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INCY - Q1 2013 Incyte Corporation Earnings Conference Call

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PRESENTATION

Operator

Greetings ladies and gentlemen, and welcome to the Incyte Corporation first-quarter 2013 earnings call. A brief question-and-answer session will follow the formal presentation.

(Operator instructions)

As a reminder, this conference is being recorded. It is now my pleasure to introduce your host, Ms. Pamela Murphy, Vice President Investor Relations and Communications. Thank you, Ms. Murphy. You may begin.

Pamela Murphy - *Incyte Corporation - VP IR & Communications*

Good morning and welcome to Incyte's first-quarter 2013 conference call. On the call today are Paul Friedman, Incyte's President and Chief Executive Officer; Jim Daly, Executive Vice President, Chief Commercial Officer; Dave Hastings, Executive Vice President and Chief Financial Officer; Rich Levy, Executive Vice President, Chief Drug Development and Medical Officer and Eric Siegel, Executive Vice President and General Counsel. Paul will begin with a brief overview of the quarter then Dave will describe our first-quarter financial results. And Jim will follow with an update on the ongoing commercialization of Jakafi. Paul will close with a description of the rest of the pipeline and then open up the call for Q and 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 as well as other

compounds in our pipeline. These forward-looking statements are subject to a number of risks and uncertainties that may cause our actual results to differ materially, including those described in our form 10-K for the year ended December 31, 2012 and from time-to-time in our other SEC documents. Paul?

Paul Friedman - *Incyte Corporation - President & CEO*

Good morning, everyone. The first quarter was quite productive for Incyte. We had solid growth for Jakafi, which is obviously important from a revenue perspective, but the new prescriptions also represent patients, who may experience the benefits of the first FDA-approved treatment for intermediate or high-risk myelofibrosis. At the same time, we've continued to progress the development of Jakafi and other potential indications. Phase III response study of Jakafi in polycythemia vera is fully enrolled and expected to read-out in early 2014. And the results from the Phase II recap study of Jakafi in pancreatic cancer are expected in the second half of this year.

These are important potential growth catalysts for Jakafi in new patient populations with high unmet medical need. Later in the call, I will share some more information with you about the pipeline and Jim will outline activities that we believe will lead to continued solid growth for Jakafi. But first I'll turn the call over to Dave to review our financial performance in the first quarter.

Dave Hastings - *Incyte Corporation - EVP and CFO*

Thanks, Paul. Good morning, everybody. Let's begin with Jakafi, for which we recorded $48.3 million of first-quarter net product revenues. Additionally, we recorded $5.9 million in product royalties from Novartis for sales of Jakavi outside the United States. In addition we announced this week that we earned a $25 million milestone from Novartis based on the formal initiation of a Phase II clinical trial with c-MET inhibitor 28060. This amount will be received and recorded as revenue in the second quarter.

Our gross to net adjustment for product revenue recognized was approximately $5.1 million, or 9.5% for the first quarter. As I mentioned in our last call, we expected our growth to net adjustment to be higher in the first quarter than the rest of the year because of our share of the donut hole for Medicare Part D patients. We still expect that our full-year gross net adjustment will range from 8% to 9%. Our cost of goods sold for the first quarter was immaterial, as our starting finished goods inventory was previously expensed as R&D prior to FDA approval. In terms of operating expenses, SG&A was within our expectations while R&D expenses came in slightly below our expectations.

From a cash perspective, we ended the quarter with $270 million. This is a strong cash position and we have multiple sources of cash flow now. Therefore we are well-positioned to fund our growth. Jim will now provide more color around Jakafi performance in the first quarter. Jim?

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

Thank you, Dave, and good morning everyone. Our first-quarter results reflect continued solid execution of our growth strategy for Jakafi and MF. We added new patients at a steady rate, consistent with previous quarters, while making gradual but meaningful improvement in persistency. In terms of quarter-over-quarter growth, net revenues grew 12% with the following components of growth. Underlying demand, as measured by bottles dispensed, accounted for approximately 7%, net price accounted for approximately 2% and inventory accounted for approximately 3%. Channel inventories remain within a consistent normal range of three to three and a half weeks.

In the quarter we continued to add new patients at a steady rate. Roughly half of new patient starts came from new prescribers, with the remaining half coming from repeat prescribers. We continue to make inroads with our target physicians. We believe later adopters are motivated by an increased awareness of the overall survival data presented at ASH while exiting prescribers are motivated by the impressive improvement in spleen volume and constitutional symptoms they are seeing in their MF patients. Through the first quarter, more than 40% of our target prescribers have prescribed Jakafi at least once and about one-third of those have written for two or more patients.

We expect breadth and depth of prescribing to continue to expand, driven by one, educational programs to help physicians identify appropriate new patients, including those who do not carry the JAK2 V617F mutation. We continue to reinforce the fact that Jakafi is targeted to the JAK pathway

and not necessarily any particular mutation. Number two, programs including direct-to-patient and allied health professional activities to assist MF patients in communicating their symptoms to their physicians. And finally, three, positive experience as a catalyst to treat more patients.

Turning to persistency, we continue to see increasing use of lower dosage strengths, which is driven by physicians individualizing treatment, in particular by starting patients at appropriate doses and titrating downward if medically necessary. In the first quarter of 2013, 5 and 10 milligram strengths represented approximately 44% of dispensed bottles versus 37% in the first half and 41% in the second half of last year. Absent the use of dose titration, or lower doses, patients with low baseline hemoglobin and/or platelet counts are at the highest risk for discontinuation in the first 8 to 12 weeks. The use of lower doses in these populations is increasing and we expect the trend to continue as a result of -- number one, rapid and appropriate follow-up by our field-based sales and medical teams with new prescribers; two, enhanced outreach to patients through IncyteCARES and specialty pharmacies; and three, increased awareness by prescribers of additional dose titration data from ASH.

Additionally, we now have data from our studies of patients with low platelets and we expect expanded dosing guidance in our label sometime in the second quarter. To assist physicians in titrating patients appropriately, we introduced the Jakafi dose modification program late in the first quarter, which enables physicians to order a lower strength bottle of Jakafi free of charge for any patient requiring a dose titration in 21 days or less from receiving their last prescription. The objective of this program is to make it as easy as possible, both financially and administratively, for a physician to down titrate to the most appropriate dose for a given patient. While early in its implementation, we are seeing active utilization of the program and it is serving as an effective tool to highlight the importance of dose modification, especially during the first 8 to 12 weeks of treatment.

In summary, our first quarter performance is consistent with our expectations for steady growth in dispensed bottles, largely driven by new patients and a realistically achievable improvement in persistency. We remain confident in our ability to deliver our guidance of $210 million to $225 million in net sales in 2013. In a moment, Paul will talk about our pipeline, which has near-, mid- and long-term catalysts. I am especially excited about the PV indication for Jakafi. With the RESPONSE trial fully recruited, the commercial team is actively preparing for potential approval and launch by the end of next year. Now I will turn it back to Paul.

Paul Friedman - *Incyte Corporation - President & CEO*

Thanks, Jim. I will start with Jakafi. While abstracts for ASCO haven't been posted, the titles are now public and there is an oral presentation involving Jakafi entitled, Exploratory analysis of the effect of ruxolitinib on bone marrow morphology in patients with myelofibrosis. The lead author, Professor Hans-Michael Kvasnicka, a world-recognized hematopathologist from Goethe University, Germany, is exploring the effects of treatment on bone marrow fibrosis in this patient population. While it's not appropriate for me to provide detail about the ASCO presentation, I can tell you that preliminary findings originally presented by European LeukemiaNet chair Professor Tiziano Barbui at a closed session of the ELN annual meeting in February, suggests that long-term use of Jakafi shows the rate of advancement of bone marrow fibrosis -- slows the rate of advancement of bone marrow fibrosis as compared to matched historical controls and with some patients can result in a reduction in the amount of bone marrow fibrosis. So we're looking forward to this presentation at ASCO in June.

Our most advanced programs in Jakafi are in polycythemia vera and pancreatic cancer. We expect to see results from response to PV trial that we're conducting in partnership with Novartis in early 2014, which keeps us on track to file a supplemental NDA in the first half of 2014. Our second trial in PV called RELIEF is evaluating symptomatic benefit. And while this study is not part of the SPA, the Special Protocol Assessment agreement with the FDA, and is therefore not required for FDA approval, when completed we do plan to submit results to support labeling claims on symptomatic benefit in PV. In the second half of this year, we expect to have results from RECAP, the double-blind Phase II trial in patients with pancreatic cancer in which overall survival is the primary endpoint.

As we previously mentioned, the trial's drug safety and monitoring board concluded -- conducted a pre-specified interim analysis of safety as well as efficacy at the end of 2012 and recommended that the study continue to completion. As there is ample evidence suggesting that this regulation of the JAK-STAT pathway plays a key role in a variety of malignancies, including solid tumors beyond pancreatic cancer, it is of interest to evaluate the therapeutic potential of ruxolitinib as well as our other JAK inhibitors in additional malignancies. In particular, given the importance of cytotoxic chemotherapy to many first- and second-line solid tumor treatment regimens, we have initiated an open label Phase I trial of ruxolitinib in combination with chemotherapy in patients with advanced solid tumors to better understand the tolerability of ruxolitinib when combined with

myelosuppressive agents. From the results, anticipated in 2014, we expect to establish the maximum dose of ruxolitinib tolerated when used in combination with given chemotherapeutic regimens. Our first proprietary JAK1 inhibitor, INCB39110 is being studied in proof-of-concept trials in myelofibrosis, rheumatoid arthritis, and psoriasis. Results from these trials should help us select the most appropriate indications for further development. We plan to share these results at appropriate scientific meetings in the second half of this year.

We have a second JAK1 inhibitor, INCB47986, which has now entered Phase I clinical development. Having two distinct JAK1 inhibitor compounds gives us a greater number of options with the program, including the opportunity to pursue both oncologic and chronic inflammatory indications, but with distinct molecules. We are planning to start a study this summer with one of our JAK1 inhibitors in combination with chemotherapy to better understand how JAK1 inhibitors could be used in this setting and will then be able to compare the results with what we've seen with ruxolitinib in a similar patient group.

Our second JAK1, JAK2 inhibitor, baricitinib, licensed to Lilly, is in Phase III for rheumatoid arthritis. There are also two ongoing Phase II trials evaluating baricitinib as a treatment for psoriasis and for diabetic nephropathy respectively. In addition to our JAK programs, there are several other compounds in clinical development, such as our c-MET inhibitor as well as an indoleamine dioxygenase, or IDO, inhibitor. The c-MET inhibitor, INCB28060, is licensed to Novartis and they recently initiated a Phase II clinical trial evaluating the compound as monotherapy in patients with advanced hepatocellular carcinoma.

Our IDO inhibitor for immunologic treatment of tumors is in Phase II development for melanoma and for ovarian cancer. The results of a Phase I study of the compound will be the subject of a poster presentation at ASCO. The program has also generated interest among other researchers, with three investigator-sponsored trials being readied for initiation. Beyond these programs, we have several early-stage programs that address attractive oncologic targets that link well with ruxolitinib and our current development pipeline, and I'd expect to see some of these programs enter clinic this year and early next year. With that, operator let's open the lines for questions, please.

QUESTIONS AND ANSWERS

Operator

Thank you. We will now be conducting a question-and-answer session.

(Operator instructions)

One moment please, while we pull for questions. Thank you. Matthew Roden, UBS. Please proceed with your question. Mr. Roden, your line is live. Ian Somaiya, Piper Jaffray.

Do Kim - *Piper Jaffray - Analyst*

Hi. This is actually Do Kim in for Ian. A couple of questions. We were wondering if you saw any sense of seasonality in the Jakafi sales number given the sort of general weakness reported by most of the other pharma and biotech companies? Also, as we look ahead to the dose titration label update, how should we think about its impact on second-half sales in terms of growth, persistence and new patient adds? Thank you.

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

On the question with respect to seasonality, as you indicated the first quarter is usually the most difficult for a couple of reasons, particularly for products that are relatively expensive and have a significant percentage of reimbursement through Medicare Part D because you have patients reentering the donut hole and you have deductibles being reset. As we look at the fourth-quarter prescriptions and compare them to the first-quarter prescriptions we probably had a small level of what we call shoe box prescriptions where patients may try to get their last prescription in December

after their through the donut hole and after their deductible has been fully met. And so there is a slight drop off in the first quarter. But I wouldn't say it was significant. As you see our underlying demand remained strong in the first quarter. So I think we were able to power through that.

The other issue is that we simply had a reduced number of shipping days in the first quarter. The first quarter had 62 shipping days versus 64 in the fourth quarter. Despite that, I think we had a very, very solid first quarter and we carry good momentum into the second. Regarding the persistence trends and the new patient start trends for the rest of the year, we are not going to quantify those beyond what we said in the prepared remarks. But we are encouraged by the fact that the new patient starts remain strong consistent with previous quarters. And we are seeing gradual but important improvement in persistence and those two drivers give us the confidence that we will achieve our guidance for the year.

Do Kim - *Piper Jaffray - Analyst*

Great. Thank you very much.

Operator

Cory Kasimov, JPMorgan.

Cory Kasimov - *JPMorgan - Analyst*

Hey, good morning, guys. Thanks for taking my questions. A couple of them for you. First of all, has there been any feedback from the field regarding potential concerns over PML? What would you expect the underlying incidence to be in myelofibrosis? And then I have a follow-up.

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

Hi, Cory, this is Jim. Cory, we have had zero feedback from the field regarding PML. And then I will turn it over to Paul.

Paul Friedman - *Incyte Corporation - President & CEO*

Yes. Rich, I don't think you can put a percentage on it. It's a rare enough entity that in myelofibrosis and myeloproliferative neoplasms -- I don't think you can put a percentage on --

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

It's hard to do. I mean, when we look back at the FDA database from several years ago, there were a number of different drugs that were looked at and there were more cases than you might expect. But when you look at the literature, you know that there's going to be underreporting even for things like PML. So it's hard to say exactly. But it's not going to be a big number spontaneous or with the use of a drug. But it's also not to say that you would never expect another one to happen, even in the absence of the drug.

Cory Kasimov - *JPMorgan - Analyst*

Okay. And then next question is just more on the relative breakdown in the Jakafi doses being used. So it's encouraging that the 5 and 10 mg doses continue to increase. But I'm wondering, is there any push back at all on using those lower doses? I guess I wanted to get your sense on if we should expect that 44% share that you have now to keep growing and become, in time kind of represent the vast majority of initial prescriptions? Thanks.

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

I wouldn't necessarily say initial, Cory. Whether it's starting dose and/or titration we do expect the 5 and 10s to increase as a share of total doses. So we would expect to see that 44% grow over time.

Cory Kasimov - *JPMorgan - Analyst*

Okay. Thank you.

Operator

Matthew Roden, UBS.

Matthew Roden - *UBS - Analyst*

Hi, guys. Thanks for taking my question. Congrats on the progress and thanks for getting me back in here. I wanted to get into the gross net a little bit. I'm trying to better understand what the potential impact of the -- or the financial impact was of the donut hole in particular, and also on inventories. You talked about the inventory accounted for 3% of the sequential growth, but I'm just trying to understand if that represents a build or if that's just the growth that's commensurate with the growth in demand, underlying demand? And I have a pipeline question, if I may.

Dave Hastings - *Incyte Corporation - EVP and CFO*

On the gross to net, as we discussed in the prepared remarks, came in about 9.5%. But the guidance overall did not change. Our gross to net for the year should range somewhere between 8% and 9%. So that should give you a sense for the impact on the increased donut hole exposure for the quarter. The inventory are at normal levels. So it's really commensurate with the growth in product sales.

Matthew Roden - *UBS - Analyst*

Okay. Understood. And then on the pipeline, Paul or Rich can you speak to the differences between your two JAK1 inhibitors? Is there something really different between these two products that you would need to bring sort of, complementary assets forward or is it just the question of being able to cover more indications across cancer and inflammation?

Paul Friedman - *Incyte Corporation - President & CEO*

They are different in terms of -- they have a distinct pharmacokinetic difference. And I just would like to leave it at that. The first compound has turned out to be much more interesting than I frankly thought it was going to be. It's a very nice compound and we're looking forward to presenting results on that compound and the three indications at which we're looking in second half of the year. We did -- with JAK1, JAK2 want, and I think it turned out to be the right way to go, to have a distinct compound for inflammatory diseases and one for oncologic indications.

And that resulted in ruxolitinib and baricitinib. And we are taking the same approach here. But the second compound, it's early days and I'd just don't think I can say much more than that. Rich, do you have anything else to add to that?

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

No.

Matthew Roden - *UBS - Analyst*

Thanks a lot.

Operator

Liisa Bayko, JMP Securities.

Heather Behanna - *JMP Securities - Analyst*

Hi. Good morning. It's Heather in for Liisa. Just a quick question. If you could give us any more color just sort of about how persistence rates have continued over time, and just give us a little bit more color on new patients versus continuing patients?

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

I can't give you much more color than what we gave you in the prepared comments. Our best quantification of persistence right now is seen in our ability to drive titration and use of lower doses, and we are seeing that happening. Again, our new patient starts are very consistent. As we have communicated previously, we do expect to see a very modest deceleration in new patient starts, more weighted toward the back end of the year than the front end of the year. And we do expect to see a modest but important increase in persistence over the course of the year. And that's really exactly what we're seeing. That takes us into our guidance of $210 million to $225 million.

Heather Behanna - *JMP Securities - Analyst*

Okay, great. Thank you.

Operator

Brian Abrahams, Wells Fargo.

Brian Abrahams - *Wells Fargo - Analyst*

Hi. Thanks for taking my question and congratulations on a good quarter. Given the recent rejection of Xeljanz in Europe, I was wondering if you and your partner had any changes to the way you might approach development of baricitinib? Any tweaks you might make to the development program? And how confident are you in the differentiation of baricitinib from Xeljanz, such that you don't believe you would fall into the same -- necessarily fall into the same pitfalls that they did? And then I had a quick follow-up.

Paul Friedman - *Incyte Corporation - President & CEO*

So this is Paul and then I'll ask Rich to add anything that he thinks I didn't cover or didn't make clear enough. I really think at the end of the day the question is best posed to Lilly. But we certainly can opine on it. And there's some very important aspects to the question that you asked. In particular, we all listened to the advisory committee that was conducted with Pfizer, and based on what we learned during that, and knowing what Pfizer's Phase 3 study was, we used the learnings from the Pfizer structure study to do a couple of things. One is to increase the sample size, and the second, very importantly, was to enrich for patients more at risk in the RA population for structural deterioration in the absence of effective treatment.

And so we, and I believe Lilly, remained quite confident in the ability to demonstrate an improvement in structure in the target population. Beyond that and I think importantly, although the proof will be in the pudding when Phase III is complete, are that the Phase II data with baricitinib, it's a JAK inhibitor that spares JAK3 in contrast to tofacitinib, the Phase I data have not been associated with opportunistic infections, other than a few cases of uncomplicated zoster, shingles for example, or with malignancies. And while the Phase III data will be important to confirm this profile, we may well see a better risk-benefit profile than we have seen with tofacitinib. So we remain confident in the potential for approval of baricitinib for RA in the EU as well as the United States and around the world. Rich?

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

The only thing I would add is I think that because tofacitinib is going to potentially be approved at the 5-milligram dose and not the 10, and they had their positive structure data at 10, I think that also had an effect. And with respect to baricitinib, the 4-milligram dose, which is the top dose that Lilly is studying, is looking really good -- looked really good in Phase II from a safety perspective as well as from an efficacy perspective. They have MRI data, which even though they haven't had x-ray data to support that it was going to have effects on bone, they have that data from their MRI studies. So as Paul said, we think it's going to be safe enough to have the top doses go through, and that should with the enhanced design of the structure study, come out positive. So I think in some ways we're looking at this as an opportunity.

Brian Abrahams - *Wells Fargo - Analyst*

That's very helpful. Thanks. And one quick follow-up, and I will hop back into the queue. With the trials, with the Phase IIs for 110 continuing to move along, can you give us any more clarity on which of those trial read-outs we might expect in the back half of this year? Thanks.

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

So -- the psoriasis study may very well get presented at EADV I think which is in October in Istanbul, I believe. The rheumatoid arthritis data may very well get presented at ACR, and the myelofibrosis data may very well get presented at ASH. All those have -- none of them have been -- some of them have not even been submitted yet and others we have not heard back as to whether they'd be accepted for presentation. Should any of those not happen, we will think about backup plans or potentially just [top line voltarily] than otherwise expected.

Brian Abrahams - *Wells Fargo - Analyst*

Great. Thank you.

Operator

Salveen Richter, Canaccord.

Unidentified Participant - - *Analyst*

Hi. This is Andrew on the line for Salveen. My question is just on the pancreatic cancer, kind of how we should think about the expectations there and what you need to see in that trial to maybe get the label expansion, if there's any significant improvement in OS would be necessary or what you'd need to see to go to Phase III? Thanks.

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

Okay. The study was designed as clearly a Phase II study, one, where we did not have expectations that this study by itself would lead to any type of approval, accelerated or otherwise, in pancreatic cancer with the idea being that we would most likely need to go to Phase III. Is there a possibility

that the results could be so robust that we might actually approach FDA, trying to get an accelerated approval on this based on a commitment to do a second study later? It's possible, but I wouldn't suggest that that's our expectation. And in terms of things like what does the hazard ratio need to be, it has to be in a range where we'd feel comfortable that it's worth doing another study that wouldn't be so large. And I think there's a good chance that that will be the case.

But in terms of a hazard ratio that would be necessary for FDA to consider this as a basis of approval by itself, I really wouldn't want to try to predict that. Things are changing a little bit at FDA, there is more emphasis on breakthrough drugs. The oncology divisions have been calling a lot of things breakthrough drugs lately, so I don't know that you can necessarily just go on past experience, given the changes that are going on down there right now.

Unidentified Participant - - *Analyst*

Okay, great. Thank you very much.

Operator

Ying Huang, Barclays.

Unidentified Participant - - *Analyst*

Hi. This Christina on behalf of Ying Huang. I know you mentioned that you are planning to submit the RA data for your proprietary JAK110 potentially at ACR. But I just wanted to see if there was any more data on the trial design, given that I didn't see it listed on clinicaltrials.gov, but I did see the MS and psoriasis trials on there. Thanks.

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

I'm pretty sure it has to be on clinicaltrials.gov, I just don't know what the -- right now we're, it's -- we had initially done some one-month data, which was kind of an accelerating dosing paradigm with a few placebo patients included. Once we got toxicology data to be able to allow us to do three months, we are now doing parallel groups of, I believe, three or four different doses plus placebo. The study is not big by any means. These are not meant to be studies that would go directly to Phase III, but to give us a real sense of what the drug does in this indication in the sense of the doses that may be necessary in a variety of anti-inflammatory indications.

Dave Hastings - *Incyte Corporation - EVP and CFO*

Three months.

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

It's a three 12-week readout now as opposed to the one-week readout we had before. And I expect that if this was to be accepted for presentation at ACR, we would present both the results of the one-month data as was the updated three-month data.

Unidentified Participant - - *Analyst*

Great. Thank you.

Operator

Eric Schmidt, Cowen and Company.

Eric Schmidt - *Cowen and Company - Analyst*

Thanks for taking my questions. I'm intrigued by Rich's comment that the Phase II pancreatic trial has a good chance of producing a good enough hazard ratio to go to Phase III and also I guess by your decision to start the Gem/Abraxane combo study ahead of reporting out the Phase II data. What do you guys know or see about the Phase II trial?

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

Maybe I misheard you or maybe you misheard me. I said I didn't think there was a good chance that the data would be strong enough to go directly to a registration just because it's a small study. It's 135 patients.

Eric Schmidt - *Cowen and Company - Analyst*

But Rich, I thought you said it would be most likely supportive of a Phase III trial based on the Phase II showing a good enough hazard ratio?

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

That's not based on data. I just didn't think -- I think the rationale that we've had all along has been a good one. And what I was trying to say is that one of the considerations would be how large the study would need to be in order to go to Phase III, depending upon the hazard ratio that we actually see. All we know in terms of data is that it passed the futility analysis, which meant that the study had at least 30% power after that analysis. So now that I've clarified that, can you remind me you're specific question was?

Eric Schmidt - *Cowen and Company - Analyst*

That's what I wanted to know, I guess that you don't see the data and you don't have any other knowledge than what the DSMB elected to do.

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

That's correct.

Eric Schmidt - *Cowen and Company - Analyst*

Okay. And then a second question, maybe for Jim, on the potential impact from this new dose titration program. Is it possible we would see negative sales impact in Q2 as more patients select the free few weeks of drug?

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

We don't anticipate any negative revenue impact. If anything, Eric, I think you will see a positive revenue impact longer-term. We just implemented in the past several weeks, but we're seeing good activity. But we don't anticipate any negative revenue impact from it.

Eric Schmidt - *Cowen and Company - Analyst*

Okay, thanks. And last question then for Dave if I may, it looks like you saw 4% pricing benefit last quarter from the November price hike, another 2% this quarter, adding up to maybe 6%. Is that all we're going to see of the 9% hike? Are you going to basically recognize about two-thirds of that, or is there more to come?

Dave Hastings - *Incyte Corporation - EVP and CFO*

Well, I think that's basically it, right? I mean, that will be fully baked in going forward at this point, Eric.

Eric Schmidt - *Cowen and Company - Analyst*

So in general for your price hikes, we should assume about two-thirds will be realized?

Paul Friedman - *Incyte Corporation - President & CEO*

Let's have that one back. We took the price increase November 16, absent any increasing gross to net, we would have realized a 5% price increase in the quarter.

Dave Hastings - *Incyte Corporation - EVP and CFO*

The 2% is net of the gross in that impact there.

Eric Schmidt - *Cowen and Company - Analyst*

Okay. So we probably will see a little more price hike as you don't have the same gross to net in Q2.

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

That's correct.

Eric Schmidt - *Cowen and Company - Analyst*

Thank you.

Operator

Rachel McMinn, Bank of America Merrill Lynch.

Rachel McMinn - *Bank of America Merrill Lynch - Analyst*

Two questions. As we go into ASCO, I wanted to try to pick your brain, Rich or Paul, on how you think about the fibrosis remodeling data that we're going to see for Jakafi. A couple of years ago there was no improvement in fibrosis and that was considered a bad thing. Now that we are seeing it, there is some discussion about I'm not sure how it matters because fibrosis is not correlated to survival outcome. So it seems like a circular argument to me, but I wanted to pick your brain on that. And secondarily, going back to the JAK1 inhibitor for a minute, you've said before that it's got to be differentiated from baricitinib in order for you to really invest in two inflammatory programs. And I wanted to again get your sense

of is that the proof that you're seeing, is there something that's differentiated enough where we should expect the JAK1 inhibitor to be further developed in RA beyond just the Phase II? Thank you.

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

Okay. So first on the fibrosis. In the past what we had seen was that we were not seeing a lot of reversal of fibrosis. As you can see, if you do a bone marrow transplant and then within six months to a year, you can often see less fiber in the marrow. So it was really only when you got to compare to a matched historical control of patients who had received HU, that we really -- the main finding is that you're seeing less progression, it's progressing more slowly in that much control. And also that there are some patients, and I can't release the percentage of patients that actually had decreases in the amount of fibrosis in the marrow.

So is that a game changer? I don't really think so. As you said, I don't know that that changes the view on -- we know we have data out there saying there is an improvement in survival. If it was dependent or independent of fibrosis? Not sure it really makes a difference there. But I think there would probably be some physicians out there that would be swayed by that sort of data that may have not been swayed by survival from studies that were not exactly planned around survival and that symptoms was one thing. Maybe there will be some patients -- maybe some physicians will start patients who are not as symptomatic.

But I don't think it's a game changer by any means. We can talk about it more when the data is actually presented. With respect to the second question on differentiation, it's not just a question of differentiated from baricitinib. It's a question of differentiation from the range of new competitors that may exist at the time. And so we're not going to get into what we may or may not know about our results at this time.

We are saving that until we have more complete data and give some of those presentations at the meetings I talked about earlier in both psoriasis and RA on the inflammation side. But I will say that these are large investments in -- to bring these drugs to market for these indications, and I would not see us going forward just to have a late entry me too. So there would need to be some level of differentiation.

Rachel McMinn - *Bank of America Merrill Lynch - Analyst*

And just one quick one. Can we assume that the PML is not going to be reported in the FDA label for Jakafi? Is that -- have you had your discussions with regulatory agencies and that's just not an issue?

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

We have actually proposed mention of PML in the package insert. I'm not going to get into exactly where and how. And FDA has verbally been very much in agreement with what we have proposed. But they still haven't made a final decision. Maybe it needs to go up to other levels before it finally gets decided. And we're not going to try to speculate just exactly what that is, but since we've actually proposed something there, I can give you a clear view that there will be something there, because they're not going to say don't put anything in.

Rachel McMinn - *Bank of America Merrill Lynch - Analyst*

Great. Thank you.

Operator

David Friedman, Morgan Stanley.

David Friedman - *Morgan Stanley - Analyst*

Hi. Thanks for taking the question. It's just around the volume growth that you guys had this quarter. It looks like if I calculate, it was about $3 million of sort of organic volume growth, which is about half of what you guys reported last quarter. And if this is the new steady-state, it puts you at the bottom end of guidance. So I guess I'm just wondering what you think is going to change this year to re-accelerate the volume growth and the organic growth that puts you above that bottom end?

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

Hi, David, this is Jim. David, I would be very careful drawing a trend line from fourth quarter to first quarter. Because as we mentioned earlier, you can see some additional sales at the end of the fourth quarter. And it's generally, as you've seen for the industry, it's a pretty difficult comparison, fourth quarter versus first quarter. Having said that, we remain very confident in our guidance. And quite frankly I think -- let me just end it right there. We remain very confident in $210 million to $225 million this year.

David Friedman - *Morgan Stanley - Analyst*

Okay. Thanks.

Operator

Skip Klein, Gauss Capital Advisors.

Skip Klein - *Gauss Capital Advisors - Analyst*

Great. Thank you. I was wondering if you could give a little bit of an update on the competitive environment, what's going on at Avid, Galapagos, Gilead or the Jakarta study stand?

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

Avid, Galapagos, they've announced that they are I think doing 875 patients in Phase 2, which is a very large Phase 2 program. Which indicates that data that has not yet been presented but might be presented at ULAR, for example, on their second one-month study was positive enough for they and AbbVie to decide to continue to invest in this program. But in the absence of data, I can't comment further. With respect to Sanofi and their JAK1 -- excuse me, JAK2 inhibitor in myelofibrosis, we've never been that impressed with their Phase 2 data in the sense that they had a fair amount of GI intolerance. It's not like its grade three or four GI intolerance, but why would you want to have that sort of profile when you don't need to? Jakafi does not have that.

Secondly, with the doses that they've studied in the past, they've had even more anemia than our higher doses. So we recognize clearly that they're going to be coming out there with strategies, strategies of looking at so-called ruxolitinib or Jakafi failures if such a thing actually exists. But I think once we actually see the data and then they actually have to promote on label, we don't really see a tremendous threat from them. But again, we haven't seen the Phase 3 data.

Skip Klein - *Gauss Capital Advisors - Analyst*

And then Gilead YM, if you would?

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

That one still remains many years behind. We estimate it as probably -- I think we estimated it would probably be in late, what was it, late 2015, early 2016 launch. And they've said that they would be starting Phase 3 in the second half of this year, which is coming up in a few months. And it's been pretty much radio silence in terms of anything there. We think that that drug is not going to have some sort of magical effect on anemia that you don't see by just simply reducing the dose of ruxolitinib to about 10 milligrams twice a day. And they do have some side effects that we don't have. But we will get closer to it when they're actually -- in about three years and see where we stand.

Skip Klein - *Gauss Capital Advisors - Analyst*

Great, thanks. And then one quick follow-up. I didn't get an invitation, but is it possible that you had some champagne to celebrate the 4,000th unique patient being put on drug, being put on Jakafi? And/or the fact that you look like you might have been positive cash flow in the quarter after adjusting for options and non-cash interest expense? (laughter) Just questions. You know, yes or no. 4,000 patients look like they've been put on drug cumulatively. And it looks like you're positive cash flow. But I'm an old, tired analyst.

Paul Friedman - *Incyte Corporation - President & CEO*

One thing to keep in mind as you're looking at new patients being put on drug, about 10% of our patients are put on drug through our patient access program. So as you are doing your models, that may be a factoid that you want to keep in mind as well.

Dave Hastings - *Incyte Corporation - EVP and CFO*

And Skip, we do have multiple sources of cash flow, so we appreciate you acknowledging that. We're in good shape from a cash position.

Skip Klein - *Gauss Capital Advisors - Analyst*

So you're positive cash flow, once you adjust for option expense and I don't know what you're spending on capital spending, but that's good. You're turning the corner. But just bottom line, 4,000 patients whether they got free drug or not, have been put on this drug.

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

We are really not commenting on a specific number of patients on the product, Skip.

Skip Klein - *Gauss Capital Advisors - Analyst*

Okay. So you didn't open a bottle of champagne in the quarter. (laughter) Okay. Thanks a lot. Bye-bye.

Operator

Josh Schimmer, Lazard Capital Markets.

Josh Schimmer - *Lazard Capital Markets - Analyst*

Good morning. Thanks for taking my question. Two of them quickly. Will you announce if and when any additional PML events occur on Jakafi? Or once that's in the label do you not feel like you need to provide updates to the street? And then second, Jim maybe you could provide a little bit

of color on the progress that you're making establishing Incyte's standing in the MF community, either funding research, conferences, other activities that reach beyond kind of the core known KOLs and how that's been evolving over the course of this year. Thanks.

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

With respect to PML, it kind of depends. We see an increase -- if we see something that is beyond what we have already seen, such that as we say now we have one in about 10,000 cases, if that was to go up, then I think we would probably say something. If there is another 10,000 you know, patients on drug exposed to the drug before you see another one, then we probably wouldn't. So it's really a change in the view of the risk of the drug that I think would really result in that. And that probably would also be the same approach to potential changes in labeling beyond that. And can you repeat the second question about -- I'm not sure if it was for you or me?

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

I think the second question more directed toward me, Josh, regarding what progress are we making to develop our relationships with key opinion leaders. Josh, I think that's one where it's more productive to actually keep your head down and do the work rather than commenting on it on too frequent a basis. But obviously we have a long-term commitment to [hemalignancy]. Jakafi is obviously the cornerstone, but as you hear more about our pipeline, we intend to be working very closely with these physicians, these oncology academic medical centers, with the societies, on a long-term basis and clearly we are making a commitment to establish Incyte as really a scientific driver in this field.

Josh Schimmer - *Lazard Capital Markets - Analyst*

Great. Thanks very much.

Operator

Boris Peaker, Oppenheimer.

Matt Palmer - *Oppenheimer - Analyst*

Good morning. This is Matt Palmer in for Boris. Thanks for taking the question. Two quick ones, actually. How significant will label expansion be for low platelet patients on your target prescriber penetration? Or do you expect label expansion to have a significant effect on the current prescriber usage?

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

Hi, this is Jim. I think it will have a positive effect on both. We still have a significant number of new patient starts, where those patients have a baseline platelet count below 100,000. And I think the expanded label will help greatly with those. I also think that there will probably be some spillover on the anemia side, which is if you manage thrombocytopenia with a start low and go slow approach, it's not a huge leap of faith for doctors to assume that that's a logical approach for patients with low hemoglobin as well. So I think there will be a dual benefit both for new prescribers and current prescribers, but I think it will also extend beyond thrombocytopenia to benefit anemia as well.

Matt Palmer - *Oppenheimer - Analyst*

Great. Thank you. And secondly, you mentioned R&D was a little bit below expectations in the quarter. Should we expect some of these expenses to be shifted into the second quarter or later into the year?

Dave Hastings - *Incyte Corporation - EVP and CFO*

Yes, it was all timing.

Matt Palmer - *Oppenheimer - Analyst*

Great. Thanks.

Operator

Doctor Friedman, we have reached the end of the question-and-answer session. I would now like to turn the floor back over to you for closing comments.

Paul Friedman - *Incyte Corporation - President & CEO*

Thank you. And thank you all for your questions and for dialing in and listening today. We look forward to providing you with further progress as we move forward. Thanks. And with that, we will end the call. Good morning.

Operator

Ladies and gentlemen, this does conclude today's teleconference. You may disconnect your lines at this time. Thank you for your participation and have a wonderful day.