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EDITED TRANSCRIPT

INCY - Q2 2019 Incyte Corp Earnings Call

EVENT DATE/TIME: JULY 30, 2019 / 12:00PM GMT

OVERVIEW:

Co. reported 2Q19 total revenues of $530m.

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PRESENTATION

Operator

Greetings and welcome to the Incyte Corporation's Second Quarter 2019 Financial Results Conference Call. (Operator Instructions) As a reminder, this conference is being recorded.

It is now my pleasure to introduce your host, Mike Booth, Head of Investor Relations. Thank you, sir. You may begin.

Michael Booth - *Incyte Corporation - VP of IR*

Thank you, Jessie. Good morning, and welcome to Incyte's Second Quarter 2019 Earnings Conference Call and Webcast. The slides used today are available for download on the Investor section of incyte.com. I am 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. (Operator Instructions)

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Before we begin, however, I'd like to remind you that some of the statements made during the call today are forward-looking statements, including statements regarding our expectations for 2019 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 March 31, 2019, 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 at the beginning of 2019, we set out to achieve a series of specific goals. And in the first half of the year, we have already executed on a number of commercial and clinical objectives. Q2 2019 was another strong quarter with 21% growth in total products and royalty revenue when compared to the same period last year. Sales of Jakafi grew by 18%, Iclusig revenues increased by 23% and Jakavi and Olumiant Royalties, collectively, demonstrated growth of 36%.

In May, we announced that the FDA granted full approval of Jakafi for use in patients with steroid-refractory acute GVHD. Our team was prepared and we launched Jakafi in this new indication immediately.

There were 2 additional important updates within our development portfolio during the second quarter: Capmatinib data in patients with non-small cell lung cancer harboring MET exon-14 skipping mutations were presented at ASCO; and Novartis continues to guide to an NDA submission in this indication in the second half of this year. If approved, Incyte could become eligible for 12% to 14% royalties on global net sales by Novartis and could receive over $500 million in potential milestones over time.

Following our prior announcement as the Phase II trial of ruxolitinib cream in vitiligo has achieved its primary endpoint, the data was presented at the World Congress of Dermatology. The data were well received and we believe ruxolitinib cream has a potential to be transformative for the treatment of the millions of patients with vitiligo. We are preparing for Phase III development in this indication, which we expect to initiate by the end of this year.

We therefore, begin the second half of the year with strong momentum, and we look forward to reporting on several other important clinical and regulatory milestones in the coming months.

One of Incyte's core strength is our discovery engine. Several years ago, in order to capitalize on this, we've tasked the separate group of scientists to review potential uses for our molecule and target outside of oncology. These efforts are now bearing fruit. In addition to our portfolio in hematology and oncology, we now have a separate and growing clinical portfolio in inflammation and autoimmunity indications. As you know, we are currently running proof-of-concept trials across several molecules and indication and the 2 most advanced projects within the IAI group are the evaluation of ruxolitinib cream in atopic dermatitis and vitiligo. The data to date have been compelling in both indications, and we look forward to future updates from rux cream as well as our other proof-of-concept IAI programs.

We believe that adding this exciting new potential growth driver on top of our well-established oncology franchise could further accelerate and diversify our revenue line and better position Incyte for sustainable long-term growth.

I will now turn the call over to Barry for an update on Jakafi.

Barry P. Flannelly - *Incyte Corporation - Executive VP & General Manager of U.S.*

Thank you, Hervé, and good morning, everyone. Patient demand for Jakafi continues to be strong. In the second quarter, demand grew by 14% year-over-year while net sales grew by 18%. As a result of these encouraging results and given early data from the launch in GVHD, we have increased the lower end of our guidance. Our full year 2019 guidance for net sales of Jakafi is now $1.61 billion to $1.65 billion.

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We are encouraged by the initial interest and excitement from healthcare professionals at bone marrow transplant centers across the nation as they learn about the approval of Jakafi for the treatment of patients with steroid-refractory GVHD. The data supporting the approval has also been very well received.

It's early to fully quantify the impact of GVHD launch and overall Jakafi performance, but indicators from BMT centers are good. And we are seeing an increase in new GVHD patients on Jakafi. For example, we have previously outlined the concentrated nature of this opportunity, which exists at a relatively small number of bone marrow transplant centers in the U.S., and our initial data indicate that over 80% of these top tier centers have purchased Jakafi since FDA approval. Insurance coverage has also been encouraging, and we are not aware of documented denials to date. And we look forward to keeping you updated on our progress over the coming quarters.

I'll now 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. Incyte is currently running 6 key late-stage development projects. These have the potential to treat a significant number of patients across numerous indications. Ultimately, these projects aim to transform Incyte into a company with multiple approved products in the United States, Europe and Japan over the next several years. We've made good progress over the last few months and we remain on track to achieve the clinical milestones that we have previously laid out. I'd now like to touch on 2 key data presentations made during the second quarter.

In June, the Phase II data of ruxolitinib cream in patients with vitiligo were presented at the World Congress of Dermatology in Milan. As previously announced, the trial achieved its primary endpoint of a facial VASI50 versus vehicle at week 24. Here, you can see the improvements by dose over the course of the trial. The highest facial VASI50 scores were achieved using 1.5% ruxolitinib cream daily and twice daily. Importantly, ruxolitinib cream was well-tolerated. It was not associated with any clinically significant application site reactions or serious treatment-related adverse events.

As you know, the facial VASI75 represents a more complete clinical response in patients with vitiligo, and this is why we have chosen this as the primary endpoint in our global Phase III development plan. On this slide, you will see the facial VASI75 data from our Phase II study.

These data show a clear dose response and that the 1.5% dose of ruxolitinib cream used twice per day was the most effective in treating vitiligo lesions. Our plans for Phase III development are moving forward, and we continue to expect the initiation of pivotal development before the end of this calendar year. We intend to initiate 2 Phase III trials with 300 patients in each. The trials will evaluate ruxolitinib cream at a dose of 1.5% twice a day versus vehicle. And our plan is to use facial VASI75 at 24 weeks as the primary endpoint of both studies.

Note that at this dosing schedule in a Phase II trial, 30% of patients treated with ruxolitinib cream achieved a facial VASI75 score, whereas none of those patients treated with vehicle achieved a facial VASI75.

We are hopeful that ruxolitinib cream will be the first vitiligo therapy approved by the FDA and that it may provide these patients with a meaningful improvement in their disease. The vitiligo data are very important to Incyte. Ruxolitinib cream is a first-in-class agent with the potentially disease modifying mechanism of action in a large indication with a clear unmet need. The transformative effect of ruxolitinib cream could have in the treatment of vitiligo has therefore placed even greater momentum behind our IAI franchise and development efforts.

Let's move on to one of our out-licensed molecules, capmatinib, which is being developed by Novartis. At ASCO in June, updated data in patients with non-small cell lung cancer harboring MET exon-14 skipping mutations from the GEOMETRY trial were presented. These data show that almost all patients experienced reduction in tumor volume when treated with capmatinib. And by RECIST, these data showed overall response rate of 68% in first-line patients and 41% in second and third-line patients. The data also show a manageable safety profile.

As a reminder, capmatinib was granted breakthrough therapy designation and then Novartis expected to file an NDA by the end of this calendar year.

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I'll end my update by reminding you of our expected key newsflow events during 2019. We continue to expect to submit the NDA of pemigatinib in second line cholangiocarcinoma before the end of this year. We are also planning for the presentation of updated data on FIGHT-202 trial, which will form the basis for the NDA submission later this year. We have multiple Phase III trials running across various types of graft-versus-host disease that are expected to deliver top line results by the end of this calendar year. REACH2 is evaluating ruxolitinib in patients with steroid-refractory acute graft-versus-host disease and REACH3 is studying ruxolitinib in patients with steroid-refractory chronic graft-versus-host disease.

Both of these trials have been conducted in collaboration with Novartis.

GRAVITAS-301 is evaluating itacitinib, our wholly-owned JAK1-selective inhibitor, in patients with treatment-naïve acute graft-versus-host disease. If GRAVITAS-301 is positive, we would expect to seek approval for itacitinib in the United States, Europe and Japan based on these data.

2019 has been an excellent year of research and development execution thus far, and we look forward to keeping you updated on our progress. With that, I'd like to turn the call over to Christiana for a financial update.

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

Thanks, Steven, and good morning, everyone. The financial update this morning will include GAAP and non-GAAP numbers. For the full reconciliation of GAAP to non-GAAP, please refer to Slides 23 and 24 in the backup section of the deck and to the press release we issued this morning.

Turning now to Slide 17. Our second quarter results reflect continued strong performance across all products, with total product and royalty revenue of $510 million, representing an increase of 21% over the second quarter of 2018. This is comprised of $410 million in Jakafi and $24 million in Iclusig net product revenues, $57 million in Jakavi royalties from Novartis and $19 million in Olumiant royalties from Lilly. We also recognized $20 million in contract revenues under our collaboration agreement with Innovent, resulting in total revenues for the quarter of $530 million.

Our total cost and expenses for the quarter on a non-GAAP basis of $379 million decreased 3% from the prior year quarter.

Ongoing R&D expense for the quarter was $237 million on a non-GAAP basis, representing a decrease of 7% from the prior year period. This decrease reflects the impact of our decision to stop co-funding baricitinib development and lower costs related to the epacadostat program, partially offset by costs to advance our other internal developing programs.

SG&A expense for the quarter of $93 million on a non-GAAP basis decreased 3% from the prior year quarter. This decrease reflects the timing of certain commercial activities, which this year are expected to take place in the second half.

Moving to our guidance for 2019. We are increasing the low-end of our Jakafi revenue guidance from $1.58 billion to $1.61 billion based on our results in the first half of the year. We are reiterating both our NDA and SG&A expense guidance as we continue to invest in both our commercial efforts and in our clinical development portfolio. I will now turn the call back to Hervé.

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

Thank you, Christiana. So our last slide, outlines our progress to date in 2019 as well as our remaining key newsflow events we expect during 2019, including those from our partners. With this list of exciting late-stage program, we are taking important steps toward our strategic goals of further diversifying the organization and driving sustainable revenue growth.

That concludes our prepared remarks, and we are now happy to take your questions. Operator, please give your instructions and open the call for Q&A.

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QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from the line of Cory Kasimov with JP Morgan.

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

Great. So my first question is regarding GVHD. Can you just help us better understand the key gating items and levers we need to think about with Jakafi's launch in this setting? And should we be looking at this as a growth driver for the company in the near-term as more of a place setter for itacitinib? And then I have one follow-up.

Barry P. Flannelly - *Incyte Corporation - Executive VP & General Manager of U.S.*

Sure. Cory, This is Barry. Well, as far as gating levers go, one of the most important thing is access, and we haven't had any problem with access at all. It's early but we really think the launch is going very well, both we have some qualitative and quantitative measures. Qualitatively, we know that even centers that have been using Jakafi for GVHD before, they might have been using it third or fourth line or even later, and now they've moved it up to second line. Quantitatively, we know that orders from the 150-or-so bone marrow transplant centers have increased. We don't know exactly why they're ordering it, whether it's for MF, PV or GVHD, but we can assume that most of the new orders are actually for GVHD. We know that specialty distributor orders are up and those are generally, as opposed to specialty pharmacy, specialty distributors ship to hospitals and we know that those are up pretty substantially. We really think that for this year, and I think I've said this before, of our top line net sales, GVHD will account for about [$80 million] and that's for spontaneous use as well as use once we have the approval.

Is it a good growth driver? For sure, it's a growth driver as we get more data and new indications for Jakafi but also ultimately, for itacitinib as we gain approval in the first-line setting in both acute and chronic GVHD.

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

Okay. That's very helpful, Barry. And then my follow-up, probably for Hervé, but I'd be interested in getting your broader thoughts on healthcare reform and all the noise that's out there and to the extent there is something that's enacted that incorporates part D, can you just remind us of your potential exposure there?

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

Now, thanks for all the question. Obviously, it's top of mind for many people. It's a situation of Medicare sales for Jakafi in the U.S., I think we said are around 50% of our total business in the U.S. for Jakafi today. So that gives you an idea of the size of our Medicare exposure.

The way we look at it is, first, we know that there are a number of patients in the U.S. on Medicare who are not taking Jakafi because of the copays that they have to contribute today. So the goal for us of any kind of reform is first to reduce the copay because it will be good for us but also because of humanitarian reasons, I think it's one of the effect of the current system in the U.S. is that there are a number of people who cannot afford the copays the way it is defined today. So one of the things of what we have seen in the draft of the Senate document is significant reduction in the copay for patients.

It's very difficult for us to quantify what kind of effect it would have on the number of patients, who could now afford to be treated with a product like Jakafi. It's not just Jakafi, I mean it's really touching on the oral cancer treatments in general, and we think it will be a huge positive for these patients as the copay is reduced.

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And we -- frankly, we wish it would be further reduced. I mean, the counterparts of that would be, for us, the contribution to the catastrophic coverage and the net-net of the two, frankly, is difficult to quantify. What we think -- what I think personally is that as we move forward for the next 10 years, for a company like us, with innovative products coming to market over the next 10 years. The fact that the patients' part of the payments for this innovative treatment is reduced is fundamentally a very good thing because it would give access to more people in the U.S.

Operator

The next question is from the line of Brian Abrahams with RBC.

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

I wanted to drill down a little bit more on the Phase III vitiligo trial design. [inaudible] if you can talk a little bit more about what shaped your choice of endpoints there for the Phase III via VASI75, whether that was driven by regulatory feedback or more about meaningful to most of patients? How we should be thinking about timelines -- potential timelines for enrollment there? And then what your goal be for potentially maximizing its differentiation versus other topicals from those studies?

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

Brian, it's Steven. Thanks for questions. So re: the Phase III design in the primary endpoint and whether it's regulatory or patient-driven or both. As you can see, as you set the bar higher as regards VASI scores whether 25%, 50% or 75%, obviously the relative percent gained in achieving the efficacy endpoint is somewhat lowered. But it's meaningfulness, right? So once you get up to 75%, repigmentation, you are proving to regulators that you've achieved something meaningful as well as to patients. So it's both in that regard. And it's been driven by discussions with regulators and obviously taking patient input into regard.

You will see the vehicle response rate is 0 at that time, at 24 weeks. What we expect and what we know from the cream in how it behaves is over time, actually, these numbers go up. So remember, the study actually goes on for a total of 2 years. We will eventually have 52-week data and then data beyond that and there's every expectation given the way it works in the natural course of this disease that those numbers will increase over time at 52 weeks and beyond. So it's a bit of both and it'll fit a standard for future studies in terms of achieving that endpoint.

In terms of time lines, again, I'll just be repetitive, the vehicle response rate is 0. So we don't require a great deal of patients to conduct these studies. We require 2 studies as per the regulations, but there are only 300 patients each given the very low to 0 vehicle response rate. So we're looking to enroll 600 patients. I expected will enroll quickly, we just can't give you exact time lines at this juncture.

Differentiation wise, we know from the atopic dermatitis program that -- and that has extensive now, patient numbers in an exposure data that the cream is extremely well tolerated in atopic dermatitis as resolution of ash -- of the itching in 48 hours or less. There is no burning on application. So we have -- as long as we achieved the efficacy we fully expect from our Phase II program, we have a differentiated profile from a tolerability point of view.

Operator

Our next question is from the line of Carter Gould with UBS.

Carter Lewis Gould - *UBS Investment Bank, Research Division - Large Cap Biotech Analyst*

Congrats on the quarter. Maybe one for Steven, just digging in a little bit more into GRAVITAS-301, just kind of wondering around kind of your assumption and the importance of showing a separation on non-relapse mortality when you think about sort of the target product profile and as we think about that Phase III readout.

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

Carter, it's Steven. Thanks for your question. So GRAVITAS-301, for everybody else, is itacitinib in steroid-naïve acute graft-versus-host disease. It has 2 very important endpoints. The overall response rate as well as non-relapse mortality. So that's death due to anything other than disease relapse. So either infections or progression of graft-versus-host disease.

In terms of the primary endpoint on overall response rate, the study is powered to show a 16% or greater increase in overall response rate. That's public and we've made that available. In terms of non-relapse mortality, it's a 40% relative reduction in non-relapse mortality at 6 months, and that we fully expect from our enabling proof-of-concept data to achieve both those endpoints.

We need to achieve both to get the study across the finish line and work towards the submission for both. So those are the endpoints we aim for. The proof-of-concept data easily exceeded those. So we have room to move.

Operator

The next question is from Salveen Richter with Goldman Sachs.

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

So with regard to your Phase III topical ruxolitinib trial in atopic dermatitis that's reading out next year, the study ongoing is an adult with surface area limits. Can you just help us understand the market targeted by this study and when you look at the adult population versus the pediatric population? And then your plan for studying pediatric patients given you have a Phase I study ongoing?

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

So you're correct. The current program looks at patients 12 years and above, and that it covers mild-to-moderate atopic dermatitis and that covers a vast majority of patients suffering from the condition. We do want to eventually, once we achieve adequate safety data to enable the work, study younger patients, but we need to first prove that there is no issue in terms of safety in that population. But as I said it doesn't represent the majority of the patients there.

The body surface limits, so it's just somewhat practical in nature. Remember, we are applying that cream and that you just can't apply to the entire body. But again, this encompasses patients with the majority of atopic dermatitis, and we are comfortable with the way the program is set up.

Operator

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

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

One thing that wasn't touched in the regulatory -- or in the recent R&D update, if maybe you could touch on the essential thrombocythemia kind of enrollment update or trying to maybe cut the trial off and get a publication out that can support something like guideline inclusion?

And then given the fact that things have been going slower than expected, but were part of long-term guidance, do you need to update that long-term guidance for Jakafi?

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

Marc, it's Steven. I'll do the first part and then I'll ask Barry to address the ET contribution to guidance. So you are correct and we said this on numerous calls that given the eligibility criteria required to get onto the study and the patients have to have a high white cell count and be post hydroxyurea and then be further randomized to either ruxolitinib or anegralide. It hasn't been an easy study to enroll at all and we said it is taking longer than expected. So we are all very much considering whether as you said, this should be changed more into a publication strategy. We are currently working with the regulatory authorities on another amendment that may help enrollment and that's to allow prior anegralide, and we'll see if that will help enrollment or not. It's too early to tell in terms of that.

Remember, the vast majority of patients with essential thrombocythemia are controlled with hydroxyurea, so it was really always for the patients who weren't in that space. It's the last myeloproliferative neoplasm that we don't have an indication for. We know from spontaneous use, anecdotal reports and others that the drug has efficacy there, and that's why we conducted the Phase III program. But it could well be turned more into a publication compendia listing type strategy. I'll ask Barry to answer your next question.

Barry P. Flannelly - *Incyte Corporation - Executive VP & General Manager of U.S.*

Marc, we are very confident with our long-term guidance of $2.5 billion to $3 billion. We, even without ET, but as Steven said, we do have some spontaneous use of Jakafi for patients with ET. I think that will continue, but the vast majority of sales really come from continued growth in MF, PV and GVHD.

Operator

The next question is from the line of Michael Schmidt with Guggenheim Securities.

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

This is Kelsey on for Michael. First, we have heard from physicians that patients stay on Jakafi for a pretty long time. I guess, in this context, how could the potential approval of fedratinib in the coming months may be affect Jakafi patient duration?

And then secondly, we were just hoping if you could provide a little more color on the FGFR tumor agnostic program. Maybe just kind of remind us what bar needs to be cleared with that data set to potentially warrant an agnostic label?

Barry P. Flannelly - *Incyte Corporation - Executive VP & General Manager of U.S.*

Thanks, Kelsey. This is Barry. I'll take the first part of the question and hand it over to Steven for the second part of the question. So the potential launch of fedratinib, we believe that patients will continue to stay on therapy as long as they benefit from Jakafi, which is both in MS and PV quite a long time. So I think that's the most important thing is that patients get the most benefit out of Jakafi before they move on to something else.

As far as the efficacy and safety of Jakafi as compared to other JAK inhibitors, including fedratinib, we're very confident that Jakafi is the best-in-class drug and that patients should start on Jakafi before they move on to something else. So we don't think it's really going to affect us much at all. Steven?

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

Thanks, Barry. Thanks for the question. So this is a very important part of the pemigatinib program. So remember the cholangiocarcinoma study is complete. We expect to file in the second half of this year. The bladder cancer work is ongoing and should complete enrollment also second half of this year, and hopefully would be part of a submission next year.

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And then the third pillar here is the tumor agnostic program. We also have an ongoing effort in a very rare myeloproliferative neoplasm that's driven by FGFR1 chromosome 8p11 translocation. But in terms of the tumor agnostic program, you're right. The -- there is -- you can't be specific in terms of our bar, but let me just give you a sense of some of the tumors. So if you look at endometrial carcinoma, there's about 10% of those patients that have FGFR2 mutations or fusions; glioblastoma is also about 10% for FGFR3; squamous cell or non-small cell lung cancer about 5% FGFR mutations or fusions; rectal cancer, about 2%; and squamous cell of head and neck also about 2%. All of those are allowed to come on the program.

The guidance from regulators to date has been if you already have an indication you have an established drug that hits an oncogene that has really been shown to work and at that juncture will have cholangiocarcinoma and hopefully, bladder cancer as well. Then there's obviously precedence. The most recent one is probably checkpoint blockade with MSI-high tumors with checkpoint blockade they got an indication. In terms of de novo indications, there's obviously NRTK inhibitors now and given across-the-board, where the histology is agnostic. So you need to see reasonable response rates that are durable. Some of those tumors are mentioned. You would require a higher number than glioblastoma, for example, where there's a lot of unmet need.

So it would be a little bit on case-by-case basis. As long as the genetic mutation is a driver, the drug hits that driver mutation and causes a response rate that's durable, we expect with a cumulative data set to possibly get a tumor agnostic indication there. The opportunity from a patient point of view, actually, if you add all those up, it becomes bigger than the whole for all the other tumor types. So it's a very, very important program to us.

Operator

Our next question is from Matthew Harrison with Morgan Stanley.

Matthew Kelsey Harrison - *Morgan Stanley, Research Division - Executive Director*

I guess I wanted to ask about GRAVITAS-301 as well, but more on the commercial side. Could you just talk, I guess 2 parts here, could you talk a little bit about given that there are a bunch of cheap generics available, what sort of efficacy differential you think you need to be able to achieve to have solid pricing premium there and uptake? And then just briefly comment on what sort of sales force expansion you think you need to have to maximize this indication?

Barry P. Flannelly - *Incyte Corporation - Executive VP & General Manager of U.S.*

I'll let Steven start off with the beginning and then I'll pick up on the sales force and potential for the drug.

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

So Matthew, let me just go back to your important question around endpoints in GRAVITAS-301. We spoke about them briefly earlier. So remember, there are 2 important endpoints, that the overall response rate at Day 28 and then there is non-relapse mortality. And obviously, there's steroid-naïve acute graft-versus-host disease. So it's a combination of itacitinib and steroids versus steroids alone and you alluded to steroids being the cheap generic.

And that's exactly why the study is conducted and powered to show an appreciable difference in both. So just let me remind you, on the overall response rate, we need to see 16% absolute improvement in response rate or better and then that has to be coupled with their 6 months in non-relapse mortality that was relatively speaking, 40% or better. So you get both to justify the use of a JAK inhibitor in addition to steroids in that population. I'll ask Barry to address your commercial question.

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Barry P. Flannelly - *Incyte Corporation - Executive VP & General Manager of U.S.*

Towards the endpoints that Steven laid out, I don't think there will be much of a problem getting premium pricing, at least compared to generics like steroids, if that's what you're implying. Non-relapse mortality is a significant endpoint. And again, I think we'll be able to have an adequate price for the -- for this drug. As far as the sales force goes. In the United States, we mostly have it covered to be honest. We might have expansions for other drugs that are coming, including itacitinib and pemigatinib that we'll think about a little bit. But in Europe, and Japan then we'll need to have a sales force that increases to certain amount.

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

Just a word on Europe. In fact, we did the calculation recently and the Iclusig sales force that we have today is in fact very much targeting the same centers that are doing bone marrow transplant. So that would be some increase, but it will be relatively marginal regarding the European side. And in Japan, we would love to have itacitinib and GVHD as our first product to launch in hematology because again the number of centers is relatively limited compared to the overall need for sales force in hematology, and it would be something that will be feasible with a number of reps, of commercial people that is really small compared to the traditional Japanese sales force that you need for oncology. So Europe, we are almost there, so there is a marginal increase and Japan, it would be very reasonable. So it's an indication for us that we would be a driver of the topline growth but would be also a very good contributor to the bottom line.

Michael Booth - *Incyte Corporation - VP of IR*

Can we go to the next question please.

Operator

Our next question is from the line of Alethia Young with Cantor Fitzgerald.

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

Congrats on the progress. I just want to go to the PI3-kinase, I know your data coming next year and obviously there are some PI3-kinases, they are starting to emerge again. So just wanted to get your updated thoughts on how you're thinking about what reasonable profile for this drug could be? And kind of some of your thoughts heading into the data in 2020?

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

Alethia, it's Steven. Thanks for your question. In terms of the PI3-kinase delta program in lymphoma. Let me remind you by the way we have the rux combo ongoing in myeloproliferative neoplasm as well particularly MF. But in terms of lymphomas, which I think is the meat of your question, there are 3 registration directed approaches: one is against follicular lymphoma; the other, against mantle cell; and the third one, against marginal zone lymphoma.

They're all enrolling really well. They will complete enrollment in the second half of this year. We'll get data as you allude to in 2020. And we expect, based on activity we've seen to date, high response rates that are durable. And then each on their own will be submitted as potential indications.

There's a potential to lump together, lower-grade lymphoma, so you could do follicular and marginal zone together for example. Mantle cell is probably stand-alone. There is a crowded space as you alluded to in terms of mechanism of action, there are BTK inhibitors, BCL2 inhibitors, CAR-T therapies, et cetera. But all those conditions remain incurable, all have unmet need attached, and we've seen regulators even more willing lately in areas of unmet need to approve additional agents. So we remain confident in the approach thus far.

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There will probably be more in the Accelerated Approval, conditional approval camp. So you will likely see -- should the data sets justify them, confirming 3 studies being set up more likely combination work. But that's the entirety of the program and all the data on those studies in 2020.

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

Sorry, just a quick follow-up on those. As far as safety goes, I mean do you think that's what really is going to differentiate kind of what have you been doing in every dose and what kind of help with that as well?

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

Alethia, I think you're right. We took a time line hit because of that. We did some very careful work with scheduling and dosing because we knew that drug is highly active and B cell tumors literally meant away with PI3-kinase delta inhibition. But then there's the long-term toxicity, particularly colitis. So we looked at induction daily dosing for 8 weeks and then switching to weekly. And then we looked at induction daily dosing for 20 milligram daily for 8 weeks and switching to lower dose daily, and we've done a lot of work in that regard.

It looks like both of those schedule and dose changes ameliorate the safety profile quite substantially. For example, we see little to no colitis at this date, at this juncture. We said to wait for the complete data set. I think it's likely at this juncture that you will see, those 20 milligrams daily for 8-week induction to get the maximum effect, maximum response and then the likely switch to lower dose daily dosing of like 2.5 mg daily. And that should get us to the therapeutic ratio we desire and that you allude to. Because it will be critical, you'll have to hit that efficacy bar and have a tolerable safety profile.

Operator

Our next question is from the line of Tyler Van Buren with Piper Jaffray.

Tyler Martin Van Buren - *Piper Jaffray Companies, Research Division - Principal & Senior Biotech Analyst*

Good to see all the progress over the course of the quarter. I had a question with respect to REACH3 in chronic GVHD that we'll by the end of the year. Much like you did for GRAVITAS-301 where you spoke about the parameters for overall response rate in non-relapse mortality.

Could you speak about the powering assumptions or what you need to achieve for success in REACH3 and your comfort with what we will see on best available therapy and what you would expect to show?

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

Sure. It's Steven. So we haven't given out the statistical analysis plan powering assumptions for REACH2 and 3 like we have for GRAVITAS-301. But I can talk to the meat of your question. Remember, both REACH2 and REACH3 are randomized against best available therapy. It's not wide-open. There is a specific list for each trial that's available on the clinical trial.gov listing. For REACH3, best available therapy and chronic includes therapies like extracorporeal photopheresis, low-dose methotrexate, mycophenolate, mTOR inhibitors and a few others including BTK inhibitors. So you are correct. I mean, the study has to beat those best available therapies.

We know from, again, our proof-of-concept data of ruxolitinib in this setting that we get higher response rate, that's what's been published to date with best available therapies. All those therapies are mentioned while not approved have had Phase II studies done and showing 30% to 50% response rate. But in totality, we'll have to beat the response and the durability for the response. But we haven't shared the powering assumptions publicly yet. Thanks.

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Tyler Martin Van Buren - *Piper Jaffray Companies, Research Division - Principal & Senior Biotech Analyst*

Okay. And just as a follow-up on REACH2. Is there any kind of -- I guess, what incremental data in that study do you think is most important to continue to facilitate uptake of Jakafi in that setting?

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

I'll talk from a clinical perspective and then if Barry wants to add anything afterwards. Again, it's different from REACH 1. REACH1 was a single-arm study. You've seen the data, and as Hervé said, we've got a full for approval from the FDA on that data set. So it's actually nothing more acquired in the U.S. from a regulatory point of view for REACH1. But obviously this is an important data set. It would be randomized against best available therapy. We'll get a sense of what the response rate is in that randomized setting with Novartis. They'll be using that globally for a file in steroid-refractory acute .And we'll get a sense of the safety versus best available therapy. But I don't expect to see a different data set in terms of response or durability of response that we've seen from REACH1 and we actually don't need it from a regulatory point of view. So Barry, do you want to add anything?

Barry P. Flannelly - *Incyte Corporation - Executive VP & General Manager of U.S.*

Yes. No obviously, from what Steven said, it's another solid data set that's for those people that might still have some hesitation, BMT healthcare professionals that might have some hesitation about introducing a drug like Jakafi, it'll just give them more confidence that in fact, this is an important drug to be used in the treatment of this devastating disease.

Operator

Our next question comes from Joshua Schimmer with Evercore.

Joshua Elliott Schimmer - *Evercore ISI Institutional Equities, Research Division - Senior MD & Equity Analyst*

Two quick questions. First, can you quantify how much of that Jakafi quarter-over-quarter growth came from MF versus PV versus GVHD versus improvement in gross to net? And then on that topical franchise, I get asked a lot whether topical drugs can be premium priced. If so, what kind of price band are you thinking that would account for both the vitiligo indication, which is less common and for an atopic dermatitis indication that might be more common?

Barry P. Flannelly - *Incyte Corporation - Executive VP & General Manager of U.S.*

Sure. So Josh, thanks for the question. So for the quarter, so MF continues to be, if there is about 14,000 patients at any given quarter, MF accounts for about 7,000 patients, PV accounts for about 5,000 patients and others is about 2,000 patients in any given quarter. So the growth -- so new patients in total, patients for MF grew quarter-over-quarter. For PV, it grew quarter-over-quarter. For other, it grew quarter-over-quarter, and we can't always break that out for GVHD. How much was accounted for in gross to net was 4% quarter-over-quarter. So as you know, the gross to net in the first quarter has the biggest impact and then it gets better in the second quarter. As far as premium price, I'll turn it over to Hervé and see if he has some comments.

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

The situation is as following, that we have a Phase III ongoing -- 2 Phase III ongoing in atopic derm with 2 different concentration being compared to a placebo. So vehicle versus 2 different concentrations. So that would be read in 2020, somewhere next year. And we are initiating the vitiligo Phase III study.

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So your comment -- your question is really about the pricing -- is the pricing identical between 2 indications, where for one of them, vitiligo we have a first-in-class disease modifying effect and another atopic dermatitis, where there is a fair amount of competition. I think it's important to remember that the duration of treatment are very, very different between the 2 indications. So you heard from Steven that the vitiligo is a 24-week data that has been published in 1 aspect, but the 52 weeks if a trend continues, which showed that the duration of treatment should go beyond 24 weeks, where in fact, the treatment in atopic dermatitis is in many cases, just a few weeks per year. If you look at it, about 52 weeks period.

So the entire pricing question is not a result yet. We need to have more data points to be able to make the right decision between the 2 indications and the different concentrations. And frankly, it will be something that will be done probably during the -- when we see the data in atopic term.

Can we have a premium price on the topical formulation? It's an excellent question. I frankly believe, looking at the vitiligo data that is accumulating, that there is a case to be made about economic value of this topical ruxolitinib formation because it is frankly, giving a level of efficacy that is better than what we can see from the data we have, what we can see with alternative treatment that are in fact, fairly expensive. So there is a value case that could be made around the vitiligo indication.

Operator

Our next question is coming from the line of Stephen Willey with Stifel.

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

Just a quick question on Jakafi guidance and then one for Steven. It looks like the high-end of the new range implies, I think, less than 4% sequential growth going forward. Just want to make sure that there is nothing implied in there from a discounting or headwind perspective.

Barry P. Flannelly - *Incyte Corporation - Executive VP & General Manager of U.S.*

Sure, it's Barry. Thanks, Stephen. So no there is no discounting. We think that the low end of the guidance is 16% growth year-over-year and net sales high-end of the guidance is 19% growth year-over-year. We're confident by lowering the lower end of our guidance that we'll come in at the upper end of our guidance.

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

Got it. And then just maybe just quickly for Steven. Is it your expectation that the competitive landscape of the GFR including pemigatinib are going to have shared mechanisms of acquired resistance?

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

Yes, it's a good question. There is, obviously the erdafitnib approved in bladder cancer, which should be the first in cholangio, but there are other inhibitors out there. They all have slightly different profiles in terms of the specificity and whether they are more promiscuous for other receptors. And because of that, the resistant profile that may ultimately emerge may be different for each of them. It's just too early to know. I mean, we highly encourage the collection of biopsy and sequencing of patients at progression. It's just not that easy to do. And if you witness historically other diseases, I mean take chronic myeloid leukemia with the introduction of tyrosine kinase inhibitors. There, you've got the entity of T315I mutations forming, which is a new disease for which a drug like ponatinib works, right? So you'll what develops. We just don't know at the moment what the resistant mutation profile will look like for our drug versus the others. I suspect they may be slight differences because each of the agents have slightly different receptors upfront. Can't give you more at the moment.

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Operator

Our next question is from Peter Lawson from SunTrust Robinson Humphrey.

Peter Richard Lawson - *SunTrust Robinson Humphrey, Inc., Research Division - Director*

Just on pemigatinib, how should be think about the durability we would need to see in the pan tumor setting? Should we think about that as kind of individual case-by-cases? Or can we kind of think about it as a collective durability?

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

(technical difficulty)

Sorry, we just -- yes, Steven.

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

Sorry, Peter we just had a microphone issue for a second. So just in cholangiocarcinoma first, and I'll talk about the pan tumor thing. Remember, it's a second line study. The standard of care, currently, is chemotherapy with 10% to 15% response rate and very short progression-free survival of a few months. So in that setting, versus that, we would have to beat the response rate and then the progression-free survival data. Pan tumor-wise as I said, if you look at different entities, endometrial carcinoma, glioblastoma, you're going to have different progression-free survival durability that you need to see. And each one will be a case-by-case to get to the point you made, it's just hard to comment now.

Peter Richard Lawson - *SunTrust Robinson Humphrey, Inc., Research Division - Director*

And just a follow-up on the PI3-kinase. Dose changes and intermittent scheduling, do you think that kind of hinders the potential uptake in what could be a crowded marketplace in follicular and MZL?

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

I think it's a good question. We did toy with purely scientifically data-driven with weekly dosing, which may or may not have had a compliance issue. But as it turns out, it's looking like and will have to back this up with data in the future that it will still be daily dosing, it will just be a different dose. So there'll be a 20-milligram induction for 8 weeks followed by a lower daily dose. So there's not going to be a scheduling issue that I think will hinder uptake. I think what we're doing with the high -- higher dose induction is the right thing because most -- just about all the responses take place in the first 8 to 9 weeks. So you maximize your response and then you scale back just to still hold the tumor in check but manage the tolerability. I don't see an uptake issue with that.

Operator

The next question is from the line of Evan Seigerman with Crédit Suisse.

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

Congrats on the progress. One on pemigatinib. So can you just remind us of the opportunity in cholangiocarcinoma. And more broadly, how would you compete against J&J in the potential bladder cancer opportunity? And then one for Christiana. You had mentioned that you have some ability to potentially do some BD. Can you remind us of your estimated capacity and how this could potentially fit into the strategic priorities of Incyte?

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

It's Steven, I'll go first. So if you look at the cholangio opportunity, intrahepatic cholangiocarcinoma, about 13% to 20% of patients have FGFR2 translocations. So we estimate there, about 2,000 to 3,000 addressable intrahepatic cholangiocarcinoma patients in major markets globally with that particular mutation then we should be first there.

You're right that J&J erdafitnib has the indication in bladder first. There's probably about 15,000 patients globally with the FGFR3 mutation there. But just a few issues. So we'll see, if you look at the label in terms of -- because obviously they hit efficacy bar they wanted, but in tolerability, they have, as I said upfront, a different profile in terms of hitting different receptors and they did have an ocular tolerability issue of around 20%, 25%. We'll see if we're able to compete there in a better way and that will achieve the efficacy desired but have a better tolerability profile. So that's one way of differentiating as long as you have the efficacy.

And then in terms of life cycle management, we have different approaches going forward on what is needed from a clinical study point of view. And you'll see, we'll be, and it's already up on clinicaltrials.gov, during the first line study in bladder cancer and they are not. So that's one other way, should that work, where we will differentiate and potentially get a jump on the market there.

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

Evan, it's Christiana. I'll take the question on BD. First of all, as we have previously discussed our focus is on diversification and long term growth. So when you look at our internal pipeline, late-stage pipeline shaping up very nicely to help us achieve that objective.

At the same time, we have $1.7 billion as of the end of June of cash on our balance sheet, and that gives us the ability to opportunistically look at BD to supplement our internal activities. So when we look at BD, it would be in line with the same corporate objective of adding to diversification on the top line and driving long-term growth and focus more on the midterm type of timeline.

Operator

The next question is coming from the line of Jay Olson with Oppenheimer.

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

Congrats on the quarter. I just wanted to follow up on pemigatinib. I think you said you would submit NDA filing later this year. I was wondering if you were going to present an updated cut of the Phase II cholangiocarcinoma data later in the year? And also, could you comment on which sales force you would use to promote pemigatinib? Would that be your Jakafi sales force? And can you just talk about the overlap there?

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

Jay, it's Steven. You're correct. The pemigatinib files -- we have the data, we have it in hand, we presently preparing the submission. It will go in the second half of this year in intrahepatic cholangiocarcinoma that have the FGFR2 mutation. With that, although we can't give you the exact meeting but there will be an oral presentation at the data and a meeting in the second half of this year that will be -- that'll have the content of what's in the NDA with that as well.

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Barry P. Flannelly - *Incyte Corporation - Executive VP & General Manager of U.S.*

Jay, it's Barry. So we're still working on exactly how we're going to roll out the sales force next year for pemigatinib, but it will add a few people to our 120 sales reps that we currently have, and we'll keep basically the same number of FTEs on MF, PV and GVHD and have a certain number of FTEs that are dedicated to promotion of pemigatinib.

You know that in fact, the hematologist and oncologists throughout the United States basically treat everything at least in the community setting, so we're really calling our managers in the same offices today as we will with pemigatinib.

Operator

We have one final question coming from the line of Andrew Berens with SVB Leerink.

Andrew Scott Berens - *SVB Leerink LLC, Research Division - MD of Targeted Oncology & Senior Research Analyst*

Just have a question -- or a couple of questions on the GVHD franchise and then maybe I can sneak one in on the derm franchise too. I was wondering with Jakafi approval in GVHD, has there been any changes to the formulary treatment of Jakafi? And then also I was just wondering in fact, itacitinib is approved in the frontline setting, how does that change the opportunity for Jakafi in the refractory setting?

Barry P. Flannelly - *Incyte Corporation - Executive VP & General Manager of U.S.*

This is Barry, Andrew. So in fact, does it change anything for acceptance and access for patients on Jakafi with GVHD? No. I mean, we've always had great access from the payers for Jakafi for PV and MF. And as far as we can tell in the launch, we really have had no restrictions whatsoever. Many of the insurers actually have no utilization management for Jakafi in GVHD, whether they'll write them in the future or not we don't know. But generally speaking, patients with getting bone marrow transplants have access to all drugs.

As far as itacitinib goes, we think that itacitinib is going to be used in first-line setting. We think it's going to help many patients in that setting for both acute and chronic GVHD. We do think that both of the drugs can live together. But obviously, itacitinib we'll have worldwide and that would be a very important to us to launch in countries around the world. So will patients get ruxolitinib after they get itacitinib? It's certainly possible.

Andrew Scott Berens - *SVB Leerink LLC, Research Division - MD of Targeted Oncology & Senior Research Analyst*

Okay. And then maybe just the question on the derm franchises for Herve. Just wondering how you're thinking about developing that opportunity outside the U.S.?

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

What we said in the past is that the case is getting more and more convincing on the U.S. side to obviously for us to book the sales, to diversify our portfolio, to do promotion, and a lot of the commercial work in the U.S. ourself as the size of the team required is fairly modest. The question is still very much open for the rest of the world. I think you can imagine Asia is a part of the world where we would probably benefit from having a partner. And the question about Europe is really 50-50 at this point. We are looking at different options of collaboration that could help us, and we have time before we make that decision because we will get the atopic derm data, let's say, midyear and the filing in the second half of the year. So from there to Europe and approvals, that will be another 12 months at least. So we are basically 2 years away from the -- at least from the launch in Europe, probably more. And we want to take that time to have a full understanding of the financial and strategic implications of that decision for Europe.

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Operator

We have reached the end of our question-and-answers session. So I'd like to pass the floor back over to Hervé for any additional concluding comments.

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

So thank you all for your time today and for your questions. So we look forward to seeing you at the upcoming investor and medical conferences. But for now, we thank you, again, for your participation in the call today. Thank you, and goodbye.

Operator

Ladies and gentlemen, this does conclude today's conference. Again, we thank you for your participation and you may disconnect your lines at this time.

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