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INCY - Q2 2014 Incyte Corp Earnings Call

EVENT DATE/TIME: JULY 31, 2014 / 12:30PM GMT

OVERVIEW:

INCY reported 2Q14 results.

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PRESENTATION

Operator

Greetings. And welcome to the Incyte Corporation second-quarter 2014 earnings call.

At this time, all participants are in listen only mode. A question and answer session will follow a formal presentation.

(Operator Instructions)

As a reminder, this conference is being recorded.

It's my pleasure to introduce your host, Pamela Murphy, Vice President Investor Relations & Communications. Ms. Murphy, please go ahead.

Pamela Murphy - *Incyte Corporation - VP of IR and Communications*

Good morning and welcome to Incyte's second-quarter 2014 conference call.

On the call today are Herve Hoppenot, President & CEO; Jim Daly, Chief Commercial Officer; Dave Hastings, Chief Financial Officer; Rich Levy, Chief Medical Officer and Head of Drug Development; and Reid Huber, Chief Scientific Officer.

Herve will begin with a brief overview of the quarter, Jim will follow with an update on Jakafi, and Rich will highlight progress made across our development portfolio. Dave will then describe our second-quarter financial results, after which we'll open up the call for Q&A.

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 expectations for net product revenue. These forward-looking statements are subject to a number of risks and uncertainties that may cause our actual results to differ materially, including those described in our 10-Q for the quarter ended March 31, 2014, and, from time to time, in our SEC documents.

Herve?

Herve Hoppenot - *Incyte Corp - President & CEO*

Thank you, Pam, and good morning, everyone. Thank you for joining this call.

Let me begin by stating how pleased I am by our great progress and commercial momentum with Jakafi in MF, as well as the rapid regulatory and clinical advances that Incyte is making across our development pipeline.

Obviously, you know, the field of oncology is evolving at a very high speed, and we are in the position, in the central position, in the transformation of cancer treatment, of the treatment of cancer patients.

So first commercially, sales of Jakafi continue to grow, reaching $84 million in the Q2. And as Jim will highlight today, we have raised our full year net product guidance from $315 million to $335 million to a range of between $330 million and $340 million.

As announced earlier this week, the FDA has approved the inclusion of updated safety and dosing information and other survivor data into the Jakafi label. So regarding PV, while the RELIEF study did not meet its primary endpoint, the sNDA has been submitted based on the pivotal data from RESPONSE, and we are confident that the results of RELIEF are not required for the approval, and we continue to believe that Jakafi has the potential to be an important new treatment for patients with uncontrolled PV.

We are implementing our strategy development plan. In the area of onco-inflammation, we have initiated two Phase III studies for ruxolitinib in pancreatic cancer, as well as three Phase II studies of ruxolitinib in other solid tumors.

Regarding immuno-oncology, we have now signed four clinical trial agreements for our IDO inhibitor, the most recent of which, with Genentech, was announced yesterday. And we have already initiated the clinical trial of '24360 in combination with Merck's anti-PD-1 immunotherapy, pembrolizumab.

In addition, our partners continue to move our products forward. The royalties we received from Novartis on ex-U. S. sales of Jakavi rose by over 100% in Q2 2014 over last year. And in addition, Jakavi has recently been approved in Japan, triggering the payment of a $25 million milestone to Incyte.

We expect Lilly to see results from the Phase III trial of baricitinib, our second Jak1 Jak2 inhibitor, which is in development for rheumatoid arthritis, beginning later this year and into 2015.

Now it's back to Jim who will provide more detail around our commercial accomplishments with Jakafi.

Jim Daly - *Incyte Corporation - Chief Commercial Officer*

Thank you, Herve, and good morning, everyone.

Our second-quarter net product sales of $84 million for Jakafi reflect continued strong underlying growth and underlying demand in intermediate and high risk myelofibrosis. Year-over-year net sales grew 55%, and quarter-over-quarter sales grew 21% with the following components of change relative to the prior quarter.

Underlying demand, as measured by bottles dispensed to patients, grew by 12%. Net price increased 8%, driven by both the price increase on April 1, and the seasonal improvement in gross to net. Inventory increased by 1% and inventory in the channel remains at the low end of the normal range of 3 to 3.5 weeks.

As a result of the first half-year performance trends, we've increased our 2014 full-year net product revenue guidance from the previous range of $315 million to $335 million to an updated range of $330 million to $340 million. Our Jakafi net sales guidance assumes no meaningful contribution of revenues in 2014 from a potential FDA approved indication in PV. We believe the increase in underlying demand in the second quarter reflects the continued effective execution of our commercial strategy to grow Jakafi in intermediate or high risk MF.

Expansion of our field force earlier this year has led to a significant increase in promotional activity and educational programs. The depth and breadth of prescribing continues to increase. There's an improved understanding of Jakafi efficacy regardless of JAK2 V617F mutation status, as well as the importance of individualized dosing.

And finally, the overall reimbursement environment for Jakafi continues to be favorable. The vast majority of payers manage Jakafi consistent with the label. Physicians are able to successfully manage most prior-authorizations that exist, and the majority of patients are able to afford their out-of-pocket costs.

We continue to see MF as a source of sustainable long-term growth for Jakafi. With an addressable population of at least 15,000 patients with intermediate to high-risk MF, we have less than one-third of these patients currently on Jakafi. While nearly 70% of target physicians have prescribed Jakafi for at least one MF patient, these physicians typically have additional MF patients in their practice who are diagnosed and are appropriate candidates for treatment with Jakafi.

These watch-and-wait patients are generally considered to be stable based upon blood counts, but in reality are experiencing a debilitating and worsening symptom burden that corresponds to the progression of the underlying disease. The primary focus of our commercial strategy today is on earlier treatment with Jakafi, as the question for most physicians have is not if Jakafi should be used, but when it should be used in the course of the disease. Our educational efforts are directed at highlighting and reinforcing the benefits of earlier treatment with Jakafi, versus waiting for a decline in blood counts as a trigger to initiate treatment.

Last week's FDA approval of the Jakafi label update, which contains the Kaplan-Meier survival curves, tables providing the probabilities of survival at one, two, and three years, from COMFORT- I and COMFORT-II, and expanded safety and dosing information, all meaningfully adds to the totality of the data available for Jakafi and supports our discussions about when to appropriately begin treatment with Jakafi.

Turning now to our next new indication for Jakafi, we believe the unmet need in polycythemia vera is clear, that it represents a major commercial opportunity, and that PV should make a substantial contribution in Jakafi sales in 2015 and beyond. Market research indicates that the primary treatment goal in PV is the prevention of thrombotic events through consistent and durable control of hematocrit. Secondary goals include symptom improvement, spleen volume reduction, and controlling leukocyte and platelet counts.

Based upon claims data, there are at least 100,000 patients in the US diagnosed and treated for PV. Two large chart audits that we've conducted, as well as independent publications, support that about one in four, or 25,000 patients in the US, have inadequate response to, or are intolerant of, HU, as indicated by a lack of consistent hematocrit control. These 25,000 patients with hematocrit consistently above 45% have uncontrolled PV, and represent the unmet need and the addressable population for Jakafi.

Based upon the results of the RESPONSE trial, we're confident in the ability of Jakafi to deliver consistent and durable hematocrit control that is superior to best available therapy. We should know in early August whether we have a priority or standard FDA review, and we will be fully prepared to launch Jakafi as the first and only FDA approved treatment for PV as early as December of this year.

As we look at the PV market compared to MF, the addressable patient population is substantially larger. Additionally, the broad base of positive experience -- positive physician experience - with Jakafi in MF, should help uptake in PV. Also, relative to MF, we believe the PV launch will be more straightforward in terms of diagnosis, mutational status, and dosing. 95% of PV patients have the Jak2 V617F mutation, and whereas a drop in hematocrit is undesired in MF, it is actually a treatment benefit in PV. Finally, based upon age and health status, we would expect a longer duration of treatment in PV than in MF.

Conversely, the urgency to treat in PV maybe less than in MF, and we expect there to be significant educational requirements during the launch phase, leading to a more gradual ramp in sales, with less of a bolus effect than we saw in the MF launch.

That said, we remain confident that MF and PV combined represent a $1 billion opportunity for Jakafi in the US. We've always said that MPNs are just the beginning. We have a deep pipeline of novel programs that represent an exceptional opportunity to make a difference for patients.

To discuss this in more detail, I'll turn it over to Rich.

Rich Levy - *Incyte Corporation - Chief Medical Officer and Head of Drug Development*

Thanks, Jim and good morning everyone.

As Herve mentioned in his opening remarks, the development team here at Incyte has made rapid progress across the portfolio and I'll now give you some additional color on the key items.

Earlier this week, we announced that the updated safety and dosing information, as well as overall survival data, has been added to the myelofibrosis package insert for Jakafi. Kaplan-Meier curves from COMFORT-I and COMFORT-II are now included in the label. In COMFORT-1, the probabilities of survival for patients initially randomized to receive Jakafi and placebo were 70% and 61%, respectively, at three years, with survival probabilities at one and two years also provided in the label.

Similar presentations are given for COMFORT-II, where at three years the probability of survival was 79% in the group initially randomized to Jakafi and was 59% in the group initially randomized to best available therapy. The median times to crossover were nine months for the group randomized to placebo in COMFORT I, and 17 months for the group randomized to best available therapy in COMFORT-II.

Now the revised label also provides new information on dosing. Specifically, it indicates that among patients randomized to Jakafi with baseline platelet counts between 100 X 109/L and 200x109/L who started at a dose of 15 milligrams twice a day, 65% required a dose reduction within the first eight weeks. This information should allow insight to provide more guidance to healthcare professionals on the expectations for dose suggestion during the first two months of therapy.

The revised label also indicates that among patients randomized to Jakafi with baseline platelet counts greater than 200x109/L, who started at a dose of 20 milligrams BID, only 25% required a dose reduction during the first two months.

The revised label also provides information on symptoms after discontinuation of Jakafi, and updated information on monitoring for tuberculosis and modified language on drug interactions.

Overall, we believe that the changes to the label will provide useful information to healthcare providers to decide if and when to initiate therapy in their patients with intermediate or high risk myelofibrosis. And to help them monitor their patients and adjust the doses of Jakafi as appropriate.

Moving from MF to polycythemia vera, and as Jim highlighted, the primary goal in PV is hematocrit control. The data from our pivotal RESPONSE trial show that ruxolitinib provides rapid and durable hermatocrit control to patients with PV. These data were presented at ASCO by Dr. Verstovsek, and are available on our website.

Incyte submitted the ruxolitinib sNDA for the treatment of uncontrolled PV in early June of this year. And we expect to be able to update you shortly on the acceptance for filing, along with whether the PDUFA date will be based on a 6 month or a 10 month review.

The results of the RELIEF study were not included in the sNDA and we're confident that efficacy results from RELIEF are not required for FDA approval. Further analysis of RELIEF are underway. These analysis will seek to evaluate what factors may have contributed to the symptom control rate for patients on stable doses of hydroxyurea, that were significantly higher than that seen in the best available therapy arm of RESPONSE. It was this difference that led to an under powering of the RELIEF trial. We expect to present the full data from this RELIEF study at an upcoming scientific meeting.

The two other data sets from our compounds were presented at ASCO in June. These presentations are also available on the Incyte website and have led to acceleration of our onco-inflammation and immuno-oncology development activities.

Based on the results from RECAP, our Phase II study of ruxolitinib in combination with capecitabine in second-line metastatic pancreatic cancer that was presented at ASCO by Dr. Hurwitz, we've initiated two Phase III trials in pancreatic cancer and several proof-of-concept trials in other solid tumors.

JANUS 1 is a double-blind placebo-controlled Phase III trial in advanced or metastatic pancreatic cancer and is being conducted under an SPA. This trial was initiated in March. JANUS 2 is almost identical to JANUS 1 and was initiated in the second quarter of this year. Each trial is expected to enroll about 300 patients with high levels of systemic inflammation as measured by C-reactive protein, or CRP, and the primary endpoint for both trials is overall survival.

The three randomized double-blind Phase II proof-of-concept trials of ruxolitinib are ongoing in non-small cell lung cancer, breast cancer, and colon cancer, with overall survival as the primary endpoint in each study.

The positive subgroup analysis from RECAP have added to our confidence in pursuing accelerate clinical development for INCB39110, the first of our selected JAK1 inhibitors in solid tumors. '39110 is currently in a Phase II trial in combination with docetaxel for the treatment of non-cell small lung cancer. We're on track to begin a second Phase II trial in lung cancer later this year.

We're currently conducting dose finding studies with the JAK1 inhibitor '39110, and also with ruxolitinib, in combination with gemcitabine and nab-paclitaxel (sold as Abraxane) to find the optimal starting dose for a possible trial in first-line pancreatic cancer.

The third ASCO presentation was given by Dr. Gibney and this described initial positive proof-of-concept data with our IDO1 inhibitor '24360. This is a trial in combination with ipilimumab in patients with unresectable or metastatic melanoma. These data show that the combination of our IDO inhibitor plus ipilimumab were generally well tolerated and suggested that response rates and time to progression were longer than seen in historical data with ipilimumab alone.

The synergistic activity observed with '24360 and ipilimumab, as well as supportive pre-clinical data, increases our confidence in the value of investigating '24360 in combination with other immunotherapies, including PD1 and PDL1 inhibitors, and we've just added Genentech's anti-PDL1, MPDL3280A to our list of clinical trial agreements for IDO. The purpose of this agreement is to evaluate the combination in patients with non-small cell lung cancer.

We've now began dosing patients in a study called KEYNOTE-037, a combination study of Merck's anti-PD1 immunotherapy, pembrolizumab, previously called MK 3475, and Incyte's '24360. The Phase 1 portion of the trial will define a recommended combination regimen and the Phase II portion will evaluate the efficacy and safety of that regimen in a randomized population of non-small cell lung cancer patients receiving pembrolizumab, combined with either Incyte's '24360 or its matching placebo. Incyte is conducting the study in close collaboration with Merck.

The Phase I/II trials of 24360 in combination with AstraZeneca at MedImmune's anti-PDL1, MEDI4736, and Bristol-Myers Squibb's anti-PD1, nivolumab, are expected to begin in 2014. These two studies will have the potential to recruit patients with multiple tumor types, and will be run by Incyte.

As we've said, we see the potential for IDO inhibitors in combination with checkpoint inhibitors, but not necessarily as monotherapy. As a result of both slow enrollment and a lack of evidence of an efficacy advantage as monotherapy, over a control of tamoxifen, were closing our Phase II study in ovarian cancer. Going forward we will focus development of our IDO inhibitor as a component of combination therapy.

Now looking briefly at a couple of our other programs, let me first give you a short update on Incyte's '47986, our second selected JAK1 inhibitor that is in development for inflammatory disorders. Based on a recent preliminary preclinical toxicology finding, we have proactively placed clinical studies of '47986 on hold while additional preclinical study data are gathered. These preclinical findings have not been observed with any of our other JAK1 or JAK1, 2 inhibitors, such as ruxolitinib or baricitinib, which is being developed by Lilly.

Our PI3k Delta inhibitor, '40093, has completed Phase I monotherapy dose escalation trial in patients with B-lymphoid malignancies, and has moved into the expansion phase. A second trial, which started in January of 2014, is evaluating '40093 in combination with our JAK1 selective inhibitor '39110. As we previously noted, these are distinct mechanisms of action and they exhibit synergy in preclinical models of lymphoma.

And lastly, on baricitinib, the rheumatoid arthritis program being run by Lilly, this is ongoing and the first of four Phase III trials is due to read out with top line data later this year. The Phase II psoriasis and diabetic neuropathy programs are also ongoing. Initial results for the psoriasis trial were presented at the American Academy of Dermatology in March, and results of the diabetic neuropathy trial are anticipated in 2015.

With that I'll now turn the call over to Dave to give us of the financial highlights for the quarter.

Dave Hastings - *Incyte Corporation - CFO*

Thanks, Rich. Good morning, everybody.

Let's begin with Jakafi for which we recorded $84 million of second-quarter net product revenues, representing 55% growth over the same period last year. Additionally, we reported $12.3 million in product royalties from Novartis for sales of Jakavi outside of the United States. Which has more than doubled from the same period last year.

Novartis also continues to make progress in obtaining formal pricing and reimbursement approval for a third major European country. Now, once Novartis achieves this, Incyte will earn an additional $60 million milestone payment, which is expected to occur in the second half of 2014.

In addition, and as previously announced, Incyte earned a $25 million milestone from Novartis in July, as a result of Jakavi's approval in Japan. This will be recorded as contract revenue in the third quarter.

Our gross-to-net adjustment for product revenue recognized was approximately $9.5 million or 10.2% for the second quarter. We still expect that our full year gross net adjustment will range from 9% to 10%.

Our cost of goods sold for the second quarter was immaterial as we continued to benefit from the fact that our starting finished goods inventory was previously expensed as R&D, prior to FDA approval. In terms of operating expenses, both R&D and SG&A were within our expectations.

And finally, from a cash perspective, we ended the quarter with $509 million. Our cash position continues to benefit from increasing product and royalty revenue, which allows us to appropriately invest in our growing development pipeline.

So with that, operator, that concludes our formal remarks, please open the call for Q&A.

QUESTIONS AND ANSWERS

Operator

Thank you. At this time we'll be conducting a question and answer session.

(Operator Instructions)

Our first question today is coming from Eric Schmidt from Cowen and Company.

Eric Schmidt - *Cowen and Company - Analyst*

Thanks for taking my question. Congratulations on commercial progress with Jakafi. Maybe for Jim, in terms of the updated label on OS and safety. Do you expect that to have an impact on sales trends, or is this just more another sort of competitive barrier down the road, should future JAKs make it to market? And then, just a quick one for Dave, it looks like SG&A is running a little bit above the annual guidance and R&D a little bit below. Is it time to adjust our thinking on those ranges?

James Daly - *Incyte Corp - Chief Commercial Officer*

Hi, Eric, this is Jim. Eric, to answer your question, I think both effects are true. I think it will help us increase the overall breadth of prescribing. I think for current prescribers, the new label should motivate them to look for patients with less obvious, less advanced disease. And I think longer term, it does represent a significant hurdle for new competitors to try to meet to come to the market. It'll obviously take the competition years to build a three year Kaplan-Meier survival curve.

In terms of trend breaks, our view is we're not expecting a trend break based upon the label update. And with a low prevalence disease, what's often rate-limiting for physicians to act upon new information, is how long it takes for them to see their next MF patient. And as a result, as a base case scenario, I would not expect any type of a trend break or step change in terms of performance.

Dave Hastings - *Incyte Corporation - CFO*

Hi, Eric, it's Dave. In terms of R&D and SG&A, we're comfortable with the current range of guidance provided for both areas. Traditionally, for our R&D spend, we do tend to see a slight hockey stick in the second half and I would expect that to continue. And SG&A is tracking fine.

Eric Schmidt - *Cowen and Company - Analyst*

Thanks a lot, guys.

Operator

Thank you. The next question is coming from Josh Schimmer from Piper Jaffray.

Josh Schimmer - *Piper Jaffray - Analyst*

Thanks for taking my question. Maybe sticking with the expense theme, how should we think, I guess, magnitude-wise about the increase in SG&A that'll be incurred with the PV label and launch, and then separately, it seems like it'll be difficult to avoid profitability with these milestones coming in the second half. So how should we think about the fully diluted share count when that happens? Thank you.

James Daly - *Incyte Corp - Chief Commercial Officer*

Hey, Josh. This is Jim. I would not anticipate a major increase in SG&A with respect to the PV launch. We've already incurred the sales force expansion costs and there is a lot of synergy between MF and PV in terms of our promotional support for the new indication. So I would not build in a major step increase in expenses corresponding to launch.

Dave Hastings - *Incyte Corporation - CFO*

Josh, as you know, these milestones can be lumpy in nature and you're right, in any given quarter, particularly the quarter we'll record a $60 million, there is a possibility for profitability, and then when you think about fully diluted shares at that point, you have to use the treasury stock method and that would take into account both employee stock options, the ones that are considered diluted, and the convertible debt.

Josh Schimmer - *Piper Jaffray - Analyst*

Can you help us with that math?

Dave Hastings - *Incyte Corporation - CFO*

Sure. So if you think about the fully diluted, if both converts were exercised, and all employee stock options were exercised, its range is somewhere between 205 million and 210 million. But there's some nuances in that calculation where you add back interest expense, and for employee stock options, you utilize a treasury stock method, so it would be slightly lower than the fully diluted count.

Josh Schimmer - *Piper Jaffray - Analyst*

Got it. Thank you.

Operator

Thank you. Next question is coming from Matt Roden from UBS.

Matt Roden - *UBS - Analyst*

Great. Thanks for taking the question and congrats on a nice quarter. I have one question on the commercial side and then another follow-up, if I may, on the pipeline. Jim, on the commercial, so you mentioned that the growth in demand this quarter was driven by MF. Can you comment on whether or not the growth in spontaneous adoption outside of MF had kept pace with that, or whether or not the proportion of sales coming from spontaneous adoption is lower this quarter?

And then, related, on the guidance, it looks to me like the last six quarters you've done about, on average, $7 million sequential in sales growth on a quarter-over-quarter basis. Your guidance implies, if I'm doing the math right, something like $2.5 million to $6 million per quarter for the rest of the year, so are you just -- is this just out of conservatism or is there some fundamental reason for us to think that maybe the sequential trends will slow down in the second half?

James Daly - *Incyte Corp - Chief Commercial Officer*

Sure, Matt. First, on the non-MF sales. That, as a percentage of overall sales, has remained relatively constant over the last several quarters. So we have not seen any type of increase proportionately in our non-MF sales. With respect to the phasing of the guidance. The low-end represents a low single-digit growth rate for the rest of the year, and the high-end represents a high single-digit growth rate for the rest of the year. Listen, Matt, our goal is to try and beat the guidance. That's always our goal. But we think that high single-digit growth rate represents a reasonable base case scenario that is both ambitious and achievable.

Matt Roden - *UBS - Analyst*

Okay. Great. And then, just on the IDO program, now that you have clinical trial collaborations with the four major players in PD-1/ PDL-1, can you give us a little insight into what the collaborators are saying when they come to the table about IDO and the combo data from ASCO. Do you think that they're interested in committing resources just because of the mechanism or is it the data or is it both? Just trying to get a sense for what industry people outside of Incyte think about '360, and whether and to what extent that program can help them. Thanks

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Rich Levy - *Incyte Corporation - Chief Medical Officer and Head of Drug Development*

It's difficult for me to comment on what other companies believe or tell us in private conversations. But I would say that in general, the fact that we have four major, either PD-1s or PDL-1s, and they've all now signed collaboration agreements with us, shows that across the board, there is interest in combining with the IDO inhibition mechanism. In addition, I think it shows that no one wants to be left out of that game by not playing at the same time. So I think they all think that there's a good potential for the combination and now it's time to get the data for each of those individual combinations.

Matt Roden - *UBS - Analyst*

And do you have a sense, Rich, for when we should expect to see the first sets of data from those collaborations?

Rich Levy - *Incyte Corporation - Chief Medical Officer and Head of Drug Development*

Yes, so in part because each of these companies are competing with each other, in terms of this, and that, release of data has to be mutually agreed between us and the other party. I don't expect that we will be giving out emerging data the way we had in our combination with ipilimumab. So there's two parts to the studies. First deciding doses. Which is uncontrolled. And potentially, as we've done before with ipilimumab, comparisons to historical controls, how long that takes depends upon how many dose levels we need to get to before we feel we have the right doses in each study. And then, randomized controlled second parts to the study which will take longer to roll out. So we're not giving specific guidance as to when, but it's not going to be in the very near future.

Matt Roden - *UBS - Analyst*

Great. Got it. Thanks very much.

Operator

Thank you. Next question is coming from Cory Kasimov from JPMorgan Chase.

Whitney Ijem - *JPMorgan Chase - Analyst*

Good morning. This is Whitney on for Cory. Wondering if you guys have any insight into how Lilly will be releasing the baricitinib data. Whether they intend to top line it as they get it or hold it until they have it all to release it?

Rich Levy - *Incyte Corporation - Chief Medical Officer and Head of Drug Development*

They have not given us specific guidance as to their plans. These are Phase III studies and I'm sure that they will need to say something about information that is material to them, but what that actually is, I don't know. We expect, based on what they've told us, that there's a likelihood that there will be some top line data on the first study sometime towards the end of the year.

Whitney Ijem - *JPMorgan Chase - Analyst*

Got it. And then, on PV, I guess you guys reiterated your expectation for MF plus PV to be about a $1 billion opportunity, but does the RELIEF miss change the way you're thinking about the commercial potential in PV at all, or what type of patients might come on drugs?

James Daly - *Incyte Corp - Chief Commercial Officer*

This is Jim. It actually does not. We knew that we would not have the RELIEF data when we filed the response sNDA. So all along, we knew that we would not have a symptom claim at launch. I think the key point -- It's a negative study so that's always a disappointment, but if you're going to have a negative study, that was the one to have. Because the primary treatment goal in PV is hematocrit control and the data contained in RESPONSE gives us the promotional evidence that we need to go after the vast majority of those one out of four patients who are uncontrolled.

Whitney Ijem - *JPMorgan Chase - Analyst*

Got it. Thanks for taking the questions.

Operator

Thank you. And next question is coming from Steve Byrne from Bank of America.

Steve Byrne - *Bank of America - Analyst*

Jim, you mentioned that, out of the addressable MF-- intermediate and high-risk MF population, you're not quite a third -- or you're less than a third penetrated. Given the survival benefit indication or information now on the label, what penetration do you think is potentially possible here in this group, and are there subsets that you think are really not likely to be dosed Jakafi?

James Daly - *Incyte Corp - Chief Commercial Officer*

That's a challenging question. And that's why we've left it at $1 billion between both PV and MF. Clearly, you're never going to get 100% of your addressable population. But at a third, we certainly believe that a 50% penetration is realistic and it is clearly within our ambition to do that. So as we look at the $1 billion, we don't know if it's a $600 million with MF and $400 million with PV, or $500 million and $500 million. But clearly, the message we want to communicate is that we do have substantial long-term upside in MF.

Steve Byrne - *Bank of America - Analyst*

Thank you. And a question for Rich. You have four of these combo studies with IDO and there's some redundancy among them. They all seem to be, at least including, non-small cell lung. Is it your view that there could be some mechanistic differences between the two PD-1s and the two PDL-1s or are you more or less casting this net fairly broad in looking at a lot of different indications? Is there a view on this that you can share?

Rich Levy - *Incyte Corporation - Chief Medical Officer and Head of Drug Development*

So we're not at this point. We have no reason at this point to believe that there are differences between the two PD-1s and the two PDL-1s. And it remains to be seen whether, in combination with ipi, we'll even see significant differences between the PD-1s and the PDL-1s. What the strategy here is is to be a partner with a range of checkpoint inhibitors and immunotherapies, and not tie ourselves down to one thing. And in fact, while there is some redundancy, particularly around non-small cell lung cancer, which is of interest to everyone, by having different partnerships, we do get to explore a range of potential indications. Depending upon initial data, there's potential to add indications beyond those that are currently planned. So I think this gives us a broad look at the possibilities for combinations in PD-1 targeted therapies.

Steve Byrne - *Bank of America - Analyst*

Thank you.

Operator

Thank you. Next question comes from Michael Schmidt from Leerink

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Michael Schmidt - *Leerink - Analyst*

Good morning, thanks for taking my questions. I had a couple pipeline questions. Number one, you know, based on emerging mechanistic understanding of how JAK -- the JAK/STAT pathway is involved in solid tumors, particularly. Do you have plans --or what are your plans to evaluate your JAK inhibitors in targeted drug combinations in solid tumors in addition to the ongoing studies? And number two, we just talked about the PD-1, PDL-1 combinations of the IDO inhibitor. Based on the understanding of the mechanism of '24360, what differences -- or do expect any differences between PD-1 versus PDL-1 combination? Thank you.

Rich Levy - *Incyte Corporation - Chief Medical Officer and Head of Drug Development*

So I'll start, and maybe Reid has some additional comments. So first of all, in terms of targeted therapies in solid tumors, we've already started a study with ruxolitinib and Stivarga in colon cancer which is a targeted therapy. And we do have others planned with solid tumors that have not been announced yet. I'm not saying whether that's with ruxolitinib or '39110, but with JAK inhibitors and other targeted therapies are planned and we'll talk about that when they're closer to starting. And then in addition, we're, of course interested in JAK1 inhibitors as other targeted therapies in hematologic malignancies, with the combination of JAK1 and our PI3K Delta in the B-cell malignancies, as an example of ongoing study.

And with respect to PD-1s and PDL-1s. As I said in the answer to an earlier question, there are theoretical reasons to believe that they may be very similar or different. We'll just have to generate the data, and our view has been that we will do the study and find out.

Michael Schmidt - *Leerink - Analyst*

Got it. And then one more. So will you present any additional data from the ipilimumab combination study before next year's ASCO?

Rich Levy - *Incyte Corporation - Chief Medical Officer and Head of Drug Development*

I don't know, probably ASCO is a reasonable time for an update. I don't know that we'd be going to any specialty meetings or anything like that.

Michael Schmidt - *Leerink - Analyst*

Got it, great. Thank you.

Operator

Thank you. Next question today is coming from that Navdeep Singh from Goldman Sachs.

Navdeep Singh - *Goldman Sachs - Analyst*

Hey, guys. Congrats on the progress during the second quarter. And thanks for taking my questions. So just a couple questions on baricitinib. Maybe a question for Rich. Rich, can you help us better set expectations for the upcoming baricitinib Phase III data. I understand you're not, in your Phase III trials, you're not comparing baricitinib to Pfizer's Xeljanz. But based on the Phase II data, how should we be expecting the efficacy and safety profile of baricitinib to look like compared to Xeljanz?

And then a question for Jim. Jim, what have you guys and Lilly learned from the Xeljanz launch that makes you more confident that you can execute better than them? Thanks.

Rich Levy - *Incyte Corporation - Chief Medical Officer and Head of Drug Development*

So there's a number of different Phase III studies that are ongoing, including a study in patients who have previously failed TNF or have inadequate response to TNF inhibitors. And a few studies in DMARD or methotrexate inadequate responders. One of the key studies is the largest study, which is a head-to-head comparison with not only continued methotrexate, but also an arm that includes continued methotrexate and Humira. And this study is larger -- and it's also the structure study. So you get head-to-head comparisons with Humira in terms of signs and symptoms, as well as structure. Which is something that was not present in the structure studies done by Pfizer.

So I think there are two key things that could lead to a differentiation. One is the safety profile, by avoiding JAK3. There are still reasons to believe that this has, in Phase II, and may very well in Phase III, lead to differentiation. The structure study has been made larger with the powering based on the results of the Pfizer study, and then again, the ability to have the head-to-head comparison to Humira. Whereas, of course, there is not a head-to-head comparison to Xeljanz, per se.

And I'll turn it over to Jim to talk about commercial aspects.

James Daly - *Incyte Corp - Chief Commercial Officer*

Sure, Nav. Now, we defer to Lily in terms of all aspects of commercial execution. But just to address your question, in RA, it's all about the product profile. Today, the three largest selling drugs in the world last year were Humira, Remicade, and Enbrel. And that is both good and bad. It's good in that it represents a tremendous opportunity. It's bad in that they're going to defend their business very aggressively and if there is a weakness or vulnerability in your product profile, it will be exploited.

And the issue with Xeljanz is that from launch, with the five milligram BID dosing, they had a -- both a real and a perceived weakness with respect to the claim that Rich has referred to, the claim to inhibit progression of structure damage. That structure claim is absolutely vital if you're going

to compete successfully against the biologics. Now if you come in with a competitive clinical profile, and you have the added convenience of once a day oral, we think that can be a very successful product.

Navdeep Singh - *Goldman Sachs - Analyst*

Okay. Thank you, both.

Operator

Thank you. The next question comes from Thomas Wei from Jefferies.

Thomas Wei - *Jefferies & Company - Analyst*

Thanks. Just wanted to ask an immuno-oncology question and then maybe a Jakafi question as well. On the immuno-oncology front, just wanted to get your latest thoughts on your interest in developing biologics capabilities, acquiring other immune checkpoints, and then on Jakafi, would love to get some of the metrics that you've provided before in the past in terms of mix of doses as well as persistence.

James Daly - *Incyte Corp - Chief Commercial Officer*

Sure, on persistence, again, we continue to see a steady and significant increase in persistence over time. That's driven by two things. One is we are seeing an overall healthier patient being put on Jakafi. As judged by their baseline platelet counts and hemoglobin levels. And secondly, we are seeing physicians being more facile into dosing. We're seeing increased use of titration. And we're also seeing increased use of lower strength doses. So we're pleased with the progress we've made on the persistence front, and because it's a moving target, we've refrained from trying to quantify it and I think we'll remain with that position.

Herve Hoppenot - *Incyte Corp - President & CEO*

Herve here. On the question on how do we move in the field of immuno-oncology in general. I must say, the first priority for all of us is to successfully develop our IDO inhibitor where we are first in class and where we have an original mechanism that has a lot of promising potential. So that's really the number one. Now, evolving in the field of immuno-oncology doesn't necessarily mean biologics. In fact, the PI3K delta field is a place that seems to be moving from "targeted therapy" to "immuno-oncology" as we speak.

So that certainly is something of interest and we have -- we are looking at small molecules as a potential way to address some of the medical needs with the mechanism in the field of immuno-oncology. And obviously, probably like everybody else, we would be looking at external opportunities the same way we look at internal opportunities, which is, what is the science around it? And how does it fit with our overall portfolio strategy, but it's really not the number one item on our priority list today.

Operator

Thank you. Next question is coming from Liisa Bayko, JMP Securities.

Andrew Prigodich - *JMP Securities - Analyst*

It's Andrew [Prigodich] on for Liisa. Thanks for taking the question. I have two. First, you talked a little bit about the casting a wide net with IDO partnerships and I'm wondering if you can comment at all about your plan to transition from that strategy to a more focused strategy as you

hopefully end up getting some hits with some different companies. Is there anything you'd be looking for in a long-term partner beside a combination that works?

And then, second question more of housekeeping thing. I think you may have commented on this earlier, but we missed it. Can you say anything about the contribution of inventory to the revenue numbers for Jakafi this year and expectations for the second half on the inventory side.

James Daly - *Incyte Corp - Chief Commercial Officer*

Yes, inventory contributed 1% to the overall 21% growth in the second quarter. We ended the quarter at the low end of our typical range of 3 to 3.5 weeks. And last year, if you remember, we saw an inventory build of about $4 million in the fourth quarter. We don't know if that's going to be recurring, a recurring, action or not this year. And as a result, we did not build that into our guidance.

Herve Hoppenot - *Incyte Corp - President & CEO*

And so regarding the philosophy behind the partnerships is really all based on science. What we are doing now is finding which indication, if there are differences between indications, for which product, if for any reason there are differences between the PD-1 and the PDL-1, will be better, if any is better for combination with IDO. If it is not the case and if we find the mechanism is truly synergistic across different indications and across different products, frankly, our goal is to develop IDO independently and to have a label that would be fitting that it's a drug that should be used and could be used in combination with multiple partners.

So the partnerships we have today are not sort of a first step before a bigger certain step. They are literally scientific partnerships, regulatory partnerships, potentially when we find the proof-of-concept and the right indication, that could lead to approval of IDO in combination with multiple products and multiple indications. That's the goal that we are pursuing and we would see the commercialization of that product as being done by Incyte.

Operator

Thank you the next question is coming from Dave Friedman for Morgan Stanley.

David Friedman - *Morgan Stanley - Analyst*

Hey, thanks for taking the question. Just as I look at the Jakafi US volume demand trends over the past six quarters, it seems like, at least and 2013, you had to 2Q, from a volume basis be about double every other quarter, and now you're seeing a similar thing here. Is there something, sort of, that happens in 2Q either from a Medicare perspective or something else that you guys are aware of that could explain this trend?

James Daly - *Incyte Corp - Chief Commercial Officer*

Yes, this is Jim. Dave, there is a natural rhythm to the business and we've seen that over the last couple years now, where typically the first quarter will be challenging. We will have headwinds in the first quarter, and that's due to a number of factors. It can -- include burning off any inventory build that you have had in the fourth quarter. It includes the phenomenon where patients may pull forward a prescription from January into December in anticipation of having new deductibles, re-entering the donut hole. And you can also have friction dealing with plan changes in the first quarter.

So typically the first quarter's challenging and then we see a very nice rebound in the second quarter. We saw that last year and we see that this year. You have to be prepared for a slight slowdown in the third quarter as you deal with, quite frankly, summer doldrums. It involves things as mundane as vacations on the part of physicians and patients, your new patient visits will tend to flatten out. And then you see strength in the

fourth quarter. And, again, that can be a reflection of the patients pulling forward an extra prescription, we can -- last year we did see some inventory build and so that's kind of the rhythm of the business that we're anticipating as we plan our phasing.

David Friedman - *Morgan Stanley - Analyst*

Okay. Great. Thank you.

Operator

Thank you. Our next question today is coming from your Yaron Werber from Citi. Please proceed with your question.

Tenjin Wong - *Citigroup - Analyst*

Hi. This is [Tenjin] and for Yaron this morning. Thank you so much for taking our question. So wanted to congratulate you on the great launch and the upcoming expansion into PV. Have a quick question on what other trials you were planning for baricitinib, and also if you could elaborate a little bit on the safety signal that you saw in for '47986 and if this was something in particular to RA or just the molecule itself. Thank you so much.

Reid Huber - *Incyte Corp - Chief Scientific Officer*

Thanks for the question. This is Reid. Just in terms of the safety signal. So in a longer-term non-rodent toxicology study, we identified two instances of retinal toxicity, which had histologic features that were consistent with degeneration. The finding was not observed in the rodent studies, nor was it observed in the 28 day study that enabled the filing of the IND. I'll also point out that we have not observed this retinal toxicity with any of the other JAK inhibitors that we've taken forward, and that includes, importantly, ruxolitinib, baricitinib, and '39110.

We're currently gathering more data from the study animals now and that includes the control animals to determine whether the finding is likely to be treatment related, but at this time we felt that prudent, and informed investigators of the finding and proactively put on hold the '986 trial while those other data are gathered. I will make the additional point that '47986 is from a distinct chemical scaffold relative to other JAK inhibitors and at this time, we consider these findings to be a potential relationship to that drug and therefore possibly arising from off target activity.

Rich Levy - *Incyte Corporation - Chief Medical Officer and Head of Drug Development*

And on baricitinib, we really can't comment beyond what has been announced by Lilly. So they presented the results of their first part of their Phase II study in psoriasis, obviously they've presented their rheumatoid arthritis studies some time ago. The diabetic neuropathy study is scheduled to read out and be presented in some form next year. There are four Phase III studies ongoing in RA, and in addition to that there's also long-term extension study. Beyond that, we're just not at liberty to say what they're either going to do or the types of things that they're thinking about.

Tenjin Wong - *Citigroup - Analyst*

Totally understood. Thanks so much for answering my questions.

Operator

Thank you and the next question is coming from Bret Holley from Guggenheim.

Bret Holley - *Guggenheim Securities LLC - Analyst*

Hi, thanks for taking the question and congratulations on the quarter. Just a quick question on PV. I'm wondering what percentage of PV patients in the US should really receive hydroxyurea and how confident are you in the 25,000 estimate in the United States. What source of information are you using to arrive at that number, just because I sense a bit of skepticism out there on that number.

James Daly - *Incyte Corp - Chief Commercial Officer*

Brett, there's about 60,000 patients in the US who are on HU or who have been on HU. About 5,000 patients were on HU and discontinued due to lack of efficacy or tolerability issues. 55,000 patients remain on HU. And in terms of the triangulation-- in terms of the one out of four, we really triangulated on that through some published studies, and we can share those with you off-line as well as chart audits that we have conducted ourselves. We're feeling very confident that one out of four is a reasonable balanced estimate of the opportunity.

Bret Holley - *Guggenheim Securities LLC - Analyst*

Great. Really appreciated.

Operator

There are no further questions at this time. I would like to turn the floor back over to Management for further closing comments.

Herve Hoppenot - *Incyte Corp - President & CEO*

Okay. Thank you. I think, I mean what you saw in this Q2 report is a lot of progress on many fronts. First, the commercial momentum is very good. We have, on the regulatory side, the filing in PV that has been achieved also in Q2. And as you see, on the development front, we are moving forward very fast and very aggressively, both in onco-inflammation and immuno-oncology with our IDO program. And in addition, we are in a very good and strong financial position. So I really look at this Q2 results as being extremely positive from our strategy objective standpoint. Thank you for attending the call and I guess will be back in three months.

Operator

Thank you. This 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.
