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INCY - Q4 2015 Incyte Corp Earnings Call

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OVERVIEW:

Co. reported 4Q15 revenue of $244m.

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PRESENTATION

Operator

Greetings, and welcome to the Incyte Corporation fourth-quarter and year-end financial results conference call.

(Operator Instructions)

It is now my pleasure to introduce your speaker, Mr. Michael Booth. Thank you, you may begin.

Michael Booth - *Incyte Corporation - VP of IR*

Thank you, Danielle. Good morning, and welcome to Incyte's fourth-quarter and full-year 2015 earnings conference call and webcast. The slides used today will be made available for download on the investor section of Incyte.com following the call. Speaking on today's call will be Herve Hoppenot, our CEO, who will begin with a strategic review and highlight our progress during the last 12 months. And then, Barry Flannelly, who leads our US Organization, will provide a commercial update on Jakafi. Rich Levy, who is in charge of Incyte's drug development activities will give

a brief update on our clinical progress. And Dave Gryska, our CFO, will summarize our fourth-quarter and full-year 2015 financial results. Dave will also outline our financial guidance for 2016. We'll then open up the call for Q&A, for which we'll be joined by Reid Huber, our Chief Scientific Officer, and by Steven Stein, Chief Medical Officer.

We'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 2016 guidance, the commercialization of Jakafi, and our development plans for the compounds in our pipeline. These forward-looking statements are subject to a number of risks and uncertainties that may cause our actual results to differ materially, including those described in our 10-Q for the quarter ended September 30, 2015, and from time to time in our other SEC documents. I'd now like to pass the call to Herve for some introductory remarks. Herve?

Herve Hoppenot - *Incyte Corporation - CEO*

Thank you, Mike. Good morning, everyone. Thank you for taking the time to participate in our call today. First, let me briefly cover the disappointing news we announced this morning that we are discontinuing our ongoing studies of ruxolitinib in solid tumors. This decision was driven by the discontinuation of the JANUS 1 trial and the high CRP sub-study of colorectal cancer Phase 2 study. Both of these studies were stopped early because interim efficacy analysis did not warrant their continuation. There were no new safety signals, but we saw no separation of the survival curves, and Rich will provide more detail on subsequent actions later in our presentation. It's also important to appreciate that this decision has no impact on our ongoing or completed studies of JAK inhibition in hematology or on our other ongoing studies of JAK1 inhibition in solid tumors which are based on different scientific hypotheses and will continue exactly as planned.

Moving now to slide 5, and as we look at the bigger picture, we can see a year of significant progress. On the strategic side, we signed two very important early-stage collaborative agreements which provide us with large molecules to further expand our immuno-oncology development pipeline. The antibody discovery alliance with Agenus has already been very productive. We expect to initiate clinical trials of our anti-GITR agonist antibody in the next few months. This is the first of several antibody candidates that we expect to emerge from the alliance with Agenus. We also in-licensed the clinical stage on PD-1 antibody from Hengrui and dose escalation is already underway. Incyte Europe is now well established, and we already have a team of medical oncologists and clinical development professionals in our office in Geneva from where we will conduct our European clinical development operations.

On the commercial side, Jakafi momentum in the US and globally remains strong. The launching period has been a success, delivering significant growth to our top line, and we are confident that Jakafi will reach a peak of $1.5 billion in MPNs alone in the US. On the clinical side, baricitinib has delivered outstanding Phase 3 data in RA and the regulatory applications for approval in the US and EU have been submitted by Lilly. We also made the decision with Merck to move epacadostat into Phase 3 development in first-line melanoma in combination with pembrolizumab. We have a robust and diverse portfolio of clinical opportunities, and it is this that made the recent result from ruxolitinib in solid tumor, while disappointing, less significant to our long-term value-creation plans.

So on slide 6, financially ruxolitinib provides Incyte with a steady growth driver and enables us to invest across the portfolio. In Q4 2015, we recorded $182 million in net product revenues from Jakafi and $24 million from Jakavi royalties from Novartis. This represents annual growth rate of 72% and 62% respectively. So revenue chart on the right with Jakafi revenue in the orange bar and Jakavi royalties in the yellow bar shows very significant growth rates for our product, now in its fifth year of commercialization. Total end-user phase of Jakafi and Jakavi combined reached over $1 billion worldwide in 2015, and Jakafi is patent-protected for at least the next 10-plus years.

We also expect baricitinib to provide us with a second significant source of revenue. All four Phase 3 studies met their primary end points, and Lilly has now submitted both the NDA in the US and the MAA in Europe. These regulatory submissions have triggered $35 million and $20 million milestone payment to Incyte from Lilly that we expect to recognize in full in Q1 2016. Furthermore, and illustrating the financial potential of our agreement with Lilly, additional milestones of $100 million will become due if baricitinib is approved in the US and $65 million if baricitinib receives a positive opinion from the European regulators. If approved, Lilly expects to launch baricitinib in early 2017, and Incyte will also be eligible for tiered double-digit royalties on Lilly's global net sales of baricitinib, which range from 20% to 29%.

Before I close my quick review, I wanted to highlight the depths of Incyte's drug development program. In the last two years, we have significantly expanded our development portfolio. In 2014, we had a portfolio that included six molecule against four different target. We now have a portfolio of 13 development molecule against 10 different target. Our biology and medicinal chemistry teams are continuing our in-house discovery work, and we expect our portfolio to continue to grow as we seek to bring innovative medicines to patients in need. With that, I'll pass to Barry for a little more commercial detail.

Barry Flannelly - *Incyte Corporation - EVP and General Manager, US*

Thank you, Herve, and good morning, everyone. Jakafi had an excellent fourth quarter and concluded an excellent year for the brand. Net product revenue from Jakafi during the fourth quarter of 2015 was $182 million, an increase of 72% over Q4 2014. For the full year, Jakafi sales were $601 million, an increase of 68% over 2014. These growth rates are the result of our robust launch in polycythemia vera and continued strong growth in the number of patients treated for myelofibrosis.

Let me share a couple of data points with you on slide 11. You can see that the awareness of Jakafi as an FDA-approved treatment for PV is very high. Awareness jumped rapidly after FDA approval, and it has remained high in our latest market research data. The middle panel shows the total number of physicians who have prescribed Jakafi for PV. This number continues to grow as we continue our educational efforts. We also believe that the duration of therapy is longer for PV-treated patients than for MF patients.

The total number of new and ongoing patients on Jakafi for both indications continues to increase. And this accumulation of patients on Jakafi therapy, together with the 10-plus years of patent life remaining, offers a compelling long-term growth driver for Incyte. Today, we confidently provide Jakafi net product revenue guidance for 2016 of $800 million to $815 million. I'll now pass the call to Rich for a clinical update.

Rich Levy - *Incyte Corporation - EVP and Chief Drug Development Officer*

Thanks, Barry. In the next three slides, I'll highlight the key clinical updates. The hypothesis that the JAK inhibition may have therapeutic utility in patients with solid tumors and high levels of systemic inflammation was initially supported by the results of the RECAP study, a Phase 2 randomized double-blind trial that suggested a survival benefit in a planned sub-group analysis of patients with high CRP levels. As a result, we and the broader scientific community believed further study was warranted in pancreatic cancer and in other solid tumors with evidence of systemic inflammation. Unfortunately, the larger studies that we carried out did not confirm the hypothesis.

Both JANUS 1, our pivotal study of ruxolitinib in pancreatic cancer patients, and the high CRP sub-study of ruxolitinib in colorectal cancer patients were stopped early because of lack of efficacy. We have therefore decided to stop all ongoing clinical trials that are based on the systemic inflammation hypothesis. These trials include the Phase 3 JANUS 2 study of ruxolitinib in pancreatic cancer as well as the Phase 2 studies of ruxolitinib in breast and lung cancer. We've also decided to discontinue the dose escalation trial of 39110, our selective JAK1 inhibitor, in pancreatic cancer as well as the companion sub-study of ruxolitinib in colorectal cancer in patients with Low CRP. We intend to present the data from these studies starting later this year.

Ongoing studies of ruxolitinib in selective JAK1 inhibitors in hematology indications will continue. Ongoing studies of selective JAK1 inhibition in solid tumor indications that are based on different hypotheses will also continue. These include a series of combination studies evaluating Incyte's 39110 with either pembrolizumab, Merck's anti PD-1 antibody; epacadostat, our IDO1 inhibitor; or Incyte's 50465, our PI3K-delta, inhibitor, to assess the therapeutic utility of JAK1 inhibition based on its effects on intertumoral immunity. Additionally, the potential impact of JAK1 inhibition on improving the benefit of targeted therapies will be investigated through a Phase 1/2 study of 39110 plus osimertinib, AstraZeneca's next-generation EGFR inhibitor.

We're also continuing Incyte-sponsored studies of ruxolitinib in MPNs and investigator-sponsored trials in a range of hematologic and solid tumors. We're also continuing with the development of topical ruxolitinib in Alopecia areata and our study of JAK1 inhibitor 39110 in graft versus host disease. Finally, it's important to emphasize that all our commercial activities with Jakafi and all investigational activities with Jakafi outside of systemic inflammation hypotheses are completely unaffected by this morning's announcement.

Moving now to slide 15. Incyte is and remains a leader in IDO1 inhibition, and ECHO, the epacadostat development program, continues to advance. During the second half of 2015 and based on response rate data emerging from the dose escalation phase of the epacadostat plus pembrolizumab trial, we and Merck decided to initiate a first Phase 3 trial of the combination in first-line advanced or metastatic melanoma. Emerging data from the dose escalation cohorts reinforce our confidence in the activity of epacadostat plus pembrolizumab in first-line melanoma, and we expect the Phase 3 trial to begin in the next few months. Melanoma is the only tumor type where we currently possess sufficient data to make a go-forward decision.

We are now in the process of recruiting hundreds of patients into the Phase 2 dose expansion cohorts of the ongoing combination trials with PD-1 and PD-L1 targeted agents. These trials are being conducted at the recommended Phase 2 doses and in a total of 13 different tumor types. By the end of 2016, we expect to have recruited approximately 600 patients across these studies and expect that these emerging data will provide us with the information we need to enable decisions on next steps beyond melanoma. We expect to provide updates in melanoma and in other tumor types starting in the second half of 2016, but note that these Phase 2 studies are single-arm studies and that we may be in a position to make a decision at any time to move forward in other indications depending upon the evolving data.

As you can see on slide 16, the GITR and LSD1 programs are the latest additions to our development portfolio. And given that both INDs were cleared by the FDA, we expect both to enter clinical trials in the first half of 2016. Everything is on track with both programs. Dose escalation trials of FGFR, BRD, PD-1, and PIM programs are also progressing as planned. We look forward to providing initial clinical data from 50465, our second-generation PI3K-delta inhibitor, during 2016. With that, I'll turn the call over to Dave for an update on our financials.

Dave Gryska - *Incyte Corporation - CFO*

Thanks, Rich. For the fourth quarter of 2015, recorded net product revenues from Jakafi of $182 million and royalties from Novartis of $24 million. Total revenue in the fourth quarter amounted to $244 million, which included $35 million in milestone payments from Novartis. For the full year of 2015, we recorded net product revenues from Jakafi of $601 million and royalties from Novartis of $75 million. Total revenue for the full-year 2015 amounted to $754 million which was a record for our Company. R&D expense for the fourth quarter was $117 million and $480 million for the full-year 2015. SG&A during the fourth quarter was $52 million and $197 million for the full-year 2015. We ended the year with $708 million in cash and cash equivalents.

Turning now to guidance, which assumes no strategic transactions during 2016. For the full year of 2016, we expect net product revenues from Jakafi to be in the range of $800 million to $815 million. With respect to contract revenue, we have recognized $55 million in aggregate milestone payments from Lilly in the first quarter of 2016, which when added to the $13 million we expect to recognize over the year related to the amortization of the upfront payment from Lilly, results in a total of $68 million of contract revenue so far this year. 2016 guidance for R&D expense is between $620 million and $640 million, including non-cash expense of approximately $55 million to $60 million related to the impact of employee equity awards. For SG&A expenses, 2016 guidance is between $255 million to $270 million, including non-cash expense of approximately $30 million to $35 million related to the impact of employee equity awards. Overall, we expect 2016 to be a breakeven year on a GAAP basis.

Our final slide presents our anticipated news flow for 2016. Lilly has already submitted the NDA and the MAA for baricitinib, and we expect to see continued growth from both Jakafi and Jakavi through the year. In the next few months, we expect initiation of the GITR and LSD1 programs and also the initiation of the Phase 3 trial of epacadostat plus pembrolizumab in first-line advanced melanoma. We expect to deliver initial results from 50465, our PI3K-delta inhibitor, in the first half of 2016. Looking further into 2016, we expect to be able to deliver additional data from epacadostat plus PD-1 and PD-L1 combinations as well as initial data from our FGFR and BRD inhibitors. Operator, that concludes our formal remarks. Please open up the call for Q&A.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Our first question comes from Matt Roden with UBS. Pease proceed.

Matt Roden - *UBS - Analyst*

Great. Hi, guys. Good morning. Thanks for taking our question. First on the guidance, I might have thought that shutting down the JAK and solid tumors program might have given you a little bit of a break on the growth of R&D, but we recognize you have several other programs ongoing, including epacadostat. Just trying to get a sense for whether or not or to what extent there's any of the existing JAK1 and JAK2 trials still in that R&D guidance, and whether or not that would be -- your R&D guidance is aggressive or conservative. And then if I'm allowed, I have a pipeline follow-up. Thanks.

Dave Gryska - *Incyte Corporation - CFO*

Hi, Matt. That's a great question. This is Dave. Our guidance includes the results from today's press releases. When you look at our guidance in terms of R&D expense, there's a lot things going on in our pipeline, a lot of value to be built for shareholders, and we believe that the guidance is appropriate and the investments we're making in the pipeline that Rich talked about today are right in line to where we have to go for our long-term plans. So there is no, I would say, conservatism in that number. It's a number that we looked at and we thought is about appropriate for where the year is going to be.

Matt Roden - *UBS - Analyst*

Okay. Great. Thanks for that clarity. And then on the pipeline side, specifically on the IDO program, we understand that you guys want to present results when you have a certain critical mass of data. But we also know that these are open-label studies, and you can probably have a sense of what you're seeing along the way. So, can you just talk in very general terms about whether or not the emerging data up until today still support the initial conclusions you've drawn on IDO and checkpoint combos in terms of efficacy and safety?

And then related, Rich, if you could just amplify your prepared comments on the triggers for starting additional Phase 3 studies. Just curious if there's competition between your collaborators about getting into lung cancer first, and at this point, whether or not you would be able to rule in or rule out starting a Phase 3 in lung this year. Thanks.

Rich Levy - *Incyte Corporation - EVP and Chief Drug Development Officer*

Thanks, Matt. In terms of the data, let's first deal with melanoma. So, as I said in my prepared remarks, the emerging data in melanoma remains consistent with what we presented before, and it continues to support our conclusions both in terms of efficacy and safety, and we remain fully confident in our decision to start the Phase 3 study in melanoma with Merck within the next few months. With respect to decisions on other programs, as you know, we had very little data in any of the other tumor types, none of which was able to allow us to make a decision based on the dose escalations in the Merck study or for that matter, in any of the other studies.

We're going to be enrolling a total of about 900 patients. We expect to enroll about 600 of them this year in the 13 different tumor types, and it doesn't mean that need to get to the end and have scans on 600 to 900 patients. What that trigger will be will depend upon the data in terms of relative response rates and other information that we have. So in no sense are we saying that there is no trigger for a Phase 3 this year but we are also saying there is not enough data to present or submit abstracts to scientific meetings that will occur within the first half of 2016. I can't really comment specifically on competition between the companies but it is clear it is not one or two companies that have interest in things like lung cancer and other tumor types.

Matt Roden - *UBS - Analyst*

Great. Thanks very much for the added color.

Operator

Our next question comes from Salveen Richter with Goldman Sachs.

Salveen Richter - *Goldman Sachs - Analyst*

Thanks for taking my questions. I just wanted to get a sense of the Q4 organic growth. So if you exclude the price increase and just maybe give us a sense of inventory here. And then when you look out to 2016, what's the contribution from PV versus existing MF demand? And then I just have a follow-up on the JAK1 studies.

Barry Flannelly - *Incyte Corporation - EVP and General Manager, US*

Hi, Salveen. This is Barry. So getting to Q4 first, so we took a 4% price increase at the end of September, so that's built into it. But we really -- our inventory remains constant at about three weeks. So there wasn't a big inventory build in the fourth quarter, so you can figure out what the rest of the demand is for Q4, and then for the rest of the year.

Salveen Richter - *Goldman Sachs - Analyst*

For 2016 just in terms of contribution from the PV ramp versus MF demand.

Barry Flannelly - *Incyte Corporation - EVP and General Manager, US*

Okay, so PV patients, as we know, continue to grow rapidly. At a certain point very soon, new PV patients will exceed myelofibrosis patients, but we have a very big base of myelofibrosis patients that continue to stay on therapy. So MF will continue to contribute to the top line, and PV sales will eventually exceed the MF sales that we have now.

Salveen Richter - *Goldman Sachs - Analyst*

But finally, just in solid tumors, we recognize that JAK1 studies are based on immune-modulating hypothesis, and that's different from the high-inflammation hypothesis for Jakafi. But do you have any thoughts on potential read-through here in the solid tumor setting?

Reid Huber - *Incyte Corporation - Chief Scientific Officer*

Hi, Salveen. This is Reid. That's a good question, and the quick answer is, no, we don't. The RECAP trial that led to the broader JANUS program and solid tumor program involving ruxolitinib was really focused on a unique and novel patient selection approach around elevated CRP. And as Rich and Herve outlined, unfortunately those studies did not meet our expectations. But beyond that in a very distinct way, our efforts with JAK1 inhibition, both with eGFR combinations and with PI3K-delta combinations, are really built upon a very different hypothesis, that namely that JAK-STAT signaling plays an oncogenic role, a cooperative oncogenic role and can offset the activity of otherwise effective targeted therapies, be they inhibitors of the eGFR kinase in lung cancer or in lymphomas inhibitors downstream of a B cell receptor.

Separate from that is the emerging role that JAK1 inhibition can play in modulating intertumoral immunity. Again, a very different approach, a very different suite of combinations that we're initiating both with IDO1 and delta as well as with pembrolizumab. And of course, that's going to be in a very different set of tumor histologies, ones that generally are viewed as immune-responsive and therefore histologies that might be able to provide us an actionable signal. So, I don't think there's any read-through, and I think it's very important to contrast the mechanistic differences between the various aspects of the JAK inhibitor portfolio.

Salveen Richter - *Goldman Sachs - Analyst*

Great. Thanks, Reid.

Operator

Our next question comes from Geoff Meacham with Barclays.

Carter Gould - *Barclays Capital - Analyst*

Hi, guys. This is Carter on for Geoff. Thanks for taking our questions. First on epacadostat. I appreciate the earlier color on your plans to report data in 2016. Just wanted to clarify, should investors expect clinical data from each of the remaining PD-1 and PD-L1 combination studies in 2016? And then real quickly for Dave and Barry on the SG&A guidance, obviously we saw SG&A reset higher following the PV approval, but we're still looking for 2016 at a pretty good growth clip, 30% plus, when I think most of the Street had already thought that you -- (technical difficulty) built into [2015 first]. Can you maybe talk about the projected drivers of that spend in 2016? Thank you.

Rich Levy - *Incyte Corporation - EVP and Chief Drug Development Officer*

Hi. So it was a little bit hard to hear. There was a lot of static on the line. But with respect to the data from the epacadostat trials in 2016, I don't specifically know yet whether every one of the four collaboration trials will have data in the second half of 2016. We used the word that we would be starting to present data in the second half of 2016, but until we see how those studies enroll and whether the data gives a clear picture, we don't know that all of them will come out in the second half of 2016.

Dave Gryska - *Incyte Corporation - CFO*

Hi. It's Dave. On the question on the SG&A guidance, it's a mix of many different things for this year. There is a slight element in there for our work that we're doing in Europe in building that out as well as what we're doing here in the US to build out further Barry's team and some more marketing expenses, plus some G&A expenses. So, we're getting ready for our growth in the future years. We're making some investments this year, and I think right now, as we look at it, it's right in line with our expectations for the year.

Carter Gould - *Barclays Capital - Analyst*

Thank you.

Operator

Our next question comes from Brian Abrahams with Jefferies.

Brian Abrahams - *Jefferies & Co. - Analyst*

Hi. Thanks very much for taking my question. A couple of questions on epacadostat. You discussed the melanoma Phase 3 trial design in your slide deck. I'm wondering if you could expand on that a little bit more in terms of potential size, timing, costs there, whether this is one single Phase 3 would be sufficient, and clarify that that will not have a CTLA-4, PD-1 control arm. And then separately, I know we're expecting to see data from several other companies, combination studies with multiple checkpoints this year. I'm curious if there's any preclinical data or clinical plans to test epacadostat on top of multiple checkpoints. Thanks.

Rich Levy - *Incyte Corporation - EVP and Chief Drug Development Officer*

Thanks, Brian. So, with respect to the Phase 3 melanoma design, we're not going to get very specific about this until we post the results on clinicaltrials.gov a little bit later in the year. I will say, however, that what we have guided to is that the study will be epacadostat plus pembrolizumab versus a control of pembrolizumab alone. The study will be typical for Phase 3 studies, but I can't in terms of size and cost. Of course, that cost will be shared 50/50 with Merck.

And in terms of combinations of a number of our drugs in our portfolio which have the immunologic approaches, which is by no means limited to epacadostat at this point, we are interested and we have plans to start to study not only epacadostat with other drugs in our own portfolio as well as drugs in our own portfolio with PD-1s. And as our own portfolio matures, we do plan to look at combinations, but we don't have anything to announce at this point in time with respect to anything beyond what we've specifically guided to in the past. I don't know if Reid wants to add anything. Apparently not.

Brian Abrahams - *Jefferies & Co. - Analyst*

Thanks.

Operator

Our next questions comes from Cory Kasimov with JPMorgan.

Cory Kasimov - *JPMorgan - Analyst*

Hello. Good morning, guys. Thank you for taking my questions. I'll stick with the two-question theme here. So I guess first probably for Reid. In addition to your R&D event, what can we be expecting at AACR in terms of potentially new data? And then I have a follow-up.

Reid Huber - *Incyte Corporation - Chief Scientific Officer*

Thanks, Cory. So we'll have more to say about the presentations at AACR once titles and abstracts publish, which is in a few weeks. I think the theme will very much be similar to last year in the sense that we want to certainly ground people in the scientific rationale for the newest entrants into the portfolio. As Rich also mentioned, we're looking forward to being able to potentially share some 50465 data with you and provide a little bit more color on that program. I think it also gives us a time to just sort of step back, look at the portfolio and strategy as a whole, and talk about what might be some of the emerging drivers within the development portfolio that are important for us and important for you to pay attention to. So a little bit early, but we'll have more to say over the next few weeks and as we get through the end of February.

Cory Kasimov - *JPMorgan - Analyst*

Okay. And then secondly for Jakafi in PV. Now that you guys are a little over a year in the market, have you noticed the discontinuation rates and compliance basically tracking in line with what was observed in Phase 3 and should we kind of continue to model it that way? Thanks.

Barry Flannelly - *Incyte Corporation - EVP and General Manager, US*

Thanks, Cory. It's Barry. So, we've only really launched -- we've only really have 12 months of data for Jakafi in polycythemia vera. I think we'll need at least 24 months, if not more, to really figure out what is the persistency discontinuation rate. We know that from the RESPONSE study that at least 80% of patients stayed on for two years. We're not saying that that translates to what happens in everyday treatment of these patients, but nevertheless it's certainly trending in the right direction, but we need more data in order to figure out what the median is for persistency.

Cory Kasimov - *JPMorgan - Analyst*

Okay. Thank you, guys.

Operator

Our next question comes from Eric Schmidt with Cowen and Company.

Eric Schmidt - *Cowen and Company - Analyst*

Thanks for taking the question. Two as well from me. Maybe first for Rich, going back to epacadostat in melanoma. I guess one of the criticisms of the SITC dataset was it was only 19 patients. With your new emerging data in this space, can you give us a sense of whether you're up to 25, 30, 35 patients when you now look at the totality of the data?

Rich Levy - *Incyte Corporation - EVP and Chief Drug Development Officer*

The emerging data from the Merck dose ranging study remains essentially those same number of patients but with additional scans on those patients. And that's part of the reason, so first, while we're not talking about the results of additional scans here, the ongoing results and more data on these patients continues to reinforce our prior decision. We are enrolling more melanoma patients into the expansion cohort, and that will contribute to future presentations of Phase 2 data in melanoma, but we have very little data in terms of results of scans on those Phase 2 patients from the expansion.

Eric Schmidt - *Cowen and Company - Analyst*

Got it. Maybe one for Herve on baricitinib and the Lilly development program. It looks like they're going forward in atopic dermatitis. Are you going to be opting into that program? And maybe you can give us an update on any Eli Lilly plans to move forward in CKD?

Herve Hoppenot - *Incyte Corporation - CEO*

Yes, I will let Rich can give you details. But in general, we are at the stage where none of these decisions have yet been formalized. So Rich, if you want to.

Rich Levy - *Incyte Corporation - EVP and Chief Drug Development Officer*

So, the way that we officially make decisions on buying in is we get the data from Phase 2 and/ or proof-of-concept data from clinical trials and a cost and development plan, and then we decide whether to buy in. So in the case of atopic dermatitis, we think it's a very interesting indication. There are data with other JAK inhibitors that have been presented suggesting that this can be quite effective, but we would not necessarily need to buy in to that until we actually see data with baricitinib in that indication.

But when we see good data, we would tend to buy in. And with respect to the planned studies in diabetic nephropathy, we've seen the data from the Phase 2 and we are awaiting receipt of the buy-in package, which would also include the cost and design of the future studies and we'll make the decision based on all the information when we have it.

Eric Schmidt - *Cowen and Company - Analyst*

Thank you.

Operator

Our next question comes from Ying Huang with Bank of America, Merrill Lynch.

Ying Huang - *BofA Merrill Lynch - Analyst*

Thanks for taking my questions as well. First one I have on epacadostat development program. If you look across all the PD-1 or PD-L antibodies, there's some subtle difference in terms of their effect in the PD-L1 ligand expression, positive or negative. Have you gone back and conducted more analysis based on the collaboration data with Merck in melanoma? Do you see any difference in terms of when you add IDO inhibitor into the PD-1, do you see any difference at all compared to monotherapy of PD-1? And then the second question I have is, you're getting up to speed in terms of developing GITR in clinics now. There are two or three other programs as well from Merck, from Bristol. Can you tell us if there's any difference at all between your program and the other programs based on the preclinical findings? Thanks.

Reid Huber - *Incyte Corporation - Chief Scientific Officer*

Thanks for the questions. I'll try to take them both. So the first one with respect to PD-L1 testing, as you alluded to, there are some differences. I would actually call them fairly significant differences between how the various PD-1, PD-L1 players try to quantify PD-L1 in the tumor microenvironment, very differences in terms of sustaining performance and whether you are quantifying L1 in a tumor cell or an immune cell. And this really leads to some pretty disparate results, as you alluded to, in terms of how those drugs perform in the various subgroups of patients. They're basically selecting in some cases quite different patients and then you have the whole other issue around tumor heterogeneity and whether a single section really gives you a faithful representation of what's PD-L1 positive and negative.

All that being said, the translational components of our portfolio, of our programs with those collaborators are very important. We will be evaluating PD-L1 with each individual company's assay as part of the translational components of those programs, and that could help us form a stronger opinion as to exactly how to select patients and which assays may be most appropriate for identifying patients more likely to respond to an IDO combination. Importantly, there's also a number of other assays that are being evaluated in those patient cohorts, including other means of assessing sort of the inflamed microenvironment and other indices that might better reflect sensitivity of patients. So that's an emerging dataset. We're not anywhere near presenting anything definitive yet, but it's an important work in progress.

The second question you had was with respect to GITR. There are several GITR agonists in the clinic right now. You mentioned Merck. MedImmune AZ has a compound. I know another small company, GITR Inc., has a molecule. We know relatively little about the preclinical performance characteristics of those antibodies, how they're engineered. For example, the Fc backbone that they're on, and certainly we haven't seen any Phase 1 clinical data. And I think that's the key piece of information that we need to be able to evaluate those antibodies and their quality and development programs.

And it's also the key piece of data that you should look for from us to be able to establish how we may be different. As we alluded to at JPMorgan, we have an IgG1 backbone on our GITR antibody. We think that's important to facilitate agonism on the effector T cell to facilitate signaling in both in Tregs as well as ADCC of the Tregs. And in our hands, that's a very important engineered part of the antibody. Whether or not others feel the same or have different views, we'll have to see as their data emerges and they make more disclosures around their programs.

Ying Huang - *BofA Merrill Lynch - Analyst*

Thanks.

Operator

(Operator Instructions)

Our next question comes from Tony Butler with Guggenheim Securities.

Tony Butler - *Guggenheim Securities - Analyst*

Thanks for taking the question. Back to the SITC data in melanoma, are the additional scans and perhaps a more robust net number of patients, which are adding in the cohort setting, will that be the subject of data presented at AACR or is that a Merck decision?

And second, if we actually think about your PD-1 inhibitor and the pathways in solid tumors, obviously a very crowded market and a market where there is a considerable amount of dollars being spent, could you provide maybe some additional color around directionally where you want to take that? And I understand you could say, well, it's where the data are, except that you have a proxy or at least two proxies in the market of where that may be able to -- for where you may be able to go. And I'm sorry, just finally on the duration, would you tell us the duration of Jakafi in both MF and PV today, and whether that has changed? Thanks very much.

Rich Levy - *Incyte Corporation - EVP and Chief Drug Development Officer*

This is Rich. I will start. So with respect to the Merck melanoma data from the dose escalation cohort that was first presented at SITC, we have not submitted abstracts to any of the first half of 2015 meetings, but we do expect that we will most likely present updated data at one of the several options in the second half of the year. With respect to PD-1, I'll turn that over to Herve.

Herve Hoppenot - *Incyte Corporation - CEO*

Maybe as the way to think about the PD-1 is obviously that there are a number of PD-1s that are in development. I think there are 10 of them; two of them are already approved, PD-1 or PD-L1. So the way we are looking at it when we did this agreement with Hengrui is that it would be a useful part of a combination strategy that involves mostly our early portfolio. So we are looking at immuno-oncology portfolio made of large molecules and small molecules and where we can see potentially from the emerging preclinical data that we have that some of these combinations would include a PD-1. And that's really why we did the agreement that we did.

The short-term Phase 3 program that we are discussing with epacadostat is already going to be done with our current partner. And then when we have established the efficacy and the safety of our own PD-1, we would be working maybe with our GITR or some of the other molecules that we have in our portfolio. So the past two registrations is really something that is going to be different maybe from what other competitors are looking at because we see it as more of a product that would be used for appropriate value combinations that we would be building in the future. Of the duration of treatment, as you know, we have not discussed the PV or MF duration of treatment in practice because it's very difficult to establish.

What we know and what we have said is that in PV, we have clearly a longer persistency than what we have been observing in MF, similar to what we have seen in the clinical trials where the duration of treatment was significantly longer in PV. As Barry was saying, if you look at the median, we cannot speak about the median yet because it's still too early. It's only one year since we launched the product, but what we are expecting to see over the next 10 years as we are developing this MPN franchise is that the duration of treatment in PV would be longer and there will be an accumulation of patients as we have new patient flow that is now well established, and where we have the existing patients staying on treatment for a longer duration of time, but we have no number that we can really share with you.

Tony Butler - *Guggenheim Securities - Analyst*

Thank you, Herve.

Operator

Our next question comes from Chris Marai from Oppenheimer.

Chris Marai - *Oppenheimer & Co. - Analyst*

Thank you for taking the questions. First, just a quick one. With respect to your 2016 breakeven guidance, does that include additional milestone payments beyond the $55 million or so expected to be recognized next quarter? And then, two, on your JAK PI3K programs, I was wondering how you're looking at potential registration paths forward there. Obviously PI3K inhibitors and JAK inhibitors, frankly, have been clinically validated. How do you look at really bringing this forward in the clinic? And in a registrational trial, would you look at perhaps indications where PI3K was disappointing and adding JAK1 would augment a response or offer synergistic response, or would you go after some greenfield opportunities? Thanks.

Dave Gryska - *Incyte Corporation - CFO*

Hi. It's Dave. On your first question in terms of milestones, our guidance of breakeven assumes the milestones that I mentioned to you earlier in my script that we've received from Lilly, and then also the amortization of that $13 million item. So that's in the breakeven guidance. Thank you.

Steven Stein - *Incyte Corporation - Chief Medical Officer*

Chris, it's Steven Stein answering your question related to JAK and PI3K delta. In terms of JAK1s that are in development, we have obviously, as Rich presented, 39110 and then 52793. 39110 is about twentyfold more selective for JAK1 if you use rux as a reference. And as Rich presented, the areas we are interested in there now are graft versus host disease. And then the combination study with the AstraZeneca third-generation osimertinib EGFR inhibitor, which is as Reid presented, builds on a different hypothesis to the CRP one. So those are both areas that are potentially registration should the data support that.

In terms of the PI3K delta program, you rightly point out this is a validated target. There's an approved product from Gilead that has indications in CLL in follicular lymphoma. We have selected our second compound there, 50465, because of its potency and to date, relative differentiated in terms of its tolerability profile. And we're developing datasets in both hema-malignancies and solid tumors, so we're interested in a single agent PARP there potentially and then in combinations in various of our combination studies. And to date, it's early but we like the look of this compound.

Chris Marai - *Oppenheimer & Co. - Analyst*

Just on the combinations, again, would you be going after some of those opportunities that have been clinically validated, for instance, with Gilead's product and just looking to augment activity there, or would you be looking to go into sort of greenfield combo opportunities?

Reid Huber - *Incyte Corporation - Chief Scientific Officer*

Hi, Chris. This is Reid. So one of the hypotheses behind the development program with delta is to evaluate the combination potential with JAK1. Preclinically, that's quite a synergistic combination. We know a lot molecularly as to why that is, the B-cell receptor signaling feeds into the JAK-STAT pathway and the NF-kappaB pathway, and there's a very productive autocrine loop that helps those cells to grow, and so it's an exciting thing to combine the two. We presented a little bit of data last year at ASCO in relapsed/refractory Hodgkin's lymphoma which I think speak to the combination potential of that doublet. And it's very much important in the program going forward once we establish the monotherapy safety and early signals of efficacy with 50465 to move into JAK1 doublets. It's a very important part of our development program going forward, and I think as that data emerge, we'll hopefully have more information to be able to share with you.

Chris Marai - *Oppenheimer & Co. - Analyst*

Okay. One last left field question here. Just given your expertise in medicinal chemistry at Incyte and recently bringing on a PD-1 from a collaborator, do you have any plans to develop and oral PD-1 agent? Thanks.

Reid Huber - *Incyte Corporation - Chief Scientific Officer*

Yes, Chris. We don't comment on our early discovery programs or what we're doing outside of the development portfolio, so I'm afraid I can't speak to that.

Chris Marai - *Oppenheimer & Co. - Analyst*

Thank you.

Operator

Our next question comes from Skip Klein with Gauss Capital Advisors.

Skip Klein - *Gauss Capital Advisors - Analyst*

Yes, thanks. I've broken I can't tell you the number of pencils trying to value baricitinib, and I was wondering if you could help me out a little bit. Given the strong clinical package, would you think I was crazy if I argued that bari could be bigger than Jakafi in terms of peak sales? And then given the very rich deal that you have with Eli Lilly, would you think I was crazy if I argued that the NPV of baricitinib is greater than the royalty stream from Novartis on Jakavi?

Herve Hoppenot - *Incyte Corporation - CEO*

Herve here. So it's difficult to judge about being crazy or not. I mean, the entire guidance on what baricitinib could be is really in the hands of Lilly. Now the comparison you are doing, I can say, I mean, the royalty rates that we have on baricitinib, and we speak about are between 20% to 29%. It's a tiered rate based on the sales worldwide, which is higher than the royalty rates that we have on ruxolitinib from Novartis. But the base is also completely different because the Novartis deal is a deal that is ex-US where in fact, the baricitinib partnership with Lilly is worldwide. And I would argue that it's relatively obvious to everybody that the potential of baricitinib in rheumatoid arthritis is larger than what we have with our ruxolitinib in PV and MF.

So, when you look at the geography, when you look at the indication, and when you look at the royalty rate, I would say it's not crazy to think that way. The overall potential of baricitinib in RA, frankly, is interesting because when you look at the clinical profile and the result of the clinical studies, the Phase 3 studies, the superiority to Humira, it is a product that, in my opinion, could be very successful in a market that is relatively large. So there is a lot of upside there, certainly.

Skip Klein - *Gauss Capital Advisors - Analyst*

And then I guess, thank you very much for that. It looks like the market, Mr. Market is saying that $3 billion was the NPV of solid tumors for Jakafi, in rough terms, and I could -- busted a lot of pencils, but mostly could only get to maybe $1 billion. So what explains the $2 billion extra deterioration in value that we're seeing today?

Herve Hoppenot - *Incyte Corporation - CEO*

I cannot say. It's difficult for me to explain everything. Frankly, it's a program that we were opportunistic about. I mean, we were confident that the scientific hypotheses we were pursuing was certainly worth doing the studies that we did. So we have obviously the proof-of-concept in pancreatic cancer with RECAP, and the confirming Phase 3 studies that we have done and in parallel evaluating in Phase 2 some other studies, if it was also applicable outside of pancreatic cancer and lung and breast and colorectal cancer. So I guess it depends what probability of success people are attaching to each of these programs.

From my standpoint, obviously there is a certain level of saying, oops, that's not what we were expecting. But at the same time, I must say that as we see the dynamic of the entire development portfolio, it is a Company that has today more opportunities for value creation in the future than we had just maybe two years ago because of the quality of the molecules that we are bringing. So it is now for us to do the work to get these products further advanced in the clinical setting, and I think what we will see is a number of opportunities to contribute to the top line over the next few years coming from our current portfolio that we have.

Skip Klein - *Gauss Capital Advisors - Analyst*

Great. Merci beaucoup.

Operator

Our next question comes from Liisa Bayko with JMP Securities.

Liisa Bayko - *JMP Securities - Analyst*

Hi, there. Thanks for squeezing me in. A quick question. First just theoretically, as you think about what you've seen so far for rux in the solid tumor setting with respect to sort of the onco inflammation component, are you more pessimistic about your particular molecule, or do you think this whole concept perhaps is not what you thought it was? As we think about if there are some other people pursuing this approach as well. I was just curious about scientifically where you lie on that.

Rich Levy - *Incyte Corporation - EVP and Chief Drug Development Officer*

This is Rich. So all I would say is that the two negative studies with ruxolitinib in pancreatic and colon were enough for us to also stop with our own JAK1 inhibitor, but we really can't comment on whether anybody else's molecules may have a different profile or not and whether they will succeed or not.

Liisa Bayko - *JMP Securities - Analyst*

Okay.

Herve Hoppenot - *Incyte Corporation - CEO*

And maybe a supportive comment on that to put some perspective on them. We get the top-line results from these studies. At the interim level, it was a primary endpoint is what we look at, and it's really a question of is there a chance for these studies to be positive as planned, and the answer was, no. And that's why we decided to change the program. Now we will have a lot of data that will be analyzed over the next few months.

And so I think to better answer your question of saying where was the sort of the problem between the hypotheses and the Phase 3 studies, I think at the end of the process when we are able to analyze the data, including the data in blood cancer, on lung cancer, for the few patients we have

in that study, I mean, that will give us a better picture of exactly what is the situation there. I think today, it was more a decision that was based on the fact that the chance of having a positive study at the end was in fact very, very, very low, and it was the right thing to do for patients and for investigators and the Company to discontinue the program at this stage.

Liisa Bayko - *JMP Securities - Analyst*

Okay. Thanks. And then just a couple of commercial questions. Can you give us any more details on the breakdown of sort of where things are right now with respect to MF versus PV? And then any gross to net info you can provide would be helpful.

Barry Flannelly - *Incyte Corporation - EVP and General Manager, US*

Sure, Liisa. This is Barry. In terms of MF, we still have a large number of patients, and they continue on therapy for a long period of time. As I said before, PV sales will eventually outpace MF sales. In terms of gross to net, obviously we have those discounts that everybody else has, and we always try to maintain the value of the brand. So in Q1, though, the question is I suppose maybe you were getting at is that obviously we have a gross-to-net decline in Q1 just because of the 50% of our patients are Medicare patients and we have to close the donut hole. So we're picking up $1,800 or so of their cost for all patients in the donut hole. So that impacts our gross to net and therefore, our growth from Q4 2015 to Q1 2016 could be impacted by a lower gross to net in the first quarter versus the rest of the year.

Liisa Bayko - *JMP Securities - Analyst*

Okay. Just wanted to clarify. This is my last question. I think I heard Herve say MPNs could be $1.5 billion in the US. Was there some timeframe around that or maybe you could clarify? I wasn't completely sure if I heard correctly.

Herve Hoppenot - *Incyte Corporation - CEO*

No, you heard correctly. In the US, MPNs, like MF and PV, that's the guidance the long-term potential number that we gave six months ago, and basically it's reflecting two things. It's reflecting the fact that we are in a market usually that way has a lot of potential. So the number of patients that could potentially be treated with ruxolitinib and where we are today gives us a lot of room to grow. We have also 10-plus year before the first possible patent expirations, so that gives us a long runway.

As you see, I mean we are speaking of a guidance for next year that is north of $800 million. So the $1.5 billion is really reflecting the fact that we see long-term growth for this franchise in the US in the current indications that is very possible. It's also an indication where in MF, we have a low competitive situation in the long term. There are other products trying to be developed in MF, but it's not the most crowded market. And in PV, in fact there are very few products that are developed for PV. So if you look forward over 10 years, what we are saying is that we see this franchise as one of the growth engines for the top line of the Company, and the $1.5 billion is a way to calibrate a little bit for everybody what we have in mind.

Liisa Bayko - *JMP Securities - Analyst*

Okay. Thanks.

Operator

Our next question comes from Reni Benjamin with Raymond James.

Reni Benjamin - *Raymond James - Analyst*

Hi, guys. Thanks for taking the question. Sorry about the rux results in solid tumors, but congrats on a steady growth in MPNs. Two questions, just one maybe for Barry. Can you talk -- I think you mentioned that there are about 1,250 or maybe 1,500 docs prescribing for PV. Can you give us a sense as to what the target number of docs may be to reach your peak numbers given the current script rate?

Barry Flannelly - *Incyte Corporation - EVP and General Manager, US*

Sure. I'm not sure it's about the total number of docs. We're very happy that more and more docs are prescribing Jakafi for PV, but it's really more about the number of patients that will benefit. So eventually, we'll have all of the docs who see PV patients and MF patients prescribe Jakafi at some point, but it's really making sure that in fact we help them identify patients that are truly going to benefit.

Reni Benjamin - *Raymond James - Analyst*

How many docs is that?

Barry Flannelly - *Incyte Corporation - EVP and General Manager, US*

Well, it's really the total number of oncologists and hematologists in the United States, which is probably about 8,000 and could be as many as 11,000 but about 8,000 practice.

Reni Benjamin - *Raymond James - Analyst*

Got it. I was just trying to get a sense is it following kind of like the 20/80 rule of 20% of the docs are giving out 80% of the scripts in an indication like PV.

Barry Flannelly - *Incyte Corporation - EVP and General Manager, US*

PV is a little bit different than lots of other tumors or lots of other cancers, and that includes MF patients, too, because each doc may have only one or two patients. So, it's really about them identifying patients that could truly benefit from Jakafi.

Reni Benjamin - *Raymond James - Analyst*

Got it. And just one last question for Rich. The Phase 3 program with epacadostat, just given sort of the changing landscape in melanoma, can you just take us through the rationale of why you guys elected maybe not to run a non-inferiority study comparing epacadostat and Keytruda with Opdivo and Yervoy, for example?

Rich Levy - *Incyte Corporation - EVP and Chief Drug Development Officer*

We agree that it's difficult to compare across studies, but based on the results that we had seen and presented at SITC and continues to be our belief, we feel that we have the ability to demonstrate that the combination of pembro plus epacadostat will both be better than pembro, which is the registration endpoint, as well as to be comparable in terms of efficacy to the published Phase 3 data and label data for nivo plus ipi. But we didn't feel that it was necessary to add a third arm to that study comparing to that other combination. And of course, the emerging data indicates that the safety profile of epacadostat plus pembro is not very different than pembro alone, which is not the case for the combination of nivo plus ipi.

Reni Benjamin - *Raymond James - Analyst*

Great. Thanks, and if I can just sneak one in for Dave. I think Lilly mentioned they are going to be filing in Japan in the next couple of months. Can you give us a sense as to the milestone you could expect from that filing?

Dave Gryska - *Incyte Corporation - CFO*

We are not, with our Lilly agreement, not allowed to go there. On that particular -- if there is any milestone payment at all. I think an earlier question said what do you project for your milestones and it was really the narrative I gave in the script in terms of the two milestones we received from Lilly already in Q1 that I talked about plus the minor amount of amortization of $13 million.

Reni Benjamin - *Raymond James - Analyst*

Got it. Thanks, guys, and good luck.

Operator

Our next question comes from Alethia Young with Credit Suisse.

Alethia Young - *Credit Suisse - Analyst*

Hello, guys. Thanks for taking my question and squeezing me in. Maybe two quick ones. Just one, I wonder if you could talk a little bit about maybe the potential for combinations with like the bromodomains or the FGFR programs that we may get data on throughout the year. And then also on the IDO, some of the newer ones that are much, much earlier stage that popped up. Just maybe help us think about like how those assets compare. Do you think that there's reasonable similarity? Just kind of help us think about how like some of the newer assets may fit since you guys are the leader there. Thanks.

Reid Huber - *Incyte Corporation - Chief Scientific Officer*

Yes, thanks. This is Reid. So on your first question in terms of combinations with the early pipeline, as we spoke about a little bit last year at AACR, and we'll revisit this a little bit coming up again in April this year at the meeting, we sort of tried to construct a portfolio that has a pretty high combination coefficient. And that doesn't mean that that's the only development path that a molecule like the bromodomain inhibitor, for instance, could take, but it's certainly one that we want to explore early on in the development program, both as a way to broaden the opportunity space where we could take a mechanism like that but also to potentially increase the depth or breadth or durability of response.

So those are all the key tenets behind why we're interested in combinations and why molecules like the bromodomain inhibitor or the PIM inhibitor or honestly, the LSD1 inhibitor are particularly attractive as they sort of coalesce in our portfolio. On the IDO inhibitor front in terms of the competition, we're very pleased with the competitive environment we have right now, which is still relatively open. We have a molecule from NewLink Genetics that is partnered with Roche, and we've seen a little bit of data on that molecule, and I'm sure we'll see other IDO inhibitors in the future, but those are all going to be relatively early stage.

And I think we have a pretty wide competitive gap that we can leverage, especially as we work towards enrolling upwards of 600 patients in a more actionable Phase 2 program across 13 histologies. So hopefully, that competitive gap only increases, and it's of course very difficult for me to comment on any of the other IDO inhibitors, particularly those that have yet to be in the clinic or show any clinical data that I can speak to cogently.

Alethia Young - *Credit Suisse - Analyst*

Great. Thanks.

Operator

Our last question comes from Eric Schmidt with Cowen and Company.

Eric Schmidt - *Cowen and Company - Analyst*

Thanks for the quick follow-up. I guess this one's for Dave. I know you've been working for a while on trying to figure out ways to moderate Incyte's future tax rate. If there's any update on that or when we might get an update on that, it would be much appreciated.

Dave Gryska - *Incyte Corporation - CFO*

Hi, Eric. Thanks for the question. We'll give you an update toward the end of the year. I think there's another leg up that we're trying to work on with our infrastructure and our supply chain in Europe right now. And again, we're working on that in terms of trying to manage that all through an international location so by the end of the year, we'll be able to give you more color on that.

Eric Schmidt - *Cowen and Company - Analyst*

Thank you.

Operator

This concludes our question-and-answer session. I would like to turn the floor back to management for closing comments.

Herve Hoppenot - *Incyte Corporation - CEO*

Okay. Thank you for your time today and for your questions. And after all, it has been a very, very robust 2015, and you see now we are looking forward to a very busy and productive 2016. Thank you and goodbye.

Operator

Thank you. Ladies and gentlemen, this concludes today's conference. You may now disconnect your lines at this time. Thank you all for your participation.
