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OVERVIEW:

Company Summary

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PRESENTATION

Operator

Hello, and welcome to the Incyte Fourth Quarter 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 Ben Strain, Associate Vice President, Investor Relations. Please go ahead, Ben.

Ben Strain - *Incyte Corporation - Associate VP, IR*

Thank you, Kevin. Good morning, and welcome to Incyte's Fourth 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 today's discussion.

On today's call, I'm joined by Herve, Barry, Pablo, Steven and 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 Herve.

Herve Hoppenot - *Incyte Corporation - CEO & Chairman*

Thank you, Ben, and good morning, everyone. So on Slide 5, we achieved another strong year with 2023 product and royalty revenues growing 14% versus 2022 to reach \$3.7 billion, continuing the strong performance we have delivered since 2018.

We also achieved a symbolic milestone in the fourth quarter. Total product and royalty revenue reached \$1 billion quarterly for the first time, driven by the continued growth of Jakafi and successful launch of Opzelura.

So moving to Slide 6. 2023, Jakafi net sales were \$2.6 billion, growing 8% versus the prior year, with growth across all indications year-over-year. And Opzelura showed strong momentum in 2023, growing 162% to \$338 million, driven by new patient and refills in both AD and vitiligo. We expect Opzelura to continue to be a key contributor to growth in the next year.

On Slide 7, our clinical pipeline has the ability to deliver transformative therapies to patients across multiple programs and provides the opportunity for 10 high-impact launches by 2030, as presented recently in San Francisco.

Importantly, some of the programs highlighted on this slide are derisked as they are post proof of concept including axatilimab, which has been submitted to the FDA for approval, RUX cream in pediatric atopic dermatitis to be submitted to the FDA by midyear, RUX cream in HS, where we have randomized Phase II data and povorcitinib, where we are in Phase III in HS, vitiligo, and in PN, where we are on track to initiate a Phase III study this year.

Each of these programs has the potential to address a significant market and provide an opportunity to contribute to the top line before the end of the decade. I would also like now to highlight the recent transaction with MorphoSys on Slide 8. As described in the press release we issued last week, we entered into an asset purchase agreement with MorphoSys, which gave us exclusive global rights for tafasitamab, also known as Monjuvi or Minjuvi.

This acquisition provides a number of benefits to Incyte in the short term. First, going forward, we will now record all revenues from Monjuvi in the U.S., while eliminating MorphoSys share of the royalties ex-U.S. and all future milestones to MorphoSys.

Second, we will realize significant operating efficiencies and cost synergies in U.S. commercialization and in global development by removing redundant position and redundant external expenses and by simplifying the (inaudible). Therefore, in 2024, this deal will add to Incyte's revenue and will have a limited impact on operating income.

For the future, while the currently approved indication of relapsed refractory DLBCL represents a smaller opportunity for tafasitamab, we see upside potential in second-line follicular lymphoma and marginal zone lymphoma with Phase III data expected later this year and in first-line DLBCL, for which Phase III data are expected in 2025.

These programs have been co-founded by MorphoSys until now, and if positive, Incyte will fully benefit from the upside from this indication. And this acquisition will be value-accretive for Incyte in all scenarios.

I will now turn the call over to Barry, who will discuss our commercial performance in more detail.

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

Thank you, Herve, and good morning, everyone. Starting with Jakafi on Slide 10. In the fourth quarter, Jakafi net product revenue grew 7% year-over-year to \$695 million and grew 8% for the full year to \$2.6 billion. Total patients increased 6% in 2023, with growth being seen across all indications. We experienced some variation in Jakafi dynamics during the fourth quarter, including an increase in patients on free drug as well as in inventory fluctuations.

Recall inventory drew down modestly in Q3 and rebounded in the fourth quarter. Additionally, we anticipate the increase in patients on free drug seen at the end of 2023 to reverse and return to more normalized levels through 2024, supported by the lower out-of-pocket expenses under the Part D redesign.

Christiana will provide more details on these dynamics in her prepared remarks. We continue and we expect continued growth of Jakafi and have updated the full year net product revenue guidance for 2024 to a range of \$2.69 billion to \$2.75 billion.

As highlighted on Slide 11, Jakafi continues to maintain its leadership and market share in MF, driven by its unmatched product profile. Based on market research, other competitors have not had an impact on Jakafi in regards to total patient market share or new patients and is consistent with our expectations. Jakafi demand remains strong, and we expect continued future growth driven by maintaining its leadership as standard of care in myelofibrosis, growth opportunities in polycythemia vera and chronic graft versus host disease as well as earlier use in chronic GVHD.

Additionally, we anticipate the positive changes in out-of-pocket expenses for Medicare Part D patients to contribute to the growth in the coming years with the biggest impact starting in 2025.

Turning to Slide 12 and Opzelura fourth quarter performance. Opzelura net product revenues in the fourth quarter were \$109 million, up 78% when compared to the same quarter last year. Total 2023 full year net sales grew 162% versus 2022 to reach \$338 million. U.S. patient demand increased during the quarter with total prescriptions growing 77% year-over-year and refills growing by 22% versus the prior quarter.

The weekly prescription trend, as shown on the right, demonstrates typical end of Q4 dynamics as well as the continued growth of Opzelura, which is coming from both atopic dermatitis and vitiligo.

In AD, growth was primarily 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, improved access and our educational initiatives. We remain very optimistic about the long-term potential of Opzelura as we continue to see strong uptake.

The launch continues to be strong and is gaining positive momentum with both physicians and patients as Opzelura becomes established as one of the best recent dermatology launches. Looking at the first 27 months post FDA approval, Opzelura continues to outperform other dermatology products on a launch-aligned basis when measured by monthly dermatologists prescribe TRxs on the left and when comparing quarterly net revenues on the right.

The successful launch of Opzelura is driven by its compelling product profile, its ability to address significant unmet need in both atopic dermatitis and vitiligo and our strong market access relative to competition, where we continue to improve access and growing net sales.

Turning to Slide 14. We have a number of initiatives in place for Opzelura to drive demand in 2024 in both AD and vitiligo. We know that based on Opzelura's compelling efficacy and safety, health care professionals want to use Opzelura sooner in the treatment algorithm. In addition to securing improved access for 2024, we are also continuing to look for ways to improve utilization management, and we have an exceptional value proposition that supports these advancements.

For vitiligo, we continue to drive patient awareness through consistent marketing campaigns with the goal of educating and inspiring these patients with positive real-world patient experiences. We believe this will drive further demand and activate patients to discuss treatment options with their dermatologist.

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. I want to highlight some of the key R&D milestones that we accomplished in 2023 and to provide a framework for how we are evolving our R&D focus with the near-term goals to increase the rigor of our decision-making accelerate the progression of our pipeline and to optimize our resource allocation.

As you can see on Slide 16, we have 3 areas of focus where we're building a robust and diverse portfolio of medicines for the treatment of MPNs in graft versus host disease, oncology and inflammatory diseases. We're advancing a pipeline to deliver impactful innovation with a focus on best-in-class and/or first-in-class differentiated medicines in areas with large unmet medical needs.

Our discovery process is targeting pathway-centric and leverage its cross-program knowledge and deep biology expertise in our established disease areas of interest to identify and prosecute novel targets as well as disease and genotype-specific dependencies with a modality agnostic approach.

In addition to our established small molecules expertise, we have expanded our drug discovery capabilities to include monoclonal antibody discovery in-house and have access to bispecific antibody discovery capabilities through a partnership with Merus.

Turning now to Slide 17. We made significant advancements across all 3 priority areas of focus in the R&D portfolio in 2023. In MPNs and graft versus host disease, we submitted the BLA for axatilimab for the treatment in third-line chronic graft versus host disease.

We presented updates for our BET and ALK2 inhibitors in MF and highlighted our new potentially transformative therapies for MF, PV and ET, our mutant collar monoclonal antibody, which is enrolling well in a Phase I study and our JAK2V617F inhibitor, for which we plan to initiate a Phase I study in the next month.

In oncology, we initiated several monotherapy and combination studies with our small molecule oral PD-L1 inhibitor and highlighted early signs of clinical activity with our small molecule CDK2 inhibitor. Additionally, we unveiled a new program in development, our KRASG12D inhibitor, which entered the clinic earlier this year. Steven will provide more detail on the KRASG12D program in his prepared remarks.

In dermatology, we continue to maximize the potential of ruxolitinib cream. In 2023, Opzelura was approved in Europe for Vitiligo as the first and only approved treatment for repigmentation. We also presented positive Phase III data in pediatric atopic dermatitis and announce that the primary endpoint was met in a randomized Phase II study in patients with hidradenitis suppurativa.

For povorcitinib, we presented positive randomized Phase II data in vitiligo and initiated 2 Phase III studies for patients with extensive vitiligo. We also announced that povorcitinib had met the primary endpoint in a randomized Phase II study in patients with prurigo nodularis and we initiated 2 randomized Phase II studies, many patients with asthma and patients with chronic spontaneous urticaria.

We believe that with ruxolitinib cream and povorcitinib, we'll be the only company with the ability to address a broad spectrum of patients from mild to severe, potentially providing both topical and oral option for a number of indications, including prurigo nodularis, hidradenitis suppurativa and vitiligo.

Apart from an exhaustive list of all the R&D achievements in the past year, this demonstrates that 2023 was a very successful impactful year for Incyte and it serves as a foundation for a number of pivotal trials that will deliver results in the next few years.

As you can see from Slide 18, we anticipate that 2024 will be another very exciting year with multiple clinical and regulatory milestones. Steven will provide more details on these, but I would like to highlight certain events. Within our oncology pipeline, we believe that our potentially best-in-class CDK2 inhibitor is an active agent and we look forward to sharing data as well as our development plan later this year.

In addition, the pivotal trial of tafasitamab in patients with follicular and marginal zone lymphoma, also known as inMIND, will read out later this year, and we look forward to sharing those results. We submitted a BLA for axatilimab late last year and we look forward to working with the FDA to make axatilimab available to patients with chronic graft versus host disease later this year and to initiate additional combination studies in

patients with less pretreated chronic graft versus host disease. Within our dermatology portfolio, we expect to submit the sNDA for Opzelura for pediatric atopic dermatitis and expect multiple data readouts throughout the year.

With that, I would like to pass the call to Steven, who will provide further details on our clinical development pipeline.

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

Thank you, Pablo. Starting on Slide 20. In December, we presented more than 40 hematology and oncology abstracts, including a plenary presentation at the ASH Annual Meeting. Key highlights included a plenary scientific session, which featured the full data from AGAVE-201 evaluating axatilimab, an anti-CSF-1R monoclonal antibody in patients with chronic graft versus host disease and additional data from the Phase I/II study of zilurgisertib. Phase I data from our BET inhibitor and preclinical data of the JAK2 V617F inhibitor.

While BET inhibitor, dose escalation is ongoing in monotherapy and in combination therapy we are seeing reductions in spleen length and volume as well as improvements in both symptoms and hemoglobin, suggesting that this is an active compound. We plan on advancing this program to Phase III later this calendar year.

As we get closer, we will provide additional details on study design and timing. Based on the efficacy and favorable safety profile, seeming the Phase II AGAVE-201 pivotal study, the BLA for axatilimab was submitted to the FDA for approval for the treatment of patients with chronic graft versus host disease. We anticipate the decision by the FDA in the second half of 2024 and are excited by the possibility of bringing a new treatment option to these patients.

We continue to expand and advance our IAI and dermatology portfolio, as seen on Slide 22. For ruxolitinib cream, we recently presented positive Phase III data in pediatric patients, where RUX cream meets its efficacy endpoints for both investigator global assessment treatment success and EZ75. We expect to submit the sNDA by the middle of 2024 with potential approval in 2025.

We also disclosed that RUX cream met the primary endpoint in the Phase II study in mild to moderate hidradenitis suppurativa and we expect to present those results at a medical conference later this year, while a Phase III study has been evaluated. Ruxolitinib cream is also currently being evaluated in 3 Phase III studies in prurigo nodularis and 2 Phase II studies in lichen planus and lichen sclerosus with data expected for both later this year.

Povorcitinib, our oral JAK1 inhibitor is currently being evaluated in Phase III studies in hidradenitis suppurativa and vitiligo, and we have recently announced that povorcitinib met the primary endpoint of a greater than or equal to a 4-point improvement in the itch NRS across all 3 treatment groups in a Phase II study in prurigo nodularis.

We expect the full data set at a medical conference later this year and Phase III planning is underway. Our earlier stage dermatology program, our IL-15 receptor beta antibody has begun evaluation in healthy volunteers.

Moving to Slide 23. Last week at the European Hidradenitis Suppurativa Foundation Conference, we presented additional data from the open-label extension of the Phase II study of povorcitinib in HS. As a reminder, povorcitinib demonstrated dose-dependent efficacy in patients with HS during the initial placebo-controlled period at week 16.

The data presented demonstrated that treatment with povorcitinib through week 52 resulted in a decrease in disease severity, as classified by the international HS Severity Scoring System, or IHS-4. At week 52, a significant decrease in disease severity was observed with approximately 25% of patients achieving an IHS4 score of 0, which represents the complete resolution of abscess, nodule and draining tunnels.

On Slide 24, an additional analysis was maintenance of response, which demonstrates that povorcitinib treated patients who achieved a response at week 16 were likely to maintain the HiSCR response through week 52. Both of these data sets build upon povorcitinib's potential as a best-in-disease medicine for patients suffering from HS. As a reminder, 2 Phase III studies evaluating povorcitinib in HS stop HS1 and stop HS2 are ongoing and enrolling very well.

Our high potential oncology pipeline is currently focused on 3 advanced programs. The first is tafasitamab, which has currently been evaluated in 2 Phase III studies in patients with follicular and marginal zone lymphoma and in patients with previously untreated diffuse large B-cell lymphoma. We're expecting Phase III results for follicular and marginal zone lymphoma or the inMIND study in the second half of this year with a first-line diffuse large B-cell lymphoma or Front-MIND study readout in 2025.

The second is our small molecule oral PD-L1 program. We have multiple ongoing studies as monotherapy or in combination with other agents such as axitinib, adagrasib and ipilimumab. And we expect to have combination data later this calendar year. And the third program is our small molecule CDK2 inhibitor, where we recently announced early signs of clinical activity with multiple patients demonstrating partial responses. We expect to share data as well as the development plan later this calendar year.

On Slide 26, we recently announced that INCB161734, a potent, selective and orally available KRASG12D inhibitor, recently entered the clinic in a Phase I study. This program has shown encouraging preclinical antitumor activity in xenograft models with no currently approved G12D targeting agents could address a high unmet need.

As a reminder, the KRASG12D mutation is found in approximately 40% of pancreatic ductal adenocarcinoma, 15% of colorectal cancer and 5% of non-small cell lung cancer and could thus represent a significant opportunity for Incyte, if successful.

In summary, we anticipate a number of upcoming pipeline updates in 2024, including sharing top line results from both the Phase II studies in RUX cream in HS and povorcitinib in PN at a medical conference in the first half of this year. The second half of the year is looking to be a catalyst-rich period as highlighted on Slide 20 that we anticipate includes, but is not limited to an approval with axatilimab, Phase III results from tafasitamab and the initiation of a number of Phase III studies, including with our BET inhibitor.

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. 2023 was another year of strong financial performance with total product revenues of \$862 million for the fourth quarter of the year and \$3.2 billion for the full year, representing a 13% and 15% year-over-year increase, respectively.

Total royalty revenues, which are primarily comprised of royalties from Novartis for Jakavi and Taveco and royalties from Lilly for Olumiant were \$150 million in the fourth quarter and \$523 million for the full year, up 13% and 8%, respectively, compared to 2022. Total revenues grew 9% in the fourth quarter compared to the prior year period, reaching the \$1 billion mark, an important milestone for Incyte. For the full year, total revenues were \$3.7 billion.

Turning to Jakafi on Slide 30. Jakafi net product revenues were \$695 million for the fourth quarter and \$2.6 billion for the full year 2023. In 2023, Jakafi net sales grew 8% compared to the prior year. Jakafi sales were negatively impacted by a significant increase in free drug in the fourth quarter of the year, driven by an increase in the number of patients seeking support from Incyte's patient assistance program.

The impact of the increase in free drug was more than offset by an increase in channel inventory levels. This increase was in anticipation of patients moving into paid demand starting in Q1 of 2024. The increase in Q4 channel inventory levels represented \$46 million in sales.

Turning now to Opzelura. Net product revenues for the fourth quarter were \$109 million, representing a 78% increase year-over-year, driven primarily by increased patient demand. For the full year, total Opzelura net product revenues were \$338 million, representing a 162% increase compared to the prior year.

Moving on to Slide 32 and our operating expenses on a GAAP basis. Total R&D expenses were \$444 million for the quarter, representing an 11% year-over-year decrease, which was primarily as a result of the \$70 million upfront payment made as part of the Villarís acquisition in Q4 2022 and partially offset by the \$20 million development milestone payment to former Villarís shareholders in the fourth quarter of 2023.

For the full year 2023, total R&D expenses were \$1.6 billion, representing a 3% year-over-year increase. This increase was primarily due to the progression of our pipeline and was mainly offset by lower upfront and milestone expenses in '23.

Total SG&A expenses were \$294 million for the fourth quarter and \$1.16 billion for the year. The year-over-year increase of 8% for the fourth quarter and 16% for the full year were mainly due to increased sales and marketing activities for Opzelura in both the U.S. and Europe, unfavorable effects and timing of certain G&A-related expenses.

Moving on to 2024. I will now discuss the key components of our guidance on a GAAP basis, which includes revenues and expenses related to the recent acquisition of the exclusive global rights to tafasitamab, but excludes any potential impact related to the accounting treatment of the \$25 million purchase price paid.

For Jakafi, we expect net product revenues to be in the range of \$2.69 billion to \$2.75 billion on track to achieve our long-term guidance of over \$3 billion in net product revenues by 2028. We expect net product revenue growth to be driven exclusively by continued demand growth and be partially offset by lower net pricing as a result of IRA imposed price increase caps and continued growth in 340B volumes.

As in previous years, we expect the gross-to-net adjustment to be higher in the first quarter of the year relative to the previous quarter and subsequent quarters due to the higher deductibles and our share of the donut hole for Medicare Part D patients, which are primarily impacting the first quarter of the year.

While for Opzelura, we will not be providing full year guidance at this point, in the first quarter, we expect to see again the effects of typical Q1 dynamics on net sales, including higher patient out-of-pocket costs due to the planned deductibles resetting at the beginning of the year and the impact of holidays, medical conferences and other events on dermatology product sales.

As of a result, Q1 Opzelura net product revenues are expected to be below the previous quarter and the subsequent quarters and represent a smaller share of the full year net product revenues consistent with what we saw in 2023.

For other hematology/oncology products, which now include Iclusig, Pemazyre, Monjuvi and Minjuvi, we expect total net product revenues to be in the range of \$325 million to \$360 million, which at the midpoint represents approximately 47% growth over '23.

Turning to operating expenses on a GAAP basis. We expect COGS to range from 7% to 8% of net product revenues, which is in line with 2023. R&D expense is expected to be in the range of \$1.72 billion to \$1.76 billion, representing 7% growth at the midpoint versus 2023, primarily driven by the progression of our pipeline.

We expect SG&A expense for the year to be in the range of \$1.21 billion to \$1.24 billion, representing 6% year-over-year growth at the midpoint primarily driven by the inclusion of sales and marketing expenses associated with Monjuvi in the U.S. under SG&A whereas prior to the acquisition of full product rights, they were included under the collaboration profit or loss share.

Operator, that concludes our prepared remarks. Please give your instructions and open the call to Q&A.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question is coming from Srikripa Devarakonda from Truist Securities.

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

On Jakafi and myelofibrosis, thank you so much for providing the market share details on our patients and the share in your patients. I was just wondering if you anticipate stabilization of classified share at these levels? And if collaborative were to be approved in combination with rock assuming it happens sometime next year, should we expect to see an inflection point.

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

So stabilization of market share in myelofibrosis. So Jakafi, as you know, is the leader in myelofibrosis because of its safety, efficacy, overall survival and really tolerability, which is really a big advantage. We think that myelofibrosis will continue to be the largest portion of our patient share until polycythemia vera patients ultimately take over because as you know, those patients stay on for a long period of time.

Your question around pascalisib if and when gets approved in combination with Jakafi. Of course, that's a good thing for us. If in fact, the profile of the drug is as it appears or the combination as it appears, then many physicians may choose to use that combination and Jakafi will only benefit, but we have to wait and see what happens with the approval process.

Operator

Your next question is coming from Andrew Berens from Leerink.

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

Wondering if you guys could expand upon the development of Jakafi XR in light of the recently announced bid by Novartis from MorphoSys. Does Novartis' control of Jakafi outside the U.S. impact how you're thinking about developing your BET inhibitor. Do they have any direction or say in any of the directions of the XR version of Jakafi? And then also just wondering if you think that an add-on drug to Jakafi and MS still requires a symptomatic improvement as an endpoint for regulatory endorsement. Or do you think that there's been a material change in thinking at the agency?

Herve Hoppenot - *Incyte Corporation - CEO & Chairman*

So let me take the piece about our agreement with Novartis on Jakafi and Steven can speak about the development of XR. So the agreement is such that both parties can be co-developing new formulations of ruxolitinib in oncology, including the once a day. It has not been the case yet, but there is still an optionality for Novartis to co-develop XR if they wish, and that would mean that they would be able to commercialize the XR formulation outside of the U.S. but not in the U.S. where, obviously, it will be commercialized by Incyte.

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

And then, Andy, I'll take the other part of your question. So for RUX XR, as Pablo communicated at the ASH Investor event, we have now clear feedback from the FDA that we need to do a new formulation strength, which are already developed, which are slightly higher and then demonstrate the EBA with those primarily around (inaudible) and AUC. That's the clear guidance from the FDA. And we estimate this should be completed in a 2-year process so well before the LOE. It doesn't affect our development of FTCs, fixed-dose combinations with any of our products. So that continues.

For our BET inhibitor, again, we showed data at ASH and alluded in my prepared remarks, we have clearly an active compound showing in very good rates of spleen reduction, both volume and length, very good symptom improvement and occasional hemoglobin increases, just like seen with the other BET inhibitor.

We have been operating like other companies under the assumption that at least in first line, you need SVR35 and symptoms to date to get approvals. I can't comment on where they are in their regulatory progresses or how the FDA may change in that regard. But that has been the standard to date.

Operator

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

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

I had 1 on povorcitinib. So as we think about the opportunity for this drug in multiple indications, I believe the HS Phase III trial is most advanced. Could you talk a bit about your expectation on how the drug may be positioned relative to some of the biologics in HS, be it Humira or some of the IL-17 antibodies.

And then also in PN where you had the positive top line data last year, Dupixent is obviously approved here again, could you talk a bit about how the drug might be fitting into that treatment paradigm relative to Dupixent?

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

Michael, it's Steven. I'll start with your question. Thank you for the question. So povorcitinib HS, we think we have outstanding efficacy data, which we've now updated with a 52-week data that shows prolonged effect that's maintained and so remember, this is a JAK1 specific agent, about 50-fold selective for JAK1 has a long half-life and a very high volume of distribution, which may translate to more penetration in the skin, which is why we see this degree of efficacy showing to date. Both Phase III STOP-HS1 and HS2 are enrolling very, very well.

So that probably speaks to also some of the belief out there in the agent, and that is clearly our lead indication as you alluded to. It's hard to always cross-compare with many caveats to other studies where the drugs aren't directly compared and you spoke about the IL-17 here and the biologics, and clearly, there's some variable activity there.

You have to look at placebo corrected rates. But I think tackles multiple aspects of the disease pathophysiology, not just 1 interleukin. And as I said, the drug profile with a long half-life and high volume of distribution may lend itself to increased efficacy here.

Obviously, time will tell with the Phase III data. It will be a once daily oral tablet, which offers that sort of convenience. In PN, when patients suffer from primarily is intense itching. And again, our Phase II proof of concept data is very strong in terms of the itch relief here and the ability to eliminate that symptom pretty quickly as well as over time, disease resolution in the actual skin manifestations.

There is, as you allude to an approved agent there in Dupixent but that has provided us the regulatory pathway on the way to go in terms of itch resolution and skin change resolution. And again, we'll offer the once-daily oral convenience, we think we'll have a really good agent in terms of high efficacy there. So we're excited about this program as well.

Operator

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

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

We had 2 on the pipeline. So first, for the ALK2 program, you've guided to POC data by mid-'24. We were just wondering what we can expect to learn with this update and what you will be reviewing specifically to decide what the next step of development could be for this program? And

then secondly, for the mutant CALR antibody. When can we expect to see initial Phase I data there? And what are you hoping to establish to get conviction that the program is headed in the right direction.

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

Yes. Thank you for the question. This is Pablo. So for the ALK2 inhibitor program, what we're in the process of doing, and we need to establish is efficacy in a larger number of patients with newly diagnosed MF in combination with ruxolitinib. And that's what the team is focused on right now, and as we mentioned, at ASH last December.

So we continue to push the dose. We need to get to doses of around 400 to 600 milligrams a day in order to get the maximum effect on hepcidin. Two, we need longer duration of therapy in a larger group of patients in combination with RUX.

So that will happen over the course of the year. We haven't provided a specific time line for when we're going to disclose the data. But as we mentioned at ASH last year, it would happen this year. And we'll provide clarity on what the next steps for that program are.

On the second question for the mutant CALR antibody program, we started dose escalation very recently. As you know, that study is accruing very well. The initial goals like for any first-in-human study, obviously, to establish that this monoclonal antibody is safe, get a good view of the pharmacokinetics in this first-in-human study and establish initial evidence of efficacy, which, in this case, will be by traditional endpoints in MPNs and also potentially a view on the effect of the mutant CALR or monoclonal antibody on a real burden in some of these patients. That will happen over the course of the year. We haven't decided yet when we're going to present data, whether it's this year, whether at some point in 2025.

Operator

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

Unidentified Analyst

This is (inaudible) on for Salveen. We had 1 question on Opzelura outside of the 1Q dynamics that you spoke to. Can you help us understand the forward launch trajectory in AD and vitiligo in the context of reimbursement and access and also gross to net in order to be fully able to capture the opportunity as you have additional indications coming in, in the coming years.

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

Yes. Thanks for the question. So of course, as far as launch trajectory, we're continuing to launch very well in both AD and vitiligo. We continue to expect growth in vitiligo just based upon our educational efforts directed both at patients and health care professionals. We know that the profile in AD in terms of its itch relief and clearance of the skin is unmatched for any therapy, topical therapy.

We even believe that in AD, for example, the profile is so good that as far as payers are concerned, they're interested in the fact that more than 80% of the patients will be clear and have their itch relieved and can delay or not even go on to biologics.

So we think those dynamics are good for both AD and vitiligo going forward and we can -- we're looking forward to future growth. I'll turn the call over to Christiana to talk about gross to net.

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

So in terms of gross to net, first of all, when you look in 2023, the average gross to net was around 55%. Our goal is to maximize the value of Opzelura and maximize net sales. If going forward, we make the decision to provide any additional discounts, it would be because we expect that this will

improve access and we'll have a disproportionate impact on volume and thus lead to higher net sales. So as such, our comments are going to be focused on net sales versus gross to net in isolation.

Operator

Our next question is coming from Derek Archila from Wells Fargo.

Derek Christian Archila - *Wells Fargo Securities, LLC, Research Division - Senior Equity Analyst*

So I just piggybacking on the last. Just in terms of Opzelura, is there 1 -- any chance we get an update in terms of potential guidance this year? And then will you ever look to kind of break out both kind of the vitiligo and AD kind of scripts or sales, if you could figure that out? And then secondly, just on tafasitamab I guess, can you quantify maybe the incremental growth opportunities you see for this assay in the follicular and marginal zone lymphoma indications.

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

So as far as breaking out AD versus vitiligo, I think we've said before, it's about 60% currently for AD, 40% currently for vitiligo, it could be changing a little bit. Ultimately, we expect vitiligo total tubes perhaps surpass AD. AD patients are many new patients who have come on for atopic dermatitis and in vitiligo, it's about continued use and refills.

As far as Monjuvi tafasitamab goes, obviously, we're looking forward to, hopefully, positive data in follicular lymphoma, indolent lymphoma and in first-line diffuse large B-cell lymphoma. So we think there's great opportunities ahead for these 2 indications. We think it's a great drug for lymphoma. Obviously, it's a crowded marketplace, but we think the profile of the drug and the trials we put together for those 2 new indications are going to serve us well in the future.

Herve Hoppenot - *Incyte Corporation - CEO & Chairman*

But in terms of calibration of follicular lymphoma, we need to see the Phase III data. It's a fairly competitive place. There are a lot of new products. So we need to see the Phase III data before we can give you a good calibration of that. I mean the number of patients we are speaking about in the U.S. is around...

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

There's 39,000 patients in first-line diffuse large B-cell lymphoma. There's about 13,000 patients in second line plus in follicular lymphoma in the United States.

Operator

Our next question is coming from David Lebowitz from Citi.

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

You said that the fourth quarter revenues were negatively impacted by the number of Medicare Part D patients receiving free product. Could you perhaps elaborate on this? And also looking ahead to 2024 and '25, you've spoken about how IRA dynamics could shift, which will drive PV share. Could you possibly give us some way to quantify the potential impacts of this shift over time?

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

So to answer the first question. In Q4, we saw a significant increase in patient seeking assistance from Incyte in the form of free drug, of course. We know that these were paid patients who had Medicare Part D and our assumption is these patients were receiving financial assistance from independent charitable foundations to cover their out-of-pocket expenses.

This assistance was no longer available to them apparently at the -- towards the end of the year. And of course, they came to us and they met our eligibility criteria for free drug. With the changes in Medicare in 2024, as you know, the out-of-pocket in 2024 for Medicare Part D is greatly reduced. Therefore, we expect these patients to return to being paid patients.

And in fact, we know already that many of these patients already have. In terms of 2024, 2025 and the changes to Medicare Part D, we think it's been very positive. We've been saying it for a long time that these co-pays out-of-pocket cost for patients -- cancer patients who are in Medicare Part D was very much too high and should be reduced. And in fact, they probably are still too high. But because of the way it happens in 2025, \$2,000 maximum out of pockets, they can spread that out over throughout the year.

So they pay about \$167 per month for a 12-month period. We think that there's lots of patients perhaps over the years who have walked away who have abandoned drug because they could not afford these out-of-pocket cost. We think that there's an opportunity at least for those patients who abandon drug or just thought they could not afford the drug. Now that the Medicare Part D is greatly reduced, they could come back. So come back or option into drug therapy now. So...

Operator

Your next question is coming from Jessica Fye from JPMorgan.

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

A couple of follow-ups on some of the previous questions. What's your expectation for the proportion of Jakafi patients receiving free drug in 2024? And then on Opzelura for Europe, how are you expecting the average price to shake out for vitiligo, and can you recap your latest thinking on pursuing AD there? And then in the U.S. I think you mentioned that recent script trends reflect kind of normal year-end seasonality. Is that to say you expect a volume reacceleration near term? I wasn't sure how to reconcile that with some of the other 1Q comments you made about Opzelura.

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

Okay. I'll try to answer the first and third question, maybe ask Herve to talk about Europe. So the expectation for free drug is easy for Jakafi. It's been 3% to 4% of our volume for years and years and years. So we expect it to go back. We think this is a one-time exceptional thing that happened because of the changes coming from Medicare Part D. So again, no more than it has been historically, which is around 3% or 4% of our volume.

As far as what we talked about seasonality. We do expect that the first quarter be down mostly because of out-of-pocket expenses, because of deductibles, because of resetting of the co-pays but then we should go back to our acceleration in volume in second quarter, third quarter and so on. And Herve, Europe?

Herve Hoppenot - *Incyte Corporation - CEO & Chairman*

So in Europe today, Opzelura is launched in Germany and Austria, in fact, where it's commercially available. The price there is EUR 750 per 100-gram tube. And then we recently received reimbursement in France under the process called AXA Direct, which is a way to make -- it's one of the first product. In fact, it's the second product to get AXA -- to be part of that program. And that gives access to patients through a special distribution system and while the price is being discussed.

So the price discussion will probably take 10 months and we will start booking sales or recognizing revenue in France when the price is finally approved. So that should be late this year in the best case. And then we are also in the process of getting reimbursement in other countries in Europe. So hopefully, we will get multiple countries launching in '24 and '25.

Regarding atopic dermatitis, we decided, obviously, to start with vitiligo for reimbursement, reason because it's a better case leading to a better price in most of these countries. And we have ongoing studies that have been, in fact, started relatively recently that could be used if we want to have a limited level in atopic dermatitis, which would be required to be able to maintain the price. So that process is ongoing, and it's not going to lead to a new indication in the next 2 years. It will be coming October.

Operator

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

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

I was just curious as to the payer mix differences, if there are any for Opzelura between the AD indication versus vitiligo. And then secondly, as both of these launches start to mature a bit, do you have a better sense of how you're going to land a number of tubes on average use per patient for a full year.

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

As far as the payer mix goes, there's no real difference between payer mix for AD. More patients perhaps have step therapies in the vitiligo. More patients don't have any steps or have 1 step. In terms of the number of tubes we've said in the past that for AD, it's around 2 tubes or a little bit more. We think that will continue to grow as people use the drug over larger portions of the body, obviously, they -- they can go up to 20% of their body surface area, which is a very large body surface area.

Some people start out in sensitive areas and now they'll continue to use it over a larger area of their skin. For vitiligo, it's just too early. We'll figure out. But we're anticipating, obviously, as we've said, the refills will be much greater in vitiligo compared to AD.

Operator

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

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

Maybe following up on a couple of the payer dynamic questions. Just on Jakafi, can you quantify the level of kind of script abandonment and things like that, that you are seeing and kind of what this opportunity is for volume gains with this redesign, recognizing, yes, some of it's not going to play out over just in 1 year.

And then similarly, in for Opzelura, you had some formulary wins late last year that came into effect at the beginning of the year. Christiana, to your comment of only wanting to give price concessions to see enough volume benefit to end up with a net sales benefit. Are you seeing early returns from that, that are consistent with that view? Or do you kind of need to recalibrate? How you do those negotiations for next year to make sure that, that trend is kept.

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

Sure, Mark. Barry first. So quantified a level of script abandonment for Jakafi, we don't actually know. We know that it's at least 10% just because we know when we go to specialty pharmacies, the patients who go through specialty pharmacies, it's a little -- we have a little bit more data there or clarity there and it's at least 10%.

But we don't know, people who -- scripts never get sent to a pharmacy. We don't know about that. So we're not exactly sure, but we think there's a significant portion of patients that could benefit from these -- from Jakafi specifically that aren't because of the out-of-pocket cost, and that's getting better and better all the time, we hope, in 2024 and 2025.

As far as Opzelura goes and formulary wins, it's for example, CBS, Aetna, that got changed this year to preferred status with 1 step therapy for AD, no step therapies for vitiligo, it's a little bit too soon to see anything because obviously, when CBS makes a decision with us, it takes a while to funnel down to the various plans at the local level.

Operator

Next question today is coming from Ren Benjamin from Simpsons JMP.

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

Given the rumors of your bid for MorphoSys, are you considering any other acquisitions in the MS space? Or was the rumor incorrect the whole time and you were just going after TAFE that's question #1.

Question #2, back to Steven on the Jakafi XR. I'm still -- I'd love to get a little bit more color on the 2 years that it takes to get to the end of this to solve this issue. What really is kind of involved? And is the probability of success, I would think it would be just quite high. It's just for the lack of a better word, an engineering problem, but maybe I'm thinking about this wrong.

Herve Hoppenot - *Incyte Corporation - CEO & Chairman*

Yes. Maybe on the first question, as I said, I think the TAFE acquisition for us is an excellent deal. It's, in fact, very, very asymmetric because it's, as I said, with all of the synergies we can realize in the short term, it can compensate for what is left in terms of development costs in these 2 indications or in fact, most of the development has already been paid for in the past year. So it is a case where the actual impact on the bottom line will be very minimal in the short term and very positive in the long term, whatever the scenario of the new indication.

Now, if any of this new indication is hitting and its positive then it becomes obviously a super deal because we get all the benefit in terms of top line. So that's the aspect. Now in the field of myelofibrosis. As you can see from our pipeline, we have a number of projects that we are pursuing ourselves.

We have our own bet. There is still the ALK2 program where, as Pablo was saying, there is some additional data that we need to get certainty, but it's very promising. And obviously, we have the (inaudible) program on top of the XR formulation. So all of that is giving us a very full pipeline in the field of myelofibrosis. So that would not be the first priority for acquisitions.

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

And Ren, your question on XR. So just to go back to the CRL, Remember, when we did the submission, we missed on (inaudible) to a small degree that per the FDA resulted in a theoretic concern on efficacy. And then we tried to do some more population PK analysis in that to reassure them, but their pathway didn't work. And as we gave more granular detail at the end of last year, the route forward is new formulation, slightly larger tablet size and then repeat (inaudible) work -- and you're right, it's not -- doesn't take a great length of time.

But to get that data in, analyze it, put it into a package and send it to the FDA and then have the discussions, an approximation of best guess is an approximately to your journey from the beginning of this year to get it done. And that, we feel, has enough conservatism in it that we should make it.

In terms of probably of success, we can model from the formulations, what we will likely achieve in terms of area under the curve, (inaudible) and even actually Cmax as well. And we think that is relatively high. Obviously, that's why we're doing it. and we'll share that data as it becomes available and then take it to regulatory agencies.

Operator

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

Unidentified Analyst

This is Navin on for Brian. We just had a couple of questions on our part. So on Opzelura, what is the latest that you're kind of seeing on patient retention so far? How many patients persisted through the 6 to 12 months so far to kind of see the benefit versus how many are kind of dropping off or perhaps seeing early efficacy. And then if you could speak to a little bit of the education around the retention strategies as well.

And then a second question on the MF space. So as you kind of see the entry of additional competitors into the space, do you potentially foresee an expansion of the market as these competitors entered?

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

Sure, Navin, this is Barry. So -- as far as patient retention, I guess what you mean is (inaudible). So obviously, the vitiligo patients stay on for a much longer period of time. Of course, atopic dermatitis patients, patients with eczema, they have flares, they use Opzelura, it goes away, and it's very effective. So some patients get immediate relief. Obviously, we talk about the itch relief all the time, they get good itch relief and then the skin begins to clear over time.

So these patients will come back, we think, year after year as long as they have their eczema and use the drug when they see the flares until it goes away and then start using it again. Vitiligo patients we've seen from our long-term data. Patients can use the drug for 2 years and continue to get benefit. So that's what we keep on reinforcing around education so that patients understand how to use the drug, what they're going to see in 3 months, 6 months, 9 months, 12 months and beyond, and that's how we'll continue to retain them.

Yes, it's very important. The strategies around patients' adherence, particularly for vitiligo. And particularly, we know we can make improvements around what health care professionals, dermatologists in their offices are telling the patient how to use the drug and then the patients themselves understanding how to use the drug.

As far as competitors in the MF space, I mean, there are 3 other JAK inhibitors approved for myelofibrosis, where we continue to be the market leader in myelofibrosis, will continue to be. As far as the combinations that have been studied recently, we'll see.

But it certainly does expand the market because you have the opportunity of going early, earlier patients starting. We know if they start early with Jakafi, their survival advantages could be better. And then, in fact, they'll go to second-line drugs and third-line drugs. So yes, we created the market, and it could expand if there are good drugs approved after Jakafi.

Operator

Our final 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'll just ask 1 on the CDK2 inhibitor. Curious if you can comment on the safety profile you've seen so far, if you're seeing any (inaudible) cytopenia.

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

Matt, thank you for the question. We have not. We are happy with the safety profile so far, which is consistent with the mechanism of CDK2 inhibition. And we have not seen ocular toxicity, which, as you know, led to a clinical hold in one of our competitors. So we're very excited about the early data of our CDK2 inhibitor as we mentioned. And we look forward to sharing data over the course of the year as well as our future development plans for the CDK2 inhibitor program.

Operator

We reached 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, IR*

Thank you for participating in today's call and for your questions. The IR team will be available for the rest of the day. Thank you.

Operator

Thank you. That does conclude today's teleconference 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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