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INCY.OQ - Q3 2023 Incyte Corp Earnings Call

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OVERVIEW:

Company Summary

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PRESENTATION

Operator

Hello, and welcome to the Incyte Third Quarter Earnings Conference Call. (Operator Instructions). As a reminder, this conference is being recorded. It's now my pleasure to turn the call over to Ben Strain, Associate Vice President, Investor Relations. Please go ahead.

Ben Strain - *Incyte Corporation - Associate VP, Head of Investor Relations*

Thank you, Kevin. Good morning, and welcome to Incyte's Third Quarter 2023 Earnings Conference Call. Before we begin, I encourage everyone to go to the Investors section of our website to find the press release, related financial tables and slides that follow the discussion related to today's call.

On today's call, I'm joined by Hervé, Pablo, Barry, Steven, Christiana, who will deliver our prepared remarks and will participate in the Q&A. I would like to point out that we'll be making forward-looking statements, which are based on our current expectations and beliefs. These statements are subject to certain risks and uncertainties, and our actual results may differ materially. I encourage you to consult the risk factors discussed in our SEC filings for additional detail. I will now hand the call over to Hervé.

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Herve Hoppenot - *Incyte Corporation - CEO & Chairman*

Thank you, Ben, and good morning, everyone. In the third quarter, we continued to deliver double-digit revenue growth, important successes in pricing and reimbursement and continued progress of the pipeline.

Product and royalty revenues were $914 million in the quarter with an 11% growth year-over-year, driven by Jakafi and Opzelura. Jakafi net sales in the quarter were impacted by inventory variation, which Christiana will detail in her prepared remarks. As you see in the first 9 months, Jakafi growth continues at a rate of around 8% this year. The growth trajectory of Opzelura continued in the third quarter with net product revenue of $92 million driven by both new patients and refills in AD and Vitiligo.

In the first 9 months of 2023, Opzelura revenues contributed $229 million, and we expect Opzelura to continue to be a key contributor to the growth of Incyte in the next years.

On Slide 6, we made important progress this quarter on 2 fronts related to pricing and access. First, as the IRA is implemented, we secured small biotech exception status for ruxolitinib. This has 2 impacts on Jakafi pricing and gross to net in the coming years. One, we expect that Jakafi will be exempted from negotiation until 2029, making it de facto neutral to our initial business plan. And two, as you can see, we expect to benefit from the specified small manufacturer phase-in schedule for part D catastrophic coverage versus the standard benefit, which will have a meaningful impact in the years 2025 to 2031.

For Opzelura coverage in the U.S., starting in 2024, Opzelura will be listed as a preferred brand on the CVS Caremark and Aetna formularies, which will benefit roughly 30 million commercial lives. This achievement will move Opzelura to preferred brand from non-preferred brand tier and will result in increased access by reducing both step-edit requirements, patient copay for many patients while maintaining Opzelura's favorable utilization management criteria.

Turning to Slide 7. We continue to make progress in our clinical development efforts across our portfolio. Just last week, we obtained new top line results from the Phase II randomized study assessing the efficacy and safety of povorcitinib, our oral JAK1 inhibitor in patients with prurigo nodularis. The study met its primary endpoint across all 3 treatment dose groups and povorcitinib was generally well tolerated. There are approximately 100,000 treated patients in the U.S. with prurigo nodularis with limited treatment options, and we are excited to move this program forward based on the Phase II data. Steven will provide additional details.

During the quarter, we had a significant presence at EADV, where we presented the full Opzelura atopic dermatitis data in the pediatric population and positive long-term extension data in Vitiligo. We also shared new positive data from the Phase IIb clinical trial of povorcitinib in adults with extensive Vitiligo. By the end of the year, we anticipate providing additional data from other key programs, including an update on our oral PD-L1 program, additional combination data of ruxolitinib plus ALK2 and BET and full disclosure of a novel preclinical program targeting the JAK2V617F mutation, which has the potential to be a disease-modifying therapy for many patients with myeloproliferative neoplasms. I will now turn the call over to Barry, who will discuss our commercial performance in more details.

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

Thank you, Hervé, and good morning, everyone.

Starting with Jakafi on Slide 9. Jakafi continued to experience increasing patient demand during the quarter as we delivered 2023 year-to-date net sales of $1.9 billion, growing 8% year-over-year while total patients for the first 9 months has also grown 8% year-over-year across all indications.

The quarter-over-quarter impact in net sales is primarily attributable to fluctuations in channel inventory. Recall that we reported exiting Q2 at the high end of our normal inventory range and inventory drew down modestly in Q3. We continue to see strong growth in underlying demand and now are tightening our full year 2023 guidance to a new range of $2.59 billion to $2.62 billion.

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As we look to the future for Jakafi, PV will be a key growth driver, particularly considering that a significant portion of patients are not receiving adequate benefit with hydroxyurea. Now for the first time, we have data that clearly demonstrates the thrombosis-free survival benefit that can be achieved with Jakafi. The data shows that patients who are not being adequately controlled and are switched to Jakafi experienced a 44% reduction in the risk of major thrombosis. We are already hearing from thought leaders that this data is game-changing in PV and reinforces the importance of early intervention for these patients. We believe this important data will help drive earlier use, allowing us to further penetrate the PV market.

Turning to Opzelura on Slide 11. The launch continues to be strong and is gaining positive momentum with both physicians and patients as we establish Opzelura as one of the best recent dermatology launches. Looking at the first 2 years post FDA approval, Opzelura outperforms all other dermatology products on a launch-aligned basis. The rapid adoption of Opzelura is driven by its compelling product profile and its ability to address significant unmet need in both atopic dermatitis and vitiligo.

Opzelura net product revenues in the quarter were $92 million, up 141% when compared to the same quarter last year. U.S. patient demand increased during the quarter with total prescriptions growing 72% year-over-year and refills growing by 19% versus the prior quarter with over 9,100 dermatologists now having prescribed Opzelura. The weekly prescription trend, as shown on the right, demonstrates the continued growth of Opzelura, which is coming from both atopic dermatitis and vitiligo. In AD, growth was primarily due to new patient flow driven by Opzelura's efficacy and impact on inflammation and itch. In vitiligo, where Opzelura is the only approved treatment for repigmentation growth was driven largely by refills and our educational and awareness initiatives.

We remain very optimistic about the long-term potential of Opzelura as we continue to see the strong uptake and positive momentum.

We are also working to drive new patient growth and adherence through ongoing initiatives. During the quarter, we kicked off a new marketing campaign called Moments of Clarity featuring Mandy Moore. The goal of this campaign is intended to bring to life the stories of real people struggling with eczema, who found relief by talking to their dermatologist and to build broad awareness of Opzelura as a nonsteroidal topical option on mild to moderate AD patients. The campaign secured several high-profile media placements, including coverage with top-tier outlets like [The TODAY Show] and People Magazine. We are also continuing to roll out DTC initiatives in vitiligo, which is building awareness, driving demand and activating patients to discuss treatment options with their dermatologist.

Turning to Slide 14. We continue to make advancements with our payer coverage for Opzelura. In AD, payer adoption continues to improve with regional plans. And as of today, we have roughly 84% commercial coverage for Opzelura and atopic dermatitis covering over 127 million lives. In vitiligo, we have made significant progress since the launch and have improved our coverage by roughly 30% throughout 2023. The most recent progress was with Blue Cross Blue Shield Federal Employee program, which accounts for over 5.5 million lives. Additionally, as Hervé mentioned, Opzelura will be moving from non-preferred to preferred brand tier effective January 1, 2024, for CVS Caremark and Aetna formularies. With that, I'll turn the call over to Pablo.

Pablo J. Cagnoni - *Incyte Corporation - President and Head of Research & Development*

Thank you, Barry, and good morning, everyone. As you may recall, earlier this year, we made the decision to increase our focus on 8 high potential programs. Consistently with this, our near-term goals for the R&D organization will be to increase the rigor of our decision-making accelerate the progression of our pipeline and increase our efficiency to optimize our resource allocation.

Before I hand the call over to Steven for an update on some of our later-stage programs, I would like to spend a few minutes highlighting some of our key earlier-stage programs to give a more clear picture of the depth and quality of our pipeline. During the third quarter, our TGF-beta receptor 2 by PD-1 bispecific antibody entered the clinic and the Phase I dose escalation study is progressing well. It has been designed with high selectivity for the PD-1 receptor combined with TGF-beta receptor 2 inhibition and it has the potential to enable a synergistic approach to target multiple immunosuppressive pathways across a number of cancers.

INCA34460 is a novel humanized anti-IL-15-receptor beta monoclonal antibody that's designed to target and deplete autoreactive tissue resident memory T cells. It has demonstrated efficacy as a treatment for vitiligo in preclinical models and received IND clearance last quarter. We have since

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initiated the Phase I single-dose ascending study. We also dosed the first patient for the Phase I study of our novel anti-mutant CALR targeted monoclonal antibody with the potential to eradicate the malignant clone in certain patients with myeloproliferative neoplasms and significantly modified disease outcomes. CALR mutations are responsible for disease development in approximately 25% to 35% of patients with MF and ET.

We're disclosing today for the first time, a program targeting the JAK2V617F mutation, the most common somatic mutation in myeloporoliferative neoplasms. The JAK2V617F mutation is located in the JH2 domain of the JAK2 receptor and is present in 55%, 60% and 95% of patients with MF, ET and PV, respectively. Unlike ruxolitinib, which inhibits both wild-type and V617F mutation positive cells, INCB160058 selectively binds to the JAK2 JH2 site, disrupting the V617F induced confirmation and thus, allowing selective inhibition of mutant activity in the JAK2 receptor while sparing wild type. We expect to file the IND by year-end 2023 and enter into the clinic in 2024.

Together with our anti-mutant CALR program, theses 2 potentially disease-modifying programs represent a fundamentally new approach to addressing MF, ET and PV and solidify our leadership in MPN. With that, I would like to pass the call to Steven, who will further highlight some of our key achievements this quarter with our Mode Advanced programs. Steven?

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

Thank you, Pablo. Starting on Slide 19. As Hervé mentioned, we obtained the top line results from the Phase II randomized, double-blind, placebo-controlled dose-ranging study assessing the efficacy and safety of povorcitinib in patients with prurigo nodularis. The study met the primary endpoint for all povorcitinib doses studied of 15, 45 and 75 milligrams and at week 16, 36.1% 44.4% and 54.1% of patients, respectively, achieved the primary endpoint versus an 8.1% rate for patients on placebo. The primary endpoint was designed to assess the proportion of patients achieving a greater than or equal to 4-point improvement in itch at week 16. Povorcitinib was generally well tolerated across all doses and the safety analyses were consistent with previously presented data with no new reported treatment-emergent adverse events. We plan on presenting the full data set at an upcoming medical conference in the first half of 2024.

As a result of these very encouraging findings, plans are underway to initiate a Phase III study in 2024.

We had a significant presence at the European Academy of Dermatology and Venereology Congress earlier this month, which highlighted our commitment to the atopic dermatitis and vitiligo communities. In a late-breaking oral presentation, we presented positive 52-week data from a Phase IIb clinical trial evaluating the safety and efficacy of povorcitinib in adult patients with extensive nonsegmental vitiligo. These results showed that treatment with oral povorcitinib was associated with substantial total body and facial repigmentation across all treatment groups at week 52 and was well tolerated at all doses throughout the study. During the 24-week post-treatment period, total body and facial repigmentation was also maintained, which suggests durability of response following treatment discontinuation.

These data further reinforced the efficacy and safety profile of povorcitinib as an oral treatment for patients with extensive nonsegmental vitiligo, and we plan to initiate the Phase III study by the end of this calendar year.

Povorcitinib has already demonstrated outstanding efficacy in the Phase II program in hidradenitis suppurativa. As a reminder, 52% to 56% of patients treated with povorcitinib achieved a HISCR50 at week 16 with responses improving to 59% to 67% at week 52. Additionally, HISCR100 response which is complete resolution of all manifestations of the disease was reported at week 52 in up to 29% of patients. The two Phase III studies STOP HS1 and STOP HS2 are enrolling very well and this reflects the strong Phase II data presented earlier this year.

We continue to expand the povorcitinib program focused on the science while leveraging our extensive dermatology capabilities. We look forward to advancing the development of povorcitinib in areas of unmet need which is currently being evaluated in two Phase III studies in HS and moving into a Phase III program for vitiligo and prurigo nodularis. Work continues in the Phase II proof-of-concept studies in asthma and chronic spontaneous urticaria.

Moving to ruxolitinib cream on Slide 23. Also presented at EADV with expanded results from the pivotal Phase III TRuE-AD3 study, evaluating the safety and efficacy of ruxolitinib cream in children 2 to 12 years old with atopic dermatitis. These data showed significantly more patients treated

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with ruxolitinib cream 0.75% and 1.5% achieved Investigator's Global Assessment Treatment Success than patients treated with placebo. Treatment with ruxolitinib over 8 weeks under maximum use conditions was also well tolerated in children.

Expert feedback on the data has been consistently positive namely that ruxolitinib cream could be advantageous to the currently available nonsteroidal topical options and an important option before resorting to currently available injectables. We are excited about the potential relief ruxolitinib cream can bring to the over 2 million pediatric atopic dermatitis patients in the United States.

As a late-breaking oral presentation at EADV, new results from the pooled analysis of the long-term extension data from the pivotal Phase III TRuE-V program were presented. The long-term study extension evaluated Opzelura in patients 12 years and older with nonsegmental vitiligo who previously experienced limited or no response to treatment at week 24. The data demonstrated that prolonged treatment of ruxolitinib cream led to increased facial and total body repigmentation in those patients who were initial nonresponders. Approximately 70% of patients saw improvements in facial VASI and total VASI at week 52 which increased to 85% by week 104.

Throughout the long-term extension, Opzelura continued to be well tolerated with no serious treatment-related adverse events. This data highlights the importance of prolonged treatment in patients with vitiligo even when limited or no repigmentation is achieved in the first 6 months of treatment.

On Slide 25, we continue to advance Opzelura development beyond AD and vitiligo and into other indications where there's the potential to provide significant value as either the first approved therapy or first approved topical therapy for patients living with these dermatologic conditions. We currently have three Phase II studies, which have recently completed enrollment in lichen planus, lichen sclerosus and mild to moderate HS, and 2 additional Phase III trials evaluating Opzelura in prurigo nodularis, which are all currently enrolling patients.

Finally, on Slide 26, we have a number of upcoming data readouts and other exciting milestones expected, and we look forward to sharing additional details throughout the remainder of this year. With that, I would like to turn the call over to Christiana for the financial update.

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

Thank you, Steven, and good morning, everyone. Q3 total product revenues were $783 million, representing a 10% year-over-year increase. In the first 9 months of 2023, total product revenues were $2.3 billion, representing a 16% year-over-year increase. Total royalty revenues, which are primarily comprised of royalties from Novartis for Jakavi and Tabrecta and royalties from Lilly for Olumiant were $131 million in the third quarter and $374 million in the first 9 months of the year.

Turning to Jakafi. Jakafi net product revenues were $636 million for the third quarter and $1.9 billion in the first 9 months of 2023. In the first 9 months of the year, Jakafi net sales grew 8% compared to the same period last year. While Jakafi demand net sales have continued to steadily increase quarter-over-quarter, in the first 2 quarters of 2023, we saw more notable fluctuations in channel inventory levels which resulted in some variability in the quarterly reported net sales. As we had previously shared, at the end of Q1, channel inventory levels fell below the low end of the normal range recovering in Q2 and ending the second quarter towards the high end of the normal range.

At the end of Q3, channel inventory levels returned to the midpoint of the normal range. In the third quarter of 2023, the decrease in inventory had a $14 million negative impact on reported net sales.

Turning now to Opzelura. Net product revenues for the third quarter were $92 million, representing a 141% increase year-over-year, driven by increased patient demand and expanded coverage. In the first 9 months of the year, total Opzelura net product revenues were $229 million.

Moving on to Slide 32 and our operating expenses on a GAAP basis Total R&D expenses were $376 million for the third quarter, representing a 2% year-over-year decrease, driven primarily by the decrease in onetime collaboration-related expenses partially offset by continued investment in our late-stage development assets and timing of certain expenses. Total SG&A expenses were $268 million for the third quarter representing a 1% year-over-year growth.

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Moving on to our guidance for 2023, we are tightening our guidance range for Jakafi to a new range of $2.59 billion to $2.62 billion. We are reaffirming our other hematology oncology revenue, COGS, R&D and SG&A guidance for the year. 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.

Unidentified Analyst

This is [Anna] for Salveen. First, could you help us understand Opzelura gross to net trends during the quarter and your expectations on the forward? And then just a quick question on the combo data with Jakafi ALK2 and BET that's expected in 4Q. I guess, in the context of where the once-a-day dosing stands and the overall combination strategy and the positioning of each asset. Can you just help us understand your thinking on how this could play out from a life cycle management standpoint?

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

[Anna] It's Christiana. I will take the first part of your question and then turn it to Steven. Regarding the gross to net for Opzelura in Q3, gross to net was 54%, down from 55% in Q2 and 60% in Q1. As we said in our prior call, in last quarter's call, we expect gross to net to continue around that 55% level. And any improvement would very much depend on the evolution of Medicaid.

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

And [Anna], in terms of your second question and the life cycle management of ruxolitinib in myeloproliftive neoplasms and beyond, including Graft-Versus-Host-Disease. Just to take the components of your question separately, the once-daily dosing, we continue to work with the FDA on a response. And one of the efforts involves modeling that may be a little shorter in terms of timeline and one may require some further work. Regardless of the effort we undertake, both will be delivered way before the LOE for ruxolitinib. So that we'll pursue and continue.

In terms of ALK2 and BET, both very important combinations, we're showing further monotherapy and combination data at the American Society of Hematology meeting in December. So you'll have to wait for those abstracts and the meeting itself to see the data. But it's more data in terms of monotherapy and combination.

Your question relates to how they may play out. ALK2 is principally addressing hepcidin inhibition and then resulting in hemoglobin improvement, and the idea there would be to treat both the anemia from myelofibrosis as well as potentially the drug-induced anemia from RUX, and we'll see how that data evolves. That is already a mechanism that has demonstrated the ability to shrink spleens, splean volume reduction to improve symptoms and also through epigenetic means improve hemoglobins. And we've already shown quite substantial efficacy with our own program. We'll see how other competitive programs play out in the short term. We'll show you data at ASH, and then we'll direct you towards our registration-directed efforts here.

It could be plays in the first-line setting in combination with RUX in the suboptimal setting in combination with RUX and even as monotherapy post JAK inhibitors, there's substantial efficacy with the BET program. And then just to round out LIMBER, let me remind you, axatilimab is a positive Phase III this year with really excellent data in third-line graft versus host disease, and that submission is going in and we'll progress that through the regulatory cycle. Thanks.

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Operator

Next question is coming from Tazeen Ahmad from Bank of America.

Tazeen Ahmad - *BofA Securities, Research Division - MD in Equity Research & Research Analyst*

Just one for me. I just want to get a sense of how you're thinking about the evolution of the competitive landscape as it relates to Jakafi. There's been a recent new approval for momelotinib for a subset of patients that might be on Jakafi. How are you thinking about marketing Jakafi in relation to this newly approved drug? And do you think that there's any risk of that drug taking market share?

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

Sure, Tazeen, this is Barry. So as we think about competition in myelofibrosis, there was already 2 other JAK inhibitors on the market. And neither of those JAK inhibitors have really penetrated and their approvals have actually been in the first and second line setting and haven't really moved at all over many quarters now in terms of their market share, or quite frankly, in terms of their net sales.

For momelotinib itself, Jakafi was compared directly in SIMPLIFY-1 study to momelotinib and momelotinib failed in that study. The approval that they received, both in the first-line and second-line setting for patients with anemia, Jakafi is, in fact, the only drug that really has superior overall survival in myelofibrosis patients regardless of anemia.

So in other words, patients who have anemia and got Jakafi for myelofibrosis, have a survival advantage. So that strong designation gives us confidence that we'll continue to be the leader in myelofibrosis. Additionally, of course, patients are started -- myelofibrosis patients are mostly started on therapy when they have symptoms. And Jakafi clearly is the most effective therapy when it comes to managing symptoms and spleen, and then momelotinib, just like the other drugs are, in fact, much more costly than Jakafi, momelotinib being $26,900 per month, 60% or so higher than Jakafi. So it seems like it was priced for a second-line drug, and we think that's where it will be mostly used.

Operator

(Operator Instructions). Our next question is coming from Brian Abrahams from RBC Capital Markets.

Leonid Timashev - *RBC Capital Markets, Research Division - Biotechnology Analyst*

It's Leonid on for Brian. I just wanted to go back to maybe some of the reimbursement dynamics with Opzelura. You guys mentioned the preferred brand designation from Caremark and Aetna. I guess I'm curious, how do you anticipate that impacting access and ultimately pulling through the utilization? And did you guys have to make any net pricing concessions for that? And I guess related to that, is this contracting that you're working on with some of the other payers as well?

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

Sure, Leonid. Barry again. So in terms of Caremark, CVS Caremark, in particular, it's very important in terms of access for the patients. We're trying to make it as easy as possible for dermatologists to prescribe the drug and then for patients to receive it. So in this particular situation, we're going from a double step for atopic dermatitis. So patients would have had this to go through topical steroids and topical calcineurin inhibitors before they get to Opzelura, and in Vitiligo also had to go through multiple steps. Now in Vitiligo as it should be because of the label and the only drug approved for vitiligo that repigments the skin for vitiligo, having no steps to go through. So first line therapy is excellent. And just having to go through 1 step because most patients will have, in fact, use topical steroids when they have AD, so that makes it much easier.

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In terms of contracting and concessions, there's always a negotiation, of course, with the PBMs and the payers over rebates and fees and so forth. So it might cost us a little bit more on the rebate and but in fact, then the co-pays generally go down. And most importantly, what we're really trying to achieve is volume. And then I suppose your last question is the negotiations with payers always continues. We don't really have to have any further negotiations unless we choose to until 2025 for Opzelura. But there's always the -- there's always a chance that we come back and decide to do something slightly different in terms of getting in terms of making access easier for patients. Most of the contracts that we have in place currently in fact, allow patients to -- allow plans to step up and change their step therapy from 2 to 1 and so forth.

Operator

Your next question today is coming from David Lebowitz from Citi.

David Neil Lebowitz - *Citigroup Inc., Research Division - Research Analyst*

Would you be able to give us insight on the current -- I guess, rate of the number of tubes per patient in AD -- excuse me, AD and vitiligo you were expecting? Have there been changes in expectations and where you think stand right now?

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

Sure. So in terms of AD, I think we had it on the slide, it's around 2. We've been saying that for a while. We expect 2 tubes per patient for atopic dermatitis on average. Obviously, some patients we'll get a lot more than that. In vitiligo, we need some more time really to evaluate exactly in the real world how patients will receive Opzelura for vitiligo. So patients who have -- might just apply the drug to the face, for example, or apply it all over their body, it varies.

But we'll continue to track the number of tubes for vitiligo, but obviously, with our data so far, long-term extension data, patient can use it safely for years, and continue to get benefit. So we'll update you when we have more information as we gather more data as we have more use in vitiligo.

Operator

Your next question is coming from Jessica Fye from JPMorgan.

Jessica Macomber Fye - *JPMorgan Chase & Co, Research Division - Analyst*

Curious if you'll be in a position to provide Opzelura sales guidance for 2024. And with respect to your bet, what you'll be looking for in the upcoming pelabresib results?

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

So Jess, I'll take the first part of the question regarding the Opzelura guidance. As we've shared with you in the past, in order to provide guidance, we want to have a few quarters of real world experience with Opzelura, especially for vitiligo, given that it is a new market. And be able to see how in the real world utilization is how many tubes on average vitiligo patients use, and also how quickly and at what rate in active patients can get in to see their physicians and get on therapy. So we are still very early in the launch of Vitiligo, and we continue to monitor the progress and we want to see a few more quarters before we are in a position to provide guidance.

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

And then in terms of your question related to BET inhibition in myelofibrosis, the competitor ongoing first-line study, which you allude to is what we consider a pretty standard first-line study in about 440 patients, the primary endpoint is spleen volume reduction of 35% or greater and already communicated, it has to be an end in terms of the secondary endpoint of heading total symptom score, 50% improvement or above versus the competitor RUX in that situation.

For our own BET inhibitor, as I said earlier, both monotherapy data, we've really shown spleen reduction, symptom response and some hemoglobin responses and then the ongoing combo work showing the same. And we'll have to see how that data plays out versus what the competitor delivers in their first-line study in terms of our registration efforts, and we'll communicate further about that at the ASH meeting coming up in December.

Operator

Your next question is coming from Marc Frahm from TD Cowen.

Marc Alan Frahm - *TD Cowen, Research Division - MD & Analyst*

Maybe first to start on the commercial side to follow up on one of the prior questions. Just Barry, on a blended basis, given this is a pretty large plan that you're moving up the formulary, but on a blended overall basis for the franchise, should we expect gross-to-net to kind of incrementally increase in '24 versus the full year '23, given that move?

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

Marc, I'm not really sure, to be honest with you, we'll have to see what the volume is and what the improvement in co-pays is to see how it affects our gross to net. But anyway, we'll see, but there's always a chance that we could actually benefit a great deal from net sales by making it much easier for patients to be able to access our drug.

Operator

Next question is coming from Vikram Purohit from Morgan Stanley.

Gospel M. Enyindah-Asonye - *Morgan Stanley, Research Division - Research Associate*

This is Gospel on for Vikram. We have 2 questions for Jakafi. I mean due to the recent approval of GSK Ojjaara. The first 1 is what portion of MF patients using Jakafi do you estimate are using this optimal dose due to anemia. And in this patient population, have you seen an increased rate of discontinuations as prescribers and patients potentially move towards Ojaarra.

And secondly, have you observed a decrease in Jakafi new patient starts in MF since Ojaarra was approved. Thank you.

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

Well, Gospel, the most important thing is that -- so -- Ojjaara only got approved on September 15. It really only launched in the last week of the year. I'd be surprised that there was actually any sales, except for stocking sales in the quarter.

So anyway, so I can't imagine that would affect any part of us yet.

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Now, what percent of patients might be receiving a suboptimal dose. What we've only said before, I believe, is that the number of patients who are at steady state on 5-milligram twice a day dose or something like that is only about 5% of our patients. I believe those patients are actually getting benefit, but that's the most. And just like in our clinical trials, COMFORT-I trial, I mean, only 1 patient discontinued for anemia. So we don't believe that's a big part of it. And like I said before, about the benefits that Jakafi provides the MF patients, whether they're anemic or non-anemic it's overall survival, it's symptom control, it's spleen control. So far, we don't really see -- we don't really anticipate an impact by momelotinib certainly in the third quarter.

Operator

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

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

I wondered on the povorcitinib Phase III planned in vitiligo, how you can structure that trial to complement the current Opzelura utilization opportunity? Is it really just around baseline VASI scores. And then as you think further out about additional opportunities for povorcitinib, what are you keeping in mind considering that it looks based on the profile so far as to work in a pretty wide range of more classical autoimmune indications, but clearly there you might have more competition.

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

Matt, it's Steven. Thanks for the question. So in terms of vitiligo, as we showed you the data in more extensive nonsegmental vitiligo, we saw a really good effect in terms of Facial-VASI, Facial-VASI 75% and above. and then total VASI as well, body repigmentation of 50% or above. We will disclose when we go on to clinicaltrials.gov what the endpoints are and what doses we'll be using. So it's premature to point you towards that, other than just broadly tell you that the population we target in is people with more extensive body surface area involvement when you compare it to the cream, which is indicated for people with 10% or below. This would open up the vitiligo community with people with much more extensive body surface area involvement where it becomes a little pragmatically hard to apply cream across the body and an oral JAK can be used in that setting with the right therapeutic ratio. And as we guided to, we want to get this study going by the end of this calendar year.

Povorcitinib is relatively JAK1-specific. You saw the program in HS, both STOP HS1, HS2 enrolling really, really well based on the -- what we think is excellent Phase II data, including that HiSCR 100 response. But as you alluded to, we have now data in purigo nodularis, that's excellent, and we want to progress that into Phase III. And then ongoing efforts beyond dermatology in asthma and chronic spontaneous urticaria, where the biology points to this kind of JAK1 agent potentially showing substantial benefit in patients with more severe asthma who on inhaled corticosteroids, long-acting bronchodilators and still having early exacerbations. That's a Phase II proof-of-concept study and then standard endpoints in chronic spontaneous early carrier. So this drug has demonstrated thus far remarkable activity in those areas where we study in Phase III now, and we'll see what happens in asthma and CSU.

Operator

Next question today is coming from Michael Schmidt from Guggenheim Securities.

Paul Jeng - *Guggenheim Securities, LLC, Research Division - Equity Research Associate*

This is Paul on for Michael. I just wanted to build on the prior question. Can you talk about how you plan to position povorcitinib in purigo nodularis the planned Phase III relative to sort of how you design the ongoing Phase III studies for Opzelura. Is there a meaningful difference in the target patient populations? And how should we think about the specific addressable opportunities within the endpoint for the 2 programs?

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

Yes. Thank you for the question. Just in terms of -- and Hervé said this upfront in his remarks, there's a prevalence upwards of 200,000-plus patients, but there are about 80,000 to 100,000 that currently get treated in the setting. And their main manifestation of their disease is itch and very severe itch. And that's what the Phase II showed that activity in that setting across the dose ranges. I think it's premature beyond that to talk about the endpoint and the dose we'll be using because we've just got the Phase II data in. But it will be, again, because it's an oral agent targeting the more severe spectrum of PN. That's what I can tell you now.

Operator

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

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

I just was hoping actually to get a little bit more color on the Medicaid penetration with respect to Opzelura. Because last quarter, it was identified as a jump in the payer mix that had an effect, right on Opzelura and the gross to net? And then secondarily, I'm just hoping maybe you could talk a little bit about PV for Jakafi. I mean it looks like the percentage just eyeballing it, right, of Jakafi sales from PV has remained relatively stable. And I'm curious as to with this new data and potentially earlier patient starts where you think the growth could be?

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

Sure. So in part as Medicaid patients for Opzelura goes, it's about 14% of paid patients. As we said in the past, we had such good coverage for Medicaid throughout all 50 states that it was sort of -- grew faster than perhaps the commercial patients. So I think that answers part of your question. For Jakafi in PV, I guess if you're looking at the slide that we had there, PV, it continued in terms of the patient share. It's about 35% or so. At any given time, for example, this year, year-to-date, there's more than 8,000 patients on PV. But PV patients stay on the drug for a long time. So we're talking about what we think now the average is about 41 months that patients are staying on Jakafi for PV. So that's important. So every new PV patient becomes that more important. And we think that there's lots of patients who are currently on other therapies, including hydroxyurea, that would benefit from moving to Jakafi earlier. And now that we have a study where there was no crossover so that you can actually evaluate the long-term thrombosis-free survival and in fact, progression-free survival for patients that, that's really an indicator that you really should start earlier with an effective therapy like Jakafi. And we think that's really where the upside is here is that each and every PV patient is valuable and we can provide them with really effective therapy to manage their disease long term. So that's what our growth expectations are.

Operator

Next question today is coming from Andrew Berens from SVB Securities.

Andrew Scott Berens - *Leerink Partners LLC, Research Division - Senior MD of Medical Supplies and Devices & Senior Research Analyst*

Can you remind us how you see INCA033989 fitting into the treatment paradigm for MF relative to the JAK agents? And then do you see the regulatory pathway leveraging surrogate endpoints for approval? Or would you want to show a decrease in malignant transformation in this subgroup?

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

Andy, were you are asking about Steven -- just to clarify your question about mutant CALR and JAK2V617F in the future, we couldn't hear clearly your first part of question.

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Andrew Scott Berens - *Leerink Partners LLC, Research Division - Senior MD of Medical Supplies and Devices & Senior Research Analyst*

Yes. Just I'm trying to understand how you see that fitting into the treatment paradigm relative to the JAK agents?

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

Okay. Great. Thank you. So as Pablo said in his remarks, a remarkable effort from our research group to come up with compounds that now target new areas of biology. So in terms of mutant CALR, it's about 25% to 30% of myelofibrosis and ET. It's a neoantigen that's expressed and the antibody targets that and could eradicate the clone. So you could be talking about a very new treatment paradigm that's disease-modifying or potentially "curable" if you eliminate the clone in those settings.

Obviously, we're early in the clinic. We need to prove it safe and get there. But there's a lot of excitement and obviously, you've got a plenary at ASH last year because of that with the mutant CALR antibody.

In terms of where it fits in, it won't be an agent that's in the way we think about spleen volume reduction and symptom improvement, it could be, as I said, to be a little bit repetitive, eliminate the clone and sort of get rid of the disease, if you will.

The same with V617F, a target that many have pursued for a long time. And again, credit to our research group for coming up with, as Pablo pointed out, a very novel way of targeting the mutation in the JH2 domain. And then again, the idea would be to eliminate the clone and disease modified, and this, it's a bigger population. It's about 50% of MF, 60% of ET and 95% plus of polycythemia vera. So for the first time now, we've been able to show you that mean -- we've come up with a target in PV where it's an area where we haven't been able yet to give you anything new beyond RAK. So we're very excited about that. Again, it's early. We have to get the IND across the finish line and get into the clinic, but it's a superb science and would be a very different way of thinking about those entities.

Operator

Next question is coming from Jay Olson from Oppenheimer.

Unidentified Analyst

This is (inaudible) for Jay. So just a follow on the prior question, just for the V617F mutations. I'm just wondering you are thinking about the monotherapy versus combination approach going forward. And just on the slide, it seems like the CALR mutations and the V617F mutations are mutually exclusive. So I just want to confirm if that's correct.

And just a quick question on Opzelura. I wondering if you can talk about the split between AD and vitiligo in 3Q, that would be great.

Pablo J. Cagnoni - *Incyte Corporation - President and Head of Research & Development*

So this is Pablo. Let me take the first part of the question. So as Steven mentioned and I explained in my remarks, it's early days for both programs. I think that when you start thinking about how to position them and the potential combination with Jakafi, I think we need to get through a few cohorts in the Phase I studies, understand the profile of these 2 new medicines, and then we'll start building a combination strategy. I think potentially that could be the case, particularly as you start thinking about symptom resolution with Jakafi early in the treatment paradigm and then using either V617F or the mutant CALR antibody to then try to eliminate the clone and potentially transform the outcomes in these diseases.

The second part of your question, I think, was related to whether these are mutually exclusive. And they are. And that's actually an important point in understanding how to position them in the future.

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And then I think you had a question about AD, which I'll pass over to Barry.

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

Yes, (inaudible), I didn't really hear you. So AD versus vitiligo, what are you trying to say? What is the -- whether there's a script volume?

Unidentified Analyst

Yes. Script split between AD and vitiligo.

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

Sure. Currently, it's about 60:40. So 60%, AD. 40% vitiligo.

Operator

Next question is coming from Ren Benjamin from JMP Securities.

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

Maybe for Steven. Steven, can you talk a little bit about how you view the competitive landscape in PN and HS. And could the landscape change prior to your Phase III readouts? Or are you the clear sort of market leader in both indications? .

And I guess, just as a second sort of follow-up question maybe for Hervé. You guys are generating significant cash flow. You have a strong balance sheet. The pipeline is largely ignored by investors and this is significantly down. Can you talk maybe a little bit about the process that you might be going through to maybe switch gears, maybe acquire an entire company platform pipeline and all versus striking kind of one-off product collaboration agreements.

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

I'll start and then hand it over to Steven. So let me remind you to povorcitinib's oral agent. In both entities, you're talking about are becoming very interesting in terms of the science, a lot of targeting with different modalities, but they're mostly intravenous IV large molecules that target things like IL-17. So a very specific biology, whereas in these entities, there's more broad biology, and that's why we think JAK may be important here both in PN and HS. An oral agent, now we've shown what we think is very strong proof-of-concept data in both entities. HS, we have ongoing 2 Phase IIIs and PN will be proceeding there. Sure, the landscape can always change. As part of any assessment we do, we look at the competitive landscape and what may occur. But in terms of an oral agent, we think that's the big differentiator here, and then I'll hand it Hervé for your second part of your question.

Herve Hoppenot - *Incyte Corporation - CEO & Chairman*

So your question about the way are we sort of turning into a new direction regarding the use of cash. And the answer is we are still continuing to look at opportunities outside of the company. We are still investing in our pipeline. But as you have noticed, our growth of the revenue continues to be faster, higher than the growth of our expenses. So we continue to generate leverage and we continue to have an increasing cash flow quarter after quarter. And we are looking at opportunities to continue to add to the growth of the corporation in the year, '25 to '30. So it's a relatively broad target. Obviously, valuations have been fluctuating a lot in the past months, and it's creating opportunities that we are looking at.

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So there is a clear willingness for the right price to add new products that would be fitting with our portfolio, if we can. We could do it through partnership or acquisition. In fact, we think both would be appropriate, and it's a financial question or it's a question of willingness to go one route or the other, but we could do it either way.

Operator

Next question is coming from Derek Archila from Wells Fargo.

Unidentified Analyst

This is [Evelyn] for Derek. A quick 1 from us. Can you provide some color on the pace of the pipeline development and whether it will be timely enough to offset Jakafi loss of exclusivity?

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

So thanks for the question. Absolutely, that's the case. So I'll be a little repetitive. The XR program, we're busy in terms of response to the FDA now, and the idea is to get the XR approval prior to the loss of the LOE for RUX. Both BET and ALK programs, we want to declare where we go in if we go into registration studies end of this year, early part of next year, and it will give us enough time to execute a Phase III program and get across the finish line there. So that's absolutely intent.

The mutant CALR and V617F, as Pablo said, are early but great promise of disease-modifying agents. And so it's a little unclear the regulatory part there, and it will depend on demonstrating safety and efficacy. But we'll see if that keeps going well, you could potentially execute a rapid Phase III program, but it's really too early to say.

Herve Hoppenot - *Incyte Corporation - CEO & Chairman*

But maybe I can add. I mean, on this view about the Jakafi patent expiration and the way we are sort of allocating resources. That's basically the 8 program. You saw 1 of the slides is speaking about the 8 programs that we are prioritizing in R&D, and that's where you have the list of the programs that will be impacting our revenue in the years that are coming relatively soon with CALR being maybe the 1 that is a little bit of a stretch. But for everything else, it could come before that time.

And the povorcitinib program, which is increasing. Today, we have the news of an additional indication in prurigo nodularis is now in Phase III now for 1 indication, it says Phase III is being planned for prurigo nodularis and vitiligo. So all of that should be coming in the years that are -- that preceded the patent expiration for Jakafi.

Operator

Our final question today is coming from Evan Seigerman from BMO Capital Markets.

Unidentified Analyst

[Malcolm] on for Evan. Just wanted to ask with the presubmission meeting with FDA planned for RUX cream in pediatric patients. Are there any nuances with that submission in the pediatric population versus adults that you think will require a special consideration for the FDA and Incyte? And has there been any indication on when that meeting may take place?

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

Steven. So we don't guide to you when we have the actual meetings, but the only nuance impede is some safety requirements to demonstrate under maximum use conditions that there's no increased levels or untoward side effects. We've completed that work. We're satisfied with the results and we're discussing with the FDA. So that will put our submission sometime hopefully, in the first half of next year in terms of having that complete data set and submitting it then, and we're very comfortable with the data.

Operator

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

Ben Strain - *Incyte Corporation - Associate VP, Head of Investor Relations*

Thank you all for participating on today's call and for your questions. The IR team will be available for the rest of the day. Please don't hesitate to reach out. Thank you.

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.

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