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EDITED TRANSCRIPT

INCY.OQ - Q2 2021 Incyte Corp Earnings Call

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OVERVIEW:

INCY reported 2Q21 total product and royalty revenues of $696m.

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PRESENTATION

Operator

Hello, and welcome to the Incyte Second 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, Investor Relations. Please go ahead.

Christine Chiou - *Incyte Corporation - Head of IR*

Thank you, Kevin. Good morning, and welcome to Incyte Second Quarter 2021 Earnings Conference Call and Webcast. The slides used today are available for download on our website. Joining me on the call today are Herve, 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-Q for the year ended March 31, 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. On Slide 4. So at the beginning of the year, we laid out several key business objectives for 2021, and we executed on a number of our commercial and clinical goals in the first half, representing a continuation of the momentum we saw throughout 2020. We believe these achievements, including the success of the TRuE-V and TRuE-AD program in vitiligo and atopic dermatitis will significantly contribute to our long-term strategy for growth and diversification.

In the second quarter, our product and royalty revenues grew 17% to reach nearly $700 million. Jakafi net product sales were up 12%, with growth driven by the return of new patient starts to pre-COVID levels. Both Pemazyre and Monjuvi revenues increased quarter-over-quarter, up 33% and 16%, as both new product launches continue to gain traction and royalties grew 30% to $121 million for the quarter with Jakavi up 24% and Olumiant up 40%.

Our performance in the second quarter shows the strength of our business and our new product launches are progressing well. We are looking forward to the second half as we await 2 important FDA decisions in September and the potential approval of tafasitamab in Europe, following the positive CHMP opinion received in June.

While we are disappointed by the PDUFA extension for ruxolitinib cream for atopic dermatitis and for ruxolitinib in steroid-refractory chronic GVHD, we remain confident in the value these medicines can bring to patients based on the robust data from pivotal programs TRuE-AD and REACH3, respectively. We will continue to work with the FDA on retifanlimab, which recently received a Complete Response Letter for the BLA submission for SCAC. Retifanlimab remains under review with the European Medicines Agency.

Moving on to our clinical development progress. In addition to the positive top line results in vitiligo and long-term data in atopic dermatitis for ruxolitinib cream, we also announced positive Phase II data for parsaclisib in patients with autoimmune hemolytic anemia and the achievement of bioequivalence with QD ruxolitinib, which is on track for an NDA submission in early 2022.

Looking outside of the U.S., we have multiple growth opportunities across several markets. In the first half of the year, Pemazyre was approved in Europe and Japan, and we have seen encouraging uptake with ex U.S. sales reaching $3 million further supporting the importance of Pemazyre as a treatment for patients with cholangiocarcinoma. NICE provided a positive recommendation for Pemazyre in the U.K.

Turning to tafasitamab in the EU. If approved, Incyte will be commercializing tafasitamab under the brand name Minjuvi bringing the therapy to many patients in need. In Europe, 16,000 patients are diagnosed with relapsed or refractory DLBCL each year, of which approximately 14,000 would be eligible for tafasitamab.

Our hematology team in Europe, which was already deployed for Iclusig, are launch-ready, and we will be leveraging resources to support the launch of tafasitamab on a country-by-country basis.

So Slide 6 shows the key business objectives that we set for the year. So first, to continue driving growth in our current product portfolio; second, to continue to expand and diversify our revenue base through new product and new indication launches; and third, to continue to progress our late-stage pipeline as well as our earlier-stage program.

So with that, I will 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. Good morning, everyone. Before we talk about our individual product performance, I wanted to mention how encouraged we are, as we see the gradual return of patients to physicians' offices, following a year of decreases in patient diagnosis and treatment due to COVID.

While pharmaceutical representatives' access to oncology offices is still lagging other therapeutic areas across the industry, we are seeing that there is now meaningful improvement in rep access to in-person meetings with oncologists. We expect these positive trends to continue and are optimistic about a stronger recovery in the second half of the year.

On Slide 8, we show that Jakafi's sales grew 12% year-over-year to $525 million -- $529 million for the quarter, with total patient demand increasing across all 3 of our approved indications. New patient starts, shown by the magenta line on the chart, are now at the pre-pandemic levels, signaling more patients are returning to their doctors and receiving the treatments they need.

Regarding Jakafi guidance, we are reaffirming our growth prospects for the year. A slight reduction in the upper end of guidance has been made to account for the increase in gross to net due to greater percentage of Jakafi volume ordered from 340B accounts, and the 3-month extension in the PDUFA for ruxolitinib in steroid-refractory chronic GVHD.

We now expect Jakafi net product sales between $2.125 billion and $2.170 billion for the year. We expect the growth of Jakafi to continue in the second half of the year with a stronger recovery of new patient starts and the potential approval of ruxolitinib for the treatment of steroid-refractory chronic GVHD, representing an additional growth opportunity for Jakafi. And we look forward to the FDA's decisions next month.

Turning to Slide 9. Pemazyre continues to outpace our expectations. Product sales grew 33% quarter-over-quarter to $18 million, including $15 million in U.S. sales as use in the second line continues to grow and the duration of therapy continues to drive performance. Since our initial launch, 60% of patients on Pemazyre have been second-line patients as reported by their physicians. However, in the recent survey of physicians, who have prescribed Pemazyre, that percentage is near 80%, indicating a shift in earlier adoption of this therapy.

Testing rates for FGFR2 fusions or rearrangements continues to grow, and a recent survey showed that unaided awareness of FGFR2 fusions relative to intrahepatic cholangiocarcinoma increased to 61%, up from 34% noted in the survey prior to the Pemazyre launch. We are optimistic for the second half as our reps continue to drive awareness for FGFR2 testing and usage in the second line.

Turning to Monjuvi on Slide 10. Monjuvi sales grew to $18 million in the second quarter, representing a 16% growth over Q1. We continue to see an increasing uptake of Monjuvi in the second-line diffuse large B-cell lymphoma and are seeing positive trends in new patient starts with momentum continuing as we exited June.

As I said before, it has been a challenge to launch an injectable therapy in the midst of COVID. However, we are seeing positive trends, including the expanded number of accounts purchasing Monjuvi, the increase in new patient share and higher percentage of Monjuvi patients in the second-line setting. Updated 3-year results from L-MIND were recently published, and we believe these data will help bring greater awareness to the potential benefit of Monjuvi in the second-line setting.

I'd like to turn now our attention to ruxolitinib cream in atopic dermatitis. As we wait for an FDA decision, we want to remind you of the high unmet need that exists for patients living with atopic dermatitis. There are currently 5.5 million patients with atopic dermatitis over the age of 12 on prescription medications. And yet a significant number of patients continues to experience symptoms. Based on a recent survey of AD patients, over 40% of patients on prescription therapy experience flares at least once a week. Clearly, the need for novel effective treatments is high.

Shifting to another survey of dermatologists. Over 70% of these dermatologists are aware of ruxolitinib cream's development in atopic dermatitis. 85% of dermatologists separately indicated that they would be highly likely to prescribe ruxolitinib cream to patients who are presented with a blinded safety and efficacy profile, and itch reduction was cited as the number one treatment driver. We are confident in the data supporting ruxolitinib cream in AD, and we look forward to the FDA's decision next month.

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

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

Thanks, Barry, and good morning, everyone. Starting with ruxolitinib cream, the FDA review of the NDA for ruxolitinib cream in atopic dermatitis is ongoing with a new PDUFA date of September 21. At the Revolutionizing Atopic Dermatitis Conference in June, 52-week data from the TRuE-AD program were presented, showing long-term disease control with as-needed use of ruxolitinib cream.

The majority of subjects achieved clear or almost clear skin by week 8, and we saw no new safety signals during the long-term safety period, including no adverse events suggestive of a relationship to systemic exposure. We also recently initiated our Phase III pediatric program in an effort to expand the patient populations, who might benefit from ruxolitinib cream.

Turning to Slide 14. We previously announced at the beginning of Q2 that the Phase III vitiligo program had achieved its primary and key secondary endpoints at week 24. Patients were randomized to receive 1.5% ruxolitinib cream twice daily or vehicle for 24 weeks, at which point a crossover occurred from vehicle to 1.5% ruxolitinib cream twice daily for an additional 28 weeks.

The overall efficacy and safety profile of ruxolitinib cream were consistent with previously reported Phase II data. As a reminder, 30% of patients in the Phase II study achieved a facial-VASI75 and continued improvement was seen through 52 weeks. With these positive outcomes, we are on track for an sNDA and MAA submissions in the second half of 2021, and are optimistic that ruxolitinib cream may be a meaningful treatment option for patients living with vitiligo.

On Slide 15, tafasitamab 3-year data from the L-MIND study were presented in June at the 2021 American Society of Clinical Oncology Annual Meeting and subsequently published in Haematologica in July. These data demonstrated significant durable responses and reaffirmed a consistent safety profile with tafasitamab treatment in patients with relapsed or refractory diffuse large B-cell lymphoma, who aren't eligible for transplant.

We are particularly encouraged by the tolerability and high overall response rates seen especially in the second-line setting, which exhibits the importance of starting therapy sooner. In addition, the study demonstrated that subsequent treatment, including an autologous stem cell transplant and CAR-T therapy is not precluded in patients with disease progression during the tafasitamab plus lenalidomide treatment. We are looking forward to the decision from the European Commission, following the positive CHMP opinion received in June.

Turning to the next slide. Tafasitamab's clinical program continues to develop with multiple pivotal and proof-of-concept studies to start later this year. As of today, there are 3 updates to the program. The first being Front-MIND, which is now ongoing and enrolling patients in first-line diffuse large B-cell lymphoma. Second, the initiation of Core-MIND, a pivotal trial evaluating tafasitamab plus parsaclisib in relapsed or refractory chronic lymphocytic leukemia based on the positive results of the COSMOS study. Lastly, we expect to initiate MINDWay, which is our dose optimization study in relapsed or refractory diffuse large B-cell lymphoma.

On Slide 17, the LIMBER program continues to evolve in a positive way. We presented positive once-daily ruxolitinib bioavailability and bioequivalence data at EHA in 2021, which demonstrated bioequivalence for area under the curve. Once-daily ruxolitinib stability testing is ongoing, and we expect to file an NDA in early 2022. Multiple trials are ongoing, including the potential for fixed-dose combinations with parsaclisib plus ruxolitinib, and we anticipate the initiation of the BET and ALK2 combination components of their respective trials with ruxolitinib in the second half of this year.

Turning to Slide 18. The results of REACH3 investigating ruxolitinib in steroid-refractory chronic graft versus host disease were recently published in the New England Journal of Medicine. This data shows that treatment with ruxolitinib significantly improved overall response rate in Week 24 as well as a much higher best overall response rate versus best available therapy.

REACH3 also achieved statistically and clinically meaningful improvements in key secondary endpoints, including failure-free survival and symptom response. With the September 22 PDUFA, we are excited at the potential to help bring this therapy to patients living with steroid-refractory chronic graft-versus-host disease, who currently have very limited treatment options.

Turning to parsaclisib on Slide 19. We presented Phase II data in autoimmune hemolytic anemia at EHA in 2021, which showed high response rates and a normalization of hemoglobin levels during the initial 12-week treatment period. Clinically meaningful improvements in fatigue related quality

of life were observed, and parsaclisib was generally well tolerated. In a disease with no currently approved treatments, we continue our commitment to patients through the development of parsaclisib and the initiation of the Phase III trial to start later this year.

In closing, we had a number of clinical development successes announcing positive data across multiple programs and making significant progress within certain key development programs during the first half of '21, and we expect an eventful second half with multiple potential approvals and additional regulatory submissions.

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 second quarter were $696 million, representing a 17% increase over the second quarter of 2020. Total product and royalty revenues for the quarter are comprised of net product revenues of $529 million for Jakafi, $28 million for Iclusig and $18 million for Pemazyre.

Royalties from Novartis of $82 million for Jakavi and $2 million for Tabrecta and royalties from Lilly of $36 million for 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 the impact of the COVID-19 pandemic subside.

Moving on to our operating expenses on a GAAP basis. Ongoing R&D expenses of $339 million for the second quarter increased 20% from the prior year period, primarily due to the product supply cost for ruxolitinib cream, the progression of our late-stage pipeline and our 55% share of the global and U.S.-specific development costs for tafasitamab. Excluding the $11 million impact of incremental product supply cost for ruxolitinib cream, ongoing R&D expense for the quarter increased 16% from the prior year.

Our SG&A expense for the quarter of $169 million increased 43% 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.

Our collaboration loss for the quarter was $10 million, which represents a 50% share of the U.S. net commercialization loss for Monjuvi. This is comprised of total net product revenues of $18 million and total operating expenses, including COGS and SG&A expenses, of $38 million. Finally, our financial position continues to be strong as we ended the quarter with approximately $2.1 billion in cash and marketable securities.

As we are at the midpoint of 2021, we are taking the opportunity to update our revenue and expense guidance. As Barry detailed earlier, for Jakafi, we are tightening the range to $2.125 billion to $2.17 billion. Based on the strong performance of Pemazyre in the first half of 2021, we are increasing the guidance range for other hematology/oncology to $155 million to $170 million.

Finally, we are lowering SG&A guidance to $725 million to $755 million to reflect lower expenses for ruxolitinib cream as a treatment for atopic dermatitis in the U.S. based on the PDUFA date extension. There are no changes in our guidance for COGS and our R&D.

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 Salveen Richter from Goldman Sachs.

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

Two for me. One is, could you just speak to what's happening on the regulatory side with regard to JAKs and how that impacts your process here on the derm franchise? And then secondly, with the $30 million reduction in guidance, how much of that is due to contribution from steroid-refractory GVHD versus impact from the 340B rebates?

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

Salveen, it's Steven. I'll answer your first question. So in terms of the regulatory aspects of the ruxolitinib cream, obviously we cannot and do not speculate on what the FDA will or will not do. But we can tell you, we have tremendous confidence in the profile of the cream, given now that we have 4 completed Phase III studies, 2 in atopic dermatitis, 2 in Vitligo, including the long-term follow-up now for both safety and efficacy in these studies that demonstrate no new safety concerns related to what one would expect from any untoward systemic exposure.

The efficacy profile in atopic dermatitis that we presented before in mild-to-moderate AD is outstanding, and the safety profile is in keeping with what I just said with the low systemic exposure of approximately 4% to 7% bioavailability compared to an oral tablet, in other words, no untoward effect seen. So given all of that, we remain obviously extremely confident in the profile, and we look forward to that PDUFA date on September 21.

I'll hand over the second part.

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

So Salveen, we don't -- we really think of it as being just a tightening, where -- as we get further in the year, we see that the range that we had was appropriate, the low end of our range was appropriate and the higher end of our range is tightened to what we're likely to hit. As far as the -- what affects the gross to net versus GVHD, we actually anticipated that our gross to net would be 1% for the year, lower than it is now -- than it seems to be now. So we're -- that's taking up a good chunk of the amount that we reduced the top line from -- the high end of the guidance from.

Operator

Next question today is coming from Brian Abrahams from RBC Capital Markets.

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

Two questions for me on Jakafi. Obviously, very encouraging to hear that new patient starts have now returned to pre-pandemic levels. I'm curious if you're seeing any recent changes with the Delta wave currently in the pandemic in terms of patient -- new patient diagnosis visits to physicians and new starts as well as your ability for sales reps to engage with physicians on the extent maybe to which that shapes your full -- your guidance?

And then secondarily, on the once-daily form, I know physicians have this perception of myelosuppression with JAKs being intrinsically linked to spleen response and activity. So I'm just wondering how you hope to educate physicians around the potential to have comparable efficacy with a once-daily form that may have less toxicity? And is there any clinical data beyond the bioequivalence that you're hoping to deploy to help support that education and awareness?

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

So Brian, this is Barry. I'll take the first part and hand the other part over to Steven. So obviously, the Delta wave -- Delta variant is concerning. But as of now, we actually see new patient starts increasing for Jakafi back to pre-pandemic levels. We know that sites are opening up for our rep access

and actually all of our field-based employees access to clinics, offices, hospitals. Obviously, we don't know what the future is going to bring, but for right now, we're getting back to where we were back in the beginning of 2020. Steven?

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

Brian, it's Steven. So thanks for the question on once-daily ruxolitinib. As you sort of alluded to albeit indirectly, the once-daily PK profile, while we demonstrated the comparability needed for area under the curve, the Cmax as you would expect from a once-daily versus the quicker release formulation is lower. We do think, although this is still need to be proven that, that is one of the aspects that drives, as you were alluding to, the myelosuppression, particularly through potentially JAK2 inhibition and that there may be less anemia with once daily.

I don't think that it's fully true in what you said, and it's more perception than reality that myelosuppression is linked to spleen volume reduction. In fact, as you know, we see SVR35 have better improvement in many patients who don't have any myelosuppression at all. So I think that is definitely more perception than reality, but it's something we will have to counter.

The route we've taken for once daily in terms of approval is a bioavailability, bioequivalence route. The forms are now in stability testing. And if stability goes well, we'll be filing that early next year. There is no clinical data yet on outcomes in terms of efficacy or safety. That's something we would do after the fact that we wanted to. So a very sort of "simple" BA/BE route to prove the needed area under curve equivalents and the stability to get the approval.

Operator

Next question is coming from Marc Frahm from Cowen and Company.

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

One for Steven. Just on the LIMBER program on the combinations, I mean, the monotherapy seems to have been running for a while. I mean, is the dose escalation just being much more extensive than maybe you thought or is it really just enrollment maybe from COVID that's kind of keeping that from being able to advance into the combinations?

And then for Barry, the increase in 340B use, I think we've been seeing that increase over time historically, but I guess it's accelerated in the first half. Do you think that's maybe a mix issue from COVID or is that something that we should expect kind of going forward that that's a more permanent change as well?

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

Mark, it's Steven. So in terms of LIMBER, I mean, it's an incredibly important program to us for all the obvious reasons, both for the company shareholder value, commercial value, but also patient value, an unmet need here. And just to give you the different aspects. Firstly, the formulation work on once-daily has gone really well with the outcome we desire as we just spoke about in terms of bioequivalence and stability now and that file should go ahead in early '22, if stability is fine, which we expect it to be.

In terms of the combination, which is what your direct question, just a reminder there, the 3 we have internally, there's a parsaclisib combination program. That went very well. We presented the data multiple times. Both of the studies are open. The suboptimal study in patients who've had at least 3 months of ruxolitinib with either an inadequate spleen response or an inadequate symptom response or both and then our randomized to continue rux or rux plus parsa is ongoing and enrolling now. And then the first-line study of the combination is also open and enrolling now. So that program is going as well as we expected and on track.

In terms of the earlier programs, the BET work with our BET inhibitor, we've always said we will do single agent safety in the first half of '21 and then the combination work in the second half. And then we'll have to make decisions on how aggressive to be in terms of a program thereafter, and we could go very aggressively, for example, into first line if the data warranted that. There has been some COVID impact on enrollment in all early studies across the board in oncology and hematology, but we're comfortable with where that program is.

And then the third program ALK2, it's a different proposition, if you will, through -- we think through hepcidin inhibition that there'll be amelioration of anemia. That is one of the main reasons patients, I'll remind you, discontinue rux, so it will be of enormous benefit if it works there. And then not only that, they'll be able to maintain rux adequate dosing, so there'll probably be an efficacy upside as well. And that program, as we've always said as well, first half of this year, a single-arm safety and then combination work second arm and then the same process, how aggressive do we want to be in terms of programs. There, again, has been some COVID impact on enrollment in early studies, but we're comfortable with where the programs are.

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

So Mark, as far as the 340B use goes, well, we have a limited controlled distribution process for Jakafi and for Pemazyre for that matter. So our volume of 340B orders is about 11% now and the industry is about 15%. So we think we do a pretty good job of making sure that 340B orders don't get out of control. But we saw, for a number of years, 340B orders rising and the discounts, obviously, going back to those institutions. And then it slowed down in this year, picked up again for a number of reasons. And some of those are that there's more disproportionate share hospitals coming on to the 340B program, so DSH hospitals.

And then their -- what's called their child sites, which is their satellite sites, more of those coming on as health systems buy up oncology practices, and they do it specifically for to take advantage of the 340B program. And then in fact, we see that some of the hospital or health systems are establishing their own specialty pharmacies -- so they don't contract with other specialty pharmacies outside of their institution or their health systems, so more orders are going through there. We think we forecasted going forward, and it's built into our forecast, the correct gross to net or the amount of gross to net that's attributed to 340Bs. And so anyway, we think that we have a good system to control inappropriate orders that might come through the 340B accounts.

Operator

Our 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 maybe the kind of scaling down the opportunity for atopic dermatitis. I know there's like 5.5 million people. But when you think about the initial opportunity is the uptake in switching from Eucrisa or are there more specific population, just if you can help us kind of think about what that initial pool might look like for modeling?

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

Well, I'll try to answer that, Alethia. I think -- we think the opportunity is quite large to help patients who have eczema, atopic dermatitis. 5.5 million is obviously those patients who are actually drug treated. As you know, throughout the United States, it's estimated that 30 million people have atopic dermatitis, from kids to adults. So we really believe that going from steroids up to biologics, there's a huge unmet need there for patients with mild-to-moderate atopic dermatitis and ruxolitinib cream is just the thing for those patients.

Operator

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

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

So 2 from my side. First, on Monjuvi, understanding it's still relatively early days, but I was wondering if you could comment on the duration of use you've been observing in patients that have been prescribed Monjuvi? And secondly, going back to the QD rux program and LIMBER. So assuming that you do receive approval following your NDA submission planned for next year, how would you envision the commercial rollout here? Would you expect this to be an option for new patient starts or would you expect to conduct a more aggressive switching campaign for all patients, including those that are currently on a BID regimen? Any color there would be helpful.

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

So Vikram, on Monjuvi itself, so as expected, when you launch a new drug in oncology, in particular, you end up getting patients who perhaps had multiple prior lines of therapy. So as we started off, the duration of therapy was shorter, but expected because patients might have been older, sicker, had multiple lines of therapy. Now we're moving into true second-line patients more and more every day, more and more new patient starts are coming from true second-line patients, and we know that the duration of therapy will be much longer. And I think that's why the demand is really starting to pick up now. As far as the second part of the question, maybe Steven will take some of it and I'll try to answer the other part.

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

Yes, Vikram, it's Steven. I think, as I said earlier, it's a bioavailability, bioequivalence route initially to approval. So we won't have a whole ton of clinical data. But as we expect, with the lower Cmax profile that there may be less anemia. So if you step back, you have a once daily, which may have a convenience aspect to patients who want to use once daily versus twice daily use. And then you'll have a potential use for which we may have to generate more data on patients who are more likely to experience cytopenias, particularly anemia being more applicable to once daily.

And then just to mention because I didn't earlier that the optionality on this for fixed-dose combinations is also really important. So for any of the combinations I mentioned earlier, parsaclisib, BET or ALK2, the ability to do a fixed-dose combination with once daily will also be there, should we elect to do so, and there will be a path forward there. So it has multiple aspects of value to both patients and potentially commercially as well.

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

And maybe adding something on this QD. I mean you can -- you see the treatment of myelofibrosis evolving with a number of combinations being developed. So 3 of them by us and other companies are also combining Jakafi with their own product, and all of them are once a day. So it's very important to realize that when you are in the combination regimen of oral products for cancer having both once a day, it's, in fact, a way to ensure that there is a mistake, and it is also a safety aspect of it.

So the way we see it is that assuming we are at the end of 2022 with an approved once a day, there will be a transition of both existing patients moving to combination when it's appropriate and new patients being started on the once a day. So there is a sort of a -- in our plan, there is a transition period where the once a day will be basically replacing the twice a day for most of the indications in myelofibrosis.

Operator

Next question is coming from Cory Kasimov from JPMorgan.

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

Two for me around rux cream. First, are you having to conduct and/or share any new safety analyses for the product for the FDA ahead of the new PDUFA in September? And then secondly, can you just speak to the anticipated timing of TRuE-AD3 evaluating rux cream in children and maybe how you see this market opportunity for a topical relative to adults?

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

Cory, it's Steven. So as I said upfront earlier, we don't comment per se on to and fro with the FDA and all I'll be doing so now. We did say with our initial delay earlier that there was an information request that we had given them data on that may have contributed to the delay. I think stepping back from us alone and what the other 3 companies have communicated in the space with the oral programs, Pfizer, AbbVie and Eli Lilly that it looks like there's quite an impact from the ongoing Xeljanz safety review from RA in the Rheum division, and that may be affecting actions across the class, so to speak, definitely with the other programs. And that's as much as I can say related to the cream.

From the peds aspect, Barry spoke about, within our current mild-to-moderate 12 and above, we're serving the majority of the population there that has the need. However, as you point out, many patients start with atopic dermatitis at much younger ages and that's the importance of the peds program and getting those Phase IIIs up and started already.

I won't give you the timing yet, it's a bit early, but our adult programs, as you know, accrued incredibly well and incredibly quickly. And we have the same expectation for the peds programs, given that there's even more knowledge now, as Barry said, of the compound. So we'll update you further once they sort of have a little bit more momentum on them. We expect them to enroll very well and quickly.

Operator

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

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

Two for me as well. On Pemazyre, that has been launching ahead of expectation in cholangio, but we noticed that 2 additional studies here starting up in lung cancer and GBM. Could you just comment on the opportunity in addition to cholangio for Pemazyre and the path to market perhaps in other indications?

And the second question on Monjuvi. I guess based on the U.S. experience so far, how should we think about the potential launch trajectory in Europe, especially since you would presumably be launching into an environment that's less impacted by COVID at that time?

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

Michael, it's Steven. Thanks for the question on Pemazyre. So what we saw, we had an ongoing tumor-agnostic program, as you know, looking at different potential biologic drivers, whether they're fusions, rearrangements or amplifications or any other FGFR thing. And we started to see signals within that program in glioblastoma multiforme that had a particular molecular driver and then in non-small cell lung cancer that also had a particular molecular driver. And we elected to pull those 2 and pursue them as standalone entity separately based on the biomarker.

So we will work that out regulatory path now over the next few months with the regulatory agency, define the program and the eligibility criteria and then the study will go up on clintrials.gov and give you a little more information and granular details you want. But I will tell you, if you look at the prevalence of whether it be FGFR2 fusions or rearrangements or in some cases, FGFR3 as well, which may be particularly important in glioblastoma, the prevalence rates are sometimes in the single digits, 5% to 10%, sometimes a little higher. But obviously, in lung cancer, that's potentially enormous opportunity, given the number of patients, even if you have a 5% to 10% prevalence of a particular driver.

So I can't give you more detail yet because we don't have regulatory agreement on the path, but you can sort of see how it would pan out. It would be a molecular-defined entity within that histology rather than a tumor-agnostic program. I'll turn the question over on the launch trajectory in Europe.

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

Yes, in Europe, I mean, as you know, launching a new product is happening in a sequence, not like the U.S. where the entire country, 1 day, the product becomes available. So you can anticipate that we'll be starting with Germany. And then from there, we will have other countries being added as we go. Interestingly, a NICE recommendation now has been obtained already. So that should accelerate the availability in the U.K., which is very important. [The reference to tafasitamab in this comment was an unintentional error. A NICE recommendation has not been given to tafasitamab; tafasitamab has received a positive CHMP and COMP opinion] (added by company after the call).

And also, it's important to realize that the treatment in -- for DLBCL in Europe is not exactly following the same path as the U.S. And I think there is a very good chance that we can see based on the data that you know, I mean, the 3-year data was recently published, it's reaffirming the duration of response, the high complete response rate, and I think it will have a very good chance to be used in second line very quickly in many of these countries.

A reminder that we are really ready to launch it because we have an hematology team in place already in many of these countries from the Iclusig franchise and the relationship with physicians, the prescribers is already very well established. So the team is really optimistic about our ability to drive Monjuvi in -- Minjuvi in Europe quickly. And I think it will be successful.

I mean the COVID situation is very different from country to country. And frankly, it's difficult to predict how it's going to evolve over the next few months. But I think it will be better than what we have seen in the U.S. where we were already at the lowest point when the approval of Monjuvi in -- tafasitamab in the U.S. took place. So everybody is fairly optimistic, everybody is prepared, and I think it would be a successful launch.

Operator

Your next question is coming from Mara Goldstein from Mizuho.

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

So just -- I apologize if I missed this because I missed the beginning part of the call, but are you able to share with us the distribution of new patient starts for Jakafi according to indication? And similarly, for Monjuvi, can you update us on the status of just also that distribution of those patients, who are being treated in the second line versus later line of therapy? And I was also hoping that you could provide an update on itacitinib in the second-line myelofibrosis trial, the anticipated timing of data and what the strategy is for that drug at this point?

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

So Mara, all I can tell you is that new patient starts for Jakafi, for GVHD, MF and PV are all back to pre-pandemic levels for a while there. Bone marrow transplants were down and GVHD was down, but now it's come back strong over the last several months or even since the end of last year. MF and PV patients that really dropped off in early spring -- in spring and early summer of 2020, all came back and just even in the last month of June, came back to about the highest new patient start level that we've had for a long time. So it's really, GVHD growth is the highest in new patient starts and then PV new patient starts after that and then MF patients after that.

As far as Monjuvi goes, again, at least from our market research in the second-line setting, we're now the #1 drug used for diffuse large B-cell lymphoma patients in the second-line setting in terms of new patient starts. So that's where all of the new growth comes from and third, fourth or fifth line is falling off after that.

Steven, itacitinib?

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

Yes. Thanks for your question on itacitinib in myelofibrosis. So this is a different JAK inhibitor in terms of its JAK inhibition profile and is relatively JAK1 selective compared to ruxolitinib, if used that as a reference. And then in MF, as everybody is saying, there are different patient populations with different needs in terms of their underlying phenotype and cytopenias and thrombocytopenia, et cetera.

So the idea here is potentially with another JAK inhibitor, with a different JAK inhibitory profile, with a different PK that we'll be able to leverage some of that difference in terms of cytopenias and look for efficacy in populations, for example, that are more thrombocytopenic than others. It's still early days in terms of this program. So although we have quite a bit of data from earlier studies, this is now a standalone study and we'll see how it goes in terms of enrollment and then update you further. But I wouldn't anticipate data in the next year or so.

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

Okay. And if I also could just sneak in one more question and it's on the SG&A spending and the delay in rux cream. And how much of that increase in SG&A spending was associated with the anticipated launch of rux cream?

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

So the adjustment that we made to the SG&A guidance is $10 million on the low end to -- at around $20 million, the high end of the range. And this is primarily or really driven by the extension, the 3-month extension in the PDUFA for rux cream. So there are certain activities that were related, for example, to direct-to-consumer that we are planning to do this year once we launch that now, given the timing, we don't anticipate doing this year anymore and will be pushed up now to 2022.

Operator

Next question is coming from Jay Olson from Oppenheimer.

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

Can you please comment on your current thinking around European strategy for topical rux? And then on the time line for the vitiligo submission, does the submission for topical rux in atopic dermatitis have any impact on the regulatory filing in vitiligo?

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

Jay, it's Steven. I'll take your second question first and then turn it over on the European strategy. So it shouldn't in the bottom line. It's just a question of whether it would be an sNDA versus an NDA, right? But the idea would be that we get the approval on the PDUFA on September 21st, and we file vitiligo as soon as possible thereafter. They would -- and it shouldn't have any impact, particularly in the U.S.. You can have multiple files in it once there's no issue related to that. On your European strategy, I will it turn it over.

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

So in Europe, what we are planning to do is to submit first with vitiligo indication and that should be happening in the second half of this year, and that will give us an approval. If it's approved, that will help on the pricing side. And that's why we are doing it in that order. It doesn't mean that

we will never submit in atopic dermatitis, but it means that we'll be setting the price first in vitiligo and then we'll have to see what kind of data will be required to obtain a reasonable pricing in atopic dermatitis.

As you know, it has to do with comparators and the way the benefit can be evaluated compared to other products that have a certain level of reimbursement. So the sequence will be vitiligo in second half of this year potentially 1 year later being approved and then moving into atopic dermatitis.

Operator

(Operator Instructions) Our next question today is coming from Andrew Berens from SVB Leerink.

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

A couple of questions from me on the commercial infrastructure you're building for the topical rux franchise. Can you just remind us how many sales reps you're planning to hire for both indications? And can we get an update on where you are in that process currently? And just to clarify Mara's question, was any of the lowered SG&A guidance that you announced today related to a delay in head count reduction or hiring?

And then as a follow-up, what percentage of atopic derm patients are treated in the community versus a center of excellence? And then what percentage of atopic derm scripts are actually written by primary care physicians?

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

So Andrew, I can tell you, our field force is fully in place. We have 120 sales representatives in the United States, and they're up, ready to go. They're in the process of training and get to know their accounts. So that's that. As far as the note, SG&A has nothing to do with headcount because we have them fully on board, they're ready to go. We're anticipating the launch in September. So we're looking forward to that.

And as far as who writes what, so dermatologists for -- overwhelmingly write, at least, for the first script anyway for drugs like rux cream or most likely Eucrisa and so forth and obviously poor drugs like Dupixent, dermatologists are writing those. So -- and most of them are being treated in the community. Most of dermatology patients go to their local dermatologists in their community, not necessarily academic medical centers. We're very happy that most of the KOLs -- or all of the KOLs in dermatology are fully anticipating the approval of rux cream and looking forward to it.

And as far as primary care goes, yes, sure, they'll write for mild steroids. Maybe they'll write a refill script, but very little as far as our research goes that they'll be writing for rux cream, at least, currently. Now in the years to come, as everybody sees the efficacy and safety of ruxolitinib cream, then that could change.

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

Okay. And how often do the most patients see their dermatologist once they're diagnosed?

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

Well, it varies. I'm not sure if I can give you an exact answer. Certainly, patients who have troublesome eczema, they'll go back to their primary care physician -- their dermatologists every month, every quarter, how many flares they have, if they're controlled by whatever medication they're currently on. Obviously, if patients are severe and they're on biologics, they will see their dermatologist more often.

Operator

Next question is coming from Srikripa Devarakonda from SunTrust.

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

Just following up on the pediatric trial in the atopic term that you recently initiated. Our KOL checks have indicated that there could be a slightly greater hesitancy amongst parents, especially for the under 12 age group to use something like rux cream, even if it doesn't get a black box label, especially the orals get a black box warning. Is there anything in your market research that gives you confidence that this opportunity is worth pursuing in this population, also in the context of other competition in the pediatric population?

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

Kripa, it's Steven. I'll start and then Barry will talk about any market research. To enable the program, we had to do a lot of work with the regulatory agencies, particularly with the FDA, to make them comfortable that there wouldn't be any harm, so to speak, right? Remember, oral rux has now been on the market since 2011, is used in myelofibrosis, P Vera and graft-versus-host-disease and has ongoing pediatric work in leukemia population with the Children's Oncology Group. So we have a lot of experience with much higher exposures, if you will, of rux.

To enable the pediatric program before we got started, we had to do work around any potential on bone harm, et cetera. And we made, obviously, the FDA comfortable and reiterating this around the world to do it. So we -- as always, with the clinical trial, we have to have equipoise and first do no harm. And so we're very comfortable in the profile, and it's potential to obviously have enormous benefit and hopefully no safety signals. From a market research point of view, Barry will answer.

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

Well, we think that rux cream could be a very good treatment for kids, let's say, 2 to 12 that have eczema, atopic dermatitis that can't be controlled by other things. Obviously, there's a problem in those patients who -- because they can -- their only other choice really is steroids. We find that kids don't like really to use Eucrisa quite frankly because it burns and the topical steroids can only be used for a short period of time. So we think once we have the clinical data for the kids between 2 and 12 that this could be a very good option for them.

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

And I have a follow-up question on retifanlimab. The CRL for SCAC was certainly a disappointment, but was sort of in line with -- was in line with how the AdCom panel voted. Can you maybe talk about the strategy moving forward? I know you don't comment on discussions with FDA. But the pivotal Phase III trial, the panel talked about the rate of enrollment, particularly. Can you comment on how things have changed in the past few months, especially with things around COVID changing a bit?

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

Yes. Kripa, it's Steven. Thank you. Yes, we were disappointed in the ODAC outcome in the 13 to 4 vote, especially given we have done, to our knowledge, the largest study ever in squamous cell anal carcinoma plus had addressed the HIV population, plus what we thought as you saw we presented that the activity was in keeping with other checkpoint inhibitors in virally driven tumors. However, you saw the outcome and we got the Complete Response Letter.

The way it works now is you work with the agency on addressing the aspects of the Complete Response Letter, which we'll do. And again, confident in the data and hopefully lead to a -- if we make the FDA comfortable, a resubmission around with data that will make them comfortable in the risk benefit of it.

In terms of the ongoing first-line study, again, it was presented at the ODAC. It's done with the biggest group in the space interact. They are the ones we've done studies in this arena and actually had documented the first-line care standard in their own study, and that study is going well. There's no real COVID impact to that, given it's the only study in the space and it's a randomized study. So we're comfortable where we are there.

Operator

Next question today is coming from Stephen Willey from Stifel.

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

Just a couple of really quick questions on QD rux. So can you maybe just speak to any significant or potential differences that might exist between the current version of QD rux, and I guess, the prior sustained release version that was published a few years back? I know both were similarly on the pharmacology side in terms of obtaining bioequivalence. So just wondering if there's any additional differences that you would highlight between the 2? And then just lastly, curious how you're thinking about a QD fixed-dose combination in the context of potentially sacrificing some titratability?

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

Stephen, this is Steven answering your question. So it's good you bring up that older publication, which was a single strength, a 25-milligram slow release, that is actually one of the formulations. It's just that now we have multiple formulations. We've done the more complete work around bioavailability and bioequivalence and obviously approved the -- have the area under the curve we need to go forward with the submission should stability be okay. But just to be repetitive, that 25-milligram strength published a few years ago is exactly one of the strengths we have now.

In terms of fixed-dose combinations, I don't think we'll lose optionality because we can make multiple of them and there are different ways of providing that. And given that it's a very set strength and then for parsaclisib, for example, there may only be 2 doses that would be needed. So you'd have the dose that's approved and then a reduction dose. So optionality wouldn't be a problem. I don't think we'd lose any ability for people to titrate dose in any way. We're comfortable with where it may head.

Operator

Thank you. We reach the 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 all for the time today and for your questions. IR team will be available throughout the day for any follow-up questions you may have, and we look forward to talking to you at investor conferences in the coming weeks. Have a good 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.