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Incyte Corporation's (INCY) CEO Hervé Hoppenot on Q3 2019 Results - Earnings Call Transcript

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Q3: 10-29-19 Earnings Summary

Press Release *10-Q* *Slides*

EPS of $0.82 beats by $0.18 | Revenue of $551.58M (22.66% Y/Y) beats by $17.28M

Earning Call Audio

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Incyte Corporation's (NASDAQ:INCY) Q3 2019 Results Earnings Conference Call October 29, 2019 8:00 AM ET

Company Participants

Michael Booth - Divisional Vice President of Investor Relations and Corporate Social Responsibility

Hervé Hoppenot - Chairman, President, and Chief Executive Officer

Barry Flannelly - Executive Vice President, General Manager, US

Steven Stein - Executive Vice President, Chief Medical Officer

Christiana Stamoulis - Executive Vice President and Chief Financial Officer

Dashyant Dhanak - Executive Vice President and Chief Scientific Officer

Conference Call Participants

Salveen Richter - Goldman Sachs

Marc Frahm - Cowen and Company

Tyler Van Buren - Piper Jaffray

Brian Abrahams - RBC Capital Markets

Michael Schmidt - Guggenheim Partners

Cory Kasimov - JP Morgan

Evan Seigerman - Credit Suisse

Jay Olson - Oppenheimer

Reni Benjamin - JMP Securities

Alethia Young - Cantor Fitzgerald

Vikram Purohit - Morgan Stanley

George Farmer - BMO Capital Markets

Mara Goldstein - Mizuho Securities

Christopher Marai - Nomura Instinet

Operator

Greetings, and welcome to the Incyte Corp.'s Third Quarter 2019 Financial Results Conference Call. At this time, all participants are in a listen-only mode. A question-and-answer session will follow the formal presentation. [Operator Instructions] As a reminder, this conference is being recorded.

I would now like to turn the conference over to your host, Mike Booth, Head of Investor Relations. Please go ahead.

Michael Booth

Thank you, Brook. Good morning and welcome to Incyte's third quarter 2019 earnings conference call and webcast. The slides used today are available for download on the Investors 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.

During the question-and-answer session, I ask that you limit yourself to one question and, if needed, one follow-up as this will enable as many of you to ask questions as time allows.

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 June 30, 2019, and from time to time in our other SEC documents.

We'll now begin the call with Hervé.

Hervé Hoppenot

Thank you, Mike. And good morning, everyone. Incyte continues to execute well across all aspects of the business and we have delivered multiple positive updates from our late-stage portfolio in recent weeks and our product and royalty revenues continue to grow at a remarkable rate for a company of our size.

Product and royalty revenues in the third quarter grew at 24% over the same period last year, totaling over $530 million and including $433 million in Jakafi sales which increased 25% in Q3.

Sales of in Iclusig in Europe as well as royalties from Jakavi and Olumiant also increased year-over-year.

At the beginning of 2019, we set out an ambitious list of R&D goal for the year and I'm pleased to report today that we have already achieved a majority of them.

The NDA for pemigatinib, seeking approval as a treatment for patients with FGFR2-driven cholangiocarcinoma, has been submitted to the FDA and the positive updated data that supported the submission were presented in September at ESMO.

We recently reported that REACH2, the Phase III trial evaluating ruxolitinib in steroid-refractory acute GVHD, met its primary endpoint of superiority over best available therapy.

These data further reinforce the efficacy of Jakafi as the standard of care treatment option for these patients following FDA approval in this indication in May.

We were also pleased to provide 52-week follow-up data from our randomized Phase II trial of ruxolitinib cream in vitiligo at EAGV. These data show that patients treated with higher concentration of rux cream experienced continued improvement in their disease with additional time on therapy. And we have already launched a global Phase III program for rux cream in vitiligo with results due in 2021.

We still have some key items we expect to deliver before the end of the year. But for now, I'll turn the call over to Barry for an update on Jakafi.

Barry Flannelly

Thank you, Hervé. And good morning, everyone. Net product revenues for Jakafi were very strong in the quarter, totaling $433 million. This is an increase of 25% when compared to the same period last year.

Growth was primarily driven by patient demand, which grew 18% year-over-year and there were no appreciable effects of inventory in the quarter.

Because of the strong demand for Jakafi today, we are very pleased to be increasing both the bottom and top end of full-year 2019 guidance for net sales of Jakafi to a new range of $1.65 billion to $1.68 billion.

We're seeing good demand for Jakafi in all three approved indications. More than 50% of eligible myelofibrosis patients in the US are currently on Jakafi. And total patients on therapy increased approximately 5% year-over-year.

We continue to be encouraged by the growth we see in this indication, especially in its eighth year since approval.

Patient growth in polycythemia vera continues to be higher than myelofibrosis. And within the eligible population, Jakafi has reached more than 20% penetration.

We saw an opportunity to increase disease awareness in both PD, patient and physician community; and in an effort to augment patient voice, we recently launched a pilot television and social media disease awareness campaign. This pilot was conducted in several key target markets where it has been very well received and we have now expanded the education campaign nationwide.

This is the first full quarter of sales since approval in steroid refractory acute GVHD. And while early, the launch is currently outpacing our internal expectations. Importantly, we're seeing comprehensive access in both the inpatient and outpatient treatment settings and we continue to see strong uptake and broad utilization across bone marrow transplant centers.

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

Steven Stein

Thanks, Barry. And good morning, everyone. Continuing with graft-versus-host disease, we were pleased to report the positive outcome for REACH2, the randomized trial of ruxolitinib versus best available therapy in steroid-refractory acute graft-versus-host disease.

We plan to share these data with the FDA for inclusion in the Jakafi label. And we look forward to sharing the detailed data with you at an upcoming scientific meeting.

REACH3, the randomized trial evaluating ruxolitinib in patients with steroid-refractory chronic graft-versus-host disease is ongoing and has almost completed recruitment.

A recent interim efficacy and safety analysis conducted by an independent data monitoring committee recommended that REACH3 should continue without modification with results expected in 2020.

Moving on to pemigatinib for cholangiocarcinoma, slide 11 shows the data that were presented at ESMO and which formed the basis of our recent New Drug Application.

As you can see, in cohort A, the overall response rate was 36%. Median progression-free survival was 6.9 months and median overall survival was 21.1 months.

Importantly, the vast majority of patients have some degree of tumor size reduction as evidenced by the 82% disease control rate and as illustrated in the waterfall plot on slide 11.

We believe that pemigatinib offers a meaningful improvement over the current standard of care in the second line, which typically results in single-digit response rates, median progression-free survival of 3 months and an overall survival of approximately 6 months.

The most common adverse event of all grades was hyperphosphatemia, which is an on target effect of FGFR inhibition that can be managed with a low phosphate diet, phosphate binders and diuretics. Hypophosphatemia occurred in 23% of patients which was likely due to the treatment for hyperphosphatemia. Serous retinal detachment was seen in 4% of patients, which is mostly grade 1 or 2.

If you recall, the only potential curative therapy for cholangiocarcinoma is surgery, but approximately 70% of patients are diagnosed with unresectable disease. So, the need for new therapeutic options for these patients is clear.

My third slide summarizes updated data from the randomized Phase II trial of ruxolitinib cream in vitiligo, which were presented a few weeks ago at EADV. These data showed continued improvement and re-pigmentation with additional time on therapy as objectively measured by VASI scores.

For example, in patients dosed with 1.5% b.i.d. and followed for 52 weeks, the facial VASI75 was achieved in 52% of patients, up from 30% of patients at 24 weeks. And the facial VASI90 was achieved in 33% of patients, up from 12% at 24 weeks.

The global Phase III program of ruxolitinib cream in patients with vitiligo is ready and rolling, with the facial VASI75 at 24 weeks being the primary endpoint and we expect the result to be available in 2021.

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

Christiana Stamoulis

Thanks, Steven. And good morning, everyone. The financial update this morning will include GAAP and non-GAAP numbers. For a full reconciliation of GAAP to non-GAAP, please refer to slides 19 and 20 in the backup section of the deck and to the press release we issued this morning.

Our third quarter results reflect continued strong growth with total product and royalty revenues of $534 million, representing an increase of 24% over the third quarter of 2018. This is comprised of $433 million in Jakafi and $21 million in Iclusig net product revenues, $58 million in Jakafi royalties from Novartis and $22 million in Olumiant royalties from Lilly. We also recognized $18 million in contracts revenues under our collaboration agreement with Zai Lab, resulting in total revenues for the quarter of $552 million.

Our total costs and expenses for the quarter on a non-GAAP basis of $365 million decreased by 1% from the prior-year quarter.

Ongoing R&D expenses for the quarter was $251 million on a non-GAAP basis, unchanged from the prior-year period, reflecting our decision to reallocate capital from the co-funding of baricitinib and the development of epacadostat to our other late stage development programs.

SG&A expenses for the quarter was $90 million on a non-GAAP basis, representing a 6% increase over the prior-year quarter.

Moving to our guidance for 2019, given the strong performance of Jakafi in the first nine months of the year, we are increasing Jakafi full-year guidance to a range of $1.65 billion to $1.68 billion.

Our guidance for both current R&D and SG&A remains the same as we continue to invest in our commercial operations and our clinical development portfolio and we expect certain of these expenses to be more backend loaded into Q4 2019.

I will now turn the call back to Hervé.

Hervé Hoppenot

Thank you, Christiana. So, our last slide reminds you of our progress to date in 2019 as the well as the remaining key news flow events we expect during the year.

These expectations includes NDA submission by Novartis for capmatinib in patients with MET exon-14 skipping mutation in non-small cell lung cancer.

Capmatinib is another development candidate discovered in Incyte laboratories and has the potential to be an important product in lung cancer. It was really positioned in the Novartis third quarter material as a key approval for them in 2020.

And for Incyte, capmatinib also has the potential to be a meaningful contributor to our top line with over $500 million in potential milestone and 12% to 14% royalties on global net sales.

We're also looking forward to having the result of the GRAVITAS 301 trial of itacitinib in first-line acute GVHD in-house at the end of the year. Itacitinib has the potential to be another key contributor to near-term revenue growth.

With this strong execution across our late-stage development programs, we're making significant progress toward our strategic goals of adding diversification to the top line and further accelerating revenue growth.

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

Question-and-Answer Session

Operator

Thank you. [Operator Instructions]. The first question today comes from Salveen Richter of Goldman Sachs. Please go ahead.

Salveen Richter

Thanks for taking my question. So, with regard to the early uptake and feedback for Jakafi in GVHD, what does that suggest for the trajectory here? And have there been any gating factors?

And then, a follow-up for Hervé, given the progress of your pipelines in both oncology and IAI, how are you thinking about business development opportunities?

Steven Stein

Sure, Salveen. So, GVHD, as I said, the uptake has been very good since the beginning. We think the opportunity for itacitinib is ultimately where the opportunity is live. Jakafi is giving patients benefit right now. We believe it will give benefit in acute GVHD as we are now and then in the future for chronic GVHD and we await the results of GRAVITAS-301 for itacitinib and a potential worldwide for that drug.

Hervé Hoppenot

So, Salveen, on the progress of the late-stage portfolio, obviously, you know our strategic goal of diversification and growth. That's really what we are aiming at. And, obviously, a lot of it is starting to take place with pemigatinib. We spoke a little bit about capmatinib, which is not always the most known of our pipeline products that Novartis – has been licensed to Novartis. So, we are on a good track to succeed on getting these products to market over the next few years.

At the same time, we're, obviously, looking at BD opportunities that would fit with our portfolio. We're mostly looking at oncology, hematology type of assets. And it's a continuous process where we're reviewing opportunities and we're expecting – we hope to be able to gain some additional products to fuel the growth of the top line in the next few years.

Salveen Richter

Thank you.

Operator

The next question is from Marc Frahm of Cowen and Company. Please go ahead.

Marc Frahm

Hey, thanks for taking my questions. Maybe for Barry. In the prepared remarks, you mentioned that the awareness campaign PV, you're having some success. Can you maybe define that a little bit better? Are you already seeing an uptick in sales within those regions or is it more qualitative measures? And then, what type of budget are we talking about, now that you're expanding it nationally and trying to broaden that success?

Barry Flannelly

Well, the way we measure uptake, it's very early. As we said, we did it in five key markets across the country first. And what we saw there was really the uptake in social media sites. For example, TakeActionPV is what we direct patients to go to or healthcare professionals to go to get more information. There is education materials there, materials they can download to track their symptoms. And we saw spikes in those first five key regions.

Now, as we expanded across the nation, which only started October 1, so we don't really have all that much data yet, but it certainly has grown dramatically on those sites that we're sending patients to.

The budget nationwide is relatively small. This is a 30-second commercial. We're placing it at time periods that we think patients will see it, but at the same time don't cost a fortune. So, it's not going to the Super Bowl, but it is, in fact, we think being very effective as an educational tool for patients and healthcare professionals.

Marc Frahm

Very good. And then, maybe a sort of follow-up on kind of market dynamics for Jakafi. Maybe some comments on what the initial impacts of fedratinib's launch that you may or may not have seen yet.

Barry Flannelly

I think it's early. We haven't really seen much of an impact yet. We know that Celgene is really positioning it as a second line agent just by their pricing strategy that they came out with and then, very particularly, their marketing materials that we have seen are positioning it as a second line drug. Maybe you also are aware that the only two clinical trials that they have ongoing now, a single arm trial and a Phase III trial compared to best available therapy, are both after Jakafi. So, clearly, they're positioning it for a second line drug and we haven't seen the impact yet on Jakafi. And we're fully confident because we have long-term follow-up data, eight years of data, more than 50,000 patients treated in the United States with the drug. So, the safety profile is there. And, of course, an overall survival advantage that I don't think that fedratinib will ever be able to achieve, particularly with their JAKARTA study because it was never followed up on.

Marc Frahm

Right. Great. Thank you.

Operator

The next question is from Tyler Van Buren of Piper Jaffray. Please go ahead.

Tyler Van Buren

Hey, guys. Good morning. Great to see the sold results on the quarter. Just had a couple follow-up questions to Marc's line of questionings. As you look at Jakafi in MF and PV, can you give us an update on duration of treatment for both of those indications? Also, as we think about long-term in terms of PV, could we see ultimate penetration of the patient population to reach kind of that 50% level that we're seeing with MF? And perhaps, just some updated thoughts on the long-term guidance that you guys gave for last year? I believe it was $2.5 billion to $3 billion by 2027. If we see the continued growth in PV and GVHD, that seems exceedingly achievable. So, I'd be interested to hear your updated thoughts.

Barry Flannelly

Sure, Tyler. This is Barry. We're still confident of the $2.5 billion to $3 billion long-term guidance. So, that's clear.

In terms of persistence, its' what we've said all along, to be honest with you. I think we have to turn to the clinical trials for persistence. When you look at PV, when you look at the response data, you saw 83% of patients were still on therapy at two years. And in the COMFORT trial, you saw that 50% of the patients were still on it three years. So, that's still our touchstone for persistence.

In PV, we continue to grow year-over-year this year. We grew total patients in PV 15% year-over-year and that continues to exceed the continued growth in patients in MF. So, we see that, in PV, we'll catch-up to the MF patients sooner or later and we certainly are confident that the clinical profile of Jakafi and polycythemia vera patients could hit the 50% mark at some point.

Tyler Van Buren

Thanks for taking the questions.

Operator

The next question is from Brian Abrahams of RBC. Please go ahead.

Brian Abrahams

Hi there. Thanks so much for taking my questions and congratulations on the strong quarter. On GVHD, can you provide any perspectives on the REACH3 stopping rule at the interim and maybe frame expectations now that that readout has been pushed out to next year?

And related to that, I'm curious your latest views on the potential impact of JAK1 versus pan-JAK inhibition on the potential for efficacy in GVHD and the bar for the itacitinib read-out now that you guys have more clinical and commercial experience in this space. Thanks.

Steven Stein

Yeah. Hi, it's Steven. So, in terms of REACH3, we don't normally guide to interim results, but this time working with our partner, Novartis, we obviously did expect to potentially have some results by the end of 2019.

As you can see, the study at interim made it through the interim analysis by the IDMC and they recommend it to continue the study to completion without modification.

The recruitment itself is about to finish. We literally have only a few patients left. There is always a higher – by the nature of an interim, there is always a higher bar to achieve at interim analysis to close the study because you have to be very careful that you do it appropriately. So, we're not at all worried. We remain extremely confident in the data set.

The primary endpoint in the chronic graft-versus-host disease study is an overall response rate at month 6, but there are numerous secondary endpoints that are important here including failure-free survival, symptom improvement, overall survival and others. So, sometime in 2020 we'll get those results. We remain extremely confident in that.

And as I – just to reiterate, it was a little unusual for us to guide to an interim, but again working with a partner, that's what we did.

In terms of reading through to itacitinib in a more JAK1 agent relatively more – hits JAK1 more than the other JAKs, we saw our proof-of-concept data for itacitinib. It was strong across the spectrum of disease. But it was even stronger in steroid-naïve acute graft-versus-host disease, which is why – which led to GRAVITAS-301.

In addition, patients with steroid-naïve acute graft-versus-host-disease are immediately post bone marrow transplant or allogeneic transplant tend to be sicker, tend to have cytopenia, particularly low white cell counts and low platelets. So, to have a relative JAK2 sparing agent that doesn't cause as much cytopenia as the others is potentially beneficial from a therapeutic ratio point of view. But in terms of the biology of the disease, it ameliorates the biology appropriately and again we remain confident in that.

Brian Abrahams

That's really helpful. Thanks, Steven.

Operator

The next question is from Michael Schmidt of Guggenheim. Please go ahead.

Michael Schmidt

Hey, thanks for taking my questions. I just had a follow-up on GVHD as well. I think you said the launch is outpacing your internal expectations. Just wondering if you could help us with a little bit more information around what treatment share do you have at this point and maybe what percentage of top line sales was contributed by GVHD?

Barry Flannelly

Sure, Michael. Well, treatment share, I'm not exactly sure. I think that we're the most used agents maybe already in the second line setting, but I can't be sure of that. Trying to get information on GVHD is a little bit harder than MF and PV since it's all hospital used. So, that's it.

So, I think, last year, I said something like – with spontaneous use and then with the approval, we'd hit somewhere around $80 million for this year. I think we're ahead of that, but I can't give you an exact – the number for that. But we're very pleased with the uptake in GVHD. And we think with now the REACH2 data, it will even be stronger in the future.

Michael Schmidt

Great, thanks. And then, maybe a bigger picture question for Hervé. So, regarding the earlier stage pipeline, I guess you're pursuing both new immuno therapies as well as targeted oncology drugs. And, obviously, there's been some very interesting data generated in the last couple of years, specifically with TKIs going after driving mutations, including pemigatinib, obviously, but there are other targets as well.

On the other hand, I think many would agree that the success rate for new immunooncology drugs has been rather mixed, I guess in that context. I was just wondering how do you see your bigger picture patent strategy evolve longer-term going after both areas.

Hervé Hoppenot

Thanks for the question. Because as you see, it's very important and it's a field where the effect of the decisions we made over the past two years are always seen with a delay. So, we were – obviously, with the very heavy share of the research effort in immunooncology and immunity in general, which led to a number of other project beyond oncology, and what has been happening over the past two years is a rebalance where we have now more targeted therapies or targeted – targeting oncogenic mutation type of projects that are the larger part of our portfolio. At the same time, we're keeping immuno projects today. So, I would say it's a balance and it's probably in the 60-40 or 40-60 kind of ratio where maybe, in the past, it was more heavy on the immune aspect. And, Dash, if you want to speak about it.

Dashyant Dhanak

Yes. Thanks for the question, Michael. Just to sort of echo what Hervé was saying, I think you're right, at some level, the promise in immunooncology has been tampered by clinical data. However, we still think there's plenty of opportunities out there in both the targeted and the immunooncology space. You'll remember or you'll know from our sort of access to modalities that we have both for molecule and biologics capability. So, having both of those options open to us does keep the entire area open. And we have a number of programs that we think will enter the clinic in the coming months that target both going after a very sort of traditional targeted therapeutic approach, as well as an immuno approach and then combinations thereof.

Michael Schmidt

Thank you.

Operator

The next question is from Cory Kasimov of JP Morgan. Please go ahead.

Cory Kasimov

Hey, good morning, guys. Thanks for taking my questions. First one for you is on expenses. So, SG&A and R&D both came in pretty meaningfully below expectations for the quarter, but guidance was unchanged, which would imply a decent step up in 4Q just

to get to the low end of your range. So, is that something we should be anticipating? And maybe to the extent you're willing to qualitatively comment on trends into 2020, do you have any kind of preliminary big picture expense thoughts going forward? And I have one follow up.

Christiana Stamoulis

Hi, Cory. It's Christiana. Thank you for your question. First of all, big picture in terms R&D and SG&A costs, we continue to invest, aggressively invest in our clinic and development portfolio as well as on our commercial operations. What you're seeing with R&D this year and the expenses coming on the lower side is that we were able to reallocate expenses that were previously for epacadostat and baricitinib to our other stage development programs. So, that allowed us to be able to push forward the other development programs without seeing an increase in R&D.

Going forward, however, as we have discussed in the past, we are looking to invest in R&D based on the quality and the progress of the program. So, based on data and merits of the programs, if those programs progress through later-stage of development, you would expect that to drive R&D expenses.

In terms of Q4, we reiterated the guidance that we provided on both R&D and SG&A because there is a timing factor for some of the expenses on both lines that we expect to be more back-end loaded into Q4 of 2019 and, therefore, we continue to be comfortable with the initial guidance that we have provided.

Cory Kasimov

Okay. That's helpful. And then, my follow-up is a quick one for Steven. How much patient follow-up will you wait for in that FIGHT-201 pemi bladder study before potentially top lining that data?

Steven Stein

Hi, Cory. It's Steven. So, typically, across the board, ballpark follow-up in these sort of studies required by regulatory agencies is around 12 months, but that's for your last responder. So, what I'm saying is you complete recruitment if that very last patient to

respond to you typically require about 12 months. So, if you think, we've just recently completed recruitment on the study, we're looking that data sometime mid-2020 or beyond to get a complete view of that picture across the board on our bladder data.

Cory Kasimov

Okay, perfect. Thanks for taking the questions.

Operator

The next question is from Evan Seigerman of Credit Suisse. Please go ahead.

Evan Seigerman

Hi, all. Thanks for taking my question and congrats on the progress. So, Christiana, one for you. How would you characterize your capacity to transact? I know Hervé mentioned some high level thoughts on BD and then I have a follow-up on that. Just, basically, what are some characteristics of assets that you would consider bringing in house. So, one for, Christiana, and one for you, Hervé.

Christiana Stamoulis

So, in terms of the capacity, as we have discussed in the past, we have a strong balance sheet. We currently have $2 billion of cash on our balance sheet. That gives us the opportunity to consider bringing in external assets to our internal portfolio.

In terms of the nature of the assets, we are looking at programs that could contribute to revenue diversification and growth in the mid-term timeframe. So, continuing to add to growth as we are getting closer to the Jakafi potential patent expiry period. So, bringing additional growth drivers then, obviously, makes a lot of sense for us.

So, do you want to…?

Hervé Hoppenot

Yeah. The type of assets is very clear. The first is, obviously, hematology oncology, anything that would be good science, that would be innovative, that would provide a benefit that is unique in the field of cancer treatment could fit with our portfolio where we

have a very strong hematology franchise both in Europe and the US and where we have this emerging solid tumor franchise also in the US and a little bit later in Europe. So, that makes sense.

In terms of timing, we're looking at the window between 25 and 30 and it's very obvious why. Because that's where we will need more diversification. So, some of the aspect is to complement our MF and PV franchises where there are new mechanisms that can be complementary to what we have in our portfolio and where obviously our leadership in MF and PV could be reinforced by external assets if any benefit could be shown from this.

And then, we have a little bit of a longer view on the non-oncology aspect. As we said, we will be commercializing our rux cream in the US. We may have partnership, if needed, but we will be leading the commercialization in the US.

We will be partnering our dermatology assets outside of Europe and US and we're still looking at what the best strategy for Europe. So, there, there could be also potential BD aspect to the dermatology franchise. We're very confident in the benefit we are showing both in atopic dermatitis and, as you saw, in vitiligo. It's a fairly striking data with the long term follow-up. And we believe there is a true value in this franchise and complementing it with external assets could be an option. It's not absolutely mandatory because we believe in the US we can build the team to successfully commercialize, but there could be some complement to it.

So, it's very clear. It's hematology oncology for 25 to 30 where – that's where the contribution to the top line would be the most valuable. It's lifecycle management of MF and PV. And potentially, if we find the right assets in dermatology or somewhere in non-cancer immunology, it could be also another dimension.

Evan Seigerman

Okay. And then, I just follow up there. Are we talking $1 billion, $2 billion or really how would you give color on that in terms of what you'd pay?

Christiana Stamoulis

So the main focus is on what I would characterize as tuck-in type of assets that we can bring in, either through licensing or M&A. So, we're agnostic in terms of the structure, whatever makes sense.

Evan Seigerman

Okay. Thank you.

Operator

The next question is from Jay Olson of Oppenheimer & Co. Please go ahead.

Jay Olson

Hey, guys. Congrats on the quarter and all the progress. I had a couple of questions. Could you comment on what were the best available therapies to Jakafi in REACH2 and is there overlap between those best available therapies in REACH2 and REACH3?

And then, just to follow-up on pemigatinib. Could you provide some additional color on how the enrollment is going in FIGHT-205 and FIGHT-207 and also the bladder cancer continuous dosing cohort?

Steven Stein

Yeah. Hi. Jay, it's Steven. Thank you for your question. So, both REACH2 and REACH3 are randomized studies against best available therapy. Just to mention, REACH2, that we've just said, reported out as positive and will be presented at an upcoming medical meeting.

To our knowledge, it's the first randomized study in graft-versus-host disease that has reported out as positive. So, that's really good news, obviously, for patients and for us.

The therapies themselves are listed on clinicaltrials.gov, but just to give you a sense, there are slight differences because they are different disease entities. For REACH2, they include things like anti-thymocyte globulin, extracorporeal photopheresis, there is mesenchymal stromal cells, low-dose methotrexate, mycophenolate and even EMTO inhibitors like Everolimus can be used.

For REACH3, there's some overlap, but they also in addition – because chronic graft-versus-host disease include therapies like rituximab and imatinib as well as ibrutinib which is approved in chronic graft-versus-host disease. The complete list is available on clintrials.gov.

In enrollment, to the second part of your question on the studies you mentioned for the entirety of the pemigatinib program, obviously, includes our completed first part in cholangiocarcinoma and then the ongoing first line study there. Then the large bladder cancer program and then the tumor agnostic as well as smaller entities that we don't speak about much, but very important to patients is an 8p11 myeloproliferative neoplasm.

We don't guide to exact dates in terms of enrollment other than when we start and sometimes when we end the studies. But just to give you a sense that the agnostic study, 207, which you mentioned has started enrollment and we'll be looking at different driver mutations there. And then, we expect to complete, as I just alluded to, the second line bladder study before the end of this year and have data latter part of next year. And then, we're about to start the first line bladder study. So, that gives you a sense of the cadence of enrollment and the entirety of the program.

Jay Olson

Great. Thanks for taking the questions.

Operator

The next question is from Reni Benjamin of JMP Securities. Please go ahead.

Reni Benjamin

Hey, good morning, guys, and thanks for taking the questions. And congratulations on a great quarter. I guess, just as a follow-up regarding the REACH2 data, Steven, is there anything there that kind of increases your confidence in regards to REACH3 or are the two diseases really separate and distinct, acute versus chronic?

Steven Stein

Reni, thank you. It was great to see a randomized study against best available therapy being positive. And again, as I just said, we look forward to sharing those results to you. So, it further does increase our confidence in what we already know, say that ruxolitinib is a really good drug for steroid-refractory acute graft-versus-host disease.

Chronic does have a slightly different pathophysiology as it's more a disease of fibrosis with more skin manifestations as opposed to more apoptotic disease in acute where there's more sort of cell death in the liver and GI tract. But there's enough overlap and our proof-of-concept data was strong enough that we remain confident in chronic graft-versus-host disease.

We do think, although the pathophysiology, there's a little bit of a difference, there's a good read through and we're confident in getting that data next year.

Reni Benjamin

Got it. And then just as a follow-up, the vitiligo studies have started, can you give us any sort of a sense of – if its enrollment is on track and on schedule and have all the sites open?

Steven Stein

Yeah. So, you're correct. The vitiligo studies have started. As you saw in my formal presentation, we just presented the 52-week data at the EADV with continuing improvement, quite dramatic in patients through one year. The studies have just recently started.

But I will tell you, it's a pleasant surprise to us working in dermatology, these studies accrue really, really well. So, with sites open quickly, we have dictated dermatology centers across the globe who are good at doing clinical research, who put patients on quickly and we're up and going with gusto and very positive about it.

Reni Benjamin

Thank you for taking the questions.

Operator

[Operator Instructions]. Our next question is from Alethia Young of Cantor Fitzgerald. Please go ahead.

Alethia Young

Hey, guys. Thanks for taking my question. Congrats on the quarter. One, maybe Steve, can you talk a little bit about best supportive care for REACH3 and how it varies across the world? And do you think there's any kind of variability there that you should consider in the trial that is ongoing?

And the second question probably is more for maybe Hervé. I guess I'm just curious how you think about kind of long-term margins for the business and where we are exactly in kind of the peak cycle for Jakafi. It seems like there's still a lot of room to move and you're building in PV kind of an awareness and there's penetration that could be had, but maybe if you can frame that from a high level perspective, that would be helpful. Thanks.

Steven Stein

Hi, Alethia. It's Steven. So, you do allude to something we see in graft-versus-host disease, not only across the world, but even within the United States and even within cities themselves, there are treatment differences in patterns at bone marrow transplant centers and how people have treated this condition to date and continue to, both in terms of preparative regimens and actual regimens, which is exactly why for best available therapy we have to account for a number of therapies.

So, there's no dramatic differences across the world compared to just, as I said, even within the US itself. We always, as a matter of course, do analyses and look at differences if there are any between different parts of the world to explain response rates, et cetera. So, those analyses will be done. Typically, you do the US, Western Europe and rest of world analyses and we'll look at those. But nothing to be concerned about.

Hervé Hoppenot

Yeah. Regarding the cycle, the sort of medium to long term cycle of the business, obviously, the growth of Jakafi in the US is very key to the entire P&L of Incyte. As you can see, this quarter, Incyte is growing even faster than the previous one versus last year. And

our Q3 last year was a little bit lower maybe than it should have been. So, the ratio of the 25% growth for Jakafi US maybe slightly higher than the true trend. Although the year, I think we are more in the 20%, which is still very, very strong for sort of a seventh, eighth year of commercialization. And we see a lot of potential for continued growth of Jakafi in the US in MF. It is still volume growth. Patient volume is increasing in MF.

And in PV, as we said, there is larger potential for two reasons. It's because treatment rate is still on the low end, below 50%, and the duration of treatment for every patient studied on Jakafi is very much longer than what we have in MF. So, what we see is sort of chronicization of the disease in MF that is leading to this growth potential that is obviously higher.

We are not changing the long-term guidance very frequently, but we have made a lot of progress throughout the number that we gave a few years ago of 2.5 to 3, and that's something we are very confident in.

Regarding the P&L itself and the margin, as Christiana said, we are investing in R&D based on the quality and the required work for the assets that we have. And so, it may be fluctuating, as you have seen. When epacadostat did not work as planned, to say the least, you could see that it has a positive impact on the R&D, which is obviously the paradox of our industry, is that if you stop a project, it will improve margins. But, obviously, our goal is not to manage the margin short-term proactively, but to maximize the value to the company and the shareholders by doing the right clinical development for each of the assets that we have in our hand.

At the same time, you may have seen, from 2014 to today, is that we are in the trend of improving ratios in the P&L where the growth of the top line has been not every single quarter, but on – if you look at it on a cumulative fourth quarter in a row, that margin has been improving over time. And that's why we're where we're today, the P&L has the shape that it has to today. So, that's something we will continue to look for, but it may include quarters where investment will increase because some of the assets that we have are requiring an increased investment at some point.

So, overall, the way we have been sort of looking at this is, certainly, growth of the top line is driving our ability to invest in R&D and they are the two components to create value that will be sustainable for the long term for Incyte.

Operator

Our next question is from Vikram Purohit of Morgan Stanley. Please go ahead.

Vikram Purohit

Hi. Good morning. Thanks for taking the question. So, I wanted to go back to long-term Jakafi and the tail on that franchise. And I had two questions on Jakafi lifecycle extension program. So, I believe earlier you'd alluded to possibly getting some extended release data in 2020. So, I just wanted to see what the status of that program was, if it's in the clinic yet or not?

And then,. secondly, I believe the last time we saw some Jakafi combination data was at ASH last year in combination with the PI3K molecule. So, I just wanted to see when further data from that combination could be available as well as from other combinations like pem and itacitinib in the MF setting. Thanks.

Steven Stein

Vikram, hi. It's Steven. So, thank you for your question related to ruxolitinib lifecycle management, which we view as something for ruxolitinib itself as well as for myeloproliferative neoplasms in general. There are three pillars to the program and you mentioned all of them.

So, firstly, in terms of formulation work, which you brought up, that's been ongoing this year. It involves an extended release approach in terms of formulation and bioavailability and bioequivalence work. That is underway. It's been going well. As you just said, complete in 2020 at some point. And then, we'll use it to have regulatory discussions probably through the middle of 2021.

We'll find an appropriate meeting to present that. But I'll remind you that we actually presented some ruxolitinib XR data in 2011 with the 25 milligram XR tablet. So, we have already and that work is ongoing and progressing well.

In terms of the second pillar, combinations, we are running, as you said, the PI3-kinase delta combination. That's the most mature of them. We also have a rux plus pim combination and a rux plus itacitinib combination ongoing.

We'll have ourselves – data inhouse to look at ourselves with rux plus delta approximately end of this year and we'll find an appropriate meeting to present it at in 2020 and make decisions – go-forward decisions or not in either first or second line on myelofibrosis when we look at the completeness of the data. We'll also – should have enough data with pim and itacitinib also to present in 2020 at an appropriate meeting.

And then, the third pillar, and very important, is new targets to look at in MF and PV in collaborations with academia and different vendors, including epigenetic screen, to look if there are any new targets there and we haven't announced anything publicly yet. But that's a very, very active endeavor as well.

Vikram Purohit

Okay. Appreciate it. Thank you.

Operator

The next question is from George Farmer of BMO Capital Markets. Please go ahead.

George Farmer

Hi. Good morning. Thanks for taking my questions. I was wondering if you could comment a bit on pemigatinib and how you believe this molecule differentiates from other FGFR inhibitors?

Steven Stein

So, it's Steven. I'll go first. Dash may want to add something to it. We're in FGFR1, 2, 3 specific inhibitor. We know the PK and PD effects of this compound really well. We've done both intermittent dosing as well as continuous dosing. And we've got a very good PD marker, pharmacodynamic marker in hypophosphatemia. So, we can dose to that and, as I said earlier, manage appropriately.

All compounds, obviously, chemically are different. Obviously, the only approved FGFR inhibitor currently is itacitinib, the Janssen compound, and that does hit FGFR 4 as well and may explain some of the difference in safety profile that we see. But we'll wait for the full data sets to bear that out.

As regards the other compounds, I don't know enough to comment on. I don't know if Dash wants to add anything.

Dashyant Dhanak

Yeah. I think you covered the major points there, Steven. We feel that pemigatinib is probably the most selective FGFR inhibitor out there. We're focused on FGFR 1, 2 and 3. We don't really touch the other isozymes. It varies in biochemical assays or cellular assays, et cetera. We have what we think is a great PK profile clinically. So, overall, we feel it's a balance of optimal selectivity for our target proteins as well as the clinical profile to sort of leverage that selectivity in an optimal way.

George Farmer

Great, that's helpful. And I know it's early days, but do you have any sense for duration of therapy in the steroid refractory acute setting with Jakafi?

Dashyant Dhanak

Well, we can only go on again the REACH1 trial and we believe, in fact, in the duration of response of 173 days that's in our label where therapy isn't changed and the patients don't come off for whatever reason. So, that's what we're going by.

But we don't really have, from a commercial standpoint, a follow-up yet on what the true nature is, but we do know that it's successful, that patients seem to be staying on it for a long time.

As you know, in graft-versus-host disease in general, but it's particularly in acute graft-versus-host disease, physicians, bone marrow transplant docs, want to taper off drugs like steroids and even like Jakafi over a period of time, but just so they can do it safely and make sure they fully manage the effects of GVHD before they do so.

George Farmer

Okay. Great. Thanks very much.

Operator

The next question is from Mara Goldstein of Mizuho. Please go ahead.

Mara Goldstein

Great. Thank you very much for taking the question. Just on a couple of questions, one is on the promotional sensitivity on Jakafi and the PV indication, you mentioned that you thought that that category could get 50% penetrated. So, I'm wondering where the resistance is among the prescribing community. And is that something that is subject to also greater promotion?

And then, just secondarily, if you could update us on the status of the commercial organization for pemigatinib as you have NDA filed for cholangiocarcinoma?

Barry Flannelly

Sure. So, Jakafi is actually promotionally sensitive across all indications. It's both MS and PV can sometimes – most of our treating physicians and healthcare professionals don't see these patients that often. Sometimes, they're often worried about some of their other patients that might have lung cancer or pancreatic cancer. So, they don't pay enough attention to the symptoms, in fact, that these patients are experiencing and other indicators that their disease might be getting worse.

So, we have oncology clinical nurse educators. We have, obviously, our MSLs and we have our sales representatives that are continuing to try to educate healthcare professionals that they need to look more closely at these patients, particularly PV patients who are suffering and that's one of the reasons we do our educational campaign, obviously, to encourage patients themselves to go out and, in fact, advocate for themselves if they don't feel like they're getting the appropriate treatment.

Your second question was – oh, the commercial footprint for pemigatinib. So, we do plan, in fact, to add a few more people in 2020 to get ready for the pemigatinib launch. So, we're going to keep the full amount of current FTEs against Jakafi for MF and PV. We're going to increase slightly the number of FTEs that we have that are targeting graft-versus-host disease in bone marrow transplant centers and then a few FTEs that will be concentrated on pemigatinib. We also have a couple of oncology clinical nurse educators and, obviously, our market accessing people that are, in fact, fully ready for and fully trained on pemigatinib and cholangiocarcinoma for the launch in 2020.

Operator

Our final question is from Christopher Marai of Nomura Instinet. Please go ahead.

Christopher Marai

Good morning. Thank you for taking the question. Just maybe touching up some of the ruxo lifecycle management plans, if I recall, previously, Incyte had a BET inhibitor in the pipeline or have been looking at that target. And [indiscernible], there was some great data for [indiscernible] in myelofibrosis and had the potential to potentially work in a second line, but also maybe augment [indiscernible] in first line myelofibrosis. And I was wondering if perhaps you could comment on your [indiscernible] how you might be looking at that particular target? Thank you.

Steven Stein

Yeah, Christopher. Hi, it's Steven. So, I'll just remind you, we ourselves had a BET BRD program. So, obviously, we had pre-clinical data that showed that rux plus that target had enhanced or potentially enhanced efficacy in myelofibrosis and we ran into toxicity in

terms of – a non-target toxicity in terms of thrombocytopenia and currently put ourselves the program on clinical hold with the regulators. You alluded to a competitor, BET BRD program which showed, you're right, some interesting data and have an abstract in for future medical meeting that they may show more and we'll follow that closely. We are interested in anything that enhances rux activity and we'll keep looking across that. Our own programs are there for us to use should we need to resurrect them.

Christopher Marai

Okay. [Technical Difficulty] the toxicities I think it sounds like the competitor had, but, as you noted, that was something you're still investigating. Any improvement on the therapeutic index there? Maybe any mechanistic reason why if you think yours might be different from the competitors? Thank you.

Steven Stein

Yeah. So, I won't address them directly, but it's known that that BRD inhibitors have on-target thrombocytopenia that can be profound. So, you have to read the therapeutic ratio carefully in terms of potentially dosing to get there. I can't speak to the competitor compound there.

Operator

There are no additional questions at this time. I'd like to turn the call back over to Hervé Hoppenot for closing remarks.

Hervé Hoppenot

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

Operator

This concludes today's conference. You may disconnect your lines at this time. Thank you for your participation.