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EDITED TRANSCRIPT

INCY.OQ - Q1 2021 Incyte Corp Earnings Call

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OVERVIEW:

Co. reported 1Q21 revenues of $605m.

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PRESENTATION

Operator

Hello, and welcome to the Incyte first quarter earnings call. (Operator Instructions) As a reminder, this conference is being recorded. It's now my pleasure to turn the call over to Christine Chiou. Please go ahead.

Christine Chiou - *Incyte Corporation - Head of IR*

Thank you, Kevin. Good morning, and welcome to Incyte's First Quarter 2021 Earnings Conference Call and Webcast. The slides used today are available for download on our website.

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.

Before we begin, I'd like to remind you that some of the statements made during the call today are forward-looking statements and are subject to a number of risks and uncertainties that may cause our actual results to differ materially, including those described in our 10-K for the year ended December 31, 2020, and from time to time in our other SEC documents.

We'll now begin the call with Hervé.

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

Thank you, Christine, and good morning, everyone. In the first quarter of this year, we continued to execute on our strategy to drive further growth and diversification. We entered the year following a strong 2020 where we were able to increase revenue by 24% and achieved multiple regulatory successes, including 3 product approvals. We continue to deliver across our portfolio in the first quarter. Our revenues grew 6% year-over-year to reach $605 million with growth driven by new product launches and royalty revenues of $100 million.

Q1, which is typically a quarter impacted by higher gross-to-net and forward purchasing patterns in the U.S., was further challenged by the ongoing pandemic. Total patients on Jakafi grew year-over-year and in March, new patient starts recover to pre-COVID level. The launches of both Monjuvi and Pemazyre continue to progress with good uptake from both academic and community physicians. Barry will provide additional details in his remarks.

We made significant progress across the clinical and regulatory landscape with Pemazyre approved in both Europe and Japan, becoming the first internally discovered product to be globally commercialized by Incyte. We also have 3 regulatory applications under priority review at the FDA as well as 2 applications under review in Europe, potentially increasing our sources of revenue in the near term.

Last month, we presented updated data for rux cream at the American Academy of Dermatology meeting, including the 2-year data from our Phase II vitiligo trial and updated pooled results from our Phase III TRuE AD program in atopic dermatitis, with each highlighting the exciting potential of ruxolitinib cream as a treatment for these 2 indications. We also announced, with our partner Lilly, 2 positive pivotal trials for baricitinib in alopecia areata. If approved, baricitinib could be the first FDA-approved therapy in alopecia areata.

Looking ahead, over the next 1 to 2 years, we have the potential to undergo a significant transformation here at Incyte with several expansion opportunities as new products and new indications are launched across the U.S., Europe and Japan. This includes rux cream in atopic dermatitis and vitiligo, ruxolitinib in chronic GVHD, tafasitamab in relapse/refractory DLBCL in Europe, parsaclisib in multiple types of lymphomas and QD ruxolitinib in MF, PV and GVHD.

As we look at our key business objectives for the year, we have 3 priorities. First, to grow our existing revenue base by driving new patient starts for Jakafi and accelerating the uptake of Monjuvi and Pemazyre. Second, to expand upon our revenue base by successfully launching new products and new indications. We expect several regulatory decisions before the end of this year. And third, to continue to progress our late-stage pipeline as well as our earlier-stage programs.

Before I pass the call to Barry, I'd like to now take a minute to speak about our ESG initiative, which we call global responsibility and which was launched in 2019. Since then, we have increased our ESG disclosures and improved upon our objectives. In this slide, we list a few key accomplishments among our 5 priority areas, and I'd like to specifically highlight our efforts on the environmental front. In an effort to reduce our environmental impact, we offset 100% of our 2019 measured carbon emissions in the U.S. through verified reforestation carbon credits in partnership with Arbor Day Foundation. Looking ahead, we have set a goal to achieve carbon neutrality through a combination of absolute reductions and offsets by 2025.

With that, I'll hand it over to Barry to cover the individual product performance.

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

Thank you, Herve, and good morning, everyone. Jakafi net sales in the first quarter grew year-over-year to $466 million. As you may recall, first quarter growth in 2020 was 22% year-over-year, due in large part to growth in patient demand, but also to a onetime increase in purchasing due to concerns over COVID-19 restrictions. Our Q1 net sales growth this year was impacted by the pandemic, a higher gross to net, and forward-purchasing

patterns. Patient demand growth of 2.3% in Q1 was softer than normal, due primarily to the decline in new patient starts since the beginning of the pandemic.

The graph on the right shows monthly new patient starts from 2019 to the end of 2021. In the first quarter last year, new patient starts were higher versus prior year, but then significantly declined in Q2 and Q3 of 2020. This loss of new patients impacts total patient growth in subsequent quarters and explains part of the slow growth in Q1 of this year.

We are seeing a gradual return of cancer patients to oncologist offices and as you can see, by following the red line, new patient starts are now at pre-COVID levels. So due to patients returning for their treatments, our representatives being able to have face-to-face meetings with oncologists, our improved gross to net for the rest of the year and our anticipated launch in chronic GVHD, we expect strong growth in the second half of this year. Therefore, we are very confident in our full year outlook for Jakafi and are reaffirming our guidance of $2.125 billion to $2.2 billion.

Turning now to Slide 10. The launch of Pemazyre continues to perform well and has exceeded our initial expectations, and we continue to see an increasing use in the second-line setting. Since launch, the rapid adoption of FGFR2 testing by oncologists has facilitated the identification of appropriate patients for treatment with Pemazyre, and as a result, we see a continuous flow of new patients.

We launched Monjuvi with our partner MorphoSys in the third quarter of last year, and our teams demonstrated their ability to launch an injectable drug in a difficult environment. Our field teams continue to generate awareness amongst physicians of the strong efficacy and safety profile of Monjuvi, and we have maintained a leading share of voice near 50%. We are seeing encouraging growth in the number of purchasing accounts, which has risen by over 25% since Q4 of 2020 to over 500 at the end of March.

Looking ahead, we expect an acceleration in the adoption of Monjuvi in the second half of this year as oncology offices reopen, patients' diagnosis and treatment rates normalize and our field teams are able to fully educate oncologists on the benefits of Monjuvi with in-person meetings.

Our focus now and going forward is on continuing to grow our market share in the second-line setting, so more patients can benefit from Monjuvi earlier in their treatment plan.

Additionally, at ASCO, in June, we'll be presenting important 3-year follow-up data from the L-MIND trial, which will provide additional insights into the use of Monjuvi and LEN in patients with relapsed/refractory diffuse large B-cell lymphoma.

Turning our attention now to ruxolitinib cream in atopic dermatitis. We recently conducted a survey of key external experts and payers assessing their perspective of ruxolitinib cream. Physicians and payers perceive ruxolitinib cream to be differentiated from other topicals and systemic therapies from both a safety and efficacy standpoint and noted improvements in itch as the most impactful for both physicians and patients. In a separate survey of nearly 300 dermatologists, results show that ruxolitinib cream has a significant opportunity to address a large unmet medical need in the treatment of atopic dermatitis and that physicians have a high willingness to prescribe. Our dermatology field force is fully assembled, and we are ready for a rapid launch upon approval.

Turning to Slide 13. Earlier this year, the FDA hosted a vitiligo panel in which patients living with the disease spoke on various subjects, including how vitiligo has impacted their quality of life and the lengths to which they go to seek treatment, again highlighting the need for a novel and effective therapy, such as ruxolitinib cream.

I'll now turn the call over to Steven for a clinical update.

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

Thank you, Barry, and good morning, everyone. Starting with ruxolitinib cream. Over the past year, we have presented data from the TRuE AD program, highlighting the safety and efficacy of ruxolitinib cream in atopic dermatitis. At the American Academy of Dermatology Conference in April, we presented additional pooled analysis from the 2 Phase III studies, demonstrating ruxolitinib cream's impact on efficacy metrics such as itch, sleep and other quality-of-life measures across multiple subgroups.

In patients living with atopic dermatitis, the cycle of itching and scratching can lead to infections or disruptions in sleep, and these results further highlight the potential for ruxolitinib cream to become an important therapeutic option for these patients.

Turning to Slide 16. We previously showed at EADV in 2019, Phase II results for ruxolitinib cream in vitiligo at 52 weeks. At AAD this year, we presented updated 104-week data from the Phase II vitiligo program, showing treatment with ruxolitinib cream produced substantial repigmentation of vitiligo lesions through 104 weeks of treatment. Nearly 3/4 of patients who received ruxolitinib cream 1.5% BID for 104 weeks, achieved a facial VASI75, and nearly 60% achieved 90% clearance of vitiligo lesions on their face by week 104. There were no treatment-related serious adverse events reported, and ruxolitinib cream was well tolerated throughout. We are excited by the potential of ruxolitinib cream in vitiligo and look forward to sharing with you the results of the Phase III TRuE-V program, which should read out in the second quarter.

On Slide 17, a reminder of the broad clinical development program for tafasitamab in combination with other therapies, including our PI3 kinase delta inhibitor, parsaclisib, across several non-Hodgkin's lymphomas in both the first-line and relapsed or refractory settings. inMIND, a pivotal trial evaluating tafasitamab plus R-squared in relapsed follicular lymphoma is ongoing, and we expect to initiate another pivotal trial, frontMIND, in first-line diffuse large B-cell lymphoma in the second quarter. topMIND, our proof-of-concept study of tafasitamab in combination with parsaclisib is expected to initiate in 2021, and our proof-of-concept study in collaboration with Xencor is expected to start later this year.

Turning to the next slide. We continue to progress our LIMBER development program. Once-daily ruxolitinib data is in-house, and we expect data release at an upcoming medical conference, followed by an NDA submission early next year. Our parsaclisib plus ruxolitinib combination trials are progressing, and our BET and ALK2 monotherapy dose escalation trials are ongoing, with planned initiation of combinations in the second half of this year.

On the right side of the slide, our results from a turpentine-induced anemia mouse model. Turpentine was used to elicit an inflammatory response, which acutely increased their levels of hepcidin production and thus anemia. As can be seen in the chart, anemia developed in mice injected with turpentine. And when given in conjunction with ruxolitinib, hemoglobin levels were further reduced. The pink data on the right side show that ALK2 treated mice, when given with ruxolitinib, had less severe anemia as demonstrated by the improved hemoglobin levels.

In closing, we have made significant progress within our key development programs in the past year, and we expect another busy year for Incyte with multiple potential approvals and regulatory submissions throughout the year.

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. Our total product and royalty revenues for the quarter were $605 million, representing a 6% increase over the first quarter of 2020. Total product and royalty revenues for the quarter are comprised of net product revenues of $466 million for Jakafi, $26 million for Iclusig and $30 million for Pemazyre. Royalties from Novartis of $66 million for Jakavi and $2 million for Tabrecta and royalties from Lilly of $32 million for Olumiant.

Jakafi net product revenues in the first quarter of 2021 were impacted by the decline in new patient starts since the beginning of the COVID-19 pandemic, forward purchasing in the first quarter of 2020 in advance of the annual resetting of copay obligations and the typical higher gross to net adjustment in the first quarter, compared to the other quarters during the year due to the impact of the Medicare Part D coverage gap or donut hole. The 1% year-over-year growth in Jakafi net product sales also reflects the higher patient demand and forward purchasing late in the first quarter of 2020, driven by concerns that the COVID-19 pandemic could cause potential supply disruption.

The decrease in Iclusig net sales in the first quarter of 2021 from the prior year quarter also reflects the impact of COVID-related forward purchasing in the prior year, partially offset by positive currency effects. Despite the impact of the COVID-19 pandemic on patient demand, we remain confident in the outlook for the year and our ability to continue to grow revenues through our existing products and new product launches like Pemazyre and Tabrecta.

Moving on to our operating expenses on a GAAP basis. Ongoing R&D expenses of $295 million for the first quarter increased 6% from the prior year period, primarily due to cost to support the continued progression of our pipeline programs. Total R&D expense for the first quarter of $307 million decreased 72% from the prior year quarter, which included the upfront consideration of $805 million for our collaborative agreement with MorphoSys.

Our ongoing SG&A expense for the quarter of $141 million increased 27% from the prior year quarter, primarily due to our investments related to the establishment of the new dermatology commercial organization in the U.S. and the related activities to support the potential launch of ruxolitinib cream for atopic dermatitis as well as the timing of certain expenses.

Total SG&A expense for the first quarter of $154 million includes a $13 million reserve related to a settlement in principle in connection with the December 2018 civil investigative demand from the U.S. Department of Justice.

Our collaboration loss for the quarter was $10 million, which represents our 50% share of the $20 billion U.S. net commercialization loss for Monjuvi. This is comprised of total net product revenues of $15.5 million and total operating expenses, including COGS and SG&A expenses of $35.5 million. Finally, our financial position continues to be strong as we ended the quarter with approximately $2 billion in cash and marketable securities.

Moving on to our guidance for 2021. We are reiterating our revenue, COGS, R&D and SG&A guidance for the year. We remain confident in our full year guidance for Jakafi based on the recent recovery of new patient starts and the potential approval later this year in steroid-refractory chronic GVHD.

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 Marc Frahm from Cowen and Company.

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

Barry, you gave a lot of detail on Jakafi new patient starts and the trends there and kind of why you have confidence that things are going to improve through the rest of the year. Can you give a little bit more color on the Monjuvi side of things and why you're so confident? It would seem that, that DLBCL would be a little less susceptible to kind of pushing off appointments, diagnoses and starting therapy than some of the indications Jakafi has?

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

Thanks for the question, Marc. Yes. So in diffuse- large B-cell lymphoma, obviously, these patients are sick. They need to get therapies. Nevertheless, we know that -- from claims data that patient visits are down by about 10%. Nevertheless, our reason that we're optimistic about Monjuvi is because Monjuvi-LEN combination is a very good combination. Every time we talk to oncologists, hematologists, they're very excited when they see the profile. Our challenge is to continue to educate health care professionals, hematologists, oncologists specifically, about the benefits that Monjuvi-LEN combination gives.

You can see the 2-year update and the duration of response just keeps getting better at 34 months. We'll have an update at ASCO for a 3-year follow-up of the L-MIND data. Again, the safety and efficacy are there. I just don't think because of the pandemic, we hadn't been able to educate to get in front of treaters of diffuse-large B-cell lymphoma as much as we want to. But now we know that the offices are opening up again, not

fully, but they are opening up again, and our field teams will be able to get in front of them and share with them what we think is exciting data for Monjuvi-LEN.

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

And how do you see -- there's a new entrant coming into the market as well. Just how do you see that playing out?

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

Well, it's approved in the third-line setting. We're the only regimen that's approved in the second-line setting. We'll see how Lonca does. We know from feedback from our hematologist/oncologists that the profile that they see from Monjuvi LEN seem superior to other regimens -- possible regimens that they have. We know that other antibody-drug conjugates like Lonca have cumulative toxicities, so that could be a problem. The other entrants that are potentially coming, all have their own toxicity problems, whether it's fusions or cytokine-release syndrome. So we think really the safety and efficacy of Monjuvi LEN will stand up and will be the first choice in the second-line setting.

Operator

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

Tazeen Ahmad - *BofA Securities, Research Division - VP*

I wanted to focus mine on rux cream. You guys will have data coming up soon for vitiligo. And I wanted to get a sense of what data we should expect at the top line press release. And what is the expectation for what should be considered clinically meaningful data? And then for the atopic dermatitis indication, I just wanted to get a sense of whether you have started any kind of label discussions with the agency?

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

Tazeen, it's Steven. Thank you for your question. So on rux cream, as you alluded to, we expect both Phase III's to get the readout during this quarter, this half of the year. We expect it to replicate the Phase II data we've seen. You just saw the 104-week update, including the continued repigmentation that's seen over time, especially you saw that facial data -- even the 90% rate now getting, greater than 60% of patients achieving that.

And there's very little spontaneous remissions of vitiligo, as you saw in our data we presented to date. Placebo rates are negligible. The studies are large because of -- to require a safety database, not to hit the efficacy numbers. So we have a profile that we've already seen now in Phase II with 2-year update that is of enormous benefit to patients should they elect to be treated for it. And then you couple that with an extremely tolerable safety profile.

From an atopic dermatitis point of view, we don't discuss regulatory interactions. It's gone as expected, and we're very comfortable where we sit. And we remain on track for achieving everything we need, hopefully, by the PDUFA date. So that's how we're comfortable in that regard. Thank you.

Operator

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

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

So another question on topical rux. The feedback from KOLs had some -- I guess, some questions around -- or unknowns around the durability of effect of typical topical AD drugs. And I'm sort of wondering if you could remind us what data you guys have produced or plan to produce that might help improve perceptions around this durability question? And what kind of education is going to be important to ensure that topical rux is utilized as a chronic rather than a bridge to biologics?

And then just maybe as a corollary to that. I know you don't give sort of a blow-by-blow of what the ongoing regulatory discussions are, but just bigger picture, just curious the degree to which the FDA is ongoing safety review of the JAK class, the oral JAKs and atopic derm ties into the regulatory discussions there, generally speaking?

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

Brian, it's Steven. Thank you. In terms of atopic dermatitis, again, from the data we've already shown publicly on a few occasions, you see, obviously, the effect in terms of Investigator Global Assessment, Eczema Area Severity Index, being about the best presented to date in mild-to-moderate atopic dermatitis. But you couple that with the itch response, which is, in our view and our opinion leaders' view, outstanding and also occurs rapidly. So you get patients having -- the dominant symptom resolve pretty quickly and then the resolution of the skin effect.

In terms of the durability of effect, we expect and what we've seen is patients treat to remission and then sort of go off the drug and then restart it again in terms of when they get recurrence because it's a chronic condition of the symptoms, including itch or the skin effect. We estimate from the clinical data that we've seen on the study that somewhere around 3 to 4 60-gram tubes a year would be used. But it's hard to see what will happen in the real setting because then patients won't be in the clinical trial and, obviously, will be managed by physicians in their own effect. But the -- that would give you a sense of the durability of response, and that's from the clinical trial setting.

In terms of -- to be repetitive -- on the labeling and discussions and the FDA review, we just, as a rule, don't speak about them and refer to the FDA in that regard. But to be repetitive, we're very comfortable where we are with the review. It's progressing well. And again, our goal is to finish this by the PDUFA date.

Operator

Next question is coming from Vikram Purohit from Morgan Stanley.

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

So I had 2 on the LIMBER program. First, for once-a-day rux, you previously mentioned that you expect BA/BE data in the first half of this year. So I wanted to see if that data set is going to be presented publicly? And regardless of whether it's public or an internal readout, what constitutes success for this data set? And then secondly, on LIMBER, it looks like there's a Phase II study expected to start soon evaluating itacitinib as part of the LIMBER program. So I was just wondering if you could speak a bit about the rationale for studying this drug in this setting.

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

Vikram, it's Steven again. You are correct. So the rux XR once-daily program has progressed well. It's a relatively preset route in terms of bioequivalence and bioavailability testing of the different tablet strengths. We've completed that. We have it in-house. And we follow the FDA guidance on what needs to be achieved comparable to the rux that's used in the clinic in terms of area under the curve. It's a very strict guidance on what you have to come within to meet that, and we -- then we have that data in house. Yes, we do expect to have a public presentation of the data this calendar year at an appropriate median and forum, and we'll give that to you.

The other rate-limiting step there is just stability. So once we completed the BA and BE, all the strengths are laid down for 12-month stability. As soon as that completes, then we expect to proceed with filing very early next year. And what should be about a 10-month review period, we should have an approval, if everything goes well, right before the end of '22, early '23 sort of time period, if you work that out. But again, to be repetitive, we will present the data publicly to you this year.

Itacitinib, It's interesting. So it's a relative JAK1 agent compared to ruxolitinib, which is more JAK1, JAK2. And we're trying to leverage that effect in terms of its cytopenias to see if we can have some benefit in myelofibrosis patients who require a modulation of the effect in terms of less JAK2 and less cytopenias. So it will be tested in a Phase II setting there for the appropriate patients to see if we achieve proof-of-concept with this drug.

Just let me remind you, it has ongoing work in multiple other settings including cytokine release syndrome, including bronchiolitis obliterans and including some other work as well in inflammation and autoimmunity. So that's not the only program it's being used for. Thanks. And sorry, also, I should mention ongoing chronic GVHD work, where we're doing some dose-ranging work, which we'll get data in towards the end of this calendar year. Thanks.

Operator

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

Andrew Scott Berens - *SVB Leerink LLC, Research Division - MD of Targeted Oncology & Senior Research Analyst*

I also have a question about the LIMBER program. As some of them start to advance, I was wondering if you could give us any qualitative comments about which you're most excited about. And then if I could sneak another one in on Jakafi. Are you seeing any commercial competitive impact in MF?

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

So I'll start on the LIMBER program, Andy, and then hand it to Barry for your second question. So remember, firstly, it's important to us, LIMBER. I mean, Barry has spoken about rux, its enormous benefit to patients, the value it brings to patients and then to the company and shareholders as well. So this is an internal effort that's cross-functional and appropriately large, directed at many different areas. So you have the once-daily program, we just spoke about, and its importance there for once-daily alone, plus optionality potentially on fixed-dose combinations with other once dailies down the line, should we decide to do that.

Then the second pillar, it's all the combination work. And you're asking more specifically what we may be more excited about versus others, and I'll come back to that in a second. But just to mention, the third pillar of the program, which we're more quiet about because it's preclinical in terms of discovery research work in both MF and PV where there are other potential targets which we may end up pursuing and Dash and his research endeavors are looking at those, plus with various collaborators.

Just to come back to that middle tier and the combos. So the rux parsa program, both registration-directed Phase III's are open. Sites are already being initiated and are screening patients. Just to remind you, there's a suboptimal setting where patients have had at least 3 months of ruxolitinib, 8 weeks of stable dose but are not having sufficient benefit in terms of spleen reduction of symptoms and are then randomized to continue rux with rux plus parsaclisib in that setting, and that study is open. And then the first-line study of rux plus parsaclisib rux alone in first line, looking typically at a 24-week spleen volume response of 35% or greater.

We also then internally have our BET program, which this half of the year is looking at monotherapy safety, and then we want to initiate combinations with rux in the second half of this year. Just also to remind you, this is not a new drug to us. We had it in the clinic a few years ago where we were dosing at multiples of where we were now, looking largely at solid tumors and MYC inhibition. So we already have experience with this compound of 100-plus patients or more in that setting, and we want to keep accelerating that.

And then as I had in my prepared remarks, the third program is the ALK2 program. Very little bit of a different mindset, probably works as we illustrated through hepcidin inhibition and ameliorating the anemia, which has a twofold effect. It will ameliorate potentially the anemia of myelofibrosis itself, plus the ruxolitinib-induced anemia. And then not only that, should that be successful, that's one of the principal reasons patients discontinue ruxolitinib. So we can ameliorate that. You'll get the added benefit of continued rux use and the efficacy thereof. So that's also an exciting program.

So I'm not giving you a priority list because they all have slightly different nuances. The one most ahead is obviously parsaclisib in terms of registration studies underway. The other two, we want to complete the monotherapy and combination safety this year and present data to you next year. I'll hand it to Barry for your second question.

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

Yes. So Andrew, so for competition in MF, the only drug that's approved besides Jakafi is fedratinib from BMS, and it's only being used second line, if at all. And BMS just reported their earnings, and really, the drug has been flat since launch. So no. And in fact, we're -- one of the reasons we're encouraged, as we continue through 2021, is MF patients grew very nicely from Q1 compared to Q4. So patients are coming back to the office. Patients are getting treated. New patients are getting started on Jakafi for MF.

Operator

Next question today is coming from Cory Kasimov from JPMorgan.

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

Your press release mentions you're advancing or you advanced the 707 JAK1 candidate into a Phase II in vitiligo. Can you just talk about the motivation here? What you see as the potential benefit of having this if rux cream works in this indication? And how you might be able to improve upon it? Or are there commercial considerations to think about to have a different compound?

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

Cory, thanks for the question. It's Steven. And thanks for bringing that up. So 707 is another in-house JAK inhibitor currently being used in hidradenitis suppurativa, also a different profile to rux, maybe in terms of more relative JAK1 effect versus JAK2. And it's good you bring this up because there's a spectrum of disease, if you will, in vitiligo that goes from mild to moderate to much more severe patients, where in the latter setting and the more severe, there may be more of a tolerance both from a patient point of view and regulator point of view for a different risk-benefit profile and need for a "more potent" effect should this work.

So the idea here would be to get, we think, JAK inhibition. We know from the cream, is really effective therapy, and I just showed you in my prepared remarks, 104-week data. But perhaps with an oral having a different profile and potentially a more potent effect with albeit a different risk-benefit profile is worth testing. And in that way, we would look after vitiligo as an entity in completeness, in a more holistic manner and be able to offer patients both a topical treatment for their illness and then also potentially an oral treatment for more severe settings, and that's the idea behind that.

Operator

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

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

On the rux cream, could you just talk about the progress on the sales force build out here and potential pricing strategies and updates on payer discussions? And then separately, just thoughts on -- given what we're seeing here with competitor JAKs on the regulatory front and read-through for your class.

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

Thanks, Salveen. So on the sales force, so I think what we said upfront was that the derm team, whether it's medical affairs, sales, market access, is complete. So they're all on board. They're being trained. Some have already been trained already. The medical affairs team has been working for a long time now on having their discussions with external experts, learning more about their preferences.

As far as the price goes, we don't talk about price at this point. But we have had ongoing meaningful discussions with payers, including the top 3 PBMs that cover 80% of the lives in the United States. They've been very productive. They've been very interested and impressed by the clinical data that's been presented to them from the TRuE AD1 and 2 studies. So we're very encouraged about that. The oral JAK inhibitors, obviously, they've been delayed, but we think the advantage of a topical JAK inhibitor like ruxolitinib cream with the profile that it has in all atopic dermatitis patients is really an advantage for us because of the safety and, of course, the excellent efficacy.

Operator

Our next question is coming from Michael Schmidt from Guggenheim.

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

Perhaps one on parsaclisib, where you're potentially filing for approval later this year as well. I guess my question is, are you planning to file in all 3 indications simultaneously? What are potential gating factors to filing? And lastly, I guess how do you think the drug will be positioned in these lymphomas, perhaps relative to other treatment options? What has the feedback perhaps been from physicians? How they might incorporate the drug in that treatment paradigm?

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

Michael, it's Steven. Thanks for the question. So again, the data sets with parsaclisib in non-Hodgkin's lymphomas are in 3 different entities: follicular lymphoma, relapsed/refractory; marginal zone lymphoma, relapsed/refractory; and mantle cell lymphoma, relapsed/refractory.

We've updated at a few meetings now, the independently reviewed response rates, which are extremely robust and durable and albeit in single-arm studies with long progression-free survivals. So we really like the efficacy profile of the compound and then the tolerability with the second-generation delta inhibitors now largely dialing out the liver effect and then acceptable profile in terms of the other effects you see with delta inhibitors.

So the intent in the U.S. is to file in all 3 indications, in follicular, marginal zone and mantle cell lymphoma together. We still are working out the filing approaches in the other regions we operate in, in Europe and Japan. But we feel that it has a competitive profile there as well. There's no other gating effect. It was merely the requirement to have a year's follow-up on the last responders, which is typical in these settings. And everything is progressing well on getting that file in, in the second half of 2021.

In terms of how we'll be positioned in lymphomas versus other options, as you indirectly alluded to, it's an area where there's chemotherapy, there's other targeted therapy with BTK inhibitors, BCL-2 inhibitors, the CAR-T therapies, as we early in the call said, antibody drug conjugates as well. And again, these are not -- these data sets are not first-line settings, they're relapsed/refractory settings. I think physicians will look at the efficacy and tolerability data on its face and use it appropriately there.

There's a little bit of a cloud over the area now early on in terms of idealisib data and some of the toxicity seen in combination that needs to be overcome. But now with a few delta inhibitors out there showing really robust data in B-cell lymphomas, different tolerability profiles, physicians getting used to it again, we feel and we're hearing that people will use it appropriate to the data sets.

Operator

Next question is coming from Alethia Young from Cantor Fitzgerald.

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

I just wanted to talk a little bit about how like some of the initial payer work you've done, kind of, how they think about kind of realizing value between vitiligo and topical -- sorry, atopic dermatitis? I just wonder if there's kind of a greater value proposition put on kind of the efficacy that has been seen so far in vitiligo versus AD? Any thoughts you have there would be appreciated.

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

So for atopic dermatitis, the payers, the discussions we've had so far, I think it's -- the efficacy and safety is compelling. They really think of it as a possibility of using a drug from newly diagnosed patients all the way up to biologics. They're always asking about can they delay the use of biologics or systemic therapies. So we're very encouraged by that.

In vitiligo, I think that it's an -- they're beginning to understand that it's an autoimmune disease, vitiligo is, that needs to be treated. And treating with a topical therapy like ruxolitinib cream that will be safe and effective is the best way to go. Whether one is better than the other in terms of value, it's very difficult to say. I think that ruxolitinib cream is going to be an excellent drug for atopic dermatitis, and it could be life-changing for vitiligo.

Operator

Our next question today is coming from Srikripa Devarakonda from Truist Securities.

Srikripa Devarakonda - *Truist Securities, Inc., Research Division - Associate*

Staying on dermatology, given that we are so close to the PDUFA date and you have talked a little bit about your launch preparedness, but I was wondering how soon after a potential approval can patients expect to have access to the drug? What steps does that entail? Finally, once the drug launches, what sort of metrics can we expect you to provide to us so we can understand and model the launch curve appropriately?

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

Thanks, Kripa. So how soon will they have access to the drug? Right away, as soon as we possibly can get it out. It should be just a matter of a few days before it's -- we're able to ship it out to the wholesalers, and wholesalers can ship it out to the pharmacies. So it will be as rapidly as we possibly can, just a matter of days, if not a week.

So what metrics can we provide for the curve? So you'll be able to follow the new Rx data and the TRx data on a weekly basis, just like many people do for every prescription drug out there. So you'll see that. We think there'll be a rapid uptake for the drug. Our gross to net may be impacted at the beginning, and it will continue to improve over time, but we think that the total Rxs and new Rxs will grow week after week, and you'll be able to follow that just like we will.

Srikripa Devarakonda - *Truist Securities, Inc., Research Division - Associate*

Great. That was helpful. And then if I can sneak in one more question. Following up on the LIMBER program, you're doing a Phase I trial with your BET inhibitor. What is the bar you have internally for you to take it forward into Phase II with the combo? Or are you comfortable enough that you do plan to initiate the Phase II combo in second half?

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

Kripa, it's Steven. So the real bar is purely safety in the beginning. And again, just to be repetitive, we mentioned we had this drug in the clinic a few years ago for quite a bit at multiples of the 4-milligram dose we're now at. We were treating above 10 milligrams and we withdrew it because of a lack of efficacy in solid tumors, plus a safety profile around thrombocytopenia.

We then watched this field evolve, modeled -- did some modeling on the Constellation 610 compound and worked out that a much lower dose may be effective in myelofibrosis. So, we're now using the 4-milligram dose in a Phase I just to document that safety, principally an acceptable profile in terms of thrombocytopenia, then quickly do a smaller number of patients with ruxolitinib again to document the safety aspect.

At that juncture, round around the end of this year, early next year, we will have choices to make which we're not there yet, which is what you alluded to, how aggressive to be. Do we then have to repeat or want to repeat in Phase II proof-of-concept work or will we be comfortable enough given the arena to be more aggressive and go straight to Phase III or registration-directed studies. And we will make that decision once we see the safety profile of the combination.

Operator

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

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

Impressive 104-week vitiligo data shown at the recent AAD meeting. But there was a notable decrease in the volume of patients there, some patients withdrawing from the study, I guess, reasonable given it's a long follow-up. But if you just look at the patients that completed 104, what percentage of those were responders at week 52? Just wondering if there's a bias in these response rates at week 104 by patients not responding, being the ones that chose to withdraw from study.

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

Matt, it's Steven. I'll have to get back to you on the second part of your question. I don't have in front of me a match on the 52-week versus 104-week data. But I do want to make some points. So whenever you have a study and you decide to lock a database, you'll just -- you'll have what's in that database at that time. And there will be, by its nature, potentially missing data or missing visits, and that's partly what you're seeing.

In addition, and I think you're indirectly alluding to this, when people have that degree of improvement, they may elect for various reasons in the extension phase not to go on to the extension because they're satisfied where they are at, at the time. These are things we have to work out, given the impressive efficacy we see with the drug over time.

For me, the major message though is -- and there's also, sorry, one more thing I want to say. There is a little bit of a COVID impact on the longer-term study, and people, for example, wanting to come back to a clinic for a formal visit when it's not really needed for the primary endpoint. But what -- for me, the major message of the study, which is really interesting in terms of the biology is you get continued improvement over time. And we think there's a twofold effect happening there. Melanocytes are repopulating the area. They're present there. Plus the T cell suppression is probably largely gone and could be long lived.

And you've seen this continued improvement over time, which is just fascinating. It leaves the remaining questions to ask is when you withdraw therapy, how long -- how durable that is, will treatment be re-needed, et cetera. And all those experience will conduct and will be ongoing here at Incyte as we understand this further. But it really somewhat surprised us in a good way to see that even at 2 years later, you're still getting an increase in the rates. But your comment's noted on smaller patient numbers down the pike.

Operator

Next question is coming from Ren Benjamin from JMP Securities.

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

I'd love to focus on pemigatinib for a quick second. Can you just talk us through maybe the longer-term strategy and the other indications that you're moving forward with? And any feedback that you might have from sales on how this continued growth, especially given the competitive environment, is going to continue? And maybe just for Steven as a follow-up, the 2 big data points, I guess, I have written down are L-MIND data at ASCO and the BA/BE data for once-daily RUX, sometime later this year, is that primarily the main ones? Or are there other key updates that we should keep in mind?

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

So I'll answer the clinical development part of your questions. Barry will talk about the sales performance question embedded there. So just to talk about our first indication in second-line cholangiocarcinoma, which, as Hervé said, is now globally approved in Europe and Japan as well and our first internally discovered global product, and then Barry showed you the excellent uptake on the launch so far in a rare entity.

However, again, in a good way, given now there's other targets beyond FGFR2, like IDH, more and more of these patients are getting molecularly profiled, more and more are discovering that they are FGFR2 driven and additionally, there's an awareness now beyond cholangio that one of the most common entities in carcinoma of unknown origin is potentially cholangiocarcinoma. So that -- when that entity gets molecularly profiled and is FGFR2 driven, there's a feeling that may be cholangiocarcinoma and lend itself to treatment with pemigatinib.

Remember, as part of our accelerated approval, we have an ongoing first-line study. So that's critical in terms of life cycle management. It's against first-line chemotherapy in terms of gemcitabine and cisplatinum. And if you look in other entities where you have a molecular profile that ends up being an oncogenic driver that drives a particular tumor. So look at melanoma with BRAF/MEK, et cetera, you see this -- or even lung cancer with EGFR, you see this migration to earlier line settings in terms of a targeted therapy. And that's the idea behind first-line cholangio, plus, obviously, a very different tolerability profile versus chemotherapy.

We have an ongoing large tumor-agnostic study that has enrolled well that looks at -- not to belabor the molecular side of this, but fusions, rearrangements, amplifications and then any other potential driver. And there are 3 different buckets there. And there's optionality around that as we gather the data now to either pursue potentially a tumor-agnostic setting if there's a strong enough signal or to look at a particular histology or 2 where there may be a driver there and then to do stand-alone work in that setting. So those are very important endeavors to us that we'll be focusing on this year from a clinical development point of view with pemigatinib.

We don't think bladder cancer is the way to go, as we've said on prior calls, largely because of how the environment has changed there in terms of treatment paradigms and the use of EV earlier and earlier plus checkpoint inhibitors. So that's the pemigatinib life cycle side, and Barry will speak about the performance side.

Just on the data releases, that we spoke about, so as Barry said, we'll have the very important 3-year follow-up on the L-MIND study with continued results, particularly on duration of response at ASCO. The -- I should have said the bioavailable and bioequivalent data with ruxolitinib XR -- the intent is actually to present it in an appropriate forum -- or publish at an appropriate forum this half of the year. And then obviously, the idea is

also to -- as soon as we have it to also present the vitiligo Phase III data, incredibly important for topical rux. Barry will speak about the performance side of pemi.

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

Sure. So Ren -- yes. So we're very happy with Pemazyre's performance so far. I think when you launch into a tumor type of disease area where there is no other therapies, sometimes you actually don't really know how many patients are out there. Steven alluded to carcinoma of unknown primary. Some of those patients may in fact be cholangiocarcinoma patients. Some of them might have the FGFR2 rearrangement or fusion. So that's what I think we're experiencing is that there might have been more patients than our initial assumption around 800 to 1,000 patients in the United States.

And then the duration of therapy, it turns out to be longer than perhaps we anticipated, both from the study and from our just estimates in the regular patient population. So that's very encouraging. The patients are getting therapy. They're getting tested, getting therapy, staying on therapy. And I think that helps us if in fact we do have competitors in this space in cholangiocarcinoma with FGFR2 alterations because, one, it's nice to launch first, and then it's nice to launch with an excellent drug like Pemazyre. So we're all prepared for any competition, but we still think that patients will ultimately benefit from starting a drug like Pemazyre with its efficacy, safety and duration of therapy that we can offer.

Operator

Our final question today is coming from Jay Olson from Oppenheimer.

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

I'm curious about your priorities for business development this year. And specifically, could you comment on any plans to seek a commercialization partner for topical rux in Europe?

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

So in terms of the BD priorities, first of all, for us, the objectives have not changed from what we have discussed in the past. So we continue to look for assets that would contribute to growth and diversification in the mid-20s-plus time frame, and where we could leverage our expertise, our existing infrastructure to develop and commercialize them. So these have remained the same. In terms of rux cream in Europe, as we have indicated in the past, we have -- we are in the process of determining what is the best way forward there.

Also, from a timing point of view, we are going to be -- to wait for vitiligo data before we file for regulatory approval. And therefore, we have a little bit more time before we finalize our decision. So we should be finalizing it in the next few months, and we can follow up on that at that point.

Operator

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

Christine Chiou - *Incyte Corporation - Head of IR*

Thank you, operator, and thank you, everyone, for joining us on the call today. We'll be available for questions following this call. Have a great day.

Operator

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