THOMSON REUTERS STREETEVENTS

# EDITED TRANSCRIPT

INCY - Q1 2014 Incyte Corporation Earnings Conference Call

EVENT DATE/TIME: MAY 01, 2014 / 12:30PM GMT

**OVERVIEW:**

Co. reported 1Q14 results.

## CORPORATE PARTICIPANTS

**Pam Murphy** *Incyte Corp - VP of IR and Communications*

**Herve Hoppenot** *Incyte Corp - CEO*

**Jim Daly** *Incyte Corp - Chief Commercial Officer*

**Rich Levy** *Incyte Corp - Chief Medical Officer and Head, Drug Development*

**Dave Hastings** *Incyte Corp - CFO*

**Reid Huber** *Incyte Corp - SVP, Discovery Biology*

## CONFERENCE CALL PARTICIPANTS

**Whitney Ijem** *JPMorgan Chase - Analyst*

**Matt Roden** *UBS - Analyst*

**Ian Somaiya** *Nomura Asset Management - Analyst*

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

**Eric Schmidt** *Cowen and Company - Analyst*

**Thomas Wei** *Jefferies & Company - Analyst*

**Michael Schmidt** *Leerink - Analyst*

**Navdeep Singh** *Goldman Sachs - Analyst*

**Steve Burns** *BofA Merrill Lynch - Analyst*

**Josh Schimmer** *Lazard Capital Markets - Analyst*

**Ying Huang** *Barclays Capital - Analyst*

**Liisa Bayko** *JMP Securities - Analyst*

**Boris Peaker** *Oppenheimer & Co. - Analyst*

## PRESENTATION

**Operator**

Greetings, and welcome to the Incyte Corporation's First Quarter 2014 Earnings Call. At this time, all participants are in listen-only mode. A question-and-answer session will follow the formal presentation.

(Operator Instructions)

As a reminder, this conference is being recorded. I will now like to turn the conference over to your host, Pam Murphy, Vice President of Investor Relations and Communications. Please go ahead.

---

**Pam Murphy** - *Incyte Corp - VP of IR and Communications*

Good morning, and welcome to Incyte's first-quarter 2014 conference call. On the call today are Herve Hoppenot, President and Chief Executive Officer; Jim Daly, Chief Commercial Officer; Dave Hastings, Chief Financial Officer; Rich Levy, Chief Medical Officer and Head of Drug Development; and Reid Huber, who leads Discovery Biology. Herve will begin with a brief overview for the quarter. Jim will follow with an update on Jakafi, and

Rich will highlight progress made in our clinical programs. Dave will then describe our first-quarter financial results. After that we will open up the call for Q&A.

Before beginning, we would 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, and our development plans for Jakafi in 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-K for the year ended December 31, 2013, and from time to time in our other SEC documents. Herve?

---

**Herve Hoppenot** - *Incyte Corp - CEO*

Thank you Pam, and good morning everybody. The field of oncology is evolving very rapidly at Incyte, with a growing marketed product and a pipeline that includes innovative targeted therapies and first-in-class compounds in onco-inflammation and immuno-oncology is very well-positioned to be an important player in this [challenge] in oncology. We had a very good first-quarter commercially and on the development side.

The sales of the Jakafi, demand are increasing at a steady rate, and we are very confident in the full-year net product revenue guidance of $3.15 to $3.35 median.

On the clinical side, we are growing our portfolio. The PV filing is on track. We launched our Phase III program of ruxolitinib with pancreatic cancer, and randomized Phase II studies of ruxolitinib in patients with colorectal cancer, lung cancer, and breast cancer have been initiated. The IDO program is advancing. The IDO and ipilimumab combination Phase I/II data will be presented at ASCO in a few weeks. We are on track to begin the trial combining our IDO inhibitor 24360 with Merck's anti-PD-1 immunotherapy in the second quarter.

Our selective JAK1 inhibitor, 39110, is expected to begin the first of two Phase II trials in non-small cell lung cancer in the second quarter, and we have advanced our PI3K-delta inhibitor 40093 in a Phase 1 trial in combination with 39110 in B-lymphoid malignancies.

Novartis continues to progress INC280, our c-Met inhibitor, and has initiated a second Phase II trial in c-Met positive HGFR TKI resistance non-small cell lung cancer. Our alliance with Lilly could deliver significant revenue for baricitinib, our second JAK1/JAK2 inhibitor, and we expect to see internal read-out of results from the first of multiple trials in our Phase III programs this year, with data presentation to come in 2015. We also plan to initiate a Phase II trial of our second JAK1 inhibitor, 47986, in rheumatoid arthritis by mid-year.

Now let me turn to ASCO. We will have three important clinical data presentations. On Monday night, following two of these presentations we will host an investor event where we will discuss the presentations that day. It's the RECAP results, as the data that supports the role of JAK inhibition as a mechanism to target systemic and local inflammation, and 24360 and the role we see for IDO inhibition in immuno-oncology. That's on Monday.

On Tuesday afternoon, following our presentation of the results from RESPONSE, the pivotal Phase III study in patients with uncontrolled polycythemia vera, we will host a second IR event, and Dr. Verstovsek will present the RESPONSE data. That will be coming in now a few weeks from now, where we will have all of this important data that will be presented.

Now Jim will provide more details around our commercial accomplishment with Jakafi.

---

**Jim Daly** - *Incyte Corp - Chief Commercial Officer*

Thank you, Herve, and good morning everyone. Our first-quarter net product sales of $70 million reflect continued steady growth in underlying demand, which was offset by one-time seasonal impacts from price and inventory draw-downs following inventory builds in the fourth quarter of last year. These impacts were anticipated, and we remain confident in our full-year guidance of $315 million to $335 million for net product revenues.

Year-over-year net sales grew 44%, and quarter-over-quarter sales declined 4%, with the following components of change relative to the prior quarter:

Underlying demand as measured by bottles dispensed to patients grew by 6%, consistent with growth relative to the same period last year. We're encouraged by this performance, given that seasonality typically makes first-quarter challenging for branded products, due to the annual reset of deductibles, increased cost sharing while in the donut hole, and patients pulling forward January prescriptions into December.

Net price declined by 4%, reflecting a temporary increase in gross-to-net discounts, driven by seasonal increases in Medicare Part D donut-hole rebates, reflecting a $3-million impact.

As expected and communicated on the fourth-quarter call, the inventory increase that occurred in the fourth quarter was given back in the first quarter. Inventory declined by 6%, and we exited the first quarter at the lower end of the normal range of 3 to 3-1/2 weeks. The dollar value decrease in inventory in the first quarter was approximately $4 million, consistent with the inventory build in the fourth quarter.

We believe the increase in underlying demand in the first quarter reflects continued solid execution of our commercial strategy to grow Jakafi in MF. Market research indicates that the expansion of our sales force, which was completed in the fourth quarter, along with high-impact educational programs, have driven expanded depth and breadth of prescribing for Jakafi. Measures of specific progress we're seeing, and an increased understanding of dosing, and recognition that Jakafi works regardless of JAK-2 V16F mutation status.

The overall reimbursement environment for Jakafi continues to be favorable. The vast majority of payors manage Jakafi consistent with the label, and patients are able to successfully manage most prior authorizations that exist.

In the first quarter we launched enhancements to our Incyte Cares patient support program. We remain committed to making this program second-to-none in terms of support levels, eligibility thresholds, and ease-of-use to benefit both current MF patients and future PV patients.

Our Jakafi net sales guidance assumes no meaningful contribution to revenues in 2014 from an FDA-approved indication in PV. We believe the PV indication will make a substantial contribution to Jakafi sales in 2015. The addressable patient population for PV is larger than that of MF, and the length of treatment of PV is likely to be longer than in MF.

Based upon claims data, there are at least 100,000 PV patients diagnosed and treated in the US. 60% of them are currently on HU, or were previously on HU, but discontinued because of side effects or lack of efficacy. We estimate that approximately 25,000 of these patients, or one in four, have inadequate response to or are intolerant of HU, and suffer from uncontrolled PV while on best-available therapies.

We've have always said that MPNs are just the beginning. We have a deep pipeline of novel molecules and innovative programs that represent an exceptional opportunity to make a difference for patients. To discuss this in more detail, I will turn it over to Rich.

---

**Rich Levy** - *Incyte Corp - Chief Medical Officer and Head, Drug Development*

Thanks, Jim. During the first quarter we took several important steps forward to broaden and strengthen our JAK inhibitor programs. Our development efforts with Jakafi and in myeloproliferative neoplasms continue to advance. In early March, RESPONSE, our Phase III registration study for polycythemia vera that's being conducted under an SPA, read out, and we announced that top-line results were positive.

The study, which compared ruxolitinib to best-available therapy for patients with polycythemia vera, who were resistant to or intolerant of hydroxyurea, met its primary end point for achieving both phlebotomy independence and reducing spleen volume by 35% or more. The safety profile of ruxolitinib was generally consistent with previous studies. Given the positive results, we remain on track to submit the sNDA this June.

Our second Phase III study in patients with PV, a double-blind study called RELIEF, is measuring disease-related symptoms, and data are expected mid-year. Our goal is to submit full results from the RELIEF for presentation at ASH in December, and to submit an sNDA label update on symptomatic benefit shortly after our expected approval of the PV indication.

I will next turn to our development efforts focusing on JAK inhibition in solid tumors. Previously we reported that the results from the Phase II, double-blind RECAP trial in second-line pancreatic cancer showed a hazard ratio for overall survival of 0.47, favoring the ruxolitinib arm in a prospectively defined set group of patients.

We will discuss these data and the sub-group in greater detail at ASCO, during both the oral presentation, as well as in our Monday evening investor event. At that event we will also describe in detail the mechanistic rationale for JAK inhibition in solid tumors, as well as the clinical basis for our patient selection methodology.

We're moving forward with randomized survival studies, not only in pancreatic cancer, but also in several other solid tumors. Our first and most advanced program is in pancreatic cancer. In March, we randomized and started treatment of the first patient in JANUS-1, a double-blind, placebo-controlled Phase III trial in the second-line setting, evaluating ruxolitinib versus placebo on a background of capecitabine. This is being conducted under a special protocol assessment.

A second, nearly identical trial called JANUS-2 is planned to begin within the next two months. Each trial will enroll approximately 300 patients who meet the criteria for the sub-group defined in the RECAP trial, and the primary end point will be overall survival.

We have also started screening in our double-blind, placebo-controlled Phase II trials in non-small-cell lung cancer and breast cancer, and have started treatment in the first patients in our colorectal cancer study, all with ruxolitinib. The breast and lung cancer studies will focus exclusively on the sub-group identified in RECAP. The breast cancer study will compare ruxolitinib plus capecitabine to capecitabine plus placebo with 148 patients. The lung cancer study will compare ruxolitinib plus pemetrexed and cisplatin to pemetrexed/cisplatin plus placebo in 156 patients.

The colorectal cancer study will compare ruxolitinib plus regorafenib to regorafenib plus placebo, and will also enroll a parallel group that does not meet the separate criterion, with the aim of demonstrating the differential benefit of ruxolitinib in the sub-group identified in RECAP. However, the primary end point will be based only on the patients in the selected sub-group. This study will enroll 373 patients.

We are also planning to evaluate our lead JAK-1 inhibitor 39110, in solid tumors, starting with two blinded Phase II studies in non-small-cell lung cancer, again with overall survival as the primary end point for both studies. The first study is planned to initiate in the second quarter, and the second study is expected to initiate later this year.

I'll now turn to our IDO1 inhibitor 24360, a mechanism that we think may provide meaningful therapeutic approach in the immuno-oncology field. We know that IDO1 inhibitors can provide anti-tumor effects in relevant pre-clinical models as monotherapy, and when combined with checkpoint inhibitors such as anti-CTLA 4, PD-1, or PDL-1, significant synergy has been achieved. We look forward to presenting the results of the ongoing uncontrolled dose-finding portion of our Phase I/II study of 24360, in combination with the approved anti-CTLA 4 antibody ipilimumab in melanoma at ASCO, the data from which continued to be encouraging.

In addition, we will soon initiative our first combination study with Merck's anti-PD-1 immunotherapy, MK3475. Under the terms of the non-exclusive clinical collaboration agreement, Incyte and Merck will co-fund a Phase I/II study in patients with previously treated metastatic and recurrent non-small-cell lung cancer, as well as other metastatic cancers. The Phase I portion should define a recommended regimen for the two combined agents in patients with a range of solid tumors.

The Phase II portion will evaluate efficacy and safety of that recommended regimen in a randomized population of non-small-cell lung cancer patients for all patients who will receive MK3475, combined with either our IDO inhibitor 24360 or a placebo. Incyte will conduct the study, though the design of the study was done in close collaboration with Merck. The IND has been cleared by the FDA, and the trial should begin enrolling patients by mid-year.

We also have additional opportunities to combine our drugs, when pre-clinical data suggest the combination may have additional clinical benefits. The first such targeted combination that we are currently evaluating in a clinical trial is with our JAK-1 inhibitor 39110 and PI3K-delta inhibitor 40093, in patients with B-lymphoid malignancies. Both are distinct mechanisms that exhibit synergy in pre-clinical studies in lymphoma. With that, I'll now turn the call over to Dave.

**Dave Hastings** - *Incyte Corp - CFO*

Thanks, Rich. Good morning, everybody. Let's begin with Jakafi, for which we recorded $69.7 million of first-quarter net product revenues. Additionally, we reported $9.8 million in product royalties for Novartis for sales of Jakafi outside the United States. We also recorded as part of contract revenues in the first quarter a $7-million milestone from Novartis, based on the formal initiation of a Phase II clinical study with c-Met inhibitor IMC 280 in c-Met positive/EGFR TKI-resistant non-small-cell lung cancer.

Our gross and net adjustment for product revenue recognized was approximately $9.6 million, or 12.1% for the first quarter. As I mentioned in our last call, we expected our gross and net adjustment to be higher in the first quarter than the rest of the year, primarily 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 9% to 10%.

Our cost of goods sold for the first quarter was immaterial, as we continue to benefit from the fact that are 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.

From a cash perspective, we entered the quarter with $519 million in cash. Our multiple and increasing sources of cash flows from net product sales, milestones and royalties, and our stable cash position give us the ability to continue to invest in our PV launch activities, and fund our expanding high-potential pipeline.

With that operator, that concludes our formal remarks, and let's 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)

Cory Kasimov, JPMorgan Chase

**Whitney Ijem** - *JPMorgan Chase - Analyst*

Good morning. This is Whitney on for Cory this morning. Two quick IDO questions for you. First, can you give us any more detail in terms of how many patients we'll see date on at ASCO, or how many cohorts have been enrolled? Also, if you could give us any detail on what data we should be expecting in the abstract, in terms of types of data versus the poster?

**Rich Levy** - *Incyte Corp - Chief Medical Officer and Head, Drug Development*

Sure. You didn't say it, but I'm pretty sure that you are talking about the IDO study.

**Whitney Ijem** - *JPMorgan Chase - Analyst*

Yes.

**Rich Levy** - *Incyte Corp - Chief Medical Officer and Head, Drug Development*

In the abstract, we will have results of the patients who were first started at 300 milligrams -- even though that dose was not tolerated, we'll present some -- there's data in the abstract on those patients. Then we went down to 25 milligrams twice a day. There were eight patients in that cohort, and that is the data that is in the abstract. At the actual presentation we will also have results of the 50-milligram VID cohort, which adds about another seven or eight patients. All together, there is a number of patients. But there will definitely be some additional data from the higher-dose cohort in the presentation that is in the abstract that we expect to come out around two weeks from now.

---

**Whitney Ijem** - *JPMorgan Chase - Analyst*

Got it. Thanks for taking the question.

---

**Operator**

Matt Roden, UBS

---

**Matt Roden** - *UBS - Analyst*

Great. Good morning, and thanks for having me on the call. I would like to ask a commercial question, and then a pipeline follow-up, if I may. First on commercial. Jim, could you maybe amplify your comments on the Jakafi demand in terms of new patient starts and persistency rates, and perhaps whether or not there is any perspective on April trends?

---

**Jim Daly** - *Incyte Corp - Chief Commercial Officer*

Sure, Matt. As we look at the underlying demand trends in the first quarter, they're rock solid. Again, 6% dispensed. Again, that's dispensed to patients -- very consistent with what we saw same period last year, quite consistent with what we saw quite frankly in the fourth quarter. We are seeing expansion of new prescribers. Quite frankly, we're seeing those trends persist through April. We've had a strong April. We feel that the impacts that we felt in the first quarter were seasonal, and the underlying business remains robust.

---

**Matt Roden** - *UBS - Analyst*

Jim, as the gross to net and inventory normalizes here, to what extent should we expect a snap-back in reported sales in 2Q? Lastly, can I just gauge your level of confidence in the guidance range?

---

**Jim Daly** - *Incyte Corp - Chief Commercial Officer*

Sure. As you know, patients, particularly when you have a branded product with a significant Medicare Part D component, patients do have a tendency to try and pull forward prescriptions from January into December. That effect only lasts for a month. You would expect to see that bounce back. We're seeing that. Price was kind of a wind in our face in the first quarter.

We had gross to net of 8% in the fourth quarter. We jumped to 12% in the first quarter. But as Dave guided, 9% to 10% for the year. We expect that to come down, so price will certainly be a wind at our back. Plus we took a price increase on April 1. We expect to have, and we think we ended the quarter at the low end of the normal range of inventory. We've got all drivers going in the right direction in the second quarter, so we think we're going to have a very strong second quarter. Then the other --

---

**Matt Roden** - *UBS - Analyst*

Sorry, go ahead on the guidance?

---

**Jim Daly** - *Incyte Corp - Chief Commercial Officer*

Yes, the implication for the guidance. Matt, quite frankly we're more confident in the guidance we issued on the fourth-quarter call now than we were when we issued it. We're feeling really good about where the business is. We've got a lot of momentum. We have a very high level of conviction in the current guidance.

---

**Matt Roden** - *UBS - Analyst*

Okay. One follow-up on the pipeline, if I may. Rich, I wanted to get your perspective on the SPA, on the Jakafi Janus study. On one hand you could say it's not terribly ground-breaking to have an SPA for a survival trial in cancer. But is the right interpretation of the SPA is that the regulators thought that the onco-inflammation approach is clinically real and significant? Does this represent sort of a blessing of the sub-group, and imply that regulators are buying into the mechanism based on the data?

---

**Rich Levy** - *Incyte Corp - Chief Medical Officer and Head, Drug Development*

Clearly there's buy-in to the sub-groups. That was not an issue and we have in writing that we don't need to study the other sub-groups, et cetera. With respect to how much FDA believes in the mechanism, they're a skeptical group in general, and they say show me more data. They've seen the early data, and they said we need another trial. You would be better off following the regulations and doing two more trials just to be absolutely safe, in case the results in the first of those trials is not quite as robust as what you saw in Phase II.

That's about all I can say. The SPA was a process that we went through, not because we wanted to get their buy-in that survival could be the primary end point, but to make sure that the sub-group was okay, and that we didn't need to do any work to develop a companion diagnostic.

---

**Matt Roden** - *UBS - Analyst*

Okay, great. Thanks, and congrats on all the pipeline progress.

---

**Operator**

Ian Somaiya, Nomura

---

**Ian Somaiya** - *Nomura Asset Management - Analyst*

Thanks, and I apologize in advance for all the background noise. First question was on the Jakafi. pancreatic cancer data presentation. Could you just give us some sense of what to expect, what additional cuts of the data we will get? I know in the press release you shared with us the (inaudible - background noise) survival of the two groups. Are we just going to get an extension of that to nine-months plus, or was there something more we should expect? I have one follow-up.

---

**Rich Levy** - *Incyte Corp - Chief Medical Officer and Head, Drug Development*

Okay. I can't go into details as to what is going to be in the abstract slash presentation. I think the main difference that you will see from what's already out there is identification of the sub-group. I don't remember the abstract per se, to remember what else is in there. But there is more information than was simply in the press release that we issued before.

Then the actual presentation will obviously go beyond the abstract. I think importantly, the investor event that we will do that evening will include additional presentations that go beyond the actual results of the RECAP study to include background on historical data, on selection of the sub-group, and why we are confident that this is not only real here in pancreatic cancer, but other solid tumors, as well; as well as more on the scientific background on the whole theory and evidence behind onco-inflammation as a therapeutic target, with Jakafi being a good choice there.

---

**Ian Somaiya** - *Nomura Asset Management - Analyst*

Okay. The one follow-up was on the combination study you are running, and the (inaudible) B-cell lymphoma (inaudible) and JAK1. I'm just intrigued by the combination of that mechanism, I was wondering if there are any sub-groups which you have identified or are enriched for in that trial, like you did in the RECAP study?

---

**Rich Levy** - *Incyte Corp - Chief Medical Officer and Head, Drug Development*

Right now we're still in the dose-finding portion of that study. We generally, and in this case as well, try to get through dose finding with a broad population of patients until we get to the drug levels where we're confident that we really want to be focusing on potential sub-groups that may be best. In that study we're not focusing on the same sub-group as in the solid tumors, although that is a possibility for later on. I'd ask Reid if he wants to add anything to this.

---

**Reid Huber** - *Incyte Corp - SVP, Discovery Biology*

Yes, the only thing I would add, Ian, is that we have some degree of interest of course in the ABC sub-type, just given the background biology of JAK-STAT signaling there, and even some of the emerging data with B-cell receptor inhibition; but I think our pre-clinical data suggests that the combination could have utility outside of that sub-group. Just to amplify Rich's statement, that's one of the underlying reasons why in rolling a broader set of patients and surveying the activity in a more broad set early on is important to us, because I think that's driven by part of the underlying thinking in the biology.

---

**Ian Somaiya** - *Nomura Asset Management - Analyst*

Okay, can you just give us a sense for what the likely next steps are going to be for that program, and for that combination?

---

**Rich Levy** - *Incyte Corp - Chief Medical Officer and Head, Drug Development*

Sure. We've already established with monotherapy with 40093 that we're able to get safely to levels that inhibit the target by over 90% throughout the dosing interval. We then took a step back when we added it in combination with the JAK1 inhibitor, and we want to get up to at least that level. Then there are several expansion cohorts in different patient populations which I'm not really ready to discuss at this time.

But Reid also mentioned for example the ABC sub-type of DLBCL is something we are interested in. That will potentially give us the answers to whether or not we want to move forward to potential Phase II or even registration trials in some of those B-cell malignancies with that combination. I'd rather just hold off on greater details until a later time.

---

**Ian Somaiya** - *Nomura Asset Management - Analyst*

Okay. Thank you very much.

---

**Operator**

Brian Abrahams, Wells Fargo Securities.

---

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

Hi, thanks for taking my questions, and congratulations on all the commercial and pipeline progress. Question on PV to start. I know we're going to see the full data in a couple of weeks, but is there anything I guess qualitative you can talk about that you maybe learned about Jakafi's benefits in treating PV from the RESPONSE study, compared to what we already knew from the Phase II experience? You guys seem pretty confident in the potential positioning once this is approved next year. I'm curious also if you're starting to see any up-tick in off-label use, or more relaxed restrictions from insurers, since the positive top-line data has come out. Then I had a quick pipeline follow-up. Thanks.

---

**Jim Daly** - *Incyte Corp - Chief Commercial Officer*

Brian, this is Jim. I'll take the second question first, which is we see just a very gradual increase in the percent of use that is non-MF. I think we had 12% non-MF in the fourth quarter, and that's gone to 13% in the first quarter. No meaningful change.

---

**Rich Levy** - *Incyte Corp - Chief Medical Officer and Head, Drug Development*

I have to be careful what I say here, because the data are not out yet. There are some differences between the designs of the trials, more so than there are differences in the results of the trials. For example, in the Phase II trial we looked at spleen by palpation, not by MRI; whereas we did MRI in Phase III. We had a run-in period where we got people into a therapeutic range for their hematocrit within the Phase II trial, and then looked for phlebotomy eligibility; whereas in Phase II we just took them where they were. There are going to be some differences based on the designs of trials, but I don't think quantitatively or qualitatively they indicate anything different.

Obviously the Phase III trial is larger, and that gives us an ability to start looking at certain things that we had no potential to look at in Phase II, including for example, even though the rates are low, rates of thrombosis in the different arms of the trial -- which is you try to keep hematocrit risk down in order to be able to avoid thrombosis; but actually doing thrombosis trials is way too long and too large, and the FDA agreed we didn't need to do that. Within this larger study, with patients studied longer, we can start to get a hint at some of that data, as well.

---

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

Thanks, Rich. That's really helpful. Just a quick follow-up. You mentioned, and I think Lilly's recently mentioned that we will see some of the Phase III data for baricitinib rolling out by the end of this year. Can you possibly clarify which of the studies -- which study or studies we might see? Is there anything you are waiting to see from those read-outs prior to starting the Phase II for 986 and RA? Thanks.

---

**Rich Levy** - *Incyte Corp - Chief Medical Officer and Head, Drug Development*

The answer is I do know which trials are likely to read-out this year, but I am not at liberty to give any information on Lilly's programs at this time. They really are in control of the message on this one, and what we've said is what we are allowed to say at this point in time.

---

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

Okay, fair enough. Then in terms of gating factors for 986, anything you are looking for in those studies before you start 986?

---

**Rich Levy** - *Incyte Corp - Chief Medical Officer and Head, Drug Development*

No. That study is pretty much ready to start. We have an investigators meeting coming up, and then patients with start enrolling. Protocol is finalized. The IND is cleared. That's pretty much ready to go.

---

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

Great, thanks again.

---

**Operator**

Eric Schmidt, Cowen and Company.

---

**Eric Schmidt** - *Cowen and Company - Analyst*

Thanks for taking the question. Maybe a big-picture question for Herve. It looks Ike you are planning quite a show at ASCO, with two analyst meetings, one focused on JAKs and solid tumors, and IDO. If there are one to two points that you want investors to take home from that analyst meeting on JAKs and solid tumors and IDO, what would they be?

---

**Herve Hoppenot** - *Incyte Corp - CEO*

Well, the reason we do two meetings is frankly mostly practical, because two of the presentations are Monday. I know many of you in fact may not stay on Tuesday. What we wanted to do is to do a meeting on Monday evening to discuss IDO and onco-inflammation. I think as you see, the data itself are going to be a big part of this meeting.

But in addition to the data, what we would like to discuss with all of you is also the scientific rationale behind onco-inflammation, and the fact that there is a mechanism there that is fairly new, where very few companies are involved, and we are in the lead. It is our responsibility to clarify for everybody what is the science behind the mechanism (inaudible) of a drug like Jakafi in solid tumors. For IDO, obviously there is data that will be disclosed for the first time, and then we will be discussing also the status of the program, and how we see combinations being a key part of the next steps for these products.

---

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

Thank you, that's helpful.

---

**Operator**

Thomas Wei, Jefferies

---

**Thomas Wei** - *Jefferies & Company - Analyst*

Thanks, just a couple on 360. Just to clarify, how many were at 300 mg?

---

**Rich Levy** - *Incyte Corp - Chief Medical Officer and Head, Drug Development*

I would say it's probably about somewhere in the range of six, but I just don't have that number in my head. Pam is whispering to me that she thinks it was seven.

---

**Thomas Wei** - *Jefferies & Company - Analyst*

Okay, so it might be seven, eight; and then seven or eight. In total, we may get around 22, 23 patients presented at ASCO in the actual presentation, is that right?

---

**Rich Levy** - *Incyte Corp - Chief Medical Officer and Head, Drug Development*

Yes.

---

**Thomas Wei** - *Jefferies & Company - Analyst*

Can you give us a sense -- because of the disparity of the doses here, when you talk about having a positive view on the efficacy signals, you are talking about at all doses here? This isn't something that's being driven by the data at 300 milligrams?

---

**Rich Levy** - *Incyte Corp - Chief Medical Officer and Head, Drug Development*

Absolutely not. That would be -- I couldn't pass a red-face test of saying we have a non-tolerated dose that works, and tolerated doses that are not working. Yes, our excitement that we had and communicated in the past was based on the results that we were seeing at 25 milligrams. The BID that we had before we submitted the abstract, that includes the data at 25 BID.

---

**Thomas Wei** - *Jefferies & Company - Analyst*

You have talked about showing data on response rates, progression-free survival, overall survival. Can you say are we going to see some data on things like depth of response at the ASCO presentation?

---

**Rich Levy** - *Incyte Corp - Chief Medical Officer and Head, Drug Development*

Two things. One, I think so, but we have not finalized the presentations yet. But I think we're going to probably show a waterfall plot where you show the depth of response on each individual patient within certain groups.

Second, as I have tried to say, we have survival data. I'm not sure what we're going to do with it because in this era, patients who fail this combination may go on to things like PD-1 inhibitors, whereas that was not true at the time when ipilimumab monotherapy was being first studied. That could be overly misleading to suggest something that we don't know is related to the drug, per se. But time to progression, or time to change in regimen as a measure of progression, is something that we believe is interesting data and will be included in the presentation.

---

**Thomas Wei** - *Jefferies & Company - Analyst*

Lastly, the Merck IDO combination study. Given the huge range of doses that you have looked at historically with this, and the 300 milligrams maybe being a very specific toxicity issue with IPE, is the plan to stick to the 25, 50 end of the range with IDO, or to start there and to go all the way up to the original proposed 300 milligrams? How should we think about that, and how many doses might this early Phase I part actually end up exploring?

**Rich Levy** - *Incyte Corp - Chief Medical Officer and Head, Drug Development*

I think we went to 600 or 900 originally with monotherapy, and that was way higher than we needed to be. I agree with you that we believe that the combination toxicity data is largely an IPI combination issue, and most likely not a PD-1 or a PDL-1 combination issue. But we have to generate the data to do that. We are going to start relatively low and work our way up. But I don't think that anyone has the view that there's a need to take the amount of time it would take to get all the way up to a 300-milligram dose.

Again, because when we looked at this we said in the range of 25 to 50 milligrams VID gives about all the efficacy that you see in the pre-clinical model. We would like to have some buffer there above that so that every patient remains in that therapeutic range. I don't think it's the case that we're going to have to go gradually from 25 VID, as an example of a starting point, all the way up to 300. But the protocol probably allows us to continue to go, but I think that we probably won't go past a few doses.

**Thomas Wei** - *Jefferies & Company - Analyst*

Thanks, that's very helpful.

**Operator**

Michael Schmidt, Leerink

**Michael Schmidt** - *Leerink - Analyst*

Good morning. Thanks for taking my questions. I had one bigger-picture question on the IDO inhibitor. With the immuno-oncology landscape evolving rapidly and becoming fairly competitive in some of the indications, what is your overall philosophy in driving development for 24360 forward, in certain indications versus others? Then I had a follow-up.

**Rich Levy** - *Incyte Corp - Chief Medical Officer and Head, Drug Development*

We're looking at a broad range of options. With respect to the PD-1 or PDL-1 targets, we think those are very good drugs. But in many of the indications there is evidence of efficacy, but not for example, as strong as they are in melanoma. What we're really looking for primarily is indications in which we know the mechanism is active, but for which there is significant room for improvement that could be demonstrated in moderately sized registration trials.

We also continue to look at opportunities for other combinations outside of PD-1, PDL-1, potentially with things like ipilimumab, potentially with things like vaccines, and potentially with some of the other novel targets that are coming forward in immuno-oncology.

**Michael Schmidt** - *Leerink - Analyst*

Got it. With regards to PV and the Novartis collaboration, have you disclosed what level or what types of milestone payments are tied to the PV approval alliance?

**Rich Levy** - *Incyte Corp - Chief Medical Officer and Head, Drug Development*

Yes, they're very typical milestones you'd see in these types of collaborations. Obviously key events such as approval and pricing reimbursement in their territory would be the most obvious.

**Michael Schmidt** - *Leerink - Analyst*

Okay, great. Then a last one on Lilly. Are you aware of development plans for baricitinib outside RA on parts of Lilly?

**Rich Levy** - *Incyte Corp - Chief Medical Officer and Head, Drug Development*

What's been publicly announced is that they are doing Phase II trials in psoriasis and diabetic nephropathy. They have not said anything beyond those two indications.

**Michael Schmidt** - *Leerink - Analyst*

Okay, great. Thanks for taking my questions.

**Operator**

Navdeep Singh, Goldman Sachs.

**Navdeep Singh** - *Goldman Sachs - Analyst*

Good morning guys, and thanks for taking my questions. Just a few questions. Maybe I'll start off with a question on Jakafi. Given the recent increase in scrutiny of cost of drugs, including oncology drugs, how much more pricing power do you believe you have with Jakafi in the US? I saw that you took another 5% increase at the end of Q1. Then I have a follow-up question on the IDO-1 inhibitor. Thanks.

**Jim Daly** - *Incyte Corp - Chief Commercial Officer*

Yes, it was 4.75. Yes, I think most of the payors are focused on the larger-use areas where you have a small orphan indication with a survival benefit. With data suggesting supportive of a survival benefit, we have had minimal push-back from payors regarding the value proposition for Jakafi.

**Navdeep Singh** - *Goldman Sachs - Analyst*

Okay, great. Then a question on the IDO-1 inhibitor. Are you guys concerned at all that a competing IDO-1 inhibitor may be able to enter into an exclusive deal with Merck, or any other pharma, if you report pretty compelling data from your study, evaluating IDO-1 inhibitor, plus the marked PD-1 antibody? Is there anything that could prevent Merck from taking such a path?

**Herve Hoppenot** - *Incyte Corp - CEO*

Maybe I can take this. I will say there's nothing that can prevent anybody from taking such a path. The reality of the field of IDO is that we are well ahead of the competition, and that's what we intend to continue -- where we intend to continue to be. We don't see that as a potential issue.

**Navdeep Singh** - *Goldman Sachs - Analyst*

Okay, thanks a lot everybody.

**Operator**

Steve Burns, Bank of America Merrill Lynch.

---

**Steve Burns** - *BofA Merrill Lynch - Analyst*

Based on your understanding of the biology of the JAK signaling pathways, do you hypothesize that there is a role for the JAK-2 inhibition in these solid tumors, or do think it's more neutral in its effect, and-or could the sub-group potentially remove a detrimental effect?

---

**Reid Huber** - *Incyte Corp - SVP, Discovery Biology*

This is Reid. The question as to the relevance of JAK-2 inhibitory activity to the data that we are going to present at ASCO around RECAP is still an open question. But we have some perspective that really are driving our more balanced approach on the development program where it involves bringing ruxolitinib forward when possible, and also taking JAK-1 (inaudible - background noise) compound forward.

The data that we'll describe, particularly at the investor event at ASCO, will go into some detail as to which cytokine are believed to play the most important driving role in both local and inflammation within the tumor mirco-environment, as well as systemically where they may manifest in some of the metabolic (inaudible) or commonly seen in advanced malignancies.

The majority of that data, I think is fair to say, supports an important role for JAK-1 signaling, and therefore likely an important role for JAK-1 inhibition in the benefits that we see in pancreatic cancer, and that underlie the rationale in other tumor types. JAK-2 can play a role in some cell types in myelo-derived suppressor cells, things like that. It may be that the importance of JAK-2 activity is more histology dependent.

These are all things that we're going to have to explore with the development program, and really underlie our view that while we can take ruxolitinib forward in regimens that are not overly myelosuppressive we'll do that. In histologies and regimens where we otherwise couldn't take Ruxolitinib, then that's a good place to explore JAK-1, and our thinking about all of these things will evolve over time.

---

**Steve Burns** - *BofA Merrill Lynch - Analyst*

Just a follow-up for you, Jim. You mentioned the price increase from March. It was roughly half the prior price increase. Do you anticipate shortening the interval between price increases? Is this a change in your pricing strategy?

---

**Jim Daly** - *Incyte Corp - Chief Commercial Officer*

Steve, as a general policy we don't comment on forward pricing actions. But if you look at oral oncolytics, there is a growing practice to move toward twice-a-year pricing actions.

---

**Steve Burns** - *BofA Merrill Lynch - Analyst*

Okay, thank you.

---

**Operator**

Josh Schimmer, Piper Jaffray.

---

**Josh Schimmer** - *Lazard Capital Markets - Analyst*

Thanks for taking the questions. First on the IDO inhibitor program, do you plan to pursue additional studies in combination with ipilimumab? What's the rationale for expecting synergy with PD-1 antibodies more to what was seen was EPI?

---

**Rich Levy** - *Incyte Corp - Chief Medical Officer and Head, Drug Development*

We are exploring all options. We clearly are focused on the PD-1s, and putting the study with Merck. If there is an opportunity with ipilimumab that is not already potentially taken by a PD-1, we would certainly be interested in exploring that. We have not closed the door on anything. I'll turn the second question over to Reid.

---

**Reid Huber** - *Incyte Corp - SVP, Discovery Biology*

Yes. Josh, this has now been published work, conducted in collaboration with Tom Gajewski at University of Chicago, and has also been a study published using the IDO-1 knock-out mouse, that describes who the pharmacology with combined inhibition or loss of IDO-1 and PD-1, PDL-1 blockade.

I think to summarize it briefly, these are mechanistically distinct intervention points. They target different aspects of the negative regulation of anti-tumoral immune response. Taking off IDO-1 as a break and if ipilimumab activity is reflective of two distinct therapeutic approaches that can give you synergy. Very similarly, in it being IDO-1 and antagonizing PD-1 gives you a very similar pharmacologic affect overall. Basically, these are multiple independent points on a cascade, and your ability to achieve synergy is very clear pre-clinically when you take off multiple breaks.

---

**Josh Schimmer** - *Lazard Capital Markets - Analyst*

Great. Then for the Jakafi and other solid tumor indications, lung, breast, and colorectal, what percent of those patients share the same mystery sub-group features as in pancreatic cancer? I wasn't clear, will those be the patients enrolled in those Phase II trials -- those sub-group patients? Or is it the broad patient population?

---

**Rich Levy** - *Incyte Corp - Chief Medical Officer and Head, Drug Development*

We will get into that in more detail when we actually do our investor meeting, when we actually disclose the sub-group. But I will say that probably the breast cancer patients, which is probably the largest of the indications, has a lower percentage that would meet this sub-group. But we should have no trouble finding them, because there are so many of these breast cancer patients. What was your second part of the question?

---

**Josh Schimmer** - *Lazard Capital Markets - Analyst*

Whether the trials will specifically only include those sub-group patients or whether it will --?

---

**Rich Levy** - *Incyte Corp - Chief Medical Officer and Head, Drug Development*

Right. As I tried to get across in my prepared remarks, the lung cancer and breast cancer studies are only in the sub-group. The colon cancer includes two groups, those that meet this definition and those that do not. But the primary end point in the colon cancer study is based on those patients that are in that sub-group. We felt that it was important to demonstrate that this sub-group was not only predictive in pancreatic cancer, but in at least one other tumor type.

We chose to do that within colon cancer, because this study, which is on top of (inaudible), the very advanced patient population, positive trial there, has some potential to be a registration trial. We wanted to make sure that we were kicking the box of showing that this predictor that we

saw confirmed in pancreatic cancer was also confirmed in one other tumor type. We don't feel that if we show this in both pancreatic and colon that we would need to show it in other types. That's the reason why that study is bigger.

---

**Josh Schimmer** - *Lazard Capital Markets - Analyst*

Got it. Thanks very much.

---

**Operator**

Ying Huang, Barclays

---

**Ying Huang** - *Barclays Capital - Analyst*

Thanks for taking my question. I have one for IDO first. For obvious reasons, the investors have been focusing squarely on the response rate you will reported at ASCO. I want to probe your thoughts on the relationship between response rate and then eventually will it see hopefully a PFS and OS benefit in this combination between IO inhibitor and (inaudible) inhibitor here. Secondly, what's the difference in protocol for the JANUS-1 and JANUS-2 trials for the Phase III pancreatic cancer trial? Does the SPA you reached with FDA stipulate that you have to meet survival end points for both? Thanks.

---

**Rich Levy** - *Incyte Corp - Chief Medical Officer and Head, Drug Development*

Okay. You may have to remind me of all the questions again. Let me start backwards. The SPA does not say that we need to have two positive trials. The SPA is around the design of the first trial, and the communications with FDA, or that if the results of that one trial are robust, that may be sufficient. But we were advised to do a second trial in case the results of this trial are not as strong as in the Phase II trial.

In terms of response rates, progression-free survival, survival et cetera, it's clear that there are long-lived patients who are not responders to immunotherapies. I think it's a good thing to start with the real responses, including as you have seen with the PD-1, some pretty deep responses in terms of the percent change in tumor volume.

The second thing is that we will present data on the duration of response in some of these patients and compared to historical data with ipilimumab. I think that response and time to progression -- again, survival data is just biased in our favor. That's why we -- no one should think that we don't think that survival is good. It's just that if someone has progressed and they go on to another therapy that didn't exist before, it's just hard to compare, and we don't to take credit where it may not be real yet.

I would look at this as an early study for which you have -- where you are limited in terms of some of the things that you have, like what is the long-term survival in patients. But for what we have, I think it remains a supportive that we are looking at something that is encouraging, something that is clearly better than ipilimumab monotherapy. I will just reserve further comments on how this may compare to PD-1s in melanoma until you see the data.

---

**Ying Huang** - *Barclays Capital - Analyst*

Can you remind us whether there is any protocol difference between JANUS-1 and JANUS-2 trials?

---

**Rich Levy** - *Incyte Corp - Chief Medical Officer and Head, Drug Development*

Yes, sorry. The differences are number one, that we are looking at symptoms of pancreatic cancer in JANUS-2, but not in JANUS-1. But that's still only an exploratory end point there, to try to fully evaluate a potential patient-reported outcome that could be a supplemental labeling statement at a later time. The second thing is that JANUS-1 is a little bit larger the JANUS-2 -- not by a lot, simply because the only real role for JANUS-2 will be if JANUS-1 is not sufficiently robust, but we need a second positive trial. It's a little bit smaller. Otherwise, the designs are pretty much identical.

---

**Ying Huang** - *Barclays Capital - Analyst*

Thank you.

---

**Operator**

Liisa Bayko, JMP Securities

---

**Liisa Bayko** - *JMP Securities - Analyst*

Hi, thanks for taking the question. Just a follow-up to something you were saying earlier. I know the colorectal study for Jakafi is large, and therefore could be eligible for registration. Could you maybe comment on that for the lung and breast? What would be necessary if the results were good here? Could those would be included in the label eventually?

---

**Rich Levy** - *Incyte Corp - Chief Medical Officer and Head, Drug Development*

First, I don't want to set expectations that the colon cancer study is a registration study and there's an expectation that we would get approved if that study is positive. We're saying if the results of that are sufficiently robust, and considering that there are no options for those patients, that's a possibility. With respect to the breast and non-small-cell, there is no possibility in my mind that those studies would actually be the registration studies. But whether if we then went on to a subsequent study, the results of those earlier Phase II studies could also be included in the eventual labeling, that remains a possibility.

---

**Liisa Bayko** - *JMP Securities - Analyst*

Okay, great. Then just a quick question. I noticed you have modified the language around PV a little bit. It used to be sort of relapse refractory intolerant, and you're talking a little bit more now, but qualifying it as uncontrolled. Is there any meaningful difference behind that?

---

**Jim Daly** - *Incyte Corp - Chief Commercial Officer*

No, Liisa. We're going through a translation process right now. I think Rich and his team translated Phase II to Phase III. Now we have to translate Phase III to a label. As a commercial team, we will translate that to messages, and then we will ultimately translate that into treated patients. The nomenclature is evolving as we go through those translation processes.

---

**Liisa Bayko** - *JMP Securities - Analyst*

Okay, great. Can you maybe talk a little bit about market readiness? I know that was a slight issue for Jakafi in MF. What are you doing in PV now to lay the foundation? That's my last question, thank you.

---

**Jim Daly** - *Incyte Corp - Chief Commercial Officer*

Liisa, I won't get into explicit details, but I want to assure you that we are doing everything that should be done that can be done, in order to prime the market in a compliant manner, so that we have a high-compression launch for PV. It will be a launch executed in a highly professional manner. Our goal is to make sure that the patients who need this product get it as quickly as possible. We're confident we're going to do that.

---

**Liisa Bayko** - *JMP Securities - Analyst*

Great, thanks a lot.

---

**Operator**

Boris Peaker, Oppenheimer.

---

**Boris Peaker** - *Oppenheimer & Co. - Analyst*

Good morning. Thank you for taking my questions. My first question is on Jakafi. You mentioned that the colorectal study is going to be the second study to somewhat validate the biomarker. I'm just curious, if the colorectal study does not support the biomarker, how would that impact some of the other studies where you are already selecting only biomarker-positive patients?

---

**Rich Levy** - *Incyte Corp - Chief Medical Officer and Head, Drug Development*

I think that it really is going to be indication by indication. The data that we saw in pancreatic cancer is pretty convincing that this is real, but was based on a hypothesis that goes back in the literature for many years, with tens of thousands of patients supporting that this is an important factor. Any one study is not necessarily going to negate the totality of that data. I certainly don't think it would have any impact on the approval on pancreatic cancer.

If we saw good results, for example, in both the patients who were in this group and those who were not in the group, in colon cancer my preference would be that they be good in both groups, then maybe there's another reason why that drug works in colon cancer. Anything can happen with an individual study, and that's what why you have to do the studies to really know.

---

**Boris Peaker** - *Oppenheimer & Co. - Analyst*

Great. My second question is on IDO. I'm just curious, are you in active discussions for additional potential combinations for your IDO compound? If so, are these partnerships specifically maybe waiting for the ASCO data with IPI prior to pulling the trigger on some other IDO combo?

---

**Rich Levy** - *Incyte Corp - Chief Medical Officer and Head, Drug Development*

Yes, we are in active discussions with other manufacturers who have PD-1s, PDL-1s, and they are not gated to any other particular data release.

---

**Boris Peaker** - *Oppenheimer & Co. - Analyst*

Okay, great. Thank you for taking my questions.

---

**Operator**

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

---

**Herve Hoppenot** - *Incyte Corp - CEO*

Okay, thank you. Thank you for attending this call. Obviously, as you see, we have had a very strong Q1 on the development side and on the commercial side. I think it can be looked at as a very good step for the organization. The next big one would be at ASCO, so I hope to see you all at our ASCO investor meetings. Thank you.

---

**Operator**

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

---