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INCY.OQ - Q2 2022 Incyte Corp Earnings Call

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OVERVIEW:

Co. reported 2Q22 total product revenues of $664m.

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PRESENTATION

Operator

Hello, and welcome to the Incyte Second Quarter 2022 Earnings 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.

Christine Chiou - *Incyte Corporation - Head of IR*

Thank you, Kevin. Good morning, and welcome to Incyte's Second 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. In the second quarter, revenues increased 29% year-over-year, reaching $911 million. Jakafi net sales grew 13% to $598 million, benefiting from growth in new patient start in all 3 indications. The contribution from our other hematology and oncology products continued to increase as the launches of Monjuvi and Minjuvi progress in Europe and Japan.

We also made significant progress with the launch of Opzelura in atopic dermatitis where we now have the third PBM GPO contract signed. This is a key milestone in achieving broad formulary access and an important step towards accelerating the growth of Opzelura net revenues. As we shift from free drug to paid prescription, we are seeing some temporary delays in the filling of prescription, which had an impact on second quarter revenues. However, patient demand and satisfaction remains strong and improvement in reimbursement are translating to an increase in covered claims with a significant increase seen in July.

These metrics are pointing to a continuation of a successful launch in atopic dermatitis. Turning to Slide 5. Two weeks ago, Opzelura was also approved for the treatment of non-segmental vitiligo, becoming the first and only therapy for repigmentation for these patients.

The approval of Opzelura was a momentous occasion for the millions of people living with the disease and generated a tremendous amount of excitement in the dermatology community with advocacy groups and patients.

Turning to Slide 6. We also had multiple approvals this quarter with our partnered products. Jakavi was approved as the first post-steroid systemic treatment for both acute and chronic GVHD in Europe. Olumiant was approved as the first and only systemic treatment for alopecia areata in the U.S., Europe and Japan. And Tabrecta received European approval for a subgroup of patients with non-small cell lung cancer. Together, these approvals provided insight with $130 million of milestone revenues and will contribute with royalties to our future revenue growth.

Finally, looking at some of the additional highlights of our pipeline on Slide 7, for povorcitinib, formerly known at 707, is now in preparation for a Phase III study in HS following the positive results from our Phase II trial. As part of the LIMBER program, IND clearance was received for CK0804, Cellenkos, cord blood-derived T-regulatory cells as add-on therapy to ruxolitinib for the treatment of myelofibrosis. We also received FDA clearance -- FDA acceptance of the NDA submission for QD ruxolitinib with a PDUFA date of March 23.

And lastly, in early development, we expect to initiate a clinical program later this year with 459, a LAG-3 PD-1 bispecific antibody developed in partnership with Merus. We have multiple ongoing studies across dermatology, LIMBER and hematology/oncology, as you can see on the right, where each represents a meaningful opportunity and puts us in an excellent position for future growth and diversification.

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

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

Thank you, Herve, and good morning, everyone.

Starting with Opzelura. The launch in atopic dermatitis continues to be strong, and we are very pleased with the progress that we have made across the number of important metrics. To date, over 10,000 physicians have prescribed Opzelura with new writers being added each week.

Physicians continue to report a high level of satisfaction with Opzelura with 67% stating that they are highly satisfied, up from 46% earlier this year. Additionally, in a recent poll, physicians indicated nearly half of their AD patients would be appropriate candidates for Opzelura, up from 37% earlier this year.

Efficacy, including rapid itch reduction, as well as tolerability and the ability to use Opzelura in sensitive areas remain the key product attributes, and we expect these attributes to continue to drive demand for Opzelura in AD.

Turning to Slide 10. Earlier this month, we announced that we now have signed contracts with the largest -- with the 3 largest PBM/GPOs, an outstanding achievement 10 months into launch, and a key step towards reaching our steady-state gross to net goal.

The contract with the third PBM became effective July 1st and individual plans will now be adding Opzelura to their formularies. The charts shown on this slide is our internal 867 data, which is the number of Opzelura units shipped from wholesalers to pharmacies.

With regards to IQVIA data, there has been an increased variability with the data in recent weeks. The overall trend shown by IQVIA data is representative of the actual kinetics. However, the number of filled prescriptions as reported by IQVIA are being over projected. It is important to take away from this slide a couple of points, both on Q2 performance and on recent trends.

In the second quarter, as NDC blocks were removed and Opzelura was added to formularies, pharmacists and dermatologists began to shift from the process of the free drug program to going through the formulary process. This shift has 2 different effects. One is a temporary delay of filled prescriptions, which you saw in the second quarter; and two, is the positive impact on covered claims, the benefit of which will be more pronounced beginning in Q3.

We are already seeing a return of 867 demand to within the range of our highest point since launch. Additionally, the percentage of covered claims, as shown by the red line, has risen rapidly from the mid-20% range at the end of June to nearly 55% today. We anticipate, with the combined effect of an increased number of filled prescriptions and improving gross to net, Opzelura will have a more meaningful contribution to net sales in the second half of this year.

On Slide 11, we're turning to vitiligo. This slide captures some of the highlights from Opzelura's FDA-approved label, as the first treatment for repigmentation in vitiligo. This is a historic approval for patients living with this disease, and the approved label includes a number of important points that will help to drive the success of the product in this indication. Opzelura is approved for patients 12 years of age and older and can be applied to affected areas up to 10% BSA.

The label allows for continuous use of Opzelura anywhere on the body, including sensitive areas, with no limit on duration of use. The 52-week efficacy data, which has been included in the label, demonstrates the continued improvement in repigmentation with longer duration of treatment, highlighting the importance of staying on therapy. The label also notes that a satisfactory patient response may require treatment with Opzelura for more than 24 weeks.

And lastly, Opzelura was well tolerated with application site acne as the most common AE in 6% of the patients.

Turning to Slide 12 for the launch in vitiligo. Remember, these are the same target physicians as with AD, where we'll be able to leverage our existing relationships with physicians and to be able to benefit from the high level of satisfaction and experience that may have -- that many already have with Opzelura today.

Our launch is underway with a comprehensive multichannel marketing campaign that will ensure broad and consistent reach to effectively drive awareness and importantly, to educate physicians on Opzelura's mechanism of action, its impact on vitiligo and its unique clinical profile.

To support the launch of Opzelura in vitiligo, from a patient perspective, we're focusing on raising awareness and providing best-in-class support. We plan to build awareness and activate patients living with vitiligo through a strong presence on social media, print and eventually TV.

We are also partnering with advocacy groups where there has been an enormous amount of excitement for Opzelura in vitiligo. This will be the first treatment for repigmentation available for these patients and the safety and efficacy profile has been proven in the largest randomized clinical trial in this setting.

It is important to drive patient adherence and compliance on Opzelura. This will, of course, begin with physicians setting the right expectations and we will provide tools to help ensure patients have successful treatment experience. We will launch a new Vitiligo app, along with other tools designed to help patients track their treatment and response as well as provide appointment reminders, which we expect to have a positive impact on patient adherence. And of course, we will continue to provide access to Opzelura with co-pay assistance that can lower co-pays to as low as $10 a month.

We see this launch in vitiligo as one of the largest opportunities for our franchise. We are starting with a very good label, and we have heard from patients and advocacy groups around the country, there is a large established medical need. This, together with the momentum from the launch in AD, will support a very successful launch.

Moving on to Jakafi on Slide 14. Jakafi net sales in the second quarter grew 13% year-over-year to $598 million. Total patient demand grew across all indications, and the growth in new patient starts continues to remain above pre-pandemic levels. GVHD patient growth of 18% year-over-year was driven mainly by the launch in the chronic setting. With strong demand for Jakafi, we are again raising the bottom end of our Jakafi full year net product revenue guidance from $2.33 billion to a new range of $2.36 billion to $2.4 billion.

Turning to Slide 15. Monjuvi net product sales in the U.S. grew to $23 million in the second quarter with more use moving into the second-line setting and a gradual improvement in duration. Minjuvi net sales were $4 million, where the launch is ongoing in Germany and share in second line continues to increase.

Pemazyre worldwide net sales were $19 million with the launch currently ongoing in Europe and Japan.

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 are making significant progress within our dermatology pipeline. As you know, Opzelura received FDA approval in vitiligo a few weeks ago and has now obtained 2 important FDA approvals in less than a year. We will continue to pursue other indications that may expand the use of ruxolitinib cream to more patient populations in need.

Additionally, we are developing our oral JAK1 inhibitor, povorcitinib, formerly INCB54707 in hidradenitis suppurativa, vitiligo and prurigo nodularis, all of which are in Phase II. And as Herve mentioned earlier, we are preparing a Phase III in hidradenitis suppurativa. There is significant potential with each of these indications where there are limited treatment options, when some cases, no FDA-approved treatments. One of the interesting studies we are doing with ruxolitinib cream is the long-term extension of the TRuE-V studies where we are evaluating the duration of response following the withdrawal of Opzelura.

On the left, you can see the study design for the TRuE-V studies. At 24 weeks, after the primary endpoint has been reached, patients could roll over into the long-term extension study for an additional 28 weeks. At 52 weeks, patients who achieved at least a facial VASI90 response are then randomized 1:1 to receive 1.5% ruxolitinib cream BID or vehicle.

Additionally, those patients who did not achieve at least a facial VASI90 response at 52 weeks are maintained on therapy with 1.5% ruxolitinib cream BID. The primary endpoint of the study is time to relapse in those who are placed on vehicle with numerous secondary endpoints.

Moving to Slide 19. We are announcing today the most recent compound moving into clinical development, INCA32459, a LAG-3 PD-1 bispecific antibody. INCA32459 has been shown to be superior to independent LAG-3 and PD-1 blocking in the LAG-3 PD-1 dual receptor assay and has increased cellular activity compared to a combination of the monoclonal antibodies.

Additionally, in a humanized mouse model, 459 controls tumor growth better than the combination and gives us confidence that it may provide differentiated pharmacology and a clinical profile relative to current treatments.

On the next slide, we have a number of opportunities within LIMBER to expand our leadership in MPNs and GVHD with multiple programs reaching important milestones in the second half of 2022 and into 2023. The NDA was accepted by the FDA for QD ruxolitinib. And later this year, we expect initial data from the BET and ALK2 programs in combination with ruxolitinib, and we plan to start a Phase I program evaluating the combination of CK0804 and ruxolitinib in myelofibrosis.

The second quarter was a very successful quarter for Incyte with multiple products and partnered product approvals, and we look forward to a busy second half of the year. I'd now 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. The second quarter results reflect continued strong revenue growth with total product revenues of $664 million, representing an increase of 15% over the second quarter of 2021. Total product revenues are comprised of $598 million for Jakafi, $50 million for other hematology/oncology products and $17 million for Opzelura.

Total royalty revenues for the quarter were $118 million and are comprised of royalties from Novartis of $84 million for Jakavi and $4 million for Tabrecta and royalties from Lilly of $30 million for Olumiant. Jakavi and Olumiant royalties for the quarter were negatively impacted by FX headwinds, and while Olumiant royalties were also impacted by a decrease in net product sales of Olumiant for use as a treatment for COVID-19.

Finally, total revenues for the quarter grew to $911 million, a 29% increase over the prior year period as a result of the growth in product revenues as well as $130 million in milestone revenues related to the multiple partner products approvals achieved this quarter.

Turning to Opzelura. We recorded gross product sales of $89 million in the second quarter. As payers add, Opzelura to formularies, we are continuing to see improvement in the gross to net discount rate. The fully loaded gross to net discount rate decreased from [86%] in the first quarter of 2022 to 81% in the second quarter of the year, leading to net product sales for the quarter of $17 million.

As you can see on Slide 25, the evolution of the actual gross to net discount rate in Q2, represented by the green line, continues to be very much on track with the forecast we showed you earlier in the year. We expect the gross to net discount rate to continue to decline in the second half of the year and normalize at a fully loaded rate of 40% to 50% by the end of the year.

Moving on to our operating expenses on a GAAP basis. Ongoing R&D expenses of $344 million for the second quarter increased 2% from the prior year period, primarily due to the continued investment in our late-stage development assets. SG&A expense for the second quarter of $253 million, increased 50% from the prior year period. The growth 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 prelaunch activities for Vitiligo.

Our collaboration loss for the quarter was $3 million, which represents our 50% share of the U.S. net commercialization loss for Monjuvi. Finally, we ended the quarter with $2.7 billion in cash and marketable securities.

Moving on to our guidance for 2022. As a result of our strong second quarter performance, we are tightening again our Jakafi guidance range from $2.33 billion to $2.4 billion to a new range of $2.36 billion to $2.4 billion. We are also reaffirming our other hematology/oncology revenue, COGS, R&D and SG&A guidance for the year.

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

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question is coming from Salveen Richter from Goldman Sachs.

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

Two for me here. On Opzelura, how do you know that 2Q revenue is not driven by lower organic demand as you shift from free drug versus reimbursement dynamics? And then secondly, for the drug in vitiligo, could you just speak to the education required around time to onset of effects so that patients do not expect an immediate improvement?

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

Sure. I think the -- well, what we're saying about the revenue is really was mostly a gross-to-net situation that Christiana pointed out that that's what we forecasted in the beginning from Q1 to Q2 is consistent where our gross to net was going to be. And then our demand, as you see in the sort of middle of the quarter, we ran into a little bit of a bump in the demand when we switched from the free drug program to fully covered for patients that are covered under the contracts that we signed. And as you can see, and that's why we showed you the graph on Slide 10, is that we believe that we've overcome these situations that we have most of the NDC blocks removed.

They're continuing to be removed as we move into the third quarter here, and it will only get better. But our last week of demand was, in fact, the biggest week of demand that we had in the last week of July. And we believe that, that trend line for demand is going to continue. The second question, as far as vitiligo, maybe Steven?

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

Salveen, thank you for asking the question. I think if you go back to label, this is why it's so great to have the 52-week data incorporated in the label, while unexpected, because it's obviously not in the placebo randomized period, to have it in was a really good win because we can educate within label now to what was seen. And so just to reiterate, in terms of the primary endpoint, the facial VASI at 24 weeks and then at 52 weeks, you see this continued absolute increase of another 20 percentage points in the primary endpoint from the 24-week endpoint to the 52-week endpoint, talking to exactly what you were alluding to that there is this gradual time to onset in terms of improvement in repigmentation.

And it's actually reflected multiple times in the label with the efficacy data, with the dosing guidance that allowed continued use, and with a statement that says you may have to wait upwards of 24 weeks or beyond to see improvement.

So we can use both the commercial channel in terms of promotional activities because it's within label, and then obviously appropriate medical communication to continually educate both the treaters, the physicians, as well as patients, advocacy groups, et cetera, that there is this continued improvement over time. And it will be very much part of our efforts across the whole spectrum involved in the dermatology program.

Operator

Your next question is coming from Tazeen Ahmad from Bank of America.

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

With regards to your guidance of 40% to 50% gross to net by the end of this year, I know you've talked about -- you're happy with the launch trajectory thus far, but what are you feeling particularly confident about, what absolutely needs to happen for you to reach that target? Is it more penetration into formulary? Is it a strong launch for Vitiligo out of the gate? Just help us try to understand how, because you're still at 81%, which is definitely an improvement, but still a decline to get to where you want to be. And then secondly, for Vitiligo, I'm just wondering, in the early days of the launch, are you able to compare how scripts have been relative to the early days of when AD was launched?

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

So Tazeen, so to get to 40%, 50%, really, we just take that from the contracts that we already signed. So the rebates and fees that we have to pay, that's really what's going to drive our gross to net. Our increased confidence in our net revenue, it will be based upon demand. So we do truly see that we're going to get to this 40% to 50% gross to net by the end of the year just because all of the -- lot of the work is out of the way. Now, utilization criteria has to be written as the downstream plans for many of these things, particularly for vitiligo. But there's no NDC, there's -- mostly no NDC blocks now. More NDC blocks continue to be removed. But they all will be removed relatively soon, and that will take us to this target that we've talked about. But really, it's going to be the demand that we continue to see great enthusiasm around AD.

And certainly, vitiligo hasn't even started yet. Now as far as vitiligo, well, versus AD. AD, as we've talked about before, I mean, there's 30 million patients in the United States that might have atopic dermatitis. We say that there's 5 million patients that are in our treatable population. That's a whole lot of patients that were already seeking treatment.

In terms of Vitiligo, we talk about 150,000 to 200,000 patients that are actively seeking treatment for their vitiligo. So there's far fewer patients that you can imagine that are going to come in perhaps right away, but we do absolutely see demand out there when we talk to the advocacy groups, when we talk to our patients, when we talk to the dermatologists who treat these patients. The demand is there.

And then there's millions of patients beyond the patients, who are actively seeking treatment for vitiligo today that we think will reenter and go back to their dermatologists to seek treatment just because now there's something effective that's going to be available. So we don't necessarily see that there's going to be a gigantic bolus today. We do know that patients are coming in today and getting scripts filled for vitiligo and getting it paid for, but we don't really know how many at this point, but it will take a number of weeks to a number of months. In fact, for all of the plans to write the utilization criteria for Vitiligo, but we have a great label, and we think that's what's going to be put into the utilization criteria by the downstream plans.

Operator

Our next question is coming from Brian Abrahams from RBC.

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

Also on Opzelura. Where are you seeing Opzelura being placed on formularies in atopic derm relative to your expectations? I guess I'm wondering whether the slower growth in end user use is because you're facing -- now facing prior authorizations and step edits or if it's just a matter of miscoding at the -- temporary miscoding at the level of pharmacy as you transition from free drug?

And then I guess along those lines, it looks like you -- another question on gross to net, it looks like your expectation range for third quarter is somewhat broad. I'm wondering if you could talk about maybe some of the puts and takes there and the degree to which this is going to be where you end up in, I guess, for third quarter, will relate to some of the formulary placement elements from that third period -- from the third PBM that got online in July.

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

Sure, Brian. So our expectations are for where they're placed on formulary. Again, it's the utilization criteria, the downstream plans end up putting into place for AD. So most of the plans can have 1 prior therapy or 2 prior therapies a TCI or TCS. All of our contracts are written so that the downstream plans can take advantage of rebates by deciding to put it after 1 step or 2 steps, but most of them are just there.

They're at 1 step or 2 steps, and we think that will evolve over time and only get better. There's not necessarily miscoding at pharmacies. There certainly was a little bit of maybe an unexpected slowdown that we believe is fixed now that when people were switching from the free drug program to the prior approvals. It was easier for some pharmacies to continue to get free drug rather than going through the prior approval process.

But in this marketplace, prior approvals are the norm. And in fact, dermatologists are used to doing prior approvals all the time. Most of them are electronic prior approvals that occur very quickly. And if not, they might take 1 or 2 days to get through the prior approval process. So we did have a slowdown, but it really picked back up again. And I'm really proud of our market access team that was able to step in and solve these problems. For the gross to net, I might hand it over to Christiana.

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

Brian, regarding the gross to net, as we showed you on Slide 25, the shape of the curve from Q2 to Q4, the second half of the year can take various forms, but we are confident that at the end of the year, we'll be getting at least 40% to 50% gross to net discount rate. What would impact the shape of that curve in the second half is how quickly the remaining plans put Opzelura on formularies and the speed in which the remaining NDC blocks get removed.

But as we showed you, we feel very good with the progress that we have made. And at this point, we have 80% of plans that -- or 80% of patients that are covered commercial patients that are under plans that are under those 3 large PBMs with whom we have contracts, and over 50% of prescriptions that currently are covered. So we are progressing well towards that 40% to 50% steady state rate by the end of the year.

Operator

Next question is coming from Jay Olson from Oppenheimer.

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

For the LIMBER program, can you talk about the potential for myelofibrosis disease modification with all the different combinations of RUX with PI3K, ALK2, BET, BCL2, and whether or not you've seen any preclinical or clinical evidence of fibrosis improvement with any of those combos?

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

Jay, it's Steven. Thanks for your question. So obviously, the endpoints in clinical trials to date have been on spleen volume reduction and then symptom improvement to give you what you need for clinical benefit. But people look at fibrosis as well and then other things like allele burden, et cetera, to get to the point you're talking about.

One of the issues with reading fibrosis from bone marrow is sampling, is inter-observer variability, central confirmation, et cetera, with the grading is not always very precise. But you do -- sometimes you can get a sense of fibrotic improvement. So to reiterate, clinical benefit comes currently, at least at a regulatory standard from this spleen volume reduction and symptom improvement, and then disease modification as an underlying secondary endpoint.

In terms of the therapies you mentioned, we'll have to see, basically. There is preclinical clues certainly in -- for example, in the BET program, certainly in terms of the new effort with Cellenkos and the T regulatory cells that we use there from the umbilical cord that you can potentially have underlying disease modification. But ultimately, it's the clinical data sets that will prove that. With parsaclisib, we've announced the primary endpoints for both the first line and the suboptimal study in terms of spleen volume reduction and certainly in first-line needing symptoms as well.

With ALK2, the promise potentially also comes from what we want is underlying anemia improvement and then the ability to continue to dose RUX at adequate levels to get maximum effect. So that's mainly what's been looked at. And again, just to be repetitive, we'll ultimately see. So there are some preclinical clues that you can do underlying modification, but we'll await the data sets.

Operator

(Operator Instructions) Our next question today is coming from Marc Frahm from Cowen.

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

Just back to the gross to net on Opzelura. Just doing some back-of-the-envelope calculations with the graph you showed. I mean, it looks like the covered claims are getting the gross to net that's maybe in the low to mid-40s. Is that accurate? And then based on that, is there any reason to expect the kind of plans that are coming online later in the year to be materially different in terms of the gross to net associated with them than the ones that are online currently?

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

So Marc, so the first part of your question, I guess what you're saying, our gross is determined by the overall number of units that we sold and obviously, the amount of reimbursement we're getting or payments we're getting for that. So right now, our gross to net, as you can see, is what we expected to continue to improve, 55% of claims are being covered now. Every single day, that's going to get better and better. gross-to-net at the end of the year, of course, is going to be in the range that we said.

So they're not materially different, but the gross-to-net will be better for each tube that we sell by the end of the year. So we're very confident of the guidance that we've given so far in terms of gross-to-net. And I'm very confident that our demand is going to continue to increase week after week, particularly now with the vitiligo approval as well as the AD approval.

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

Just to comment, I mean, on that, I mean -- there are 2 ways to look at it. I mean you can look at it over the entire set of prescription over a period of time. And that's the graph we have showing that over a given quarter, the gross-to-net for all of this prescription, it's an average, has been 81% and improving. Obviously, in -- will be improving in Q3. And then you have the other aspect, which is the percentage of covered claim. And when the claim is covered, the net price for a given tube, that 1 tube that is covered is, in fact, very much in line with our target that we have given for the full year, the 40% to 50%.

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

Okay. That's very helpful. And then maybe just on the pipeline, Steven, the decision to move forward in hidradenitis. One, is the Phase II data just available internally this year or should we expect to see it? And then as you go towards Phase III, what's kind of -- given the safety labeling of the JAK class, kind of what's the clinical profile that you think you need to be able to establish on the efficacy side in order to be a good option for hidradenitis patients?

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

Yes. Thank you, Marc. So the -- yes, the intention is to show the complete Phase II proof-of-concept data set at a meeting this year. So you will see it in 2022. We expect to be treated with JAK class labeling here because it is after all in an inflammatory condition. Again, these are patients with a lot of unmet need. They tend to have higher body mass indexes and a lot of abscess and nodules. So the profile we need to see -- there are numerous ways to measure it. We looked at abscess and nodule count. We looked at this established combination endpoint called HiSCR, it's a scoring system that was used with the HUMIRA approval. And then we'll work out with the regulatory agency what's the best one to use for a Phase III study.

And then there is a reasonable placebo response rate here as well. Again, you'll see that when we show you the full data set. So you want to see a large delta between the placebo and then the efficacy effect. Given that you're going to have class labeling likely a black box because it's an inflammatory condition. And we're confident in what we've seen thus far with 707 in this entity.

Operator

The next question today is coming from Evan Seigerman from BMO Capital Markets.

Evan David Seigerman - *BMO Capital Markets Equity Research - MD & Senior BioPharma Research Analyst*

So now earlier on the call, you had mentioned some of the commercial dynamics that you saw during the second quarter were temporary. I'm just wondering how temporary they were and now that we're a month into the third quarter, have you seen some of these trends reverse? And then looking ahead, with the gross-to-net around 40% to 50% for Opzelura, is that what we should be expecting come '23 and 2024? Is that really the steady state kind of in the years beyond 2022?

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

Yes. So it was -- Evan, it was temporary. We believe we had a problem mostly with the large portion. Our prescriptions are filled by independent pharmacies. So it took us a little while to work together with them to work out them getting back to doing prior approvals, which they're very familiar with. And we're very confident that, that was in fact temporary.

Now the gross-to-net of 40% to 50% going forward in '23 and beyond, we're certainly going to do everything we can to protect our gross-to-net. As you know, the PBMs and payers will always come back and try to get more and more and more. So we just keep on working to maintain that gross-to-net because we think the value that this product offers is exceptional, and we don't want to lose that value.

Operator

Our next question today is coming from Michael Schmidt from Guggenheim Partners (sic) [Securities].

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

I had another one on Opzelura. Just maybe talk about your confidence in the script data and the increase in demand in the third quarter. It sounded like you said that prescription data was overestimated in the second. And when I look at your gross sales, it looks like they declined slightly from 91% in the first quarter. Just wondering how confident you are in those forecasts? .

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

Yes. So our script data is very accurate. Obviously, we know exactly how much we're shipping. We know what -- we've reported the 867 data is what our wholesalers shipped to the pharmacies, which we think really reflects prescription volume. Just getting to your last part, the demand in Q2 was actually higher than Q1. I believe it was 42,000 tubes in Q1 for demand and 47,000 tubes in Q2 for demand. So the difference in the gross sales that we reported last time and this time is really an inventory issue. So inventory was lower at the end of Q2 than we anticipated. So that's really the difference there. So we're very confident in it.

Now when we've talked about TRxs, that's IQVIA's TRxs. So there is a misalignment that often happens with the products that IQVIA sells, particularly at the beginning of a launch, and they happen to be -- and this is the data, obviously, that you guys get, other analysts and investors get. So it worries us a little bit when they're over projecting.

We've worked with IQVIA, and they will, in fact, at some point, make the corrections and -- as they often do, and they go back and send out to their customers what they believe the real data is today. So we're very confident about our data. We're very confident that now week after week as it was in the beginning of the year, prescriptions will continue to grow from this point on. And I don't see -- I don't anticipate any barriers to demand growth going forward.

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

Okay. Super helpful. And then there was another topical approved yesterday in the dermatology space that could enter the AD market next year and the WAC price was at a significantly lower than what Opzelura is priced. And I was just wondering how you think that might impact competitive dynamics longer term?

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

Well, I don't know why Arcutis priced as they do or anybody else does pricing. We're confident in the value that we offer, and that's the price. Now roflumilast, at least the data they released so far in atopic dermatitis, is not that impressive. So it didn't come near the efficacy and safety that Opzelura offers to AD patients. So their approval is completely different indication, plaque psoriasis. So apparently, it's okay in plaque psoriasis and they have lots of competition there. So maybe their price point is based upon both the systemic competition as well as the other topical competition.

So that was their decision. But we're confident in the way we priced our drug and we're confident that both of these drugs that have recently been approved for plaque psoriasis will not equal the efficacy that we've demonstrated in our 2 Phase III trials thus far.

Operator

Your next question is coming from Srikripa Devarakonda from Truist Securities.

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

One question on Opzelura. Just wondering how long do you expect the co-pay assistance to continue? And then on the chronic GVHD, it looks like the uptake is pretty strong. I was just wondering if this strong launch is due to a bolus of available patients. Do you expect the growth to continue in a similar manner? Also, any additional color you can provide on when we can see data from the -- from axatilimab, the Syndax collaboration?

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

So I'll take the first part and hand the axatilimab question over to Steven. So co-pay assistance. So there's a couple of different parts to that. So as we launch the program as many other companies do, when they launch a new drug in this sort of marketplace, is that you pick up the full cost of the drug. So we fully anticipated doing that. We wanted to have a very generous program. So that full buy down program essentially will be phased out over time, and it's being phased out even now.

But the co-pay card program to assist patients to have a high co-pay will always be in place. So we'll always do that. Plus, even patients that have -- maybe they go through the prior approval process and they're denied through our Incyte CARES program, they'll be able to make -- they'll be able to get drug.

So in terms of GVHD, it's the chronic launch. So we did have a bolus in 2021 that we talked about. We had an expanded access program. We switched 200 or 300 patients over from an expanded access program to GVHD. That's all gone, and we continue to grow, as we've demonstrated, 18% year-over-year growth. Chronic is -- we -- acute and chronic steroid-refractory GVHD, Jakafi is the standard of care. Hands down. And we're very proud of that. Chronic patients are getting a lot of benefit from Jakafi and they'll continue to get benefit.

We'll see continued growth there. I think we've talked about before how we divided up GVHD, and you can see that it's about 15% of our units going out. Our net sales are approximately 15%. We expect that to continue to grow. There's about 14,000 chronic GVHD patients out there. The prevalent population is about 14,000. But the incident population is relatively small. So it's an exciting area that we're in. We think axatilimab will build upon that franchise that we have in chronic GVHD. And I'll hand the call over to Steven now for...

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

Thanks, Barry. Thanks for the question, Kripa. With our partner, Syndax, the AGAVE study is ongoing and is enrolling excellently. It should complete enrollment this year. Then we wait for the primary endpoint, and we'll present the data in 2023. That's a registration-directed study in third-line chronic graft versus host disease with monotherapy axatilimab. In addition, we will start combination work with a JAK inhibitor, which is now going to be ruxolitinib.

And that will be to get a safe dosing schedule. And then we'll move that up the treatment paradigm, look at earlier lines, earlier settings with a nonoverlapping mechanisms of action plus the likelihood that there's no overlapping toxicity makes it a potentially exciting combination. So just to repeat, data in 2023 on the pivotal registration study, which has gone really well.

Operator

Your 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 was wondering if we could get some more color on who's prescribing Opzelura and the co-pays? Are the majority of the prescribers, the docs that have been detailed, by your sales reps? And then IQVIA has a breakdown of the co-pays and it has a fair number of patients, who have 0 copays and also those that have over $75 copays.

I was just wondering if those data points are accurate. And I probably should know this, but is your patient assistance, the co-pay offset part of the gross-to-net calculation? And then lastly, do you have any data on the abandoned scripts, the ones that are presented to the pharmacy but not filled by the patient because of the co-pay or lack of coverage?

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

That's a lot of questions, but we'll try to answer them one at a time. So who's prescribing? So dermatologists and dermatologist offices are prescribing, but that's dermatologist, physicians assistants and nurse practitioners, of which there are many and they're all prescribing. There are some allergists, who are prescribing as well. So that's what's happening there.

Breakdown of co-pays. It's sort of all over the place. We do expect an average co-pay that a patient might have once they're -- once their plan covers Opzelura either for AD or for vitiligo and it could settle somewhere around $40.

Unfortunately, at the beginning of the year, many patients also have a deductible that they have to meet before they get to their co-pay. So we picked that up as well. And yes, co-pay assistance is part of the gross-to-net. That's a factor in our net sales. So we -- any co-pay that we pick up, of course, is removed. But it's relatively low compared to a full buy down or something like that.

And number of scripts turned away by patients due to co-pays, I don't know. Like I said, there shouldn't be any due to co-pays, because we'll help them to pick up the co-pay if they have co-pay that is difficult for them to afford.

But how many scripts did people walk away from because of that, it shouldn't be any, to be honest with you. Like we said, we did have a little bit of a hiccup there where patients might have not been getting their prescriptions as fast as they should have or may have walked away because it was taking too long to get them filled.

We think we have that completely fixed now. And there's always going to be problems in this marketplace that we have, in this health care system that we have, patients running into barriers, but in fact, we do everything we possibly can to make sure those patients get the scripts that they need.

Operator

Thank your next question today is coming from Mara Goldstein from Mizuho.

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

I just wanted to circle back on the Opzelura physician survey that you showed. Do you have any insight, I guess, no pun intended there. As to the driver behind the increase in that proportion of treated patients that are considered candidates for the drug? And then also, I'm hoping you might talk a little bit about RUX QD and the potential positioning for that once approved or assuming approval next year?

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

Sure. As far as survey goes, I mean, all that's really saying is that when we first asked physicians what percent of patients that they believe are eligible for Opzelura, and this was in fact in AD, they gave a number. But now that more and more have used, they've seen the safety and efficacy that Opzelura provides. We have many patients and physicians, who send in pictures of their eczema resolving relatively quickly or very quickly because of the use. So they're very excited about it.

So the more they get experienced with it, the dermatologist, physicians, nurse practitioners, PAs, the more they decide that this could really help a greater number of patients than we imagined.

So I think that's only going to continue to increase both for AD and for Vitiligo, as dermatologists really see how the efficacy and safety of this product. For RUX QD, we're going to launch in next year. How we're going to position it? Well, we think that this once a day versus twice a day is a very good option for many patients.

So across all of our indications, obviously, the real reason that we're having RUX QD rollout is because we want to combine it with other products that Steven talked about before that we have in our pipeline that we think will add to the safety and efficacy of -- or the efficacy that Jakafi already provides. So that's the real purpose of launching it, but we think many people will benefit just from the convenience factor, the better compliance that they'll get from a once a day versus twice a day.

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

Okay. And if I could just ask on povorcitinib in vitiligo. Can you just speak to the difference in the body surface area criteria and how that aligns with how physicians treat vitiligo or current standard of care for vitiligo?

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

Sure. It's Steven. Thanks for the question. So our current label with Opzelura is in patients with 10% or less body surface area involvement, which incorporates about 80% of patients with nonsegmental vitiligo. And for practical purposes, it gets pretty difficult to treat people with more body surface area involved because of the amount of cream potentially you have to use. For povorcitinib in this vitiligo program, there's a little bit of

overlap and worked with regulators, it's 8% or above. So these are people with much more extensive skin involvement and they can go up to 20%, 30%, 40% involvement.

And there, again, practically, it becomes impossible to put that much cream on, the therapeutic ratio changes, and you can use an oral therapy to treat an oral systemic JAK inhibitor to treat the vitiligo. Because of that overlap, the numbers can get a little confusing, but that represents about 30% of patients. So you can sort of do the math there that have more than 8% involvement and require an oral JAK inhibitor because of the extent of disease involvement there.

Operator

Your 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*

I guess on that -- on the QD RUX and then the BET and ALK data comment, is the next step after we see the data in the second half to move right to a fixed-dose combination with QD RUX or is there an additional Phase II trial or something that will happen? And then separately, on Monjuvi, I'm just wondering if you still see this -- the $500 million to $700 million opportunity given the rollout, and in particular, the broader label of Breyanzi to include transplant ineligible patients that impacts your kind of long-term opportunity for Monjuvi?

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

Yes, Matt, it's Steven. I'll do the first part. So because it's once daily, and it was a submission that involved bioequivalence and bioavailability data to get there, we will be developing other clinical data. But at the same time, we've started developing fixed-dose combinations because all of our other combinations are once daily as well. So whether it's parsaclisib, the BET inhibitor or the ALK2 inhibitor, they're all once daily and have the ability to have fixed dose combinations.

The parsaclisib registration studies are obviously ongoing and enrolling well, both the suboptimal in the first-line study and obviously aren't with fixed dose combinations at the moment. So once we have an FTC there, we would work out a transition, again, likely through our BA/BE route in conjunction with regulators to get there.

But the future programs, should we go there with BET and ALK2, would have the potential to go straight away to an FTC with each of those. So that's the promise there. And then I'll hand the question over to others for the second part.

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

Yes. So Monjuvi. We certainly still have confidence in Monjuvi. We certainly still think that we're going to get to -- in the relapsed refractory setting, we can get to $500 million. Obviously, it's taken us longer than we anticipated. The marketplace has changed in diffuse large B-cell lymphoma over time. It's a very dynamic market. Obviously, there is more data with the CAR-Ts. There's more data with frontline Polivy. There's more products entering that are the bispecifics, but Monjuvi and LEN is an excellent combination for patients, who have failed R-CHOP therapy or relapsed on R-CHOP, and we really believe that there's really only a couple of options for patients who aren't going on to transplant and that could be CAR-T. But the vast majority of patients should be eligible for Monjuvi/LEN.

So we just need to keep on doing a better job of educating because this is a product that really has great CR rates and the duration of response is 44 months, at 3-year follow-up. There's really not much better data or any better data in that particular setting for duration of response than Monjuvi/LEN. So we really anticipate that this is a product that can serve a lot of patients in the relapsed/refractory setting. And then, of course, we'll wait for data in follicular lymphoma and in the first-line setting because that's where the ultimate real value of the product will come from.

Operator

Your next question is coming from Stephen Willey from Stifel.

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

Just a quick one on Opzelura. So I guess, following the initial approval in AD, I know your guidance implied about 3 to 4 tubes for AD patients per year. Just wondering how the reorder rate that you're seeing at this point of the launch still informs some of the persistency and utilization assumptions that are embedded within that unit guidance on a per patient basis?

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

Yes, Stephen, it's Barry. So until we really see all of the NDC blocks removed, utilization criteria stabilized, it's really hard to know exactly what the refill rate is currently and is going to be in the future for AD. So these patients, we know that 25% of the data -- 27% of our units this quarter were from refills. Is that the right amount? Or is it going to be more than that? It's hard to say at this point until we get fully stabilized on the payer situation. Once we do, then we'll really see what the refill rate is going to be.

The drug works really well and some patients get relief very quickly, and some patients will have to have -- will have flares, we know that from the clinical trials, and have to come back for a refill again. So it's not clear at this point. But like I said, it's 27% of our units currently and that may grow into the future, but we'll have to get some more data before we can finalize that number.

Operator

Our final question today is coming from Gavin Clark-Gartner from Evercore ISI.

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

So just on the LIMBER program. For the BET and ALK2 Phase II combination data that's coming in the second half of this year, could you just help us with some expectations for what data exactly we'll see? So I know you mentioned it will be the initial and somewhat limited efficacy data, but just wanted to clarify, like what exactly you're planning to show?

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

Gavin, Steven. Thanks. So the -- it'll -- you're correct. It's actually mostly Phase I safety data, but we'll try and incorporate as much of the efficacy component as we can in time for the abstract cutoff, et cetera. And then for -- again, BET, just to mention briefly, it's a drug we had for a long time. We treated solid tumor patients at multiples of the dose years ago and 100-plus patients. So we know its safety profile at higher doses very well in terms of on-target thrombocytopenia. And now it's really about getting the right therapeutic ratio in combo with RUX and then make decisions to go forward. So it's largely a safety update to some efficacy.

On ALK2, it incorporates some translational data as well, particularly as regards in iron kinetics and hepcidin inhibition. So you'll see that as well in the data set that's presented. And we've seen favorable movements in terms of hepcidin inhibition and some iron kinetics, but we'll have to see whether that translates to hemoglobin increases or not over time. So largely, safety updates, minimal efficacy, some translational data for ALK2.

Operator

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

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 webcast. You may disconnect your line at this time, and have a wonderful day. We thank you for your participation today.