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EDITED TRANSCRIPT

INCY.OQ - Q4 2020 Incyte Corp Earnings Call

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OVERVIEW:

INCY reported 2020 total revenues of $2.67b.

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PRESENTATION

Operator

Greetings, and welcome to the Incyte Corporation Fourth Quarter Year-End 2020 Earnings Conference Call. (Operator Instructions) As a reminder, this conference is being recorded. It's now my pleasure to turn the call over to Mike Booth, Head of Investor Relations. Please go ahead.

Michael Booth - *Incyte Corporation - Divisional VP of IR & Corporate Social Responsibility*

Thank you, Kevin. Good morning, and welcome to Incyte's Fourth Quarter and Full Year 2020 Earnings Conference Call and Webcast. The slides used today are available for download on the Investors section of incyte.com.

I'm joined on the call today by Hervé, Barry, Steven and Christiana, who will deliver our prepared remarks, and by Dash, who will join us for the Q&A session.

Before we begin, I'd like to remind you that some of the statements made during our call today are forward-looking statements, including statements regarding our expectations for 2021, including our financial guidance, the commercialization of our products and our development plans for the compounds in our pipeline as well as the development plans of our collaboration partners.

These forward-looking statements are subject to a number of risks and uncertainties that may cause our actual results to differ materially, including those described in our 10-Q for the quarter ended September 30, 2020, and from time to time in our other SEC documents.

We'll now begin the call with Hervé.

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

Thank you, Mike, and good morning, everyone.

So 2020 was a year of strong growth for products commercialized by Incyte and those commercialized by our collaboration partners. Total product and royalty revenues grew 18%, fueled by continued growth demand for Jakafi, which grew 15% year-over-year, and revenue from other hematology and oncology products was up 46% versus the prior year, benefiting from a strong launch of Pemazyre and good performance from Iclusig.

The launch of Monjuvi is progressing well as we continue to observe market share gains.

Royalties were up 28% to nearly $400 million, with Jakavi up 23%; Olumiant up 38% and the launch of Tabrecta now contributing to our royalty revenues.

We also received over $200 million in milestone payments during 2020, resulting in an increase of 24% in total revenues year-over-year.

Turning to Slide 5.

In 2020, we presented positive data from several pivotal trials and submitted 7 regulatory filings, and we expect to have decisions on all of these during this year. These decisions include the potential FDA approval of Jakafi in chronic GVHD, retifanlimab in squamous cell anal carcinoma, tafasitamab in DLBCL in Europe and pemigatinib for cholangiocarcinoma in Japan and Europe, where we recently obtained a positive CHMP opinion.

We are also just a few months away from the potential approval of ruxolitinib cream in atopic dermatitis and the expected sNDA submission for vitiligo.

I will now pass the call over to Barry for additional details on product performance as well as our commercial preparation for the launch of ruxolitinib cream.

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

Thank you, Hervé, and good morning, everyone.

Jakafi performance was excellent in 2020, with revenues growing over $250 million to reach $1.94 billion. The demand for Jakafi remains high with the total number of patients being treated, continuing to grow across all 3 indications. We are also encouraged by the partial recovery of new patient starts in the third and fourth quarter of 2020.

For 2021, we expect strong Jakafi growth as we reach a normalization of oncology visits with a broader availability of COVID-19 vaccines. The potential approval of Jakafi in steroid-refractory chronic GVHD would represent its fourth indication and an additional important growth driver.

The range of Jakafi guidance we have provided today for 2021 of $2.125 billion to $2.2 billion reflects the ongoing impact of COVID-19, especially in the first half of the year as well as the expected increase in the gross to net adjustment with the largest impact coming in the first quarter.

Turning to Slide 8.

The launch of Pemazyre has gone quite well as we have been able to capitalize on our relationships and experience in oncology. Since launch, over 300 physicians have prescribed Pemazyre. As expected, community-based oncologists are driving adoption, and testing patients for FGFR2 alterations is going smoothly.

Given the refill rate, we know that appropriate patients are being identified and are being treated with Pemazyre, and it is very gratifying to know that we have been able to bring this much needed therapy to a previously underserved patient population.

The launch of Monjuvi is also progressing well.

Sales in the fourth quarter reached $17 million versus $5 million in Q3. We believe the strong safety and efficacy profile of Monjuvi is resonating with physicians, and as expected, we are seeing good utilization in the community setting. Since our Q3 update, the number of accounts purchasing Monjuvi has more than doubled to over 400, and we are also seeing good uptake from the vast majority of our top 100 key accounts. According to market research in BMT and in eligible diffuse large B-cell lymphoma patients, the Monjuvi LEN regimen is the most used treatment in the second line plus patient population.

Turning to Slide 10.

We submitted the NDA for ruxolitinib cream for atopic dermatitis in December last year, and we expect a regulatory decision midyear.

There are an estimated 21 million atopic dermatitis patients aged 12 and above in the United States, of which approximately 5.5 million receive prescription therapy today. The number of prescriptions for the treatment of atopic dermatitis has grown significantly in recent years, as new therapies are introduced. However, only approximately 20% of patients report their atopic dermatitis is controlled with their current treatment, highlighting the significant unmet need that currently exists.

We expect the initial uptake of ruxolitinib cream to be driven by specialists in medical dermatology and allergy. Our team has identified approximately 11,000 high prescribers who collectively account for approximately 80% of total prescriptions written for the treatment of atopic dermatitis in the U.S.

Over the past several months, we have been able to recruit an exceptional team with significant experience in successfully launching dermatology products in the United States. We expect a fully recruited field team of 150 FTEs by mid-April, which is optimal to reach these high-volume prescribers.

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

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

Thanks, Barry, and good morning, everyone.

In 2020, we made significant progress across our development pipeline, as shown on Slide 12.

Some highlights include positive results from our pivotal trials of ruxolitinib in chronic graft-versus-host disease, ruxolitinib cream in atopic dermatitis, retifanlimab in squamous cell anal carcinoma and parsaclisib in non-Hodgkin's lymphomas, with each study forming the basis for regulatory submissions in their respective indications.

We also announced multiple product approvals, including Pemazyre and Monjuvi in the United States; and Tabrecta in the United States and Japan and a new indication for Olumiant in atopic dermatitis in both Europe and Japan.

We also recently announced the positive CHMP opinion for pemigatinib, a crucial step towards bringing the first targeted therapy to European patients with cholangiocarcinoma.

As you can see on Slide 13, we are expecting multiple regulatory actions during 2021, with 7 expected approvals and 6 additional submissions during the year.

For ruxolitinib, we expect an FDA decision for Jakafi in chronic graft-versus-host disease, and our partner, Novartis, is expected to submit Jakavi for acute and chronic graft-versus-host disease, in both the EU and Japan during the first half of 2021.

Within hematology and oncology, we await an EMA decision for tafasitamab in diffuse large B-cell lymphoma and an FDA decision for retifanlimab in squamous cell anal carcinoma.

We expect pemigatinib to receive European approval in cholangiocarcinoma, following the recent positive CHMP opinion, and we also have a submission under review in Japan. Later this year, we plan to submit an NDA for parsaclisib monotherapy in non-Hodgkin's lymphoma based on the pivotal CITADEL trials.

Within dermatology, we expect an FDA decision for ruxolitinib cream in atopic dermatitis in June, and we look to submit an sNDA in vitiligo shortly thereafter, assuming our Phase III program in this indication is successful.

As you can see, it is shaping to be a very eventful and exciting year ahead for Incyte in terms of clinical development and regulatory action.

Slide 14 provides a brief overview of the LIMBER clinical development program.

Once-daily ruxolitinib is the furthest along with potential FDA approval before the end of 2022. We have multiple combinations planned and in development with PI3 kinase delta, BET or ALK2, which we believe have the potential to significantly improve outcomes for patients living with myelofibrosis.

As you can see on the right-hand side, we expect the patent protection for many of these novel assets to extend well into the 2030s.

Moving to Slide 15.

This year with our partner, MorphoSys, we intend to initiate 2 Phase III trials.

frontMIND is expected to enroll approximately 900 patients and will evaluate the combination of tafasitamab plus lenalidomide and R-CHOP versus R-CHOP alone in first-line diffuse large B-cell lymphoma. inMIND is expected to enroll approximately 600 patients and will assess the combination of tafasitamab plus R squared versus R squared in patients with relapsed or refractory follicular or marginal zone lymphoma.

We also plan on initiating 2 proof-of-concept trials in non-Hodgkin's lymphoma, investigating tafasitamab in combination with our own PI3 kinase delta inhibitor parsaclisib, and in combination with lenalidomide and plamotamab, a CD20 x CD3 bispecific antibody.

Moving to Slide 16.

We recently announced the acceptance under Priority Review of the BLA for retifanlimab. The BLA was submitted based on the results from POD1UM-202, data from which were shared at the ESMO Congress last year, and the PDUFA date has been set at July 25. We have also been informed that the FDA expects to convene an advisory committee meeting as part of the review process.

This slide also gives me an opportunity to remind you of our development strategy for retifanlimab. The first part of the strategy is to develop retifanlimab as monotherapy in certain niche indications where accelerated approvals are available. And other registration-directed trials beyond squamous cell anal carcinoma are ongoing in Merkel cell carcinoma and MSI-high endometrial cancer.

We also have an ongoing global Phase III study in lung cancer, which, of course, offers a much more substantial potential opportunity.

A key part of our development strategy is related to the utility of having an in-house PD-1 antibody, which gives us the option to run numerous internal clinical combinations with other assets within our immuno-oncology portfolio, including AXL/MER and adenosine 2A, 2B, where there is potential for synergistic activity and enhanced efficacy.

With that, I would like to turn the call over to Christiana for the financial update.

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

Thank you, Steven, and good morning, everyone.

Turning now to our financial results.

Our fourth quarter results reflect continued strong revenue growth with total product and royalty revenues of $680 million, representing an increase of 17% over the fourth quarter of 2019 and reflecting growth across products commercialized by Incyte and by our partners. Total product and royalty revenues for the quarter are comprised of net product revenues of $517 million for Jakafi, $29 million for Iclusig and $14 million for Pemazyre, royalties from Novartis of $87 million for Jakavi and $2 million for Tabrecta and royalties from Lilly of $31 million for Olumiant.

For the full year 2020, total product and royalty revenues were $2.46 billion, an increase of 18% over 2019. Total revenues for 2020 of $2.67 billion increased 24% over 2019, reflecting the higher product and royalty revenues and an increase in milestone payments from our collaborative partners for the achievement of development, regulatory and commercial milestones.

Moving on to our operating expenses on a GAAP basis, ongoing R&D expenses of $380 million for the fourth quarter increased 23% from the prior year period due to our 55% share of the global and U.S.-specific development costs for tafasitamab and product/supply-related costs to support the potential launch in 2021 of ruxolitinib cream as a treatment for atopic dermatitis. Ongoing R&D expense for the full year 2020 of $1.24 billion increased by 10% over 2019 also driven by the impact of our 55% share of tafasitamab development costs and ruxolitinib cream product supply-related costs. If ruxolitinib cream is approved, the product supply costs expensed in 2020 will ultimately contribute to lower cost of goods sold for a period of time subsequent to the product launch.

As a reminder, our total R&D expense of $2.2 billion for the full year 2020 includes the upfront consideration of $805 million for our collaborative agreement with MorphoSys and $120 million of expense related to our purchase of an FDA priority review voucher utilized to accelerate the review of ruxolitinib cream in atopic dermatitis.

SG&A expense for the fourth quarter of $167 million increased 23% from the prior year period due to the timing of certain expenses. For the full year 2020, SG&A expense grew 10% compared to 2019, driven by an increase in sales and marketing spend to support the commercialization of Pemazyre in the U.S. and to prepare for the potential launch of RUX cream in the U.S.

Our collaboration loss for the quarter was $12 million, which represents our 50% share of U.S. net commercialization loss for Monjuvi. For the full year 2020, the total collaboration loss was $43 million and was comprised of total net product revenues of $22 million and total operating expenses, including COGS and SG&A expenses of $107 million.

Finally, we ended the year with $1.8 billion in cash and marketable securities.

Looking at the evolution of our P&L over the past 5 years, you can see how the growth in our product and royalty revenues has exceeded the growth in both our ongoing R&D expense and SG&A expense leading to increased operating leverage and reflecting our commitment to prudent management of our financial resources.

Moving on to 2021. I will now discuss the key components of our 2021 guidance on a GAAP basis.

Given the expansion of our commercial portfolio, we are providing 2021 net product revenue guidance for Jakafi and as a total for other hematology/oncology products. For Jakafi, we expect net product revenues to be in the range of $2.125 billion to $2.20 billion, which at the midpoint represents approximately 12% growth over 2020 driven by continued growth across all indications. We expect our gross to net adjustment in 2021 to be approximately 18% with the adjustment in the first quarter of the year being higher relative to the previous quarter and subsequent quarters.

For other hematology/oncology products, which currently include Iclusig in Europe and Pemazyre in the U.S., we are expecting total net product revenues to be in the range of $145 million to $160 million.

As in previous years, we are not providing guidance for milestone or royalty revenues. We are also not providing revenue guidance for any potential new product launches during 2021 or for Monjuvi in the U.S., which was recently launched and which we are commercializing, together with our partner, MorphoSys.

Turning to operating expenses, we expect COGS to range from 6% to 7% of net product revenues.

We expect R&D expense to be in the range of $1.35 billion to $1.39 billion, representing mid single-digit growth at the midpoint versus 2020, excluding the impact of the MorphoSys upfront consideration and the PRV in 2020.

Our SG&A expense guidance includes the investment related to the establishment of the new dermatology commercial organization in the U.S. and the related sales and marketing activities to support the potential launch of ruxolitinib cream for atopic dermatitis; the expansion of our sales and marketing activities in Europe to support the potential launches of pemigatinib for cholangiocarcinoma and tafasitamab for DLBCL; and the establishment of a commercial organization in Japan to support the potential launch of pemigatinib for cholangiocarcinoma.

As a result, in 2021, we expect GAAP SG&A expense for the year to be in the range of $735 million to $775 million. Excluding the impact of these investments, we expect our SG&A expense for 2021 to remain flat compared to 2020.

I will now turn the call back to Hervé for further discussion of the year ahead.

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

Thank you, Christiana.

Slide 24 provides a list of the important updates we expect in 2021. These include pivotal trial results for ruxolitinib cream in vitiligo as well as the approvals for ruxolitinib cream in atopic dermatitis, retifanlimab in SCAC and Jakafi in chronic GVHD.

So before moving into Q&A, I want to take a minute to let you all know that Mike Booth will be leaving Incyte at the end of the month ahead of his planned return to the U.K. Mike's role as Head of IR Incyte will move to Christine Chiou, who joined us in 2019 and who has been working very closely with Mike as part of a planned transition. I want to take this opportunity to thank Mike very much for all of his contribution to Incyte over the past 7 years, and we all wish him well in his future endeavors.

With that, operator, please give your instructions and open the line for Q&A.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question today is coming from Vikram Purohit from Morgan Stanley.

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

So I wanted to touch on the dermatology franchise. And I had 2 questions for RUX cream in advance of the Phase III vitiligo data that we're going to be getting over the next couple of months here. So first, could you characterize for us any key differences between the Phase II and the Phase III patient populations that you're looking at for vitiligo? And then second, how should we think about which portion of the vitiligo patient population that RUX cream could be most suitable for? How are you thinking about segmenting this patient population? And where do you think RUX cream is going to be most valuable?

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

Vikram, it's Steven. I'll take your question. In terms of the question on the translatability of the Phase II to the Phase III, given the magnitude of the size of the Phase II, the geography we conducted it in and eligibility criteria, we actually expect there to be no differences in population or in outcome. We expect the read in the Phase III to be of similar efficacy, magnitude to the Phase II and the safety to be the same. I'll just show the one nuance on the difference is we in Phase III, limit the body surface area of vitiligo patients with depigmentation to be up to and including 10%, whereas in the Phase II, we are a little more liberal and allowed up to 20%. But that is the only difference. We expect no other differences in outcome and in read-through of the population.

In terms of vitiligo itself, it's probably a much more common disease than everybody realizes. If you look at the United States, there are several million "sufferers" with vitiligo. Not all of them view it as a disease and not all of them want treatment. But currently, given the available therapy, about 100,000 to 150,000 people, we estimate seek different treatments including steroids, phototherapy, which is reimbursed as well and not -- they're not very effective in terms of ameliorating the disease and improving it and nothing to the degree we saw in the Phase II with topical RUX. There's also, as you know, a large psychosocial component to the condition where people are often depressed from it as well. So we expect to work in the same population as the Phase II; it'll include the majority of sufferers with vitiligo, particularly on the face and hands. And that's the label we'll aim for, should the Phase III be as positive as we expect it to be. Thanks.

Operator

Our next question is coming from Michael Schmidt from Guggenheim.

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

I had a few on the ruxolitinib cream launch coming up here as well. Maybe could you help us understand how far in are you with your launch prep in AD, especially when it comes to interactions with payers around pricing and market access?

And my follow-up question would be in context of the recent post-marketing safety data emerging from Xeljanz, so I was wondering how you think this may potentially affect utilization of oral JAK inhibitors more broadly and across indications, and how that might position ruxolitinib cream in AD in that context?

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

Michael, it's Barry. I'll take the first part of your question, and I'll hand it over to Steven for the second part of your question. But as far as the preparation goes for the launch, it's going very well. We started off at Incyte with an excellent clinical development team that's very experienced in dermatology and immunology. We built the medical affairs team in the U.S., that's outstanding and has deep experience in dermatology and immunology. Now we're building out the sales force, and we built out an excellent market access team, again, that has deep experience in immunology and dermatology. We have had interactions with payers across the nation with advisory boards, and we'll begin the process of negotiations with the payers in the very near future. So we think the launch's preparation is right on schedule. Steven?

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

Yes, Michael, thanks for the question. Given the Xeljanz non-inferiority data versus TNF therapy, particularly in RA patients, particularly looking at venous thromboembolism, malignancy and in major adverse cardiac events, you asked a question on the read-through to RUX itself and then, I guess, potentially to topical RUX. We've been with RUX on the market since 2011. So we have many, many thousand years of patient exposure, including with our partner, Novartis, as well as long-term follow-up on our clinical trial programs.

So let me just talk a little bit about the clinical trial programs. If you look at the COMFORT data in MF, now with 5 years of follow-up on those studies, there's been no signal for any of those events that are worrying in that particular exposure. In polycythemia vera, the RESPONSE studies, that is a prothrombotic disease, also now have 5 years of published follow-up, and we've looked across the board at thromboembolic events, cardiac events and malignancies there. And in fact, on the treated arms, the rates are lower in both the primary treated arm, the crossover arm versus the best available therapy arms there. So as in keeping as well with our market experience that we're not seeing a signal for any of those events as we're asked to on a yearly basis by regulatory authorities. And just to remind you, RUX has no warnings or black box for any of these. Topical RUX itself, as we have in 2 published papers now, one in AD and one in vitiligo, shown that the bioavailability of the cream is about 4% to 7% of that applied, on average about 5%. So -- and those are 2 published papers, one in AD, one in vitiligo. And thus, the effective oral exposure there is very small and not at pharmacologically relevant concentrations.

So given the parent compound itself not having an issue, RUX cream having that sort of bioavailability and our safety from those clinical programs, we don't expect any read-through there at the moment.

Operator

Our next question today is coming from Cory Kasimov from JPMorgan.

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

I'll stick with the same line of questioning here on RUX cream. And Barry, I wanted to follow-up with -- around your comments on the pending launch for AD. And just given everything you've said so far, what do you see as the key impediments in this kind of market introduction? And how should we be thinking about the heavy lifting required here versus perhaps some of that potentially low-hanging fruit you could relatively quickly capture given the data, the mode of administration and the number of patients who just aren't benefiting from existing meds?

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

Cory, well, as far as impediments go, I don't really see very many impediments. We've actually -- we think we're really in a very good situation. We think we really can help patients with mild-to-moderate eczema, atopic dermatitis from steroids all the way up to Dupixent, to biologics.

So we think that there is a broad range of patients who will be very happy to use a cream like RUX cream as opposed to using systemic therapy that may in fact suppress their immune system in general. So we're very excited about it. We know that in talking to dermatologists across the country, that when they look at the data from TRuE-AD1 and TRuE-AD2, they're very excited. They've never seen anything like this that has targeted -- that is a targeted therapy, that's topical, that has biologic-like activity. So we think that the safety and efficacy we demonstrated so far in TRuE-AD1 and TRuE-AD2 is going to help the uptake and patients throughout the United States.

Operator

The next question is coming from Kripa Devarakonda from Truist.

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

Staying on RUX cream. I was wondering what sort of conversations have you had around the NDA that you filed with the FDA following your submissions? Have you had any further conversations? And also, can you talk about your strategy for RUX cream in pediatric populations? Can we expect it to be similar between atopic derm and vitiligo?

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

Kripa, it's Steven. Thanks for your question. We don't talk in detail about any ongoing conversations with regulatory authorities. But I will tell you, as we've said publicly, the submission went in successfully in December. We utilized a priority review voucher that will give us a 6-month review, and we expect an action in the middle of the year on that. Given that it's now early February, it's still early days of that submission and review, and it's going exactly as expected.

It's in 12 years and above, the TRuE-AD studies, which covers the majority of the population Barry was talking about with atopic dermatitis. However, there is a population that is younger that does also have atopic dermatitis. And we have a commitment to continue to study that. We have to do more safety-enabling work in the pediatric population to enable those studies to look, for example, is there any bone effect, et cetera, as you look at young ages. And we've got through those hurdles successfully, and we'll determine this calendar year, given that the Phase II is successfully completed, what sort of Phase IIIs we'll be conducting in conjunction with regulatory authorities to address the population 2 years and above and conduct those studies. And we'll let you know soon as we have those studies in place, but it's going well.

Operator

Our next question today is coming from Brian Abrahams from RBC Capital Markets.

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

First off, I just want to thank Mike for all his help throughout the years and wish him well in his next endeavors. And congratulations to Christine.

Maybe shifting gears to Monjuvi. I'm curious if you could talk a little bit more about how that's being used in the real world, in particular, where it's fitting in relative to CAR-T? And what you may look towards to further the reach in academic settings, where I would imagine cell therapy and investigational treatments like bispecifics are more available? In addition to the community setting, how important that's going to be to continue the current uptake momentum?

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

Sure, Brian. Well, the uptake of Monjuvi, like I said, is going very well in the second-line plus patient population. Like any new therapy that launches, you end up starting in later line therapies, third and fourth-line therapy, for example, and we continue to try to move patients -- try to move physicians up into the second-line setting because we think that's where the patients will benefit the most. Our uptake at launch was mostly in the academic centers, and we do follow the academic centers that actually have CAR-T therapies available to them. And we're actually doing very well. Patients who are referred to academic centers for CAR-T therapy sometimes get there and they're actually not eligible for CAR-T therapy. So then they need another therapy to choose.

As we progressed with our launch, more and more of the community oncologists are taking up Monjuvi and that's surpassing the number of patients who are being treated in the academic center. But we still have some of the largest centers in the country that are using this regimen of Monjuvi and LEN.

As far as bispecifics go, we don't know that, that's a problem necessarily yet. And in fact, we think that the safety and efficacy profile of Monjuvi will match up very well to any of the new therapies that might be coming next year. As far as the CAR-T therapies go, again, physicians will choose

their patient population based upon their ability to tolerate the side effects of the CAR-T therapy. So generally, it might be younger patients who are healthy that they might select for those therapies. But again, that's a limited number of centers around the country. So we think that Monjuvi has a long way to go with treating patients with diffuse large B-cell lymphoma.

Operator

The next question is coming from Tyler Van Buren from Piper Sandler.

Tyler Martin Van Buren - *Piper Sandler & Co., Research Division - Principal & and Senior Biotech Analyst*

Just had another one on Monjuvi. You talked about the successful launch and the uptake in the academic community settings and market share gains. So curious to hear your latest thoughts and if you believe Monjuvi could be $1 billion product in the existing indication? Or if you need the frontMIND and inMIND studies to be successful? And I noticed that B-MIND wasn't mentioned in the presentation and barely mentioned in the press release. So just curious to hear if that was like a deliberate deprioritization of what's going on there.

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

So Tyler, I'll just take the first part of your question and hand it over to Steven about B-MIND. But what we said several times in the past is that in the current indication, Monjuvi could reach $500 million to $750 million -- and we'll -- as we continue to develop more combinations and move up to the front-line setting, and that's $500 million to $750 million in the U.S., by the way. So anyway, that's where we're at. And I'll hand it over to Steven for B-MIND.

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

Just a word. If you look at the worldwide sales for Monjuvi in second-line DLBCL, assuming it's $500 million to $750 million in the U.S., it will be around $1 billion or north of that for the world.

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

Tyler, it's Steven. In terms of your question on B-MIND, just that it's an ongoing study. There are no changes to it, and there are no news updates. It's a very relevant study. It's comparing to bendamustine/rituximab, which is a regimen used in that particular setting and studying the utility then of a CD19 antibody in tafasitamab there. We hopefully will have data on that study if the events track as expected in 2022, but just that it had nothing new to report.

Operator

Our next question today is coming from Alethia Young from Cantor Fitzgerald.

Alethia Rene Young - *Cantor Fitzgerald & Co., Research Division - Director of Equity Research & Head of Healthcare Research*

Mike, congrats on being one of the greatest IRs out there in the biotech field, keeping us on check.

I did want to ask 2 questions. One, just about your thoughts on your PI3 kinase with the approval of TG Therapeutics yesterday. And how do you think about positioning in that market after them?

And then also, I just wanted to get kind of your perspective on the adenosine access of the CD73 PD-1 combination. Is that something that you would use in non-small cell as a potential option? Or how do you think about like non-small cell combinations with your PD-1?

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

Alethia, it's Steven. Thanks for the question. I think the umbralisib approval from TG Therapeutics is good for patients. Obviously, we are believers in the PI3 kinase delta class. We think it has somewhat of an unfair overhang from idelalisib years ago and that many have now addressed many of the untoward side effects. So we view that as a positive outcome. It doesn't in any way impact our plans in terms of where we're going with the CITADEL studies and the filings this year, hopefully, in follicular, marginal and mantle cell lymphoma.

If you look on the face of it, with many, many caveats on cross-trial comparisons, but our independently reviewed activity in all those indications, follicular, marginal and mantle cell is higher than that reported with drugs like umbralisib, again with lots of caveats. So we're very encouraged by the efficacy we've seen with parsaclisib and obviously are proceeding with our plans. Tolerability is important as well. And obviously, we looked at their label and their discontinuations versus ours, et cetera. And we, again, think the class has been somewhat unfairly burdened by prior products.

We like our -- both our efficacy and safety profile. And we see, again, to be repetitive, no impact.

In terms of switching to earlier programs, you spoke about adenosine and the adenosine-targeted compounds. We have one in the clinic already, a small molecule, A2A, A2B inhibitor that's open and enrolling that we announced at JPMorgan.

We also said we'll be following very shortly with a CD73 antibody that will inhibit adenosine production higher up in the pathway. And Hervé showed in his presentation that the 2 together, at least in a preclinical model are synergistic. We also feel that this is potentially an area where you may require triplet therapy, and you'll have to add checkpoint on top of a PD-1. It's too early to say where these will be going in terms of histology. Lung would always be of interest, particularly in lung patients that don't respond to current IO therapies. So that will remain of interest.

I'll just remind you also that both the adenosine program and the CD73 antibody are in-house programs, and we're very, very proud of them. Thanks.

Operator

Our next question today is coming from Tazeen Ahmad from Bank of America.

Tazeen Ahmad - *BofA Securities, Research Division - VP*

As you approach the RUX cream launch, I just wanted to get a little bit more color on how you're thinking about how the gross margin for RUX cream, let's start with atopic derm might differ from the gross margins that you see for Jakafi? And then I have a quick follow-up.

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

So in -- Tazeen, this is Christiana. In terms of the COGS for RUX cream, the guidance that we provided on COGS, that is 6% to 7%, it does reflect RUX cream as well. In the near term, as we indicated, we have been building on the supply of API for RUX cream, and that would result in COGS being lower as we use up the supply that we have already expensed in 2020 and which was reflected under R&D.

Tazeen Ahmad - *BofA Securities, Research Division - VP*

Okay. So would you expect that once you have a second indication that, that COGS will continue to improve?

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

So the COGS that we have -- the COGS benefit from the API that we have already expensed will take place over a period of time, starting with the launch. And then obviously, will go back to more normalized levels. So we will -- as we use what has already been expensed, it would be reflected in lower COGS.

Tazeen Ahmad - *BofA Securities, Research Division - VP*

Okay. And then as it relates to how physicians are viewing RUX cream now just kind of based on -- you can't officially market it, but how are you thinking they understand the difference between RUX cream and Eucrisa? And where the benefits of RUX cream might be?

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

Tazeen, it's Barry. I'll try to handle that. Well, the -- I think as I said before, that the physicians we've spoken to, and there's many across the country, all the dermatologists see the TRuE-AD1 and TRuE-AD2 data as really something unique. They really like -- dermatologists really like using topical therapy, and they see this as the most effective topical therapy that they've seen ever. So Eucrisa had some disadvantages to it when it launched. Certainly, it actually burns on application and doesn't seem to be that effective. The side effect profile is pretty good. But I think physicians -- dermatologists have turned away from it, and they're very excited about what they see so far from RUX cream.

Tazeen Ahmad - *BofA Securities, Research Division - VP*

And so Barry, if it does get approved, do you think that it would have a steep uptick? Or do you think there still would need to be some physician education initially?

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

Well, there's always physician education that's necessary as well as perhaps patient education, but we think that the uptake is going to be -- go very well.

Operator

Next question is coming from Salveen Richter from Goldman Sachs.

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

Could you remind us where the QD formulation of Jakafi study stands from the LIMBER initiative? And then Hervé, if you could just give us your kind of updated thoughts on business development strategy as you look to 2021 and beyond?

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

Salveen, it's Steven. I'll start. The once-daily formulation of ruxolitinib continues to go well. The bioavailability and bioequivalence work has been completed. We're now in stability, and we need 12 months of stability to complete to then put the submission in. We would expect a 10-month review from that and thus expect an approval before the end of 2022, if everything goes smoothly. We are within everything expected in terms of the strict guidance required on BA/BE. So we're hopeful this will be a successful submission.

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

So Salveen, regarding BD, in fact, looking at what we did this year in 2020, last year, is a good way maybe to see what we are -- how we are approaching the BD strategy. We had a deal like MorphoSys where it was very complementary with our portfolio. You can see we have combinations that we are doing now with parsaclisib. There are a lot of synergies on the commercial side, both in Europe and in the U.S. So if there are opportunities looking like that, I think it will certainly be interesting to us to continue to grow our revenue line and to diversify. So that will be one aspect.

We also did a technology deal with a company called Cellenkos, and that was about myelofibrosis. So you can imagine also that we are looking at opportunities that we will be adding to our internal portfolio as part of the LIMBER program. And in general, the way we are thinking about it is, if there are products that could be available, that would be fitting with our hematology/oncology portfolio, that would be the priority. And if there were opportunities that are also providing additional revenue to our dermatology team in the U.S., it could be also something that we look, but mostly on the different timelines, as we will be launching first atopic dermatitis this year and then vitiligo next year. So there is no urgency to add to that in the short term.

So I would say it's -- in the short term, hematology oncology; maybe over a longer period of time, we could be looking at immune-dermatology and the type of assets we are looking at are products that we'll be launching between 2023 and 2026.

Operator

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

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

Just a follow-up perhaps on RUX cream. And just trying to understand a little bit around the dynamics of launches, as most derm products are associated with some type of support, couponing program and the like and so on. I'm curious as to what your thoughts are on that? And also, one of the areas that the company hasn't touched on in a while is Jakafi in PV and some of the efforts pre COVID to enhance that patient population. I'm wondering if you could touch on that as well.

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

Sure, Mara, I'll try to answer both of those on RUX cream and then on Jakafi in PV. So we have plans in place, just like many products that you see, particularly in dermatology, but throughout the United States for newly launched products, where we're going to ensure that when a dermatologist, when a physician prescribes RUX cream, that it's as easy as possible for the patient to obtain it. So that begins first with market access, working with PBMs and payers to make sure that there's as few restrictions as possible, as few prior approvals as possible. And then once we get to the pharmacy counter, to be able to help the patients with their co-pays and deductibles through, as you say, a couponing program or other ways for us to manage that.

As far as Jakafi goes, Jakafi continues to -- Jakafi in PV goes, Jakafi continues to grow in PV faster than it does in MF. And even though MF continues to grow, the total number of patients continues to grow. I suppose our biggest activity that we're doing in PV, well, is, first, talking about the long-term follow-up of the response studies, which are very, very important. Over time, the data just continued to get more impressive and look better. But also, we had our -- we had our disease awareness campaigns around polycythemia vera and the number of patients who are suffering because of the symptoms that they undergo when they're getting PV. So we're very encouraged about the future of Jakafi in polycythemia vera as well as our other indications. But as you indicated, it's a pressing need for those patients to make sure that they have the most effective therapy to take care of their symptoms and their hematocrit.

Operator

Our next question is coming from Marc Frahm from Cowen and Company.

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

Let me offer my congratulations also to Mike to next step in his career.

Maybe, Barry, with vitiligo and your comments and Steven's comments, yes, there certainly are people who do get reimbursed today for off-label use of various products. But we also hear from consultants that a number of plans consider this to be a cosmetic indication. I guess, Barry, what's your sense as to kind of what percent of the relevant population already has this covered and recognized by their plan as a true medical reimbursable condition? And then kind of what efforts do you need to do between now and launch to grow that number?

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

Well, I'm not sure I can tell you what number are currently covered for therapies because there aren't very many therapies. Steven talked about phototherapy. That's one way. Other topical therapies may or may not be reimbursed. But I think it's -- Steven talked about the millions of patients in the United States, somewhere between 2 million and 4 million patients that have vitiligo, but maybe only 150,000 to 200,000 patients are seeking therapy. And that's because, in fact, there aren't very many effective therapies. We do have to continue to educate both payers -- I don't think we really have to educate dermatologists very much. Dermatologists know that this is an autoimmune disease that drastically impacts patients' lives. So having a therapy like RUX cream for vitiligo, we think, can greatly enhance the quality of life for those patients, and it's essential upon us to educate payers that this is not a cosmetic issue, that it is an autoimmune disease and that the responsible thing is actually to pay for it.

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

Are there kind of similar launches that have happened historically that you can point to that kind of faced the same type of dynamic?

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

Well, that comes to mind. So I think there's lots of diseases that we come across that haven't had payers wanting to pick it up. You might even say eczema for example, when older products were launching, they might have thought that this is something that's not important, but in fact, it impacts patients' lives very much where they don't want to go out of the house and where they're suffering, not just itching and staying awake at night, but of course, even bleeding and infections. So that's one example. I'm sure there's many other examples where education of payers and prescribers is very important. We think that is vitiligo, but we think that we can manage -- overcome that hurdle.

Operator

Next question is coming from Evan Seigerman from Crédit Suisse.

Evan David Seigerman - *Crédit Suisse AG, Research Division - VP & Senior Equity Research Analyst*

I just want to quick shout out to Mike for everything over the past couple of years. You will be missed.

So I wanted to ask on the LIMBER program. While it might be early, can you characterize kind of maybe some demand or feedback you've gotten on the QD RUX option among most physicians and patients? And what do physicians really want to see from this QD formulation in terms of efficacy to potentially switch patients from the current Jakafi?

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

Okay. Evan, thank you, it's Steven, I'll start. Others may want to add comments. The LIMBER program itself is an umbrella program with numerous pillars. The formulation work was one of the pillars. Obviously, once daily has potential compliance improvement over twice daily, although in oncology, people tend to do very well with twice daily, but that was one of the efforts behind it for those people who would potentially benefit from that.

Additionally, it does give us down the line, very important optionality on fixed-dose combinations should we develop, for example, PI3 delta or BET or ALK2 as a once daily, it could lend itself to be combined with a once-daily ruxolitinib in one FDC. So that would be really, really important from that. After we pursue the 505(b) route through bioavailability and bioequivalence, finish the stability file and hopefully have it approved at the end of 2022, we could look at things that may be slight differences in the clinical profile of the once daily. For example, just by its very nature from a pharmacokinetic point of view, it will have a lower peak, a lower Cmax. If that is one of the causes of anemia from the drug, which we think it is, it may tend to have a lower rate of anemia with the once daily, which would be of benefit in MF patients because that's one of the reasons they discontinue and then allow patients to stay on drug longer and they, as a direct result, actually enhance efficacy as well. So there are lots of aspects to the program. It's step-wise. It's about getting approval first, which may lend itself to compliance, optionality on fixed-dose combinations and potentially an upside on ameliorating anemia.

Operator

Ladies and gentlemen, we have time for 2 more questions. Our next question is coming from Ren Benjamin from JMP Securities.

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

Congratulations on an amazing quarter, great guidance, and congrats, Mike as well.

Maybe just starting off the LIMBER program. This is probably for Steven. Can you just talk a little bit about these 2 Phase III trials that are ongoing, maybe the timing as to when we might see readouts? And how the optimal dosing was determined for both RUX and parsaclisib?

And maybe just as a follow-up, Hervé mentioned Cellenkos. I'm just kind of curious what was the rationale to lead to this collaboration? Is there an unmet need that this collaboration seeks to address? Or is it more just trying to find a best response rate in MPNs?

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

Yes, Ren, it's Steven. Thanks for your questions. So again, back to the LIMBER program, we just spoke about in the prior question about the first pillar around formulation work. The second pillar is around important combination work with combinations that either enhance efficacy or enhance safety like the ALK2 or both because you ameliorate anemia with ALK2 and you can stay on RUX. The delta program that you alluded to has 2 very important Phase IIIs that are open site initiations ongoing now. One is a suboptimal setting for patients who have had at least 3 months of ruxolitinib, but have not had an adequate response in terms of spleen or symptom control and are then randomized to RUX plus delta in that setting PI3 delta versus RUX alone. The dosing, because you asked the question specifically, is for RUX itself. Obviously, we know optimal dosing and how to titrate based on potential safety issues like thrombocytopenia.

The delta dosing came from proof-of-concept work we did in prior patients who had inadequate responses to long-term RUX. And that's how we determined that the 5-milligram was active there as well as had a tolerable profile. And that's what we're using in both the suboptimal study and the first-line study, which are now open and site initiations ongoing.

In terms of Cellenkos, it's a completely new mechanism of action. It's -- there's some enticing small clinical anecdotes. It's umbilical cord derived regulatory T cells that they have a way to enrich for CXCR4, which are then regulatory T cells that would then hone to the bone marrow. And they've

shown in a small number of patients who are heavily pretreated, some enticing data of clinical response, drop in allele burden and maybe even some fibrosis improvement. It's very early. We like the way the deal is structured because we go in with a small upfront, we finance the proof-of-concept work, and then we have the option to take it up. And we really -- it's exciting, it's an off-the-shelf umbilical cord with a completely new MOA. So that's the drivers behind that one.

Operator

Our final question today is coming from Jay Olson from Oppenheimer.

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

Thanks to Mike Booth for all his help over the years. Maybe just to continue on the theme of your LIMBER program. I appreciate the progress there. And I was wondering if you could provide any details on your BET inhibitor. And what level of incremental benefit for the combination of BET inhibitor plus RUX versus RUX alone would be clinically meaningful on SVR35 and TSS?

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

Yes, Jay, it's Steven. Thanks for the question. So just a reminder, this is not a new compound. It's a compound we had in the clinic years ago. We dosed more than 100 patients in a very solid tumor mind frame at the time. We were trying to drive Myc inhibition with our BET inhibitor, and we treated, as I said, north of 100 patients. We had adequate inhibition, but we had a lot of on target toxicity in terms of thrombocytopenia and not much efficacy in solid tumors. So we put that program ourselves on hold or on the shelf, so to speak. And then obviously, the externally, the field evolved, CPI-0610 showed data as monotherapy in MF patients in second-line setting and then in combination with RUX in the first-line setting that we think has an interesting signal.

So we reinvigorated our program. It's up and open now for enrollment. And the idea is this calendar year, in the first half, hopefully, COVID behaves, but is to get monotherapy safety, and then in the second half of this year, get the combination safety with RUX with our own BET inhibitor and then potentially go ahead with pivotal studies. You ask how does it differentiate? So we were able with the external data to model a completely different dosing scheme from our prior one. We had about 1/3 to 1/4 of the dose we were in the clinic before. We've looked at the external environment, and we think that will weave the therapeutic ratio in terms of effect because we know it's effective in MF with our own data preclinically as well and then not have unacceptable rates of thrombocytopenia. But it's not a different BET inhibitor in any way in terms of targeting otherwise. And then we'll make bigger decisions once we have the safety data at the end of this calendar year.

Operator

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

Michael Booth - *Incyte Corporation - Divisional VP of IR & Corporate Social Responsibility*

Thanks, Kevin. Thank you all for your time today, for your questions and also, of course, for your kind words. You will be in excellent hands with Christine, I'm sure, and both of us are available for the rest of the day for any follow-up questions. But for now, thank you all very much, 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.