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INCY.OQ - Q3 2022 Incyte Corp Earnings Call

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OVERVIEW:

Co. reported 3Q22 total product revenue of $713m and expects full year 2022 net product revenue to be $2.38-2.40b.

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CORPORATE PARTICIPANTS

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

Christiana Stamoulis *Incyte Corporation - Executive VP & CFO*

Christine Chiou *Incyte Corporation - Head of IR*

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

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

CONFERENCE CALL PARTICIPANTS

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

Eva Xia Privitera *Cowen and Company, LLC, Research Division - Associate*

Gavin Clark-Gartner *Evercore ISI Institutional Equities, Research Division - Analyst*

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

Kelsey Beatrice Goodwin *Guggenheim Securities, LLC, Research Division - Associate*

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

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

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

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

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

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

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

PRESENTATION

Operator

Hello, and welcome to the Incyte Third Quarter 2022 Financial and Corporate Update Conference Call and Webcast. (Operator Instructions) As a reminder, this conference is being recorded.

It's now my pleasure to turn the call over to Christine Chiou, Head of Investor Relations. Please go ahead.

Christine Chiou - *Incyte Corporation - Head of IR*

Thank you, Kevin. Good morning, and welcome to Incyte's Third Quarter 2022 Earnings Conference Call and Webcast. The slides presented today are available for download on the Investors section of our website. Joining me on the call today are Herve, Barry, Steven and Christiana, who will deliver our prepared remarks; and Dash, who will join us for the Q&A.

Before we begin, I'd like to remind you that some of the statements made during the call today are forward-looking statements and are subject to a number of risks and uncertainties that may cause our actual results to differ materially, including those described in our reports filed with the SEC.

We will now begin the call with Herve.

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

Thank you, Christine, and good morning, everyone. During the third quarter, our product revenues increased 20% year-over-year to $713 million, benefiting from strong Jakafi sales growth as well as an increasing contribution from Opzelura net sales. Jakafi net sales grew 13% to $620 million, driven by robust growth in chronic GVHD as well as new patient growth in MF and PV. Opzelura net sales more than doubled versus prior quarter to $38 million, and we continued to execute on the successful launch in AD and vitiligo, driving increased demand, while also significantly improving formulary access. The ex U.S. launches of Pemazyre and Minjuvi, which are both still in early stages, contributed to the 19% growth coming from other hematology and oncology products.

Turning to Slide 5. We have multiple opportunities for significant growth in both oncology and dermatology with our recent approvals and the potential for multiple new products and new indications over the next several years.

For our oncology franchise, recent launches in new indications and new markets provide further growth opportunities for Jakafi, Pemazyre and Minjuvi. In LIMBER, pivotal data from 2 programs, axatilimab in chronic GVHD and ruxolitinib plus parsaclisib in MF are expected next year. And we expect data for BET, ALK2 in 2022 and 2023 to define the path forward for this program.

Outside of MPNs and GVHD, we have multiple early and late-stage clinical programs, including our oral PD-L1 program, which was the first to show clinical activity as an oral PD-L1, and we have updated data at SITC next week.

In addition to oncology is our dermatology franchise, where Opzelura is a key near-term driver with launches currently underway in atopic dermatitis and vitiligo. Our dermatology pipeline is expanding with new indications being developed for ruxolitinib cream as well as povorcitinib and auremolimab in areas of high unmet medical needs. This positions us well for significant growth and diversification.

With that, I will turn the call over to Barry.

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

Thank you, Herve, and good morning, everyone. The launch of Opzelura continues to be very successful with double-digit demand growth in atopic dermatitis and strong uptake in vitiligo.

Net sales grew 130% quarter-over-quarter to reach $38 million, led by strong patient demand and broader reimbursement coverage for Opzelura. Over 62,000 units of Opzelura were shipped in the quarter, representing a growth of 32% versus Q2. The positive feedback loop between patients and physicians, driven by the efficacy of Opzelura, continues to fuel the uptake in atopic dermatitis.

Opzelura in vitiligo has been well received by both physicians and patients and is adding further to growth in demand. Opzelura access continues to improve as NDC blocks are removed and payers continue to add Opzelura onto their formularies.

Turning to Slide 8, and Opzelura in AD. Opzelura is now the #1 prescribed agent for new AD patients amongst dermatologists with a new patient share of 17%. Opzelura is changing the treatment paradigm, helping to break the cycle of repeated failures on topical corticosteroids and calcineurin inhibitors.

The number of dermatologists gaining experience with Opzelura continues to increase and 96% of prescribers are reporting satisfaction with Opzelura. Efficacy and rapid itch reduction continues to be a top driver for prescribing. And when it comes to selecting patients for therapy, dermatologists consider half of their AD patients as candidates for Opzelura. We expect the number of patient initiations per prescriber to continue to increase over time.

Turning now to launch in vitiligo, where we are seeing positive early momentum. Awareness levels are high, with 9 out of 10 dermatologists aware of Opzelura as a treatment for vitiligo. Dermatologists view Opzelura, which is the first-ever approved treatment for repigmentation, as a transformative therapy for patients living with vitiligo.

In a recent survey, as shown on the left, dermatologists indicated their use of Opzelura in vitiligo would more than triple in the next 6 months. Of their currently treated vitiligo patients, dermatologists consider nearly 70% could be candidates for treatment with Opzelura.

For the 1.3 million diagnosed vitiligo patients who are currently not seeking treatment, we are launching several initiatives, including direct-to-consumer campaigns, patient advocacy group engagements and branded patient meetings to raise awareness and encourage those patients to seek treatment now that there is a new approved therapy. Both AD and vitiligo are substantial opportunities, and we expect Opzelura to become a meaningful growth driver over the next several years.

On Slide 10, payer coverage for Opzelura continues to improve, with a percentage of covered claims increasing from an average of 39% in the second quarter to 63% in the third quarter and reaching 70% in October. With an increasing number of plans adding Opzelura on to formularies and the continued removal of NDC blocks, we have started to gradually shut down the full buy-down program and transition to a more traditional free drug bridging program.

We expect to fully discontinue the full buy-down program around the end of the year. Please note that during this period of transition to the free drug bridging program, we expect variability in how IQVIA captures those prescriptions, which may lead to data not being representative of the actual prescription levels and trends.

Moving on to Jakafi performance on Slide 11. Jakafi net sales in the third quarter grew 13% year-over-year to $620 million, driven by growth in new patients across all indications. Within myelofibrosis, new patient starts grew by 8% and in polycythemia vera by 9%, total GVHD patients grew 20% year-over-year with the continued successful launch in the chronic setting. With strong demand for Jakafi, we are again tightening the full year net product revenue guidance from a range of $2.36 billion to $2.4 billion to a new range of $2.38 billion to $2.4 billion.

Turning to Slide 12. Monjuvi net product sales in the U.S. were $22 million in the third quarter. We continue to see gradual improvement in duration of therapy as use continues to expand in the second line. Minjuvi net sales were $6 million for the quarter, with the launch going well in Germany and where we have seen several months of consecutive growth.

Pemazyre worldwide net sales were $23 million, with the launch continuing to progress in Europe and Japan. During the quarter, we also received approval of Pemazyre as the first targeted therapy in the United States for myeloid lymphoid neoplasms with FGFR1 rearrangement, an extremely rare and aggressive blood cancer.

With that, I'll turn the call over to Steven.

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

Thank you, Barry, and good morning, everyone. We recently presented positive Phase II data of povorcitinib in hidradenitis suppurativa at the 2022 European Academy of Dermatology and Venereology Congress, which demonstrated that patients on povorcitinib had significantly greater decreases in total abscess and inflammatory nodule count versus placebo from baseline to week 16.

In addition, HS Clinical Response, or HiSCR, which is defined as a greater than or equal to 50% reduction in the total abscess and inflammatory nodule count and no increase in abscess count or draining fistulas compared to baseline, was achieved in a greater percentage of povorcitinib patients than placebo at week 16. Hidradenitis suppurativa represents a significant opportunity where there are more than 150,000 patients with moderate-to-severe disease in the United States.

In October, our pivotal Phase III data of ruxolitinib cream in vitiligo was published in the New England Journal of Medicine, and these data highlight the positive efficacy and safety profile of Opzelura as a treatment for repigmentation in vitiligo. The MAA for Opzelura in vitiligo is under review, and we expect a regulatory decision in the first half of next year.

Moving to Slide 16. Last month, we announced our agreement to acquire Villaris Therapeutics and their lead asset, auremolimab, a highly potent and selective anti-IL-15 receptor beta monoclonal antibody. IL-15 signaling occurs upstream of the JAK-STAT pathway and demonstrates a strong scientific rationale for the evaluation of IL-15 blockade in vitiligo and other dermatologic conditions.

In vitiligo, preclinical data suggests that maintenance and relapse is driven by resident memory T cells, or TRM, in the skin. IL-15 is critical for the survival of TRM and IL-15 blockade may result in the depletion of resident memory T cells, leading to a longer and more durable repigmentation effect.

The addition of auremolimab to our dermatology portfolio bolsters our commitment to patients living with vitiligo and potentially offers optionality based on severity of disease as well as different dosing options that may allow for combination therapy, all of which is complementary to our JAK franchise. We are planning on entering clinical development with auremolimab in 2023.

On Slide 17 is an updated table of our extensive clinical development pipeline in dermatology. With regards to ruxolitinib cream in hand eczema, after discussions with the FDA, it was deemed not necessary to run a larger Phase III clinical trial in chronic hand eczema as the indication is covered by the current label.

We've also added 2 new indications in the development plan for ruxolitinib cream with 2 Phase II trials in preparation for lichen sclerosis and lichen planus. Additionally, auremolimab in vitiligo has been included, which is expected to enter clinical development in 2023, as I mentioned earlier.

Turning to Slide 18 and axatilimab. As a reminder, the Phase I/II study in chronic graft-versus-host disease, this was an open-label study evaluating axatilimab, an anti-CSF1R antibody, in patients 6 years and older with active chronic graft-versus-host disease in the third line plus setting. In this heavily pretreated patient population, axatilimab monotherapy resulted in a best overall response rate of 68% across both doses of 1 milligram per kilogram every 2 weeks and 3 milligrams per kilogram every 4 weeks. 53% of patients reported a clinical meaningful improvement in their symptoms via the Lee Symptom Scale. Axatilimab was also well tolerated and demonstrated an acceptable safety profile with no viral reactivations in the study.

Looking ahead, we anticipate data from the ongoing AGAVE-201 pivotal trial in chronic graft-versus-host disease in mid-2023 and thus the potential BLA filing later in 2023. In addition, a combinational trial of axatilimab and ruxolitinib in steroid-naive chronic graft-versus-host disease is in preparation with an expected initiation in the first quarter of next year.

On the next slide and our progress in myeloproliferative neoplasms and graft-versus-host disease in general. We continue to advance our LIMBER pipeline and expect to achieve many important milestones in the remaining months of 2022 and into 2023.

The Phase I study of ruxolitinib in combination with Cellenkos' CK-0804 in myelofibrosis has initiated with the first patient dosed in October. Later this year, we expect to present initial data from the BET and ALK2 programs. The target action date for once-daily ruxolitinib is March 23, 2023. And we expect top line results from the Phase III study of parsaclisib plus ruxolitinib in inadequate responders in 2023 as well.

Turning to Slide 20 and our oral PD-L1 program. We continue to progress the development of our oral PD-L1 program with 2 compounds, 280 and 318, which have been prioritized based on observation of tumor shrinkage and to date, no evidence of peripheral neuropathy with either compound. We will be presenting updated data on both compounds at the Society for the Immunotherapy of Cancer Annual Meeting in Boston next week.

The third quarter was successful for Incyte across regulatory, clinical and business development, and we are looking forward to an exciting close to the year.

I'd like to turn the call over to Christiana for the financial update.

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

Thank you, Steven, and good morning, everyone. Our third quarter results reflect continued strong revenue growth with total product revenues of $713 million, representing an increase of 20% over the third quarter of 2021. Total product revenues are comprised of $620 million for Jakafi, $55 million for other hematology/oncology products and $38 million for Opzelura.

Net product revenue growth was primarily driven by increases in Jakafi and Opzelura net revenues. Hematology/oncology net revenues, which include revenues from Iclusig, Pemazyre and Minjuvi, were impacted by unfavorable changes in foreign exchange rates. On a constant currency basis, other hematology/oncology net product revenues grew by 32% over the prior-year period.

Total royalty revenues for the quarter were $110 million and are comprised of royalties from Novartis of $86 million for Jakavi and $4 million for Tabrecta and royalties from Lilly of $20 million for Olumiant. Jakavi and Olumiant royalties for the quarter were negatively impacted by FX headwinds, while Olumiant royalties were also impacted by a decrease in net product sales of Olumiant for use as a treatment for COVID-19 and a onetime deduction taken by Lilly related to securing additional intellectual property rights.

Excluding the impact of onetime IP payments, COVID-19 related sales and currency fluctuations, Olumiant royalties were essentially flat on a constant currency basis compared to the prior-year period. Opzelura net product revenues for the quarter were $38 million, driven by robust demand and broadening payer access. As payers add Opzelura to formulary and the share of covered claims increases, we are continuing to see improvement in the gross to net discount rate.

As Barry previously presented, the percentage of covered claims is increasing, and the average quarterly gross to net discount is decreasing, as shown at the bottom of the slide. The fully loaded gross to net discount rate decreased from 81% in the second quarter of 2022 to 71% in the third quarter of this year. We expect the gross to net discount rate to continue to decline in the fourth quarter and reach a fully loaded steady-state exit rate of 40% to 50% around year-end.

Moving on to our operating expenses on a GAAP basis. Ongoing R&D expenses of $351 million for the third quarter increased 6% from the prior-year period, primarily due to continued investment in our late-stage development assets. The growth of SG&A expenses was primarily due to our investments related to the new dermatology commercial organization in the U.S. and the related activities to support the launch of Opzelura in atopic dermatitis and vitiligo. Our collaboration loss for the quarter was $2 million, which represents our 50% share of the U.S. net commercialization loss for Monjuvi.

Moving on to our guidance for 2022. Based on the strong performance of Jakafi, we are tightening our guidance to a range of $2.38 billion to $2.4 billion. Given FX headwinds that we experienced year-to-date and expect to continue to experience in the fourth quarter, we are revising our other hematology/oncology revenue guidance to a range of $200 million to $210 million.

Finally, we are reaffirming our R&D guidance, which now includes the $70 million upfront payment to Villaris anticipated in Q4 as well as SG&A guidance for the year.

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 today is coming from Salveen Richter from Goldman Sachs.

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

Congratulation on the quarter. On Opzelura, can you help us think about the trajectory from here just given the moving parts with [free drug] and gross to net and the uptake in the vitiligo population? Just maybe some color there would be helpful.

And then secondly, in Opzelura, just if you could help us understand the reimbursement dynamics that are playing out around writing a script and how (inaudible) maybe, and what you're doing to kind of alleviate that burden on the part of the physician?

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

First, Salveen -- this is Barry. So as far as the uptake in vitiligo goes, we're very happy. As you see from the prepared remarks, our dermatologists are excited about having this new therapy -- first ever therapy to repigment the skin in patients with vitiligo. We know that, as soon as the launch, which really we began in August, vitiligo scripts began to accelerate, and we know they'll continue to accelerate. As we've told you before, there's about 150,000 to 200,000 patients that are actively being treated for vitiligo now. There may be 1.3 million or more patients that have vitiligo that may choose to come back to their dermatologists now that they have an active therapy that can help them there.

So we're very happy. We can't really break out the actual number of percentage of vitiligo versus atopic dermatitis for you just at this point, just because the -- we're uncertain about the actual number since many of the claims that we can look at are really don't have diagnostic codes associated with them, so where we know that atopic dermatitis, for example, because we have more data with that it's growing at least double digits quarter-over-quarter. We know that vitiligo is accelerating week after week, and we assume that's going to continue to occur.

In terms of reimbursement and the dynamics there, of course, most patients have to go through a prior approval process, those patients that have commercial insurance. But as we've said, the coverage has continued to get better and better over time, so that the vast majority of commercial patients do have access to therapy.

As far as problems go, prior approval is something that dermatologists deal with all of the time. Most of the AD utilization criteria do, in fact, include 1 or 2 step therapies that they have to go through, but dermatologists are used to doing that now. There may have been a little period of time where they were getting used to their prior approval process, the step therapy process. But certainly, since July 1, it's really taken off.

And if there were barriers, they're mostly removed. Sometimes there is geographic barriers. One region of the country may be easy. Another area of the country may be a little bit more difficult. But with our own people that are out in the field, we try to help as best we can. We have an excellent market access team that can help the dermatologists and pharmacists go through the prior approval process so that most patients now and into the future should have little problem accessing Opzelura for both AD and vitiligo.

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 wanted to follow up on gross to net. Where are you with the free drug program as of right now? Are you withdrawing that? And where do you expect that to be on a go-forward basis as you try to get closer to your 40% to 50% gross to net for the year? And just to clarify, you're planning on exiting the year with 40% to 50% gross to net. Is that correct?

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

Tazeen, it's Barry again. Yes. So our gross to net, we do plan on having it get better as we exit the year. The most important factor is we are changing over from what we call a full buy-down program, where it was a very generous program at the beginning of the year, at the beginning of launch,

where it was the very easiest thing to do for patients and for dermatologists so that they could go to any pharmacy. And even when there was really limited coverage because of NDC blocks, they were able to access the drug because we were paying for the drug for full buy-down.

Now that we have increasing coverage and the vast majority of commercial patients do have access to the drug, we're switching over to a more typical bridging program where patients will be able to -- that have commercial insurance and they go through the prior approval process and for whatever reason, they are, in fact, denied coverage, then they would end up getting through our bridging program, free drug, at cost of goods for us so that, that has a big impact on gross to net. But that number will continue to go down over and over. As we've said, 70% of the claims currently are going through and being paid, and that will increase as we go through the year and towards the end of the year. So that will improve as well.

So we'll continue to improve our gross to net just through that switching our programs, but also we're continuing to increase coverage for those payers out there that we still have some work to do, and we'll increase our -- will improve our gross to net by working with each of the plans to improve the utilization management criteria so that we are in the proper tiers, where we should be, so that co-pays are lower. So those things will affect the gross to net and bring it down to the targeted range that we're looking for.

Operator

Your next question is coming from Jessica Fye from JPMorgan.

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

A couple more on Opzelura. You mentioned you're still working to increase coverage. And I know you gave the percent of covered claims. What's the current percent of lives covered today? And where do you want that to go?

And then second, how good is your visibility on patient retention and, say, annual tubes per patient in each of these settings? Where does that stand now? And how do you see that evolving?

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

Well, I think we said that, as of now, 70% of the claims are going through and being paid. The coverage really is approaching 84% of plans have -- 84% of patients that have commercial insurance have access through the contracts that we have signed. So that's there. As far as patient retention is concerned, because most of the scripts that come through are new Rxs or new to brand Rxs, so, in fact, we'll need some more time and data to figure out exactly what the refill rate will ultimately be both for AD and vitiligo, but we're still projecting for AD, the average per year scripts will be 2 to 3 tubes -- will be 2 to 3, and the average for vitiligo around 10 tubes per year for vitiligo patients.

Operator

Next question is coming from Evan Seigerman from BMO Capital Markets.

Unidentified Analyst

This is Keith, on for Evan. I guess first one, it just looks like, looking at the numbers by some measures, we could be seeing ex U.S. growth later in 2022 and then 2023, but we're seeing this quarter lower royalties. Just want to get a sense of how this -- you are seeing this evolve in 2023 given regulatory progress?

And then secondarily, if you could comment on the differences between the 2 oral PD-1 inhibitors that are in parallel development? And at what point would you decide to focus on 1 versus the other?

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

So in terms of the royalties, as I indicated in the prepared remarks, we have seen FX headwinds having an impact on royalties given that Jakavi and Olumiant are very much ex U.S. -- based on ex U.S. sales. In addition to the FX impact, for Olumiant, we saw sales associated with COVID-19 treatment going away. And as a result, there were no royalties associated to COVID-19 sales this past quarter.

And in addition to that, there was onetime payment associated with securing some additional IP, which was deducted from the royalties that we get for Olumiant. If you take out all those impacts, FX, COVID-19 related sales and the onetime IP payment, then we see royalties being pretty flat year-over-year.

Going forward, we don't provide the guidance on royalties, but we would expect for Olumiant to continue not to have any COVID-19 related royalties. And also the FX impact, obviously, is something that everybody has been experiencing. And at this point, we continue to see that impact continuing in the fourth quarter.

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

Keith, it's Steven. I'll answer your second question on the oral PD-L1 franchise. Firstly, just to say, it's an extremely important franchise to us. We are first in class here, and this is a very important program. The initial compound, 550, was dropped because of the peripheral neuropathy signal, which we have not seen with either 280 or 318. 280 is slightly ahead of 318. There are differences structurally in terms of the chemical structure, and there are slight differences in terms of the PK. But for now, both continue to progress, both are enrolling well. And we continue to accumulate efficacy and safety data that we want. You'll see next week at SITC, poster presentations on both compounds.

In terms of going forward, sometime next year, we'll probably declare registration directed-wise, which compound will be taken. But all I can tell at the present time, we'll keep both going. They both look good. And we want that optionality given the importance of this program.

Operator

Next question today is coming from Vikram Purohit from Morgan Stanley.

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

So going back to dermatology. I wanted to ask a question on IQVIA capture ratios. So we recall that in 2Q '22, you mentioned that there was an overstatement. I just wanted to see if there's any color available about how that's trended in 3Q versus 2Q? And then you mentioned that there could be some more irregularities going forward because of the transition from the full buy-down program to the bridging program. And I was wondering if you could comment on directionally how you think the irregularities might trend if you think that's going to be an overstatement or understatement, and to what degree do you think the capture ratio might be irregular? And then I had a follow-up.

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

So Vikram, in Q2, we saw IQVIA overstating the level of Opzelura prescriptions, and that's something that we discussed last quarter. However, at that time, the trend in prescriptions was pretty representative of the actual trend. So if you were to look at the trend lines, they were moving in parallel, the IQVIA line in parallel with [actuals]. What we have since seen is that the gap between the level of actual IQVIA reported scripts has been narrowing. But the trend line is no longer representative of the actual trend line.

So for example, when you look at the IQVIA data over the last few weeks of the quarter, you saw that it was flattening, while this was not the case. As we now transition from the full buy-down program to the more traditional free drug bridging program, there is actually a high level of uncertainty as to how IQVIA will be capturing the scripts. And it's unclear whether that would result in an overestimation of scripts or an underestimation.

So as a result, we expect that, for a period of time, at least through the fourth quarter, the IQVIA data would not be representative of actuals , both in terms of the level of scripts as well as the trend line.

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

Okay. Understood. And then I had a follow-up on povorcitinib. So you mentioned that a Phase III study there is going to start in hidradenitis suppurativa by the end of the year. Could you just talk a little bit about what the study could look like from a design perspective? And what patient population you think you would enroll in this program?

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

Yes, Vikram, it's Steven. Thanks for the question. We just showed that data at EADV recently from our Phase II proof-of-concept work. And there was a very good reaction from people in the field and opinion leaders in the field as to the potential for povorcitinib to treat patients with unmet need in HS. The morbidity from the condition comes from abscesses, nodules and fistulas, and there's a large inflammatory component speaking to probably why JAK-STAT inhibition is important there.

The regulatory endpoint that was established from the initial approval of the first drug in the setting is, as I mentioned in the prepared remarks, something called HiSCR. It's a composite endpoint that looks at abscesses and nodules and then the lack of further fistula formation. It'll -- it's an endpoint that's captured at 16 weeks.

We will go into this population with 2 doses. And you can see from our Phase II work, there was a dose response generally speaking, but there wasn't a great differentiation between the 2 higher doses tested in the Phase II setting. So both will be taken into Phase III. And then otherwise, a standard endpoint from a HiSCR point of view. The current approved therapies don't seem to give patients a benefit they desire and aren't used a great deal in HS. So there's a lot of unmet medical need here.

Operator

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 wanted to understand a little bit better on the gross to net exit rate. When you say around the end of the year, does that include the possibility of that figure slipping into the first quarter?

And then secondarily, on the hidradenitis suppurativa, can you talk a little bit about the market and where porvacitinib could fit into that space right now?

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

So Mara, this is Barry. On the gross to net, yes. So we're saying that we get to the 40% to 50% by the end of the year for all of the factors that I pointed out before about the transition to the bridging program, about the improved coverage, about our working with the payers to have better utilization management criteria, lowering tiers, lowering the co-pay. What we didn't mention before is that you're picking up co-pays and you're picking up deductibles and deductibles go down as the year goes down. So that improves that.

And I'll turn it over to Steven for the HS.

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

Yes, it's Steven. Thank you for the interest in the condition, and it's the same thing we hear after we presented the data. So it's estimated that if you look at moderate-to-severe HS in the United States, there are about 150,000 patients in terms of prevalence of the condition. Again, with a lot of unmet need that's not been currently addressed by the current approved therapy. So the study will be focused on those moderate to severe and then will include control arm plus 2 doses, as I mentioned earlier. It's in preparation. We'd like to begin towards the end of this year, perhaps early next year. And then we've already demonstrated probably because of the excitement in the area and the unmet need that these studies enroll really, really well.

So that's the population we go in after and that's the current prevalence figure that we want to address with this particular study.

Operator

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

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

This is Leonid, on for Brian. I wanted to go back to Opzelura. So earlier, you had mentioned that there were some challenges with scripts being abandoned and formularies -- or pharmacies not coding properly. I guess, can you talk about how these have been resolved, and if there's any challenges there that may continue to occur due to the free drug wind-down program?

And I guess, do you have a sense of what percentage of patients that are actually on the free drug, then go and start using the paid product and what you might need to do to get those claims higher? And then I guess, sort of just related to that gross to net aspect, I mean, do you have any visibility into the 2023 contracting, given that inflation is fairly high? Do you think you'll have to give back a lot of any potential price increases you might take into gross to net?

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

Sure. Well, I'll try to answer your last question first. The 2023 contract -- the contracts that anybody -- that the payers are working on now is for 2024. For 2023, there's no changes that will occur. As far as -- I didn't -- don't think I mentioned anything about abandoned prescriptions at pharmacies at all and not coding correctly. No, the only thing we said was that as we were changing over from mostly free drug to now mostly paid drug, dermatologists and pharmacies had to go through a prior approval process that before they were essentially just getting free drug because there are NDC blocks in place.

So now moving forward, in fact, we should have less and less problems with prior approvals or used to any step therapies that the utilization management criteria has. And obviously, like I said before, we have our market access people that try to help any dermatology offices or pharmacies that are still having problems with that. But we think we're through those challenges. There's always going to be prior approvals for drugs like these. So -- that's part of our system that we're currently dealing with.

So I think we said before that most of the claims that are going through now are being paid, and that's only going to get better as we move into the future.

Operator

Next question is coming from Jay Olson from Oppenheimer.

Unidentified Analyst

This (inaudible), on for Jay. So maybe 1 question on povorcitinib for HS. Can you just maybe talk about the unmet needs with Humira that you can maybe potentially address with povorcitinib? And also on the auremolimab, you recently acquired, just if you can provide some color on how we can complement your vitiligo franchise, especially I think povorcitinib is also being studied for vitiligo? And any other potential indications you are planning, what you're thinking about with auremolimab?

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

Yes, it's Steven. Thanks for the question again on HS. So just to be somewhat repetitive, these patients have a lot of morbidity, particularly in skin folds, like the armpits, the axilla and other parts of the body in terms of abscesses and nodules that drain and cause a lot of morbidity to these patients. It looks like the currently approved TNF inhibitor doesn't fully address that unmet need. And again, that speaks to the interest in new mechanisms of action here that look like from our Phase II proof of concept may be addressed very well from -- in terms of povorcitinib and JAK inhibition.

So that's the reason we're excited about the data. That's the reason we want to go fast into a Phase III. There is a very good in my -- in the slide, in the prepared remarks, response in terms of abscess and nodule formation. And we'll be testing, as I said earlier, 2 doses there. It's about somewhere around 0.1% of the U.S. population, but we estimate approximately -- excuse me, upwards of 150,000 patients in U.S. prevalence-wise and maybe about 50,000 currently get treated. But if you have a therapy that addresses that need, then that will be a really important thing to develop.

In terms of auremolimab and its IL-15 receptor beta monoclonal antibody, as I said, this addresses resident memory T cells in the skin, which are felt to cause the melanocytes not to produce the pigment and then to keep the disease present. So by addressing this and there's a very good preclinical model, you can potentially result in "cure" or at least prolonged responses in terms of repigmentation. So we view this completely complementary.

Just to go over the entirety of our vitiligo studies, our first indication with Opzelura is in patients with 10% or below body surface area involvement and requires long-term treatment to get the effects that improve over time. If you look at the data, if you look at the 24-week data, it goes up by another 20% absolute points when you get to 50 weeks.

And then with povorcitinib, our vitiligo program is looking at patients with more severe vitiligo, more body surface area involvement, so 8% or above. And again, we have data there that's really encouraging, and we'll be presenting it early next year at a major meeting and then make go-forward decisions for povorcitinib there in terms of an oral therapy with a different therapeutic ratio.

And then just to round it out, now with the anti-IL-15 receptor beta antibody, we get their entirety, and we expect that will have activity on its own based on the preclinical models, and that's how we'll start testing it initially. But you can imagine a world going forward where these therapies will complement one another and be used interchangeably depending on the disease and how it evolves. And we really want to address the unmet need here. We're excited about our vitiligo franchise and what it can do for patients who require and want repigmentation.

Sorry, your last question. Other indications, I think it's pretty early, but the mechanism may be important in areas like systemic sclerosis, sarcoid, et cetera, but it's very early in that journey. So we'll just see how this program goes going forward.

Operator

Next question is coming from Michael Schmidt from Guggenheim Securities.

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

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

Congrats on this progress. I was wondering if you could help us set the stage a little bit for the LIMBER updates coming soon. Maybe an idea of how many patients you'll have with the ALK2 or BET plus Jakafi combinations. And later this year, do you think that's enough data to make a determination on how you're moving either or both of those programs forward?

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

Yes, it's Steven. The LIMBER program in terms of combinations is again key to how we want to address unmet need in patients with myeloproliferative neoplasms. We're looking very much forward to the ASH meeting, and it's been a really important meeting for us.

In terms of each of the programs, ALK2 is a little more advanced than the BET program. We've already showed data from a translational point of view that we get the hepcidin inhibition we want, the iron kinetics are favorable in terms of the way they're moving, and we expect to follow with hemoglobin increases. I can't -- you'll have to wait for the actual presentation at a meeting at the end of the year to show the entirety of the data, but we expect to show a reasonable number of patients with monotherapy and some in combination with ALK2.

BET, as I said, is a little bit behind that, given the abstract cutoff for the particular meeting and the poster presentation. There'll be a little less data quantitatively with BET at that meeting, mostly in the monotherapy setting and not yet a combination data to show given the cutoffs.

In terms of decisions, this will be in 2023 on where to go with these programs. Once we have established safe doses and schedules, we'll look at the particular populations that need to be addressed. Of interest with ALK2 are obviously patients potentially with anemia given its mechanism of action, but it could be beyond because it will result in ability to maintain RUX dose intensity. And with BET, we'll see also given the competitive space where that is on where to go in terms of first-line and suboptimal populations. But those decisions to answer your questions will be in 2023.

Operator

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

Kelsey Beatrice Goodwin - *Guggenheim Securities, LLC, Research Division - Associate*

This is Kelsey, on for Michael. Apologies for getting disconnected there. I guess how do you kind of anticipate the MF market landscape evolving in the coming years with the recent approval of Vonjo and potential approval of momelotinib next year? And are you seeing a change in patient new starts, particularly those with low platelets, given Vonjo is now available in the U.S.?

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

Sure, Kelsey. So in myelofibrosis, as you know, Jakafi has been approved now for about 11 years in myelofibrosis. 2 other JAK inhibitors, pacritinib and fedratinib, have been approved. Fedratinib from BMS, as you probably know, really has been flat to declining, mostly used in the second-line setting, if used at all. As far as Vonjo is concerned, at least the data that we look at, we don't really see much Vonjo usage, but it must be being used in the second-line setting, and that's the way that it seems to be positioned for those patients that have low platelets.

Evolving over time, I mean, obviously, there could be some combination data in the future with other products for momelotinib. We'll have to wait and see what the label says. But because of the survival advantage that Jakafi has, because of the unprecedented symptom improvement that Jakafi has with low GI toxicity, we think it will be the standard of care for a long time.

We do not see any changes in -- or noticeable changes at all in the duration of therapy for patients. We -- as I said before, that we continue to grow new patients in MF after all of this time. So we grew 8% in terms of new patient growth for myelofibrosis. And we continue to position Jakafi as first line, and we believe it should be started as soon as possible before patients have a possibility of progressing and getting worse.

So we're confident in our position. We'll have to wait and see what momelotinib label says, but we think that Jakafi will still be the standard of care because of its efficacy and safety profile.

Operator

Next question is coming from Eva Privitera from Cowen.

Eva Xia Privitera - *Cowen and Company, LLC, Research Division - Associate*

Can you give an update on the progress made towards establishing utilization management criteria in vitiligo? Approximately what percentage of plans now have UMs in place?

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

Well, because most of the contracts were -- that we established for AD carried over to Vitiligo. Now some of the vitiligo utilization criteria that's in place, there was vitiligo criteria for maybe half of the plans throughout the United States before Opzelura was approved for vitiligo and has only increased over time. Some of them -- some of the utilization criteria that we've seen have Opzelura as first line, some have 1 step, some have 2 steps. Now we'll continue to work with each and every one of those plans every single day to optimize utilization criteria to actually reflect the clinical data because, in fact, there's no reason to use any step therapy for vitiligo for these patients that have vitiligo because the clinical data -- because it's the only drug approved, first and only drug approved for that condition.

So in a way, we'll continue to see the utilization criteria only get better because the drug is so good, and it should be used in the first-line setting when patients come in and want to be treated for their vitiligo.

Eva Xia Privitera - *Cowen and Company, LLC, Research Division - Associate*

And a quick follow-up. When do you expect to start running DTC ads for vitiligo?

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

Well, we're already doing DTC for vitiligo in a variety of locations, of course, through social media, things like Facebook, Instagram and so forth in terms of Internet search optimization. So if you go looking for vitiligo, you'll find Opzelura. You go looking for Opzelura, you'll find that vitiligo is there. We also have patient webinars, and we work with patient advocacy groups. So the DTC is going on. If what you mean by television commercials, as you know, we're running TV advertisements, both linear and nonlinear, so connected TV and non-connected TV for atopic dermatitis now. So the vitiligo commercials for -- again, for connected and non-connected TV will start either in December or January. We have to figure that out yet just for what's the best placement, what's the best timing for these ads to have the most impact.

Operator

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

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

I'm sorry if I missed this, I've been jumping from call to call. But I was wondering if you could give some color on the inventory levels. When I do a back of the envelope calculation, it appears that, that may have gone up about $3 million based on the numbers you've given. And then also just wondering if you guys are still confident in the $1.5 billion guidance for Opzelura in AD in the U.S. alone.

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

So as far as inventory levels go, Andrew, I'm not really sure what you mean. I assume you mean for Opzelura. I certainly don't see -- our inventory levels have maintained about 2 weeks period of time. It's actually a little lower than we really thought it was going to be when we first got into this endeavor.

And as far as the guidance goes, we're confident that with the almost 30 million patients in the United States that have atopic dermatitis and the 5.5 Million that are actively being treated now, that $1.5 billion guidance is certainly within our range -- our possibilities.

Operator

Next question is coming from Gavin Clark-Gartner from Evercore.

Gavin Clark-Gartner - *Evercore ISI Institutional Equities, Research Division - Analyst*

I just wanted to confirm something I heard earlier. Did you mention that patients are using 2 to 3 tubes per year for Opzelura in atopic derm in the real-world setting?

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

So Gavin, what I said was that on average, over time, we'll see -- we believe that 2 to 3 tubes per year per patient with atopic dermatitis is what it will work out to be.

Gavin Clark-Gartner - *Evercore ISI Institutional Equities, Research Division - Analyst*

Okay. Got it. So I mean, what's driving the difference from the 3 to 4 tubes that we've been guiding towards previously?

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

Well, quite frankly, we'll find out as we move forward into the coming years because it takes time for refills to be clear. And plus, as I was sort of alluding to before, sometimes you can't tell a difference between a new-to-brand prescription, meaning that's the first time the patient got the drug and a new prescription that might be for a patient that already had it, but it came from either a different prescriber or went through a different pharmacy. So sometimes those are hard to match up.

So over time, we'll see whether it's 2 to 3, 3 to 4. But also the drug is great, and it works really well. So I think that if there is any difference, it's because that patients come in, they get the drug, it clears their skin up, clears their itch up. But we will see over time what the real usage is going to be. And like I said, we really have to sort out which is truly a new patient and which is a patient that's just getting a new script that may have gotten a different script 3, 4 months ago.

Operator

Next question is coming from Kripa Devarakonda from Truist.

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

A quick question on vitiligo. Now that you've launched and you have an early idea of how it's being received and the awareness amongst doctors and maybe even patients, when do you think you'll be able to provide how big of an opportunity this could be in line with the $1.5 billion opportunity, talked about AD in the U.S.?

And then you have $3 billion in cash. As a competitive landscape in myelofibrosis with all the different combinations that are currently under investigation, it was -- any changes in your thinking around capital allocation and the size -- you did the Villaris acquisition recently, but the size of deals?

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

Kripa, in terms of vitiligo, as Barry indicated, we are very pleased with the launch and the initial progress. But we are very early in the launch. And this is a very different market than AD. It's not an established market. You have only a small percent of the patients that have been diagnosed with vitiligo currently seeking treatment. It's around 10%. And you have a very big part of the patient population that is inactive.

So we want to wait to see a few quarters of uptake to get a better understanding, not only of the currently active patients seeking treatment and how quickly do they come into the therapy, but also how quickly the inactive population gets activated and the uptake there before we provide any type of guidance around vitiligo.

In terms of your second question on BD, there is no change in our thinking in terms of the type of transactions and the objective that we have with BD. We are looking to bring in assets that fit well with our current areas of expertise and can leverage our capabilities, can leverage our infrastructure and can add to our revenues and diversification in the second half of the decade.

Villaris fits very nicely with that objective. It is at an earlier stage and smaller deal. But we will continue to actively look for others. I would say, bolt-ons is the nature of acquisitions that we are primarily focusing on.

Operator

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

Christine Chiou - *Incyte Corporation - Head of IR*

Thank you all for participating in the call today and for your questions, the IR team will be available for the rest of the day for follow-up. Thank you, and goodbye.

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.