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EDITED TRANSCRIPT

INCY.OQ - Q3 2021 Incyte Corp Earnings Call

EVENT DATE/TIME: NOVEMBER 02, 2021 / 12:00PM GMT

OVERVIEW:

Co. reported 3Q21 total product and royalty revenues of $778m.

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PRESENTATION

Operator

Hello, and welcome to the Incyte Third Quarter 2021 Earnings Call and Webcast. (Operator Instructions) As a reminder, this conference is being recorded. It's now my pleasure to turn the call over to Christine Chiou, Head of Investor Relations. Please go ahead.

Christine Chiou - *Incyte Corporation - Head of IR*

Thank you, Kevin. Good morning, and welcome to Incyte's Third Quarter 2021 Earnings Conference Call and Webcast. The slides presented today are available for download on the Investors section of our website. Joining me on the call today are Herve, Barry, Steven and Christiana, who will deliver our prepared remarks; and Dash, who will join us for the Q&A.

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-Q for the period ended June 30, 2021, and from time to time in our other SEC documents.

We will now begin the call with Herve.

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

Thank you, Christine, and good morning, everyone. I'm happy to report today an important quarter for Incyte. But before we do that, I would like to take a moment to speak about the significant transformation our company has undergone over the past 2 years.

From the third quarter of 2019 to today, Incyte has more than doubled its number of approved products from 3 to 7 and has increased the number of approved indications from 5 to 12, a significant achievement for patients around the world. Within the same time period, quarterly product and royalty revenues have grown nearly 50% from $534 million to $778 million in the most recent quarter. This $778 million in product and royalty revenue for Q3 2021 does not yet reflect revenue contribution from our 2 most recent U.S. approval. Opzelura in atopic dermatitis and Jakafi in steroid-refractory chronic GVHD. In addition, we expect further growth from the recent approvals of Pemazyre in Europe and Japan and Minjuvi in Europe, where the launch is ongoing in Germany and will expand to other countries as reimbursement is secured.

As you see on Slide 5, we have provided long-term guidance for some of these products and there is significant upside to the current sales number. Within hematology/oncology, our MPN/GVHD franchise, which includes Jakafi and other innovation is expected to surpass $3 billion in peak sales. Additionally, Monjuvi approved for the treatment of relapsed or refractory DLBCL has the potential to reach $500 million in this indication in the U.S.

While we have not provided guidance in Minjuvi, Pemazyre and Iclusig, this product represents additional growth potential and generate further value to our business.

Turning to dermatology. Over the past year, we have successfully established our dermatology commercial franchise in the U.S. Given the product profile of Opzelura and the transit commercial team we have in place, we are confident in the potential for Opzelura and we expect peak sales to reach at least $1.5 billion in the United States in atopic dermatitis.

While still very early in the launch of Opzelura, the initial uptake has been strong, and Barry will be providing details in his prepared remarks. Looking ahead in 2 other areas of our portfolio, we are anticipating multiple regulatory decision in 2022, including ruxolitinib cream in vitiligo in both the U.S. and Europe, parsaclisib in 3 non-Hodgkin lymphoma indication in the U.S. as well as once-daily ruxolitinib late in 2022 or early 2023.

This 2022 regulatory decision which closely follow multiple product approval in 2021, position us well for further growth and diversification of our product revenues in the coming year. Our partners are also making headway with Novartis, ruxolitinib is currently under review in Europe and Japan for acute and chronic GVHD. And capmatinib is under review in Europe for non-small cell lung cancer.

In addition, Lilly is planning to submit an sNDA to the FDA for baricitinib in alopecia areata by the end of this year. If approved, these opportunities will provide valuable growth to our royalty revenues, which have already surpassed $400 million during the first 9 months of this year.

We have seen 2021 has been an important year of commercial, clinical and regulatory success for Incyte. With that, I will hand 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 sales grew 12% year-over-year to reach $547 million for the quarter. And we are reiterating our full year guidance range of $2.125 billion to $2.17 billion. Jakafi was first approved -- was the first approved treatment in myofibrosis polycythemia vera and steroid-refractory acute GVHD. And years later, remains the standard of care in each of these indications.

Growth across MF, PV and GVHD continues to be strong. And as you can see on the left, new patient starts have returned to pre-pandemic levels. With patients staying on therapy longer and new patients coming in, the total number of patients on Jakafi continues to increase year-over-year.

Myelofibrosis patients, the largest proportion of patients on Jakafi comprised 45% of total patients, while polycythemia vera and GVHD patients accounts for 34% and 14% of total patients, respectively. At the end of September, Jakafi was approved for its fourth indication for the treatment of steroid-refractory chronic GVHD.

To put this in this recent approval into perspective, approximately 2,000 patients with graft-versus-host disease are currently using Jakafi. The majority of whom have acute form of the disease. There are over 14,000 patients in the U.S. living with chronic GVHD, of which have required therapy beyond systemic corticosteroids. We expect the recent approval to accelerate new patient starts with Jakafi.

Turning to Slide 8. Monjuvi sales grew 22% sequentially to $22 million in the third quarter, with growth driven primarily by demand. We are seeing an increase in the number of total accounts across both academic and community settings, and there has been a swift shift towards adoption of Monjuvi earlier in the treatment paradigm.

We now have a greater proportion of Monjuvi patients initiating therapy in the second line, which should result in patients experience in longer and more durable responses, leading to a longer duration of therapy. Feedback from health care professionals continues to be positive with efficacy, duration of response and safety being the key drivers of adoption. HCP awareness of Monjuvi's differentiated profile continues to increase and the L-MIND 3-year results have been well received by the physician community.

As patients continue to return to the office and as our reps continue to educate health care professionals, on the clinical profile of Monjuvi, we are confident in our ability to build on this improving momentum.

Turning to Slide 9. We are very excited to receive the approval of Opzelura, the first FDA-approved topical JAK inhibitor for the treatment of mild-to-moderate atopic dermatitis. Prior to launch, we had identified 11,000 dermatologists and high priority allergists. The top 20% of which are responsible for nearly 80% of atopic dermatitis prescriptions.

Our patient assistance programs are in place to help reduce the barriers to access for Opzelura and our negotiations with payers are advancing well. To date, we have made significant progress with our stakeholders in the launch of Opzelura. Since our launch on October 11, our field-based representatives have actively engaged with 76% of our target prescribers and have conducted 8,500 HCP calls in the first 3 weeks of launch, of which 95% are being conducted in person.

We're also receiving a significant amount of interest in Opzelura from patients. And in the first 2 weeks of launch, we have approximately 61,000 unique website users, and this number continues to climb. Further highlighting, the level of engagement from patients, there were over 1,500 patient registrations for our co-pay card program.

And lastly, on the payer front, our discussions with PBMs, which include the top 3, who account for nearly 80% of commercially insured patients in the U.S. have been very positive, as they realize the value proposition of Opzelura. As a result, we expect to secure a broad coverage in Q1 of next year.

In the meantime, during this contracting period, we have multiple efforts underway to ensure patients are able to access their medication. Although it is still early in launch, our efforts are translating into the first signs of a very successful launch. As you know, there are limitations to the accuracy of script data, it's important to note that IQVIA's capture rate of prescriptions are under representative of actual demand, especially in the initial weeks of launch.

Over time, the capture rate is expected to continue to improve. There are 2 different metrics that we are using to track performance consisting of new brand -- new-to-brand Rxs and 867 data. New Rx data shown on the left captures the patients who are either new to the market or have switched to Opzelura.

In the first 2 weeks of launch, there have been close to 1,000 new-to-brand prescriptions with nearly 2/3 of scripts coming from patients who were previously on topical corticosteroid therapy. On the right-hand side, we are showing 867 data, which is the number of units of Opzelura 60-gram tubes that our wholesalers are shipping to pharmacies. While 867 data doesn't translate directly into scripts, we believe it captures demand appropriately given the low level of inventory retail pharmacies typically hold for specialty dermatology products.

Pharmacies order Opzelura when a prescription is received and approved by the patient's insurance or processed through our patient access programs. In its third week of launch, 1,115 tubes of Opzelura was shipped by wholesalers, bringing the total shift since launch to over 2,200. Based on early data, we are now tracking towards 300-plus units shipped in the first 4 weeks of launch. Now I'll 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. The third quarter brought numerous achievements on both the clinical and regulatory fronts. Starting with the 3 recent regulatory approvals, Minjuvi was approved in Europe for second-line diffuse large B-cell lymphoma in August. In September, Opzelura was approved in the United States for mild-to-moderate atopic dermatitis, and Jakafi was approved in the United States for second-line chronic graft-versus-host disease. In addition to these regulatory milestones and successes, we presented pivotal data from our Phase III TRuE-V studies of ruxolitinib in Vitiligo at the European Academy of Dermatology and Venereology.

The full data set highlighted the significant improvements in facial and total body repigmentation seen in vitiligo patients after treatment with ruxolitinib cream. Also presented at EADV was positive pivotal data for baricitinib, our partnered product with Eli Lilly in alopecia areata. These data showed that treatment with once-daily baricitinib 4 milligrams was superior to placebo in achieving significant scalp hair regrowth at 24 weeks in adults with severe alopecia areata.

We also announced the global collaboration with Syndax Pharmaceuticals, which is pending regulatory clearance to develop and commercialize axatilimab, an anti-CSF1 receptor monoclonal antibody for chronic graft-versus-host disease and other fibrotic diseases.

Lastly, we recently announced the acceptance of the marketing authorization application by the European Medicines Agency for ruxolitinib cream in vitiligo and yesterday, we announced that the FDA accepted the NDA for parsaclisib in 3 types of non-Hodgkin's lymphomas.

We received priority review for parsaclisib in 2 of the indications, including for relapsed or refractory marginal zone lymphoma in adult patients who have received at least 1 prior anti-CD20-based regimen and for mantle cell lymphoma in adult patients who have received at least 1 prior therapy.

The PDUFA date for these 2 indications is April 30, 2022. There will be a standard review for parsaclisib in relapsed or refractory follicular lymphoma in adult patients who have received at least 2 prior systemic therapies with a PDUFA target action date of August 30, 2022.

Let me remind you of the efficacy across non-Hodgkin's lymphoma. In relapsed or refractory marginal zone lymphoma, response rate seen and independently reviewed were 57% with the duration of response in PFS not yet reached. In mantle cell lymphoma, this was a 71% response rate with the duration of response of 9 months and a PFS of 11.1 months.

And in relapsed or refractory follicular lymphoma, there was a 75% overall response rate with a duration of response of 14.7 months and a PFS of 15.8 months. All this data is with a once-daily regimen of 2.5 milligrams.

Remember, this drug was designed to avoid hepatotoxicity associated with first-generation PI3 kinase delta inhibitors. And thus, we have seen low rates of liver toxicity with less than a 5% rate of grade 3 ALT and AST elevations. In addition, cases of serious diarrhea and colitis were manageable and reversible.

Turning to the next slide. The clinical development of parsaclisib in hemolytic anemia continues to progress with the Phase III study expected to start by the end of this year. The study will evaluate the efficacy and safety of parsaclisib versus placebo with the primary endpoint of durable hemoglobin response at week 24. Patients must have a diagnosis of primary warm antibody autoimmune hemolytic anemia. Hemoglobin levels of 7 to 10 grams per deciliter and FACIT-F score of less than or equal to 43.

This program represents another significant opportunity to address an unmet medical need where there are currently no approved therapies for patients. Moving to our LIMBER development program. We have multiple studies ongoing looking to improve upon the standard of care in myelofibrosis, polycythemia vera and graft-versus-host disease. We expect data and/or regulatory action for a few of these programs by the end of 2022, including the NDA submission for the once-daily formulation of ruxolitinib. We also recently entered into a collaboration with Syndax for axatilimab, an anti-CSF1 receptor monoclonal antibody, which is currently being evaluated as a monotherapy in third-line chronic graft-versus-host disease.

In addition, we will have the opportunity to evaluate axatilimab as a combination therapy with our JAK inhibitors, where the ultimate goal would be to arrive at a safe and effective combination that could lead to a steroid-free regimen for chronic graft-versus-host disease. Turning to dermatology and ruxolitinib cream in vitiligo. The Phase III TRuE-V data presented at EADV showed meaningful superiority to vehicle with 30% of patients achieving a facial VASI75 at week 24, which is in line with our Phase II results.

As a reminder, facial VASI75 response in the Phase II trial, continued to improve with ruxolitinib cream treatment with an over 51% response rate at week 52. We expect the 52-week data from the TRuE-V pivotal studies to be available in 2022.

We are extremely encouraged by these positive results and the impact ruxolitinib cream may have for patients living with vitiligo in the United States and Europe. The MAA was recently validated by the European Medicines Agency and the U.S. sNDA is in progress.

Turning to Slide 18 and an update on our dermatology programs. We continue to focus on developing our dermatology pipeline with ruxolitinib cream and INCB54707, an oral selective Janus Kinase 1 inhibitor. Multiple studies are ongoing with ruxolitinib cream in atopic dermatitis, including TRuE-AD3, a pivotal trial in atopic dermatitis in pediatric patients.

In addition to our TRuE-V program in vitiligo, we are also looking at 707 in a Phase II study in patients with nonsegmental vitiligo with a body surface area of greater than or equal to 8%. Additional studies for 707 are currently underway in other indications, including 2 Phase II trials in hidradenitis suppurativa and prurigo nodularis. We look forward to updating you on these programs next year.

In closing, we had a very successful quarter with a number of clinical and regulatory accomplishments, including 3 approvals. The FDA acceptance of an NDA for parsaclisib as a treatment for 3 types of non-Hodgkin's lymphomas and the EMA acceptance of the MAA for ruxolitinib cream as a treatment for vitiligo.

Later this week, we invite you to join an analyst and investor call to discuss our oral PD-L1 program, including data for 86550, which was accepted for presentation at the SITC Annual Congress on November 13.

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. Our total product and royalty revenues for the third quarter were $778 million, representing a 25% increase over the third quarter of 2020. Total product and royalty revenues for the quarter are comprised of net product revenues of $547 million for Jakafi and $48 million for other hematology oncology products.

Royalties from Novartis of $95 million for Jakavi and $3 million for Tabrecta and royalties from Lilly of $87 million from Olumiant. The 12% year-over-year growth in Jakafi net product sales reflects higher patient demand across all indications and a continued recovery of new patient starts as we continue to emerge from the COVID-19 pandemic.

The tripling of the Olumiant royalties is due primarily to the use of Olumiant for the treatment of COVID-19. Per our agreement with Lilly for global [net] (corrected by the company after the call) sales of Olumiant for the treatment of COVID-19, we are entitled to receive royalties equal to the base double-digit rate applicable to all global net product sales, plus an additional 13% royalty.

Moving on to our operating expenses on a GAAP basis. Ongoing R&D expenses of $331 million for the third quarter increased 11% from the prior year period, primarily due to the progression of our pipeline. Our SG&A expense for the quarter of $191 million increased 58% 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 launch of Opzelura for atopic dermatitis.

Our collaboration loss for the quarter was $9 million, which represents our 50% share of the U.S. net commercialization loss for Monjuvi. This is comprised of total net product revenues of $22 million and total operating expenses, including COGS and SG&A expenses of $40 million.

Finally, our financial position continues to be strong as we ended the quarter with approximately $2.3 billion in cash and marketable securities. Moving on to our guidance for 2021. We are reiterating revenue, COGS, R&D and SG&A guidance for the year. We remain confident in our full year guidance for Jakafi based on our continued recovery of new patient starts and the approval 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 is coming from Tazeen Ahmad from Bank of America.

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

I'm going to focus on atopic derm. So it looks like out of the gate, as you mentioned, the metrics are looking pretty strong. Can you give us an idea of what are the physicians that are picking up use initially? Is there a particular patient population that you're hearing that doctors want to try this out on first at least feedback from your sales force? And if you were to say, right now, what is your biggest, I guess, roadblock to pick up? Is it getting on insurance formulary? Or is it just trying to educate doctors on the product.

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

This is Barry. Thanks, Tazeen. First thing I'd like to say is that I realized I said that we were going to ship in my prepared remarks, 300 tubes of Opzelura in the first 4 weeks. And of course, I meant 3,000 tubes, which would actually make it on par or better than the last 2 launches in atopic dermatitis.

So we expect those 3,000 shipments to pharmacies to actually translate into more than 3,000 prescriptions in the first full 4 weeks of our launch. So what patient population are they really looking at it? It's just the indication essentially patients who are 12 years or older. There's no difference. I've spoken to many dermatologists, and they're confident that they can use this drug in teens all the way up to the older adults.

So the biggest roadblock patient access is always an interesting problem at the beginning of the launch. But in fact, I think we're making great headway there. And as I said in my prepared remarks, I think we will, in fact, have broad coverage in the first quarter of next year. As you know, when new products are launched, particularly products like this in dermatology, sometimes the big PBMs will just block you for 6 months or more.

And we think we can overcome that as quickly as possible. We've presented many times to payers across the country, big and small payers with our clinical data, and they're really impressed by the value that Opzelura will provide to these patients.

So even though it is always a barrier or worried about patient access, I think we're going to be fine in the relatively near future. As you know, in fact, when they start a new year is really when you want to ensure that your formulary is fully blown out and all of your customers know exactly what's going to be covered and what's on the formulary. So we think in the beginning of the year, we'll have good progress there.

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

And just to clarify, do you know how long it's taking from the time the doctor writes the script at the time the patient is receiving products in the early days of the launch?

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

I don't. It's very early. I can't give you a medium or an average. Some patients are obviously have to have prior approval. Other patients go through our Incyte cares, patient assistance program. I'm sure some patients are getting it very quickly. and other patients, it might take a few days. But I don't have an average for you yet.

Operator

Next question today is coming from Brian Abrahams from RBC.

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

I have a question on the MF dynamics overall. It looks like -- and life cycle. It looks like patient volume has been very stable year-over-year in MF for Jakafi and you're seeing a lot of the growth being driven by the other indications. Just wondering if you could talk about, I guess, what goes into your out-year guidance in terms of overall market dynamics across the indications?

And then as we think about sort of longer term you didn't talk too much about the ongoing Phase II -- Phase I/II work for the BET and ALK2. And just sort of wondering where those stands and your level of confidence that, that can drive potential growth and durability in the MF indication?

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

Sure. This is Barry. I'll start and then hand it over to Steven for the BET and ALK2 and where they stand. But as you can see from the slide that we showed, the remarkable thing about Jakafi is that month after month, year after year, the total number of patients on Jakafi continues to increase, whether it's MF, PV or GVHD. The number of patients who are on MF for a very long period of time are -- is amazing. In fact, we know that we really only penetrated about 50% of the market. Our biggest competition is really watch and wait. So getting physicians to fully understand the survival benefit that Jakafi offers to myelofibrosis patients is really what our challenge is, and we know we're making headway all the time.

As I said in my -- at the beginning of my prepared remarks that myelofibrosis, PV, GVHD, the standard of care is Jakafi and it will continue to be that way. PV patients, same thing. They continue to grow year after year, month after month. And GVHD, especially for chronic GVHD, we know is going to grow very well. Those patients are -- the prevalence of those patients are greater than the prevalence of acute GVHD patients and the chronic GVHD patients stay on for a much longer period of time. So I'll hand it over to Steven now for BET and ALK2.

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

Thanks, Barry. Brian, thanks for your questions. So let me deal with each separately. Firstly, I'll start with ALK2, which is a mechanism now we have data in hand that we're understanding more and more. So if you look iron metabolism in humans, hepcidin, the way it works is high levels of hepcidin inhibit iron absorption from the gastrointestinal tract and stop its release from macrophages.

So there's less iron available to make red blood cells. If you are able to inhibit that hepcidin pathway through an ALK2 inhibitor, irons released and made available, both from absorption and both from macrophages to make new red blood cells. And we've shown that this compound does that from a mechanism of action point of view.

So where we are? So we're very excited about its potential. We completed the monotherapy safety and then the combo safety, and then we'll be ready to make more decisions on the path forward in terms of more pivotal studies, which, let me remind you, which I've said repeatedly, will hopefully address both the anemia of the underlying disorder, which we think is hepcidin-mediated plus the anemia induced by ruxolitinib, which we also think is hepcidin-mediated.

And if we achieve both of those, you'll get the safety aspect and less discontinuations when it works, and then maintain ruxolitinib dose and enhance efficacy. So the program really has a lot of potential. We hope to have a recommended Phase II combo dose ready to go early next year and then make those decisions.

For the BET program, again, a compound we've had in our hands for a long time, years ago, we dosed it to much higher multiples in patients with solid tumors and the dose-limiting toxicity there, as we know with BET inhibitors, was on target and was thrombocytopenia.

We're now dosing it at 20%, 25% of where we were before gathering monotherapy safety in myeloproliftive neoplasm patients and then combo safety, and then well again, just like with the ALK program, have to make decisions on where to go, looking at the competitive space as well. Would we be looking -- given its profile, in suboptimal patients and in addition, would we consider first line? So those data sets for the mono safety and the combo safety will be available in 2022. And as soon as we're ready and put up on clintrials.gov, we'll be able to show you our clinical programs there, but we're comfortable where they are at the moment.

Operator

Our next question is coming from Cory Kasimov from JPMorgan.

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

I wanted to go back to Opzelura. Now that you're early on in the launch and deep in discussions with payers, curious if you're thinking around expectations for gross to net have changed at all? How we should be thinking about this short term and then kind of longer-term trends on this front? And then the follow-up is, as we think ahead to the anticipated approval of Opzelura for vitiligo, how did the tubes per patient likely differ for a typical patient in that setting versus atopic derm?

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

Cory, it's Barry. So what we're thinking about the gross to net is that what we said in the past is that long term, we anticipate the gross to net to be 25% to 50%. But in this quarter, in particular, and then as we move into next year, the gross to net will be much higher just because of the NDC blocks and the patient assistance programs that we provide, the co-pay assistance.

And as you know, in this therapeutic category, over time, the use of those programs declines as there's more broader coverage. So our gross to net will continue to improve. For vitiligo, maybe I'll start out and hand over to Steven. We know it's going to be greater.

I think we've forecasted, perhaps we said that we think in atopic dermatitis, 3 or more tubes will be used per year, 10 tubes per year perhaps for vitiligo. I forget exactly what the clinical trial was, how many tubes we got. But obviously, we want to -- patients are going to use this for 24 or 52 weeks, and we'll see how much further after that, but I'll let Steven comment as well.

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

Thanks, Barry. Thanks, Cory. The data in my prepared remarks for the TRuE-V Phase III studies thus far have completely replicated the Phase II data in terms of the facial VASI75 at 24 weeks hitting the 30% plus range. We know from the 52-week and the 104-week long-term follow-up on our Phase II studies, that one of the phenomenons with treating vitiligo is continued improvement over time.

And in fact, most of the patients, the vast majority, elected to go on to long-term treatment in the long-term safety extension because of continued improvement. So what Barry is alluding to is continued use overtime and over a 1-year period, the current estimate is at least 10 to 11, 60-gram tubes would be needed to achieve what I just spoke about. And then we'll get more data in the second year, as we continue to follow these patients.

Operator

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

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

So with the approval of Opzelura in atopic derm and the regulatory progress in vitiligo, it looks like the dermatology franchise is off to a great start now. You also have additional trials going on. Can you talk about how you're thinking about the future of the derm franchise, given what you've already targeted with Rux, would you be looking for something to complement that? Or should we look -- expect something more broad?

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

Herve here and Steven will speak about the specifics of what's going on in derm and beyond dermatology with our current portfolio. I mean the whole idea from the beginning was that we do research and discovery of new products somewhere in between immunology, inflammation and cancer. So some products are typically cancer product.

But many of the products targeted therapies type of product, antibodies, et cetera, but many of the mechanisms we are studying in fact, have application outside of cancer. And that's where it came -- that's where it started. And what we see today, when you look at the 10-plus mechanisms that we are studying in early studies is that they can have applications outside of cancer. That's what we found with PI3-kinase delta in hemolytic anemia.

That's what we see in many dermatology indications. So the goal is really to continue on that sort of follow the science type of approach and obviously because dermatology of the skin is the largest immune organ I guess, we see a lot of applications in dermatology in the short term, but it could also go in other type of inflammatory immune type of disease. So maybe, Steven, if you want to talk about it?

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

Thank you, Herve and Kripa thanks for the question. So Herve is right. The way we view in dermatology, and I'm glad you called the franchise, even from an R&D point of view, is absolutely not a one and done. So there's life cycle management of the cream itself ongoing within atopic dermatitis and some of the manifestations thereof, like chronic hand eczema, et cetera.

There's still questions to be asked and addressed in vitiligo, including the -- what happens with -- in patients on for the long term with really good improvements in facial VASI90 and beyond and what happens with withdrawal in those situations. And then beyond those indications, as Herve was alluding to, given the mechanism of action of the cream in terms of JAK-STAT pathway, there are a number of other indications that we're extremely interested in addressing, which are actually relatively from an R&D point of view, certainly with an oncology context, really easy to study in terms of time.

So stay tuned. We view this now as a life cycle management opportunity with a scale that we can address in a very, very efficient manner. And then because derm, as you also -- as others have said, they've alluded it has become really important to Incyte both from R&D and then a commercial point of view, it's beyond in terms of other compounds.

So I alluded to in my prepared remarks with 54707 are relatively JAK1-specific oral inhibitor that there are other indications for which we already have really good Phase II data in hidradenitis suppurativa. We have an ongoing Phase IIb there in approximately 200 patients that will deliver data next year and then we can make a decision on what to do from a pivotal aspect.

We're studying that compound in prurigo nodularis. Again, the [mechanism] (corrected by the company after the call) of action is very relevant there. And then in my prepared remarks, for a nonsegmental vitiligo with body surface areas of -- total body surface area involvement of 8% or

greater, we think the risk benefit may well be favorable for an oral JAK there. So you can see the derm thinking from an R&D point of view has expanded in an appropriate proportional way, and it's relatively efficient to do so. Thanks for the question.

Operator

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

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

So back to Opzelura. Could you just give us any qualitative feedback you're getting on the launch and with regard to the safety profile and use in the context of which populations? So would they be looking to combinatorial use, for instance? And then in vitiligo, is there any change to the outlook for market opportunity here?

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

Salveen, it's Barry. So regarding the safety in the black box, I guess you're alluding to, is that dermatologists are very used to explaining to patients the difference between a systemic product and a topical product. For most skin diseases, in fact, dermatologists would rather use a topical product.

So they know that, for example, the safety profile between oral JAK inhibitor and a topical JAK inhibitor is going to be very different. So they're very comfortable with that. As I said before, I've spoken to many dermatologists. We've gotten a lot of feedback from the field. There really hasn't been a pushback on the types of patients they are going to use this Opzelura in.

So it's approved for the indication from 12 and over, and that's what they're telling us they're going to use it for. In terms of combo use, I don't know. Sometimes they do cycle through -- dermatologist will cycle through different therapies as they're trying to control patients with atopic dermatitis, but we can't say in the future what they're going to do.

In terms of vitiligo, it's a game changer. It can change patients' lives and how they feel about themselves. It's the only drug that will be approved for re-pigmentation of the skin, and we really think that's going to be something that patients and dermatologists health care providers will want to utilize because it is such a unique treatment and it's going to help maybe hundreds of thousands of patients, if not more, live a better life, I think.

Operator

Our next question is coming from Jay Olson from Oppenheimer.

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

And congrats on the 3 parsaclisib filings and acceptances. Can you comment on FDA's rationale for granting MCL and MZL priority reviews while FL received a standard review? And then on the last call, I think you mentioned the tumor-agnostic program for parsaclisib would transition to a molecular-defined approach. And I was wondering if you have any more details on those plans? And then lastly, on Monjuvi, can you talk about any impact that you're seeing from Polivy, especially as it moves to the frontline setting and any feedback from physicians in terms of how they compare those 2 drugs?

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

Jay, it's Steven. Thanks for your questions. On the parsaclisib acceptance of filing, so it's one of the biggest submissions I've ever been involved in, in a positive way because we submitted all 3 indications at the same time with the entire package realizing that diseases, although under the umbrella of non-Hodgkin's lymphoma, in general, are different in terms of some of their pathophysiology and the way they behave.

And that's exactly what happened in terms of the review cycles you allude to. So for both marginal zone and mantle zone lymphoma, given the unmet medical need there, the FDA felt that they warrant a priority review and also given the data we've seen. For follicular, I think their feeling is maybe it's a little more of a crowded space, less unmet medical need. But also -- and I think very importantly, it's a condition that they want long, long-term follow-up in terms of the responders.

And I think that's what's driving the review cycle there being lengthened. Obviously, our intent is to try and match these through all at the same time and get them approved at the same time. But if they end up separating out follicular to get longer follow-up on the responders, I think that's what's driving the standard review cycle there.

In terms of your second question, I think you were alluding to pemigatinib tumor agnostic program, our FGFR inhibitor, and we had a tumor-agnostic study underway for patients either with FGFR2-driven arrangements or FGFR3 or any others. And what we saw within that program, although early in small numbers, is some encouraging signals in certain areas like glioblastoma that felt to be more FGFR3-driven. And like some areas of non-small cell lung cancer that were more FGFR2-driven.

And we felt that the likelihood of getting a wide tumor-agnostic indication was perhaps more limited and it was more efficient to stop the agnostic program enrolling across the board and go at those -- exactly at those 2 histologies directly. So there'll be Phase II studies underway in both glioblastoma multiforme, that's FGFR3-driven and in non-small cell lung cancer, that's FGFR2 driven. And then for your Monjuvi/Polivy question, I'll turn it to Barry.

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

Sure, Jay. So in terms of Monjuvi and how it relates to Polivy. We think -- well, first of all, we're approved in the second-line setting for a diffuse large -- diffuse DLBCL patients. And we really think that our profile is always going to be attractive to patients and to physicians. In fact, perhaps, as you know, Polivy reported over the last 2 quarters that their sales have declined. And we actually believe that because we're continuing to make inroads there, but Polivy approved in the third-line setting we're approved in the second line setting.

As far as moving to the first line for Polivy, if they do move to the first line, we haven't seen the data yet. But that wouldn't bother us. It actually gives us more faith that our frontline trial will be positive for these patients. And that even if they're in their first-line setting before we get there, we'd be the choice for the -- in the second-line setting going forward. But we really believe that if their study is positive in combination with R-CHOP, our study could be positive in combination with R-CHOP.

Operator

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

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

Maybe start with -- one follow-up for Steven, on your comments of ALK2, when you were discussing that you've seen pathway engagement in the hepcidin pathway. Were you speaking to iron release? Or have you seen rises in red blood cell counts in that monotherapy trial?

And then for Barry, maybe if you can give a little more granularity on what you mean by broad access? I guess, one, have any meaningful contracts been signed yet or at least getting very close to finalization where maybe you can speak to what type of step edits you're expecting to be in -- in the final agreements?

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

Marc, it's Steven. Thanks for the question. So we have not presented publicly clean data yet on hemoglobin improvement, if that's what you were asking directly, but we have demonstrated preclinically and then in clinical samples that it's doing exactly what we want it to do from an MOA point of view in terms of iron dynamics and ferritin. We don't have the clinical endpoint yet on actual rise in hemoglobin. And hopefully that will follow, and we'll be able to present that next year to you. And then Barry can answer the second part.

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

Sure. As far as negotiations with payers, like I said, they're ongoing. We think they're very positive. We think in the first quarter, we'll actually have broader access. And so we're negotiating not just with the large PBMs, but all of the regional payers that are important throughout the country.

And so I'm very confident that we will, in fact, in the near-term sign contracts, but don't forget patients do have access to the drug now, not just through our patient support program, but they're being paid for. You asked about step edits. We think that this drug is going to be used after steroids. And I think that's perfectly appropriate.

We think, in fact, we have a very good situation where from steroids all the way up to systemics, all of those patients for mild-to-moderate disease. This will be the drug to use for them. And we know that thousands and thousands of patients have already failed steroids, so the patient population is just there for us to -- for them to begin to utilize a drug with the profile that Opzelura has. So we're confident about our future market access and we're confident that patients are getting drug now. And we don't think that step edits will be a problem or if there is one step edit, just like in our label, that should be used after prior topical therapy, that's exactly where it's going to be used and we're fine with that.

Operator

Your 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*

Maybe just a little color on the sample program. What size of the tubes that are being given? And are there any mechanics that the physician has to go through before giving a sample. Just trying to get a sense for how confident you are that the samples are going to be converted to paying patients?

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

Well, I'm not sure if I exactly understand your question. But the sample size are, in fact, 5 grams. So it's a very small tube. Health care professionals don't really have to go through anything in order to utilize samples and we...

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

Right. Well, I'm just trying to -- so they don't have to have a longer-term prescription to get the free sample initially.

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

No, they don't have to -- no, they can just write prescriptions and many just write the prescriptions upfront right away. So what we did decide to do, in fact, was to temporarily suspend our sample program that we had a report for the samples of a texture problem. So we just temporarily decided to stop the samples right now and that we will, in fact, investigate the root cause of any texture problem. Of course, we have to get the tube to be sent back to us, we have to verify lot numbers and that sort of thing. But we just thought it was the best thing to do at this point to temporarily suspend once we figure out what that report really means, then we'll see if we can restart the sample program again.

Operator

Your next question today is coming from Michael Schmidt from Guggenheim.

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

I just need a clarification on Opzelura and then one on Pemazyre. On Opzelura, of the 3,000 tubes shipped that you mentioned, is there any expected inventory in-stocking or build up? Or is that expected to directly translate into prescriptions? And then on Pemazyre, I guess, just thinking about market dynamics here in cholangiocarcinoma, given the sort of flattish sequential sales and how much additional growth opportunity you see in CCA? And again, help us understand the opportunity in non-small cell lung cancer and upcoming data disclosures for the Pemazyre program?

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

Sure. Michael. So for the first one, 3,000 tube ships, no, I don't think there's really much inventory. I think all of those tube shipped to pharmacies will be turned in prescriptions. The reason is simply that a drug like this, they don't keep on their shelf for a long period of time.

They're going to make sure that, in fact, patients have insurance coverage or they have access to the drug before they're going to order this from the wholesalers. So I don't think there's very much inventory there at all. Obviously, there's inventory at each of the wholesaler sites that will eventually go out to pharmacies.

In fact, most of these pharmacies are independent pharmacies. So pharmacies that are very used to working with dermatologists as there is -- that's most of their practice. So that's actually very encouraging because the dermatologists like to work with their local pharmacy that's experienced in working with dermatologists.

As far as the pemigatinib goes -- Pemazyre goes and the cholangiocarcinoma market in the United States, sure, there's growth opportunities there. Obviously, we have a first-line study moving into the first-line setting would actually mean a whole lot to us.

That we know that there's -- patients are being tested for FGFR2 alterations and rearrangements. But there could be more patient tests. So the more patients that are tested identify that they might have this FGFR2 alterations, then they would be candidates for Pemazyre. So I think there is growth there. But it is, as you know, a very small patient population. And as far as the lung cancer patient population to go, we'll have to see. We'll have to see how many patients actually do have an FGFR alterations in lung cancer. And we'll see what the future opportunity is there, as we continue to roll out our studies.

Operator

We have time for one more question that comes from the line of Matt Phipps from William Blair.

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

This is Rob Andrew on for Matt Phipps here. Just wanted to follow up on the earlier question there. On the sample products and the potential issues there. How is that sample product actually different from the prescription product, if at all, are they produced separately? And are there likely to be any issues with the commercial product at all?

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

So yes, they produced differently. Obviously, it's a 5-gram tube. It takes different pressure to get into the 5-gram tube. So there are separate batches, and we produced about 140,000 of the samples. As far as the 60 grams, we're investigating all of the batches just to make sure that the texture and problem, if there is any, we can fix and address. We actually do have -- we're following up on information that was reported to us that we may actually have a texture problem with a 60-gram tube, but we're working through that right now. But we have to do a root cause analysis, and we have thousands of tubes out there, and we have to know -- get them back from the patients or from the health care providers, have that analyzed, see what the storing conditions were. And once that analysis is done, then we'll go forward from there.

Operator

We've reached the end of our question-and-answer session. And ladies and gentlemen, 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.

Editor

[Refer to Incyte Corporate Statement at Incyte.com/media/company-statements]
