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INCY - Q4 2014 Incyte Corp Earnings Call

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PRESENTATION

Operator

Greetings and welcome to Incyte Corporation fourth-quarter and year-end 2014 earnings conference call.

(Operator Instructions)

As a reminder, this conference is being recorded. It is now my pleasure to introduce your host Michael Booth, Vice President of Investor Relations for Incyte. Thank you sir, you may begin.

Michael Booth - *Incyte Corporation - VP of IR*

Thank you, Kevin. Good morning, and welcome to Incyte's fourth-quarter and full-year 2014 results conference call.

Herve Hoppenot, our President and CEO, will begin with a few words summarizing the quarter, and Jim Daly, who leads to our commercial organization, will provide a commercial update on Jakafi, which is now FDA approved for patients who have intermediate or high-risk myelofibrosis and for patients who have polycythemia vera who have had an inadequate response or are intolerant of Hydroxyurea.

Rich Levy, who is in charge of Incyte's drug development activities, will update you on our clinical portfolio; and David Gryska, our CFO, will describe our fourth-quarter and full-year financial results and outline our financial guidance for 2015. Then we'll open up the call for Q&A, for which we'll be joined by Reid Huber, our Chief Scientific Officer.

Before beginning 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 the commercialization of Jakafi, our development plans for Jakafi and other indications and for other compounds in our pipeline, and our 2015 financial guidance.

These forward of the statements are subject to 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, 2014, and from time to time in our other SEC documents.

Herve?

Herve Hoppenot - *Incyte Corporation - President & CEO*

Thank you, Mike, and good morning, everyone.

Before we get into more of the details of Incyte's achievements in the last quarter and our expectations for this year, 2015, I wanted to take a short look back at what has been a very successful year, 2014.

Financially, the growth of our top-line continues to outpace both our R&D and SG&A expenses. In 2014, sales Jakafi grew over 50% in the US, and Novartis sales of Jakavi have grown over 70% in ex-US territories when compared to 2013.

We also recorded revenue of over $100 million from milestones in 2014, and ended the year with $600 million in cash. So this leaves us in a very strong financial position as we move into 2015.

We have also been very successful in attracting top talent to Incyte over the last 12 months, adding more than 100 positions across the company, and the vast majority of these in our R&D organization, managing our growing portfolio.

And speaking of our R&D portfolio, firstly our goal is to maintain and extend our leading position in JAK inhibition. And our recent FDA approval of Jakafi in PV is further evidence of that, as is the initiation of pivotal studies of Ruxolitinib in solid tumors. Our next-generation JAK1 selective inhibitors will give us further potential to extend our competitive advantage here.

The second piece is our IDO1 inhibitor, which provides us with a potentially exciting entrance into immuno-oncology, and we are moving forward quickly to recruit our combination studies with PD1, PDL1 inhibitors. Our global alliance with Agenus also gives us additional strategic flexibility within the immuno-oncology area.

The third piece is our targeted therapy portfolio. We have made a lot of progress in the development of our two PI3K Delta inhibitors, and we have recently disclosed two new compounds. An FGFR inhibitor and a BRD inhibitor that I expect to enter the clinic soon.

The fourth segment of our portfolio contains our two partnered compounds, Capmatinib with Novartis which continues to move forward quickly, the c-MET inhibitor; and Baricitinib with Lilly, which has recently reported positive top line results in the first of its phase III trials in RA.

So I will now pass to Jim to give some additional detail on the commercial performance in MF, and the launch of Jakafi in PV. Jim?

Jim Daly - *Incyte Corporation - EVP & Chief Commercial Officer*

Thank you, Herve, and good morning, everyone.

Our fourth-quarter net product sales of $106 million for Jakafi reflect continued strong growth in underlying demand in myelofibrosis, growing 46% over the same period last year. In terms of quarter over quarter growth, net sales grew 8%. Overall our fourth-quarter performance was

consistent with previous quarters. With a steady increase in new patients, an increase in the breadth and depth of prescribing, and a continued shift toward the use of lower dosage strengths.

For the full-year 2014, we recorded net Jakafi sales of $358 million, growing more than 50% over 2013.

Turning to 2015, we expect full-year net product sales to be the range of $525 million to $565 million, reflecting year-over-year growth between 47% and 58%. Our guidance assumes continued growth in MF sales as well as the contribution from our newly approved indication in PV.

On December 4, Jakafi was approved by the FDA for the treatment of patients with polycythemia vera, who have had an inadequate response to, or are intolerant of, Hydroxyurea. Jakafi is the first and only FDA approved treatment for these patients with uncontrolled PV.

We're still very early in the PV launch, but we can confirm that our initial impressions of launch progress are consistent with our pre-launch expectations. Firstly, there is substantial unmet need for PV patients who are not well-managed on hydroxyurea. Physicians acknowledge having these uncontrolled PV patients in their practices and are open to considering new and better treatment options. We continue to estimate an addressable population of approximately 25,000 patients in the US.

Secondly, as we've shared with you in the past, the urgency to identify specific patients and initiate a new treatment is less than in MF or in other more acute forms of cancer. As we expected, it will require time and education to realize the peak potential of Jakafi in PV.

Importantly and again as expected, the clinical profile of Jakafi as represented by the product labeling and the recent publication of the RESPONSE trial in the New England Journal of Medicine is being well received by physicians. This is evidenced by the rapid uptake of the 10 milligram, 28 day sample starter program for PV patients that we initiated after approval in December.

We look forward to providing of the additional feedback on the PV launch progress on future earnings calls.

With that, I'll turn it over to Rich to give us an update on the clinical portfolio.

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

Thanks, Jim.

I will begin with JAK inhibition. Starting with Ruxolitinib in solid tumors, the pivotal phase III studies, JANUS 1 and JANUS 2, in combination with Capecitabine in second line pancreatic cancer, continue to enroll patients and we expect top line results from these trials during 2016.

Similarly, the randomized phase II trials of Ruxolitinib in non-small cell lung cancer, breast cancer, and colorectal cancer are enrolling patients as planned, with results expected in 2016. We believe the JAK1 selective inhibition, sparing JAK2, may lead to equivalent efficacy but with less mylo-suppression relative to inhibiting both JAK1 and JAK2. Minimizing mylo-suppression may potentially enable the combination of JAK1 selective inhibitors with other, more mylo-suppressive therapies.

The proof of concept phase II trial of our lead JAK-1 inhibitor, 39110, in patients with EGFR wild type non-small cell lung cancer in combination with docetaxel is under way, as is the phase II trial 39110 in combination with erlotinib in patients with EGFR mutated non-small cell lung cancer.

Later this year, we intend to initiate a fully powered randomized, blinded, controlled study of 110 in combination with Gemzar and Abraxane in first-line pancreatic cancer. We expect data from 39110 in combination with our PI3K Delta inhibitor, 40093, in patients with B-lymphoid malignancies to present at ASCO this year. This proof of concept combination trial was based on internal research, which revealed significant synergy between JAK1 selective and PI3K Delta inhibition in models of lymphoma.

We have a second JAK1 selective inhibitor, 52793. This molecule is currently in a phase I dose escalation study, and is several fold more selective for JAK1 than 39110.

We plan to initiate both mono- and combination therapy trials with 52793, potentially in multiple myeloma. 52793, as the more JAK1 selective compound, was selected to be studied in myeloma as improvements in anemia is a therapeutic goal in this disease.

Moving to immuno-oncology. Recruitment into all four phase I/II studies of epacadostat, our IDO1 inhibitor, and the anti PD-1 or PD-L1 therapies from Merck, BMS, and AstraZeneca, and Genentech is progressing well. Once we determine the doses to be used in each combination, we expect enrollment in expansion cohorts to be quite rapid. If these trials generate positive proof of concept data, we would anticipate moving swiftly into potential registration studies.

In the targeted therapies segment of our portfolio, we have two of the PI3K Delta inhibitors in clinical development, and each of these compounds provides the potential to differentiate from the marketed PI3K Delta inhibitor, idelalisib on potency, PK, and safety. 50465, a highly selective PI3K Delta inhibitor, has now entered phase I development and 40093, our first Delta inhibitor is advancing with both monotherapy, as I mentioned earlier, combination proof of concept trials.

The discovery team at Incyte continues to create molecules with best in class potential. We recently disclosed two new candidates. An FGFR inhibitor, 54828, and a BRD inhibitor, 54329. Both of which are expected to enter the clinic very shortly.

The FGR family of receptor tyrosine kinases can act as oncogenic drivers in a number of tumor types. Most notably squamous cell non-small-cell lung cancer, gastric and bladder cancer, and glioblastoma.

Bromodomain containing proteins, or BRDs, play important roles in mediating gene transcription, most notably by facilitating the expression of oncogenes such as MYC, one of the most frequently disregulated oncogenes in all of human cancer.

Lastly, a quick update on our partner programs with Novartis and Lily. Novartis continues to make progress in the clinical development of Capmatinib our potent selective c-MET inhibitor, and with respect to Baricitinib, the rheumatoid arthritis phase III program being run by Lilly is ongoing. The BEACON phase III trial of Baracitinib in RA patients with inadequate response to TNF inhibitors met its primary endpoint, and during 2015, we look forward to seeing data from the additional phase III studies.

With that, I will now turn the call over to Dave to give us the financial highlights of the quarter and further outline our financial guidance for 2015.

David Gryska - *Incyte Corporation - CFO*

Thanks Rich, and good morning, everybody.

I will start today by discussing Q4 results, and then review our 2015 guidance.

We recorded $106 million of fourth-quarter net product revenues, and $15 million in Jakavi royalties from Novartis for sales outside of the United States. Our cost of product revenues of $2 million for the fourth quarter reflects the payments of royalties to Novartis on Jakafi sales.

Both R&D and SG&A in the fourth quarter and the full year were within our expectations. For the full-year 2014, R&D expense was $348 million, and SG&A was $166 million. From a cash perspective, we ended the year with $600 million, which includes a $60 million milestone payment that we received from Novartis in Q4.

Now, moving to 2015 guidance. As Jim mentioned, our net product revenue from Jakafi is expected to be the range of $525 million to $565 million, reflecting continued growth in underlying demand in MF and including revenue from the launch of PV. We do not intend to break out Jakafi sales by indication, either historically or in guidance. But, we do not intend to provide a more comprehensive update on the PV launch after six months, at our Q2 earnings call.

Looking now at contract revenue expectations for 2015, we expect to recognize $13 million in contract revenue from the continued amortization of the upfront payment we received under the Lily collaboration agreement. We do not anticipate earning any milestones under the collaboration agreement with Lily during 2015.

Under the Novartis collaboration agreement, we expect to earn up to $45 million in milestone revenue during 2015. Included in this figure is $25 million we earned with the positive opinion issued by CHMP on Jakavi in PV in late January.

Novartis continues the successful global rollout of Jakavi ex-US, and reported over 70% sales growth in 2014 versus the previous year. We look forward to anticipated continued growth of our royalty receipts from Jakavi.

We expect that the cost of product revenue as a percent of net Jakafi sales in 2015 will be between 4% and 5%, which includes our tiered low single digit royalty payments to Novartis on net sales of Jakafi in the United States.

In 2015, we expect R&D expense to be in the range of $450 million to $500 million, this includes non-cash stock compensation expense of approximately $40 million to $45 million. The increased to R&D expense over 2014 includes the investments we're making across the clinical portfolio, as well as upfront and some ongoing costs related to the Agenus alliance included in this amount, is a front one-time payment to Agenus of $25 million.

We expect SG&A expense to be in the range from $180 million to $200 million for full-year 2015. This includes non-cash stock compensation of $30 million-$35 million. This moderate increase in SG&A expenses is primarily a result of additional programs to support ongoing commercialization of Jakafi in MF and PV.

We expect our interest expense this year to be $49 million, including a non-cash charge of $36 million, related primarily to the amortization of the discount on our convertible senior notes. So as we enter 2015, the company has never been in a stronger financial position than it is today to fund our expanding pipeline.

Finally, I would like to thank Pam Murphy, our VP of IR and Corporate Communications, for all that she has done for Incyte over the past 12 years. Pam has announced her intention to retire at the end of April this year, and we wish of the best of luck in her retirement. As part of the planned transition within our IR group, we have promoted Mike Booth to VP Investor Relations, and he will now be the day-to-day contact person with the Street.

Operator, that concludes our formal remarks. Please open up the call for Q&A.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Eric Schmidt, Cowen and Company.

Eric Schmidt - *Cowen and Company - Analyst*

Pam, we're going to miss you very much, but congrats to Mike and, for that matter, Dave on the new positions.

Question maybe for Jim on Jakafi and the quarter over quarter growth you saw. You mentioned that was 8%. It's down a little bit, even last quarter I think you had organic growth of about 11%. Was there any inventory or other fluctuations, or did you just not pick up anything yet from the PV launch? How do you reconcile?

Jim Daly - *Incyte Corporation - EVP & Chief Commercial Officer*

Sure, Eric.

If you look at the total demand for the quarter, we grew 7% with dispensed bottles and we had 5% on price, for again total demand of 12%. Now, that was partially offset by inventory. If you remember, we finished the third quarter with a $4 million inventory build due to price speculation in advance of the October 1 price increase.

So, in the fourth quarter we essentially burned off that $4 million, and we did not see an inventory build at the end of the fourth quarter. So as a result, we finished the fourth quarter at the low-end -- at the very low end of our normal range of 3 to 3 and a half weeks. With respect to PV contribution, we really expected a minimal contribution from PV in December, and that's what we saw.

Eric Schmidt - *Cowen and Company - Analyst*

Thanks a lot.

Operator

Ian Somaiya, Nomura Securities.

Ian Somaiya - *Nomura Securities - Analyst*

Thanks, and Pam, again, we are going to really miss you. Mike will do an adequate job, but you will always be our favorite.

Just maybe a follow-up question to Eric's, and Eric focused on 4Q, I was really curious about 2015 guidance. Again, you are basically pointing to numbers that are higher than what most of us were looking for. I was curious if you were to just help us think about what the contribution is from myelofibrosis, continued contribution from there versus the incremental pick up from PV.

Just keep in mind that historically you have said to expect a slow, steady launch in PV.

Jim Daly - *Incyte Corporation - EVP & Chief Commercial Officer*

Ian, I think the answer is almost contained within your question. Again, the low end of the guidance still reflects a 47% year-over-year growth. It does reflect the uncertainties that we have with the ramp of PV.

But it does assume that we continue to grow MF, and that we have a meaningful contribution from PV. Clearly, the high end of the guidance with a 58% growth assumes a faster ramp from PV largely, and a consistent, steady growth in MF.

At this point we really can't add much more quantitatively than that.

Ian Somaiya - *Nomura Securities - Analyst*

Okay. Just one other point I was hoping to clarify was R&D guidance for 2015. I was hoping that, or at least thinking that, with the baricitinib trials concluding in 2015 that the R&D would start to come in or come down. Is that just something we should expect to occur in 2016?

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

Yes. So baricitinib -- our contribution of baricitinib will be less this year than last year, but not a whole lot less, but there will be a significant drop-off in the baricitinib support in 2016.

And then the overall growth represents new programs that are getting more advanced phase 3 programs and late phase 2 programs. So the overall is an increase from last year.

Ian Somaiya - *Nomura Securities - Analyst*

Okay, thank you very much.

Operator

Steve Byrne, BofA Merrill Lynch.

Steve Byrne - *BofA Merrill Lynch - Analyst*

This one is probably directed at Reid. Based on your understanding of the effects of JAK-STAT inhibition on the tumor environment, do you see the anti-tumor effects as being primarily a direct impact on the tumor versus enabling other targeted inside-of-toxic therapies being more effective? Or the third bucket being restoring that patient's immune system? Is it all of the above, or one more than another based on your understanding of the mechanism of action?

Reid Huber - *Incyte Corporation - Chief Scientific Officer*

Thanks for the question, Steve.

It's a good one, and as you can appreciate, a difficult one to tease out in the clinic, at least at the stage of development where we are right now. As you pointed out, there are data to support the role for JAK inhibition, both in a cell intrinsic manner, in terms of supporting the direct proliferation and growth of the tumor.

There is certainly data that supports the role for JAK inhibition in attenuating the effect of targeted or cytotoxic chemotherapy, and that is certainly an important mechanism. And, as we'll talk about more, Herve outlined at JPMorgan and we'll present more at AACR this year in April, there is an emerging data set including data derived from our own group here, that JAK-STAT inhibition can shape the inter-tumoral micro environment.

Exactly how those three aspects of the biology play out in any one histologic setting is difficult to say. I think what is important is that they all support the potential for JAK inhibition in a number of solid tumors settings. They help contribute to our confidence in continuing to explore ruxolitinib in solid tumors, and very much substantiate our interest in JAK1 selective inhibition in the solid tumor landscape as well.

Steve Byrne - *BofA Merrill Lynch - Analyst*

Just regarding the last bucket, or last comment. Would you see potential for it to be used in combination with other immune therapies that are either driving a stronger T cell response or the checkpoint inhibitors? Do see much opportunity for synergy in those combinations?

Reid Huber - *Incyte Corporation - Chief Scientific Officer*

We think that there is a potential there. Those will be data that we will describe a little bit more in detail at AACR. Exactly what the development program looks like for JAK1, and how those specific combinations evolve over the course of the year is still up for discussion.

But I would say that it is something that we are very interested in thinking through carefully.

Steve Byrne - *BofA Merrill Lynch - Analyst*

Okay, and just one for Jim. How would you view the outlook in this 25,000 patient targeted market in PV in terms of what you think is a realistic peak penetration?

Jim Daly - *Incyte Corporation - EVP & Chief Commercial Officer*

I think our goal is always to have a 51% share of the addressable population. I think we would be disappointed if, after extensive commitment of educational resources, we couldn't get half of the patients who need this product on it. Now, the question is how long that's going to take.

As we've said, it's going to take time, and it's going to take education in order to increase the sense of urgency for patients -- to identify these patients, and to identify them as appropriate candidates for Jakafi.

Steve Byrne - *BofA Merrill Lynch - Analyst*

Thank you.

Operator

Matt Roden, from UBS.

Andrew Peters - *UBS - Analyst*

This is actually Andrew Peters, in for Matt. I wanted to add my congratulations, and say that we will miss Pam as well.

First question for Jim I guess. You mentioned the kind of an uncontrolled PV patients currently in practice. I just wanted to understand, I guess a little bit more, on the dynamics there, and why is there a little bit less urgency to get those patients treated? And why you would not expect a bolus of the need-to-treat patients?

And then, the second one for Rich. Just looking at the Jakafi solid tumor trials that are ongoing. Given the kind of unfortunate short outcomes for the colorectal patients, just want to understand if there's any potential for earlier than expected readouts from the data? Maybe by the end of 2015? Just from a timing perspective.

Thanks.

Jim Daly - *Incyte Corporation - EVP & Chief Commercial Officer*

I will take the uncontrolled PV question first. So question, why wouldn't you expect to see a bolus of patients or a more rapid initial uptake? I think there's several parts to the answer.

The first is just the nature of the disease. It is viewed as a chronic, less severe disease, with less of an urgent need to intervene on the part of physicians. Number two, I think there's still a lot of need for education in terms of the disease burden, and specifically which patients are at greatest risk for complications of uncontrolled PV.

And then finally, the patients who are most acute, most obvious, are already on the drug for PV due to commercial availability. That's why we did not see of bolus of patients going on the product at the time of approval. Unlike MF, where you simply did not have commercial availability.

Now, if you think about why it takes time for physicians to work through that progression, our reps have to go in and it takes multiple calls for them to educate physicians on the data, themselves, on the response trial. Then they have to translate that to the indication statement, which is patients who are have an inadequate response to or are intolerant of -- That's a relatively abstract indication, and our reps have to work closely with physicians to translate that into specific patients. And they're doing that right now.

But again, that takes time, and the good news is that the challenges in the PV marketplace are all addressable. And, we're making good progress in addressing each of them.

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

This is Rich. On your question about the colorectal study. We certainly take into account the relatively short survival in these last line patients when we came up with our original estimates of data in 2016.

The study is enrolling well, but that remains the rate limiting step to when we will have enough patients, and enough, unfortunately, deaths to analyze the study. So I would still guide to data in 2016, and think that data in 2015 is almost impossible.

Andrew Peters - *UBS - Analyst*

Great, thanks, and congratulations on all the progress.

Operator

Salveen Richter, SunTrust Robinson Humphrey

Salveen Richter - *SunTrust Robinson Humphrey - Analyst*

Pam, we will miss you, and Mike, congrats.

Two pipeline questions. Firstly, how does your second PI3K Delta differ from the first? Are we looking for combinations with JAK molecules and with IDO here?

Secondly on baricitinib, any details on the diabetic nephropathy data? When we might see that, and then how we should think about the alopecia opportunity?

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

Yes. So, first starting with the Delta inhibitors. The second of the Delta inhibitors, I said in my prepared remarks was more potent, also has absolutely no liver toxicity in preclinical models, and with 40093, at the doses we're studying, it's clean. But it limits how high you might be able to go.

So, 50465 has the potential to go to even higher levels of inhibition. We don't know whether that would be clinically relevant or not.

Secondly, we do intend to look at combinations with JAK1's -- with the combination. But at this point in time, we're still in the dose finding portion as monotherapy, and the combinations will start relatively soon.

And with respect to the Lilly diabetic nephropathy data, we expected data to be in the public domain in the first half of the year, including presentation at a scientific meeting, if accepted -- if the abstracts that are going to be submitted are accepted to the intended meetings.

Salveen Richter - *SunTrust Robinson Humphrey - Analyst*

(inaudible - multiple speakers)

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

Can you repeat that question?

Salveen Richter - *SunTrust Robinson Humphrey - Analyst*

How should we think about alopecia and what you might do there, going forward?

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

Yes. So as was reported publicly, the oral ruxolitinib, which was used by investigators at Columbia University showed very dramatic responses in terms of with alopecia, and we have the exclusive rights to our topical ruxolitinib product. And we are planning to start a study later this year in patients with alopecia areata to determine whether a topical formulation can be as or nearly as effective as the oral formulation seem to be.

So, we might be able to provide greater details on the specifics of that study at the time when that is posted on clinicaltrials.gov. And, would hope that there would be data also next year.

Salveen Richter - *SunTrust Robinson Humphrey - Analyst*

Okay thank you.

Operator

Brian Abrahams, Wells Fargo Securities

Brian Abrahams - *Wells Fargo Securities, LLC - Analyst*

My congratulations to Pam, as well, on your retirement, and to Mike on the new position.

There was an interesting article published in the Journal yesterday about the order of JAK2 and TET2 mutations determining clinical manifestations and sensitivity to ruxolitinib. So, I am just wondering if this finding might have any practical, commercial implications in terms of what it might mean? Could this get physicians to intervene earlier in the course of the disease?

Separately on the earlier stage pipeline, wondering if you could talk a little bit about the FGFR inhibitor, and what differentiates that from some of the other small molecules in development? Perhaps in terms of its selectivity profile and therapeutic window?

Reid Huber - *Incyte Corporation - Chief Scientific Officer*

Sure. I'll take the FGFR question first, and then we will discuss briefly the first question you had.

So, for FGFR, it is a competitive space. We recognize that, and the field has evolved quite a lot over the last few years, now with a number of VEGFR sparing FGFR selective inhibitors, and those are showing a very interesting clinical profile, and they have shown the first objective responses in patients with FGFR-mutated solid tumors. Those have been seen in squamous cell lung, bladder cancer, and even in glioblastoma.

As we look at the programs that are ahead of us, and we study those molecules carefully. We think that the best in class molecule has not yet been made, and our effort internally over the last year and a half was to try to discover and develop that compound. So we like the pre-clinical profile of 54828, both in terms of potency, selectivity, PK, and safety. What the challenge is now on the development side is to try to leverage the learnings from the competitors in the space to make a much more efficient, expeditious phase 1 proof of concept clinical program.

We have a companion diagnostic effort that is well underway in parallel with this program, and if the drug lives up to its pre-clinical billing, we are going to look to try to move that molecule and that companion diagnostic forward as rapidly as we can.

In terms of the paper you mentioned, I'm not aware of the paper, so I don't want to comment on it. I may want to see if Jim wants to say anything about earlier use in MF as to how physicians get comfortable with the drug, but I certainly don't want to comment on a publication that I have not read.

Jim Daly - *Incyte Corporation - EVP & Chief Commercial Officer*

The only Journal I read yesterday was the Wall Street Journal, and not the New England Journal. (laughter)

So, I don't think I can make an informed comment, either.

Brian Abrahams - *Wells Fargo Securities, LLC - Analyst*

Fair enough. Maybe just one quick follow up for Jim. I think in response to one of the earlier questions, you sort of suggested that the patients with PV at greatest need may already have been on Jakafi, given that it was commercially available.

Can you give us any sense of the proportion of patients on Jakafi who had PV prior to the launch? Just so that maybe we can true up a little bit better how to think about what the existing unmet need that remains in the sickest patients, and how to think about the ramp going forward.

Jim Daly - *Incyte Corporation - EVP & Chief Commercial Officer*

Sure Brian.

We don't want to get into specific numbers, but what I can tell you is that we did not see any increase in the non-MF usage leading up to the approval.

Now, there's two ways that a patient -- that a PV patient could be of Jakafi. One is if the physician wrote for the product, coded the patient as PV, and the patient received it as a non-MF reimbursement. The other is that the patient was quite frankly in a continuum between PV and MF, and the patient was coded as MF and received the project.

So, it's very hard to delineate with precision how much PV business did we have prior to the formal approval. But, again we did not see any increase in non-MF use, as based on coding, prior to the approval.

Brian Abrahams - *Wells Fargo Securities, LLC - Analyst*

That's very helpful. Thanks again.

Operator

Cory Kasimov, JPMorgan

Unidentified Speaker - - *Analyst*

This is Whitney, on for Cory, and I would like to add my congratulations to Pam as well. You will be missed. Question that might go to earlier one. But earlier this year, you guys talked about synergies between JAK inhibition and IDO specifically.

Any color you can give there in terms of how we should be thinking about the path forward there? Is that kind of the AACR data that we should be looking for for more clarity?

Reid Huber - *Incyte Corporation - Chief Scientific Officer*

That's exactly right. We will be presenting the data at AACR and have a pretty full discussion of the potential impact of the data on our own clinical development efforts there. Little bit too early to say exactly what the next steps are, but I would say that that combination and potentially other combinations are certainly on the table to consider.

Unidentified Speaker - - *Analyst*

Great, and not sure you will comment, but I will ask. Can you give any color in terms of where you are in terms of dose escalation in the IDO Pembro study, with an eye towards when the expansion phase could get going?

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

Because of our established relationships with each of these companies, who don't want company number two to get information from company number one on where the doses are, we really can't comment. But, things are going very well.

The Merck study has been a underway since last summer. Basically, the design is that you enroll three patients, you wait two months. If everything goes well, move up to the next. If you need to enroll another cohort because of any event, you would do that again. So things are progressing well, but I can't be quantitative as to where the data are.

But we are optimistic that we will be into the expansion phases -- well into the expansion phases this year. Not only with the Merck compound, but most likely with others as well.

Unidentified Speaker - - *Analyst*

Great, thanks for taking the questions.

Operator

Josh Schimmer, Piper Jaffray

Josh Schimmer - *Piper Jaffray & Co. - Analyst*

My congrats to Pam and Mike, and also my congrats to the topical JAK inhibitor.

A quick question for Reid, actually. There are a myriad of targets in oncology to choose from. Maybe you can help us understand the theme that links the clinical stage programs with BRD, PI3 Kinase, FGFR3, and just help us understand the prioritization process and why this is the right fit for an Incyte portfolio?

Thanks.

Reid Huber - *Incyte Corporation - Chief Scientific Officer*

Thanks, Josh. Good question.

I think one of the luxuries that we have as a discovery organization now that is different, let's say, from the situation seven or eight years ago, is that we have a growing pipeline now that we can consider as sort of tools in the toolbox, and look differently at new potential programs as to how they may fit in synergistic ways with other agents in our pipeline.

The Delta program, as you know, was really advanced in very large part because of that reason. And synergies that we have observed with JAK1 and potentials that we thought we could bring to bear in terms of combination regimens in lymphoid disease. It's a similar line of thinking as we look at programs like the bromodomain inhibitor program, which is a very novel mechanism but one has shown a very broad activity in hemolignancies, and even has the potential in some solid tumor settings. So, there's a lot more we don't know about BRD inhibition than we do know, but the internal data shows quite nicely synergies with JAK1 inhibition, even with PI3K Delta inhibition, and some of those data will be presented at AACR.

So that's one underlying theme of the early discovery portfolio, is trying to leverage in clever ways the existing clinical portfolio to come up with novel combinations and the belief that those sorts of regimens will put us in a much more advantageous competitive position going forward. A program like FGFR, while it's -- sort of doesn't follow that same exact rule in terms of combinations, although it could, really gives us an accelerated path to approval.

Those kind of opportunities, we'll always look very careful at, and when we can be opportunistic to have a very, very rapid phase 1 to proof of concept to registration program, those kinds of efforts where you have a targeted population, as you can appreciate, rise up to the top of the list pretty quickly.

Josh Schimmer - *Piper Jaffray & Co. - Analyst*

Okay thank you.

Operator

(Operator Instructions)

Thomas Wei, Jefferies.

Thomas Wei - *Jefferies & Company - Analyst*

Thanks. Just wanted to get a little bit more detail on how the original IDO / IPI trial has matured, and what exactly we should be expecting to see at ASCO in terms of patients and doses, and then also, just on the PV launch, initially.

I know you are still early in it and there isn't much to share. But what have you -- have you learned anything from some of the early feedback here that is different? More positive, negative? The higher end of the guidance, here, may be a signal that you have seen some things that they have surprised you positively in this market? Any help would be great.

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

I'll answer your first question. With respect to the IDO-IPI, remember that this is not a combination that we are pursuing at this time. We do plan to give an update on the data. In collaboration with the investigators, it was decided that we would have a more robust data set for presentation at ESMO rather than ASCO, so that is the current plan.

But in terms of what to expect, we have somewhere close to 40 patients that are now included in that data set, where it was a little bit less than 20, I think, at the ASCO presentation in 2014. So, not only will you have a larger number of patients, but you also have longer-term follow-up. Not only on the patients that were talked about last year, but even with waiting for the data for ESMO, longer-term follow-up on the patients who have been enrolled in the past year.

Jim Daly - *Incyte Corporation - EVP & Chief Commercial Officer*

And Thomas, in terms of PV, it is extremely early, so I think the only thing that we can share with you are preliminary impressions. But I'll give you a few impressions. First one is, clearly, the patients are there, having been out with the representatives.

These patients, who are poorly managed on Hydrea, they're definitely there. Now, it requires multiple representative visits in order to identify them. As we talked about in the past, docs tend to be lumpers. When you ask them about their PV patients, they tend to generalize and say they're doing fine.

It is not until you really focus on the minority of patients, but it's an important minority, who are either experiencing tolerability issues with Hydrea - with Hematacrit above 45. It is not until you are able to focus on those patients that you really get traction, and that takes multiple visits.

From an access and reimbursement perspective, I think things are going according to plan. Prior authorizations are consistent with the label, and patient out-of-pocket costs have been reasonable and very manageable. But again it's very early. I think it's too early to call victory on access and reimbursement.

We have been pleasantly surprised by the uptake of samples. I think there's a good rationale to use samples in PV. It's a symptomatic disease with a measurable treatment target. The benefits of Jakafi manifest pretty early. So it really is an ideal situation to use samples to create risk-free trial, generate positive experience, and create an autocatalytic process.

So sample uptake has been robust. Now it's going to take time to see how that translates into patients paying drug. How long it takes, and what type of pull through we get. But the initial sample uptake has been positive.

So as we look at all of the puts and takes, I would say that we remained pretty balanced and realistic in our view of the commercial potential in PV. But again, our conviction is high that it represents a major opportunity to improve care for patients and a major opportunity for our business.

Operator

Ian Somaiya, Nomura Securities.

Ian Somaiya - *Nomura Securities - Analyst*

Thanks for the follow-up. Just wanted to think about a confirmed timing for the baricitinib diabetic nephropathy trial. According to clintrials.gov that trial finished in the fourth quarter?

Just a question for Reid, just was wondering if you have any programs or any development activities related to CDK-46 inhibitors?

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

The diabetic study, as I said, I think Lilly intends to submit the data to a scientific meeting, and one possibility for example would be the ADA meetings in June, but they are not willing to comment on exactly what the likelihood of that is, in terms of being presented.

I think that's when the data will come out. It's not something that I think they feel like they need to top line immediately, as was the case with their phase 3 registration studies in RA.

Reid Huber - *Incyte Corporation - Chief Scientific Officer*

With respect to the CDK-46, it's an interesting mechanism, but it's not one that we're pursuing internally. Although, we certainly keep our eyes on it, and it may be an important point of combination with some of the agents in the emerging pipeline.

Ian Somaiya - *Nomura Securities - Analyst*

Thank you.

Operator

Liisa Bayko, JMP Securities.

Liisa Bayko - *JMP Securities - Analyst*

Just to ask a little bit more about the alopecia, do you think this is something specific to ruxolitinib? Is it JAK1-2 phenomenon? The results in a couple of people look pretty spectacular. What is driving this? Have you seen that as a kind of side effect benefit for other patients in MF? Trying to understand the magnitude.

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

So, we believe that JAK1's would probably work as well as JAK1-2's, but we don't have models, and we have not done the experiments to be able to prove that. But we do know that ruxolitinib, as a JAK1-2, works incredibly well as an oral.

And we believe that we can get drug into the hair follicle topically, and therefore it may have benefit there as well. But in terms of what may emerge over the years, as other potential therapies and what their profiles might be, I cannot really say.

Liisa Bayko - *JMP Securities - Analyst*

The results that we are seeing, what dose where they using there?

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

I think they were generally starting at around 20 mg BID. But, I don't remember whether they said that those patients needed any dose adjustments or they just stayed at 20 mg.

But, that does not mean that a dose of 5 mg or 10 mg or 15 mg -- And I would suspect 5 mg is going to be less effective, but for most things we see with ruxolitinib, 10 mg BID is a very good dose. And may very well have worked similarly at lower doses as well, but they just don't have that data either.

Liisa Bayko - *JMP Securities - Analyst*

And your vision for the topical. Would that be like a cream, or some sort of solution? Just trying to understand.

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

The only formulation we have developed is the cream. If the proof of concept study in alopecia is positive, then, either us alone or us with a partner or potential licensee -- and all of those things are possible, might then decide to develop other formulations that for the long-term may be a better option for some people in certain circumstances.

But, the cream is a very nice formulation and can certainly not only be used to do the study, but we think could be a successful commercial product on its own, should the results be positive

Liisa Bayko - *JMP Securities - Analyst*

And is there any anecdotal evidence? Just in the commercial setting, where you have had obviously a lot of patients with MF and PV on drug?

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

I'm not aware of that, per se. It may be and we were never told. But I think -- if I remember correctly, I think that tofacitinib, which is the Pfizer drug, might have had an on label use of the drug in a patient that happened to also have alopecia, and that might have been what led to the clinical study at Columbia.

But, I also think that the Columbia group is very focused on the biology and believed that JAK inhibition should work, and that was not based on anecdotal report, but based on the science and then proven in the clinic. I don't know what their plans are to potentially give any updates on the clinical data that was reported, I think, in Nature Medicine last year.

Liisa Bayko - *JMP Securities - Analyst*

Okay, fair enough. Enough on that. For FGFR, have you said which R you are targeting?

Reid Huber - *Incyte Corporation - Chief Scientific Officer*

I think we have, Liisa. It is FTFR1, -2, and -3.

Liisa Bayko - *JMP Securities - Analyst*

Okay. And then, you said there was a PV -- some off label usage that's been going on for a while. Can you maybe characterize them in some way? Like, how many patients or percentage-wise to get a sense of that?

Jim Daly - *Incyte Corporation - EVP & Chief Commercial Officer*

I think it would be false precision. We really don't want to get into a specific quantitative assessment of that. It has been relatively small portion of our overall business. Again, we have not seen increase prior to the approval.

Liisa Bayko - *JMP Securities - Analyst*

Okay, and then final question. You kind of commented that you would move swiftly forward with IDO if some of these combinations look promising. Could that be a 2015 event, or is that a 2016 event? That's my last question, thank you.

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

You mean in terms of the data with IDO in combination with the PD-1's or PD-L1's?

Liisa Bayko - *JMP Securities - Analyst*

Exactly. Would that moving forward mean next year?

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

We still think that the data is most likely to come out in 2016. For the data to be clear enough to talk about in 2015, things would need to move very rapidly and the results in a small number of patients would need to be very clear.

So, nothing is impossible. But, I think the expectation should be 2016 data presentation of IDO information.

Liisa Bayko - *JMP Securities - Analyst*

Okay, thanks, and congrats to Mike and Pam.

Operator

Thank you. We have reached the end of our question-and-answer session. I would like to turn the floor back over to Mr. Hoppenot for any further or closing comments.

Herve Hoppenot - *Incyte Corporation - President & CEO*

Thank you all for your time today, for your questions. As we discussed with you, we are looking forward to a series of important and exciting value drivers over the next year.

And with that, I thank you again for your time, and look forward to talking to you again at our first quarter conference call in April and at AACR. Thank you.

Operator

Thank you. That does conclude today's teleconference.

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