications that are sort of less developed, are you looking at combinations or both?

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

Yes. So again, to step back, we acquired this compound to use on its own and then in various combinations, which we needed for within our own program, and that's what we've been doing. At the same time, the intent was, obviously, to get it registered and we had upfront the niche tumor approach in squamous cell anal carcinoma, merkel cell carcinoma and MSI-high endometrial, and those studies have all enrolled well, and this is the data you see come to fruition. In terms of squamous cell anal carcinoma, the benchmark is the KEYNOTE 158 study from pembro, but the mature data set where the pembro overall response rate was 11%. You can see our response rate is a little bit north of that territory in the 13%, 14% range that's independently reviewed.

In addition, there's a subgroup of patients who are HIV-positive with this that are have that unmet need and were addressed in our study, which hasn't been addressed in other studies. So we're very encouraged, obviously, by that data set and thus, initiated a Phase III and it's right in the territory of what's seen, just to be repetitive with other PD-1 inhibitors in this entity, plus other entities that are very similar, like cervical carcinoma. Beyond the niche tumors, we have an ongoing lung program that's now initiated globally, a lung study. And then as I said, we continue to utilize retifanlimab with various internal combinations.

Operator

We've reached 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 participating in the call today and for your questions. Of course, Christine and I will be available for the rest of the day, and we look forward to engaging with many of you in the coming weeks at investor and also at medical conferences.

For now, though, thank you again, and goodbye.

Operator

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