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INCY - Q3 2015 Incyte Corp Earnings Call

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OVERVIEW:

INCY reported 3Q15 total revenue of $187m.

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CORPORATE PARTICIPANTS

Michael Booth *Incyte Corporation - Vice President IR*

Herve Hoppenot *Incyte Corporation - President & CEO*

Barry Flannelly *Incyte Corporation - EVP & General Manager US*

Richard Levy *Incyte Corporation - EVP, Chief Drug Development Officer*

David Gryska *Incyte Corporation - CFO*

Reid Huber *Incyte Corporation - EVP & Chief Scientific Officer*

CONFERENCE CALL PARTICIPANTS

Carter Gould *Barclays - Analyst*

Matthew Roden *UBS - Analyst*

Marc Frahm *Cowen and Company - Analyst*

Brittany Turner *JPMorgan - Analyst*

Maury Raycroft *Jefferies & Co. - Analyst*

Christopher Marai *Oppenheimer & Co. - Analyst*

Michael Schmidt *Leerink Partners - Analyst*

Catherine Hu *Bank of America - Analyst*

Liisa Bayko *JMP Securities - Analyst*

Tony Butler *Guggenheim Securities - Analyst*

PRESENTATION

Operator

Greetings and welcome to the Incyte third quarter 2015 financial results. At this time all participants are in a listen-only mode.

(Operator Instructions)

As a reminder this conference is being recorded. I would now like to turn the conference over to your host, Mr. Michael Booth, Vice President of Investor Relations for Incyte. Please go ahead.

Michael Booth - *Incyte Corporation - Vice President IR*

Thank you, Diego. Good morning and welcome to Incyte's third quarter 2015 earnings conference call and webcast. The slides used today will be made available for download on the Investor Section of incyte.com following the call.

Speaking on the call will be Herve Hoppenot, our CEO, who will begin with a few words highlighting our progress during the quarter. And then Barry Flannelly, who leads our US organization, will provide a commercial update on Jakafi. Richard Levy, who's in charge of Incyte's drug development activities will update you on our clinical programs, and then David Gryska our CFO, will outline our third quarter financial results. We'll then open up the call for Q&A, for which we'll be joined by Reid Huber, our Chief Scientific Officer and Steven Stein, Chief Medical Officer.

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 2015 guidance, the commercialization of Jakafi, our development plans for Jakafi and other indications, and 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 10-Q for the quarter ended June 30th, 2015, and from time to time in our other SEC documents.

I'd like to now pass the call to Herve for some introductory remarks. Herve?

Herve Hoppenot - *Incyte Corporation - President & CEO*

Thank you, Mike, and good morning everyone. I believe that the third quarter of 2015 could be viewed as a period of transformational progress for Incyte. This belief is driven by two very important announcements we recently made on epacadostat and baricitinib as these two assets have the need to push Incyte forward on a global basis over the next several years.

Science drives our success here at Incyte, and we aim to create value through the investments we make in innovation. This investment in innovation has already translated into a unique portfolio of exciting opportunities - both in Immuno-Oncology and across our targeted targets.

There are currently 12 molecules in clinical development in our portfolio and apart from the recently in licensed PD one antagonist all have been discovered in Incyte laboratories. There are three main benefits that arise from this.

Firstly, risk mitigation. Having numerous molecules in development reduces our dependence on the success of any one of them.

Secondly, our portfolio gives us significant combination optionality. We can seek to develop our agents alone, as additions to standard of care, and we can also seek to develop them in novel/novel combinations.

And, thirdly, as we look further forward to the commercialization of our compounds, we believe that the financial benefit to Incyte's shareholders may be greater than industry norms because of the relative lack of third party payments.

As we review our progress, since we spoke at the end of Q2, we have seen two landmark events in the ongoing transformation of Incyte.

The first was announcement, with Merck, of our plans to advance the combination of epacadostat plus pembrolizumab into phase III development for the first-line treatment of advanced metastatic melanoma. This trial is expected to begin in the first half of 2016. The expanded collaboration with Merck shares the financial burden and also demonstrates our shared confidence in the clinical program. This is a key landmark in the history of Incyte because this will be Incyte's first phase III program for a compound for which we intend to keep global commercialization rights.

The second landmark was the positive outcome of the baricitinib phase III program with Lilly. The key announcement here was a BEAM study showing oral baricitinib to be superior to Humira, the injectable form of care, in controlling the signs and symptoms of rheumatoid arthritis.

The third quarter was also very successful for us commercially with Jakafi continuing to show strong growth, both from our continuing MS as well as the ongoing launch in PV. Jakafi has fueled our business for the past four years and we expect this will continue for years to come, but Incyte is now answering entering a new phase in its evolution. We anticipate having a second valuable source of income coming from baricitinib and we can see a path to registration for epacadostat.

We also have a clinical portfolio that is rich in optionality and potential synergies. Combined I think we can say that Incyte is now on a new track as we continue our transformation into a world-class biopharmaceutical organization.

With that strategic overview I will pass the call to Barry for some additional details on Jakafi's performance in the quarter.

Barry Flannelly - *Incyte Corporation - EVP & General Manager US*

Thank you Herve, and good morning, everyone.

Net product revenues for Jakafi during the third quarter were $161 million, an increase of 65% year-over-year. As a result of the continued growth, we are raising our net product revenue guidance for Jakafi for 2015. We are raising it from a range of $560 million to $575 million to a new range of $580 million to $590 million.

When we spoke to you at the end of Q2 we provided a detailed look at the launch of Jakafi for the treatment of patients with polycythemia vera. I'm very pleased to be able to tell you that the launch in uncontrolled PV remains strong. And we are also seeing continued growth in demand from patients with intermediate or high risk myelofibrosis.

The graph on the left of slide 8 shows the total number of Jakafi subscribers, quarter-by-quarter, over the last year. The graphic shows a consistent increase in our prescriber base. We believe that this reflects the ongoing and successful efforts of our US organization to educate physicians about the unmet need inpatients with polycythemia as well as Jakafi's therapeutic profile in MPNs.

The graph on the right shows the percentage increase, Q3 over Q2, in the total number of MF and PV patients taking Jakafi. While we see strong growth in a number of PV patients on Jakafi it is also good to see continued growth in the use of Jakafi in patients with MF.

With that I'll pass the call to Rich for the clinical highlights.

Richard Levy - *Incyte Corporation - EVP, Chief Drug Development Officer*

Thanks, Barry. In the next few slides I'll highlight the key clinical updates. First on epacadostat, and then on baricitinib before providing a summary of the portfolio.

First on epacadostat our selective IDO1 inhibitor. We are currently conducting four proof of concept studies of epacadostat plus PD1 axis antagonists, and all these trials are continuing to enroll patients.

In October we announced the acceptance by the Society for Immunotherapy of Cancer, or SITC, of a late breaking abstract detailing safety and efficacy data from our phase I/II study evaluating epacadostat in combination with Merck's pembrolizumab. This will be the first presentation of data from epacadostat in combination with a PD1 or PDL1 directed antibody.

As we announced this morning, the embargo on the abstract of the upcoming presentation by Dr. Gangadhar at SITC has now been lifted and we can share those data with you. At the time of the data cutoff made to generate the abstract, safety information was available for 28 patients and efficacy data was available for 19 patients. In Dr. Gangadhar's presentation on Friday, there will be 56 patients in the safety analysis and efficacy data from 47 patients.

The data in the abstract are summarized on slide 10 and reveal an emerging clinical profile we're very pleased with. The combination of epacadostat and pembrolizumab was generally well tolerated and the efficacy data suggests promising clinical activity. We believe that the safety is an important aspect of the product profile, especially compared to the recently approved Immuno-Oncology doublet in melanoma.

On the efficacy side and focusing on the melanoma cohort, the data table shows an overall response in 4 of 7 patients and disease control in 6 of the 7 patients. We believe these data also compare favorably to historical benchmarks. In the presentation on Friday, there will be efficacy data from 19 valuable melanoma patients and it is these data that have driven our decision to progress into a phase III trial.

Moving now to slide 11. I'd like to remind you that we recently announced with Merck that we're expanding our clinical collaboration to include a pivotal phase III study of epacadostat plus pembrolizumab. The trial is expected to be given in the first half of next year, and will be conducted in the first line treatment of patients with advanced or metastatic melanoma. We'll co-fund the study with Merck.

We believe that conducting this study with Merck has numerous advantages. We're able to work alongside a great clinical partner. Merck has global reach and access to a significant network of melanoma centers. This in turn has the potential to enable rapid recruitment into the study.

We also hope that a pivotal trial in melanoma is just the beginning for our plans with epacadostat. We'll continue to build the clinical databases in different tumor histologies with Merck and our other collaborators. And if the data warrant it, we will seek to move as quickly as possible into additional pivotal studies in other indications.

Moving now to baricitinib. We've recently announced, with Lilly, the results of a two-Phase III rheumatoid arthritis studies evaluating baricitinib head to head against two of the most widely used RA treatments. In RA BEGIN, baricitinib showed efficacy superior to methotrexate monotherapy in treatment-naive patients.

And in the second study, RA BEAM on a background of methotrexate, baricitinib showed superior efficacy to Humira the market leading biologic for patients with inadequate responses to conventional DMARDs. In both studies, baricitinib was generally well tolerated and we look forward to the presentation of the detailed efficacy and safety results at the upcoming American College of Rheumatology meeting in San Francisco. The RA begin presentation is scheduled for November 8th, and the RA beam presentation is scheduled for November 10th.

Incyte and Lilly will host an Investors Day and Conference Call and Webcast on November 11th to review the results with you and we hope you can participate in that event.

We and Lilly agree that these are outstanding results and the Lilly team is now squarely focused on global regulatory submissions.

I'll now discuss a few highlights from across our clinical portfolio. JANUS 1, our pivotal phase III trial of ruxolitinib in pancreatic cancer continues to enroll patients on schedule and we continue to expect data in 2016. We have reached full target enrollment in the ruxolitinib phase II trials in breast cancer and colorectal cancer, and the data from these studies are also expected during 2016. These are all event driven studies and so we're not able to pinpoint the time lines to data with more precision at this stage.

As indicated on slide 13, we have new two candidates in clinical trials since we've spoken to you at the end of quarter two. Our pan PIM kinase inhibitor '53914, and our newly acquired PD1 inhibitor '1210 have end of proof of concept studies in the hematological malignancies and solid tumors respectively.

We've also initiated a phase II trial of a topical formulation of ruxolitinib in patients with patients with alopecia areata. We have previously studied topical ruxolitinib in patients with psoriasis, and this new study builds on published data showing efficacy of oral JAK inhibitors, including ruxolitinib, alopecia areata.

With that I'll turn the call over to Dave for an update on our financials.

David Gryska - *Incyte Corporation - CFO*

Thanks, Rich. For the third quarter of 2015, we recorded net product revenues from Jakafi of $161 million and royalties from Novartis on exUS Jakavi sales of $18 million. Total revenue in the third quarter amounted to $187 million.

R&D expense for the third quarter was $132 million, which included the $25 million up front payment made to Hengrui related to license agreement for the anti-PD-1 antibody 1210. SG&A for Q3 was $48 million.

In addition, we recorded an unrealized loss of $31 million related to our investment in Agenus reflecting the change in the Agenus stock price during the quarter. The unrealized loss on the investment in Agenus year-to-date is approximately $4 million. We ended the quarter with $635 million in cash and cash equivalents.

Moving now to financial guidance for the full year 2015. Driven by the strong underlying demand for Jakafi, we are updating our full-year 2015 net product revenue guidance. We are now expecting that product revenues for the full year to be between $580 million to $590 million up from $560 million to $575 million.

During the third quarter of 2015, we recognized a $5 million milestone payment from Novartis in relation to initiation a phase II trial for capmatinib in glioblastoma. We have also recently received notice from Novartis that they have received approval for Jakavi in Japan for PV, which will trigger a $15 million milestone payment from Novartis that we expect to recognize in Q4 of 2015. Accordingly, we now expect our full-year contract revenue to be $78 million, up from our previous guidance of $58 million.

As previously announced, our contract revenue guidance for 2015 also includes the anticipation of an additional $20 million milestone payment from Novartis. This milestone is related to the commercial performance of Jakavi, and given the year to date sales and sales trends of Jakavi, we expect this milestone to be recognized in the fourth quarter of 2015.

We are leaving our R&D guidance for the full year 2015 unchanged despite the payment of $25 million to Hengrui in the third quarter. This reflects the changes and timing of other anticipated R&D expenses from Q4 of 2015 into Q1 of 2016.

We have tightened the range for full-year 2015 SG&A guidance to an updated range of $200 million to $210 million.

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

QUESTIONS AND ANSWERS

Operator

Thank you. Ladies and gentlemen, we'll now conduct our question and answer session.

(Operator Instructions)

Our first question comes from Carter Gould with Barclays.

Carter Gould - *Barclays - Analyst*

Thanks for taking the question. First off, congrats on the transformative progress in the third quarter. First question, will we see data, the response rates broken out by dose at SITC and secondly, is there anything you can say about how your approach towards your strategic optionality has changed after the Merck deal? Thank you.

Richard Levy - *Incyte Corporation - EVP, Chief Drug Development Officer*

Yes, so this is Rich. There will be data broken out by dose on both safety and efficacy at SITC, but with that said I'm not going to get into the any of the details until that -- until those data are presented there. And this does not really change our strategy with respect to trying to continue to work with multiple partners going forward. So we have this one arrangement to do a phase III study in melanoma with Merck. There are many other potential indications, and we look forward to doing those studies when the data are fully supportive to make that decision to go forward, either with Merck or with any of our other collaborators.

Operator

Thank you. Our next question comes from Matthew Roden with UBS. Please state your question.

Matthew Roden - *UBS - Analyst*

Great, congrats on the progress both on the commercial side and on the pipeline side. And thanks for taking the question. First on IDO, I guess, typically when you look at early stage oncology results, as the sample size increases as you go into larger trials you tend to see a little bit of an erosion of response rates in efficacy just as you go into larger populations. I guess the question would be as we think about the SITC presentation on Friday, is this the sort of phenomenon we should be thinking about in terms of going from 19 patients evaluated up to 47? And then, you know, assuming that there is still, you know, real differentiation with this asset, with these data versus the currently available PD1 axis inhibitors and combinations thereof, you know, at what point do you feel like it warrants consideration for FDA breakthrough designation. Is that something we should be thinking about, and then if I'm allowed, I'll come back with a commercial follow-up.

Richard Levy - *Incyte Corporation - EVP, Chief Drug Development Officer*

Yes, thanks Matt. This is Rich again. So with respect to the SITC data, it's obviously more robust. I would say that as a very broad statement, the changes -- there are not major changes in the data from what you're seeing, but you're just going to have to wait for the data, per se. And, you know, really not going to comment on our regulatory strategies with respect to breakthrough or not.

Matthew Roden - *UBS - Analyst*

Okay. Thanks for taking that. And then I guess on the commercial side, you mentioned consistent growth in your prescriber base, now it looks like you're up to about 3500 if I'm reading the graph right. You know, how high can this go? What do you think the target prescriber base could be, and then I guess related, Barry if you can talk about from what extent you're seeing early year utilization in myelofibrosis INT1 patients on label. I think, historically, it's been a lower penetrated segment. If you can just talk about where you are with that. Thanks very much.

Barry Flannelly - *Incyte Corporation - EVP & General Manager US*

Sure, so the target for prescriber base that we presented in the slides it really are physicians who are prescribed in the last 12 months. There's more physicians who have prescribed, and, obviously, you know there's somewhere between 10,000 and 11,000 hematologists, oncologists in the United States, some of whom don't practice. You can only go so high in the total number of prescribers that you have, and lots of those oncologists, hematologists may not even see any MPN patients at all. And then in terms of earlier, we certainly have patients now who are being treated who are intermediate 1 myelofibrosis patients.

Matthew Roden - *UBS - Analyst*

Okay. Thanks very much.

Operator

Our next question comes from Mark Frahm with Cowen and Company. Please state your question.

Marc Frahm - *Cowen and Company - Analyst*

Thanks for taking my questions, and congratulations on all the progress. First of all, with the phase III trial with epacadostat, are you going to be selecting patients based on any sort of biomarker PD1 or maybe anything else and along those lines will we see any of that type of data at SITC?

Richard Levy - *Incyte Corporation - EVP, Chief Drug Development Officer*

I'm really not going to get into the details of the trial until we have finalized it and I will likely put it up on clinicaltrials.gov. And I'm really not, at this point, going to go into the details of what will be protected at SITC beyond what's in the current abstract.

Marc Frahm - *Cowen and Company - Analyst*

Okay. And then, thinking forward to, you know, hopefully go to more tumor types than just melanoma, I mean where do you guys see the hurdle being to justify going to a phase III and say lung cancer? And then, you know, if you get to that point, do you see the melanoma collaboration with Merck as kind of a model or would you maybe not go with an exclusive relationship?

Richard Levy - *Incyte Corporation - EVP, Chief Drug Development Officer*

So I'll take the first question, and, you know, what we look for is it has to be, you know, generally these studies are going to be done as an add on to the PD-1, where a PD-1 or PDL-1 is already established to be effective. So in order for those trials to come out positive, you have to have the expectations that the combination will be more effective than the monotherapy with the PD-1 agent alone. And then secondly, in terms of our profile in this -- in the cases where there is comparative data in the public domain with other doublets such as nivolumab and ipilimumab -- we would be looking to at least mirror the efficacy in those trials with a safety advantage or potentially have clear efficacy advantages over those other doublets. And with respect to the designs of deals around other trials, I'll ask somebody else to take that question.

Herve Hoppenot - *Incyte Corporation - President & CEO*

Maybe I can take it. You have to think about it as an individual program. Our best interest is to develop the product in multiple indications, and in multiple lines of therapies. So the way the relationship with Merck is working is really specific to the line of therapy in melanoma where the phase III study is. So we would be obviously looking for other patient groups where we could do phase III studies. So what I'm saying is that don't think of this two-year exclusivity as limiting us for other indications, other combinations, other lines of therapy. It's not. So from this other standpoint, we could imagine in the future doing different types of relationship with a partner, or to have it under the same type that we have seen here. In both cases it would not prevent us from developing multiple indications in the future if we choose to. That's really what's important to us.

Marc Frahm - *Cowen and Company - Analyst*

Okay. So I mean, we really shouldn't look at this as kind of the model that will be applied, maybe with different companies, but the same type of structure. It shouldn't really inform us or other tumor types or other lines of therapy?

Herve Hoppenot - *Incyte Corporation - President & CEO*

What I'm saying it could be under the same type of relationship, or not. In fact, none of that has been decided yet, but in both cases it would not limit us from developing epacadostat in multiple indications in the future if the clinical data justifies doing it. That's really what's important.

Marc Frahm - *Cowen and Company - Analyst*

Okay. And then one last if I can on the commercial side. On Jakafi guidance, you know, it kind of implies a slowing in growth, a pretty significant slowing in growth in Q4 compared to what Q3 had. And at least we've seen that there's been base about a 4% price increase late in Q3, so why would we expect the growth to slow so much even if you also have the tail wind of wind of a price increase.

Barry Flannelly - *Incyte Corporation - EVP & General Manager US*

We think our guidance is prudent. At the high end of guidance it's about a 7% quarter-over-quarter growth. Fourth quarter can be a little bit unpredictable, just because of the number of holidays you have in November and December, so, again, we just think it's prudent going forward to have that range that's now tight, of course, because we're getting to the end of the year.

Marc Frahm - *Cowen and Company - Analyst*

Okay. Thank you.

Operator

Our next question comes from Cory Kasimov with JPMorgan. Please state your question.

Brittany Turner - *JPMorgan - Analyst*

Hey, guys, this is actually Brittany on for Cory. Thanks for taking the questions. You previously talked about the PV launch to be more gradual than that in MF given, I guess, less urgency to treat. Is that still your view? And then secondly, on baricitinib is there anything you could say on the potential next steps for the diabetic neuropathy indication? Thanks.

Barry Flannelly - *Incyte Corporation - EVP & General Manager US*

So I'll take the first part of your question if I heard it correctly. So you're just saying that the MF -- the urgency to treat in PV versus MF? Is that what you're trying to get at?

Brittany Turner - *JPMorgan - Analyst*

Yes, just if you expect the launch to be more gradual in PV still.

Barry Flannelly - *Incyte Corporation - EVP & General Manager US*

I think we said it all long is that PV patients are, you know, sometimes perfectly controlled with phlebotomy or aspirin or sometimes with Hydroxyurea. However, there's lots of patients who are intolerant to Hydroxyurea or get an inadequate response from Hydroxyurea, and those patients are coming on Jakafi now, and we have great expectations for this launch to continue into next year and beyond.

Richard Levy - *Incyte Corporation - EVP, Chief Drug Development Officer*

This is Rich on your second question. Just to clarify it's diabetic nephropathy, not diabetic neuropathy. It's about the kidney. Second, the decision as to exactly how and if that product will, you know, go into registration studies is up to Lilly and they have not announced their intentions as of yet. And we also have the option to buy into participation in that study as we bought into rheumatoid arthritis, and that period of time in which we make that decision has not come yet until we see the final development plan and cost, in addition to the data that we've already seen from the phase II study. But, you know, those decisions should be made in the next, you know, relatively modest period of time.

Brittany Turner - *JPMorgan - Analyst*

Great. Thank you.

Operator

Thank you. Our next question comes from Maury Raycroft with Jefferies. Please state your question.

Maury Raycroft - *Jefferies & Co. - Analyst*

I'm on for Brian Abrahams. Congrats on the progress and thank you for taking my question. Kind of as a follow-up to Matt's question, so it sounds like the response rates may carry through to larger data set on Friday. And I was wondering if you have any views into the durability of response and how the IDO plus pembro mechanism may compare to NIVO plus IPI on a durability standpoint.

Richard Levy - *Incyte Corporation - EVP, Chief Drug Development Officer*

So again, I'm not going to go into the details of how the data that will come out on Friday compared to the data here other than to say that there are not major differences,. And I don't want anybody to over interpret that to say that there are differences that are just short of major. It's just that I'm not really commenting. With respect to durability, the data are still early. With respect to how far out patients have been followed, there will be some durability presented, but it's not as long a follow-up as you would see, for example, from registration trials that already exist. You'll get to see the data, but it's -- it is less mature in terms of how long these responses or stable disease last.

Maury Raycroft - *Jefferies & Co. - Analyst*

Okay. Great. Thank you.

Operator

Our next question comes from Christopher Marai with Oppenheimer. Please state your question.

Christopher Marai - *Oppenheimer & Co. - Analyst*

Good morning, guys. Thanks for taking the questions. First, I was wondering if maybe you could comment on any mechanistic rationale for epacadostat to potentially have a more profound benefit when treating patients in earlier lines of therapy. And then secondly maybe on the commercial side, could you comment a little bit about how you may see the eventual cost of therapy going forward for patients? Do you see this as really something of an IPI replacement and pricing coming in at that range? And then maybe more broadly could you comment on how the pricing potentially of epacadostat fits into your model of certainly combination therapy, whether it's with your own PD-1 eventually down the road or other combination therapies that you're thinking about at Incyte. Thanks.

Reid Huber - *Incyte Corporation - EVP & Chief Scientific Officer*

Yes, Chris, this is Reid. With respect to your first question about whether there's a mechanistic rationale for epacadostat to be more effective in earlier lines of therapy. That's something we don't yet know. We learned a little bit about that question from the ipilimumab experience where we presented some data to indicate that responses were more robust, deeper responses in patients who were naive to immunotherapy. That perhaps isn't that surprising, but it's the first time we've made that observation. I think going forward, it's going to have to be something that we continue to monitor in the trials.

I think overall in the field, we don't really understand too well what resistance mechanisms are in play as patients unfortunately progress through successive lines of immune therapy. And we may learn from those types of studies that there are some mechanisms that are more applicable to patients in earlier lines of treatment and other mechanisms which are more important with respect to the resistant population.

Barry Flannelly - *Incyte Corporation - EVP & General Manager US*

And for your second question, it's a long way away from pricing strategies for epacadostat, but we really believe that we'll continue to create drugs and combinations of drugs that provide real value to patients - and so the clinical benefit to patients ultimately will determine the value.

Christopher Marai - *Oppenheimer & Co. - Analyst*

Okay. And just maybe one follow-up on that resistance mechanism to epacadostat or the epacadostat combos, is there any reason to believe that you guys would have any early hints of that data, in the data set presented at SITC, or is it just too soon to tell? Thanks.

Richard Levy - *Incyte Corporation - EVP, Chief Drug Development Officer*

You'll have to wait to see those data presented before we comment on that, but that's going to be a question that's evolving in the program over time. I think we'll have much more clarity as the program matures than we will at this early stage.

Christopher Marai - *Oppenheimer & Co. - Analyst*

Okay. Thanks. Congrats on the quarter.

Operator

Thank you. Our next question comes from Michael Schmidt with Leerink Partners. Please state your question.

Michael Schmidt - *Leerink Partners - Analyst*

Hey, good morning, and thanks for taking my question. I just had a follow-up to the prior speaker. The pembrolizumab combination study, is that limited to immunotherapy naive patients, or are you looking at IO experienced patients there as well?

Richard Levy - *Incyte Corporation - EVP, Chief Drug Development Officer*

The patients have to be naive to pembrolizumab, but they can have had some degree of prior treatment with immunotherapies.

Michael Schmidt - *Leerink Partners - Analyst*

Okay, understood. And then on your proprietary PD-1 inhibitor. Can you speak to your plans there and how do you see that fit into your portfolio?

Richard Levy - *Incyte Corporation - EVP, Chief Drug Development Officer*

Sure. So right now, that molecule has entered into phase I, patients are now being dosed with it. We will first need to establish the safe dose with that drug, and then potentially look at development, both as monotherapy and in combination with our internal portfolio of agents that are potentially -- are proven to be active in immunotherapy of cancer. It is clearly behind and would not cause us to slow down any of our paths to registration with existing PD-1 or PDL-1 therapies.

Michael Schmidt - *Leerink Partners - Analyst*

Great, and then one more on the SITC data set. Are you in a position to comment on biomarkers in that initial data set, or is that -- will you not have taken biopsies until later those expansion cohorts are enrolled?

Richard Levy - *Incyte Corporation - EVP, Chief Drug Development Officer*

I'm just going to really ask that people wait to see the data at the upcoming meeting.

Michael Schmidt - *Leerink Partners - Analyst*

All right. Thanks so much.

Operator

Thank you.

(Operator Instructions)

Our next question comes from Ying Huang with Bank of America. Please state your question.

Catherine Hu - *Bank of America - Analyst*

Hi everyone, it's Catherine for Ying. I just have a couple quick ones. I know you don't want to comment about the data at this stage, but can you tell us out of the 47 patients how many will be lung? And then, have you seen any liver enzyme elevations with the patients as you did with IPI? And then lastly, just a quick one, can you break out unit growth versus price and inventory this quarter for Jakafi? Thank you.

Richard Levy - *Incyte Corporation - EVP, Chief Drug Development Officer*

I'm sorry, I didn't really get your first question. Of the 47 patients how many are what?

Catherine Hu - *Bank of America - Analyst*

Are lung patients.

Richard Levy - *Incyte Corporation - EVP, Chief Drug Development Officer*

Oh, lung. It's -- you'll have to wait, but it is not an enormous number of patients at this point in time. More data will be coming, and we continue to enroll patients in each of these indications. With respect to LFTs, all I'd say is that we're quite happy with the emerging safety profile, and we'd ask you it wait for the detailed data coming. And the last question was not a development question.

Barry Flannelly - *Incyte Corporation - EVP & General Manager US*

Yes, hi Catherine, it's Barry. The unit growth accounted for almost all of the growth quarter-over-quarter. We took a price increase in the middle of September, so that really only added about $1 million to the sale, so almost all of it was unit growth.

Catherine Hu - *Bank of America - Analyst*

Great. Thanks so much.

Operator

Thank you. Our next question comes from Liisa Bayko with JMP Securities. Please state your question.

Liisa Bayko - *JMP Securities - Analyst*

Hi, congrats on the data, and most of my questions have actually been answered, but just a question about PV. Are you seeing the same sort of discontinuation and compliance rate as you have between PV and MF?

Barry Flannelly - *Incyte Corporation - EVP & General Manager US*

For peristency, we don't have that much data in PV. Obviously we just launched really in January. You can look to our clinical trials. So, if you look at RESPONSE, for example, and the follow up on RESPONSE, you have 83% of patients who are still on drug at about two years. In MF, if you looked at the COMFORT trials, you had 50% of patients were still on drug at three years. We believe that persistency will probably end up being greater with PV, but we still need to accumulate more data. Thanks.

Liisa Bayko - *JMP Securities - Analyst*

Thank you.

Operator

Thank you. Our next question comes from Tony Butler with Guggenheim Securities. Please state your question.

Tony Butler - *Guggenheim Securities - Analyst*

Thanks very much. If we look at what was presented in the abstract from a grade 3, 4 immune-related event there was one patient, and I'm simply trying to extrapolate. And I know it's small numbers, but if we look at NIVO IPI, immune related events are substantially higher somewhere in the order, depending on the trial of course, at least in melanoma, of as much as 50%. I wanted to comment on the safety of epacadostat, which seems to be, at least with respect to immune-related events, a bit better. And again, it's small numbers I recognize, but I'd love some commentary on it. And then the next question is, again, around corporate development to some degree as it relates to your IDO franchise in conjunction with your PD1. Are there tumor types that you wish to retain that you would not be interested in actually partnering for future studies? Thank you.

Richard Levy - *Incyte Corporation - EVP, Chief Drug Development Officer*

This is Rich on the first question. The data that's in the abstract that was released this morning does show that in these patients the rate of all grade 3 or higher, and they were all only grade 3, was lower than the rates of related grade 3s with the ipilimumab/nivolumab combination. There will be more data, more robust data, later in the week. And as we said, our goals here are both to be able to have more effective therapy than the background treatment in this case, pembrolizumab. And in terms of comparison to establish combinations to either have better efficacy or equivalent efficacy and better safety. And as we've said, we're pleased with the data so far and we look forward to sharing more data with you on Friday.

Tony Butler - *Guggenheim Securities - Analyst*

Thank you for that.

Herve Hoppenot - *Incyte Corporation - President & CEO*

On the second part of your question on the PD1 optionality and how it's adding potential for our portfolios, the way we think about it is really in the timelines. In the short-term, which is the next three years, if we see indications where combinations with existing approved PD-1 or PDL-1 is possible, we would not delay or "retain" that in any way. We would go ahead as quickly as we can with epacadostat in combination with this other product.

Our own PD-1 program is opening a number of different options in terms of combination, but not only with epacadostat. It's also true for many of the other products we have in our portfolio, and this will come at a later stage. I don't think it will be right to delay or reserve any indication. At this point, if we see a path towards to registration, if we have a willing partner who would be ready to go with us, I think we will always be ready to take -- give priority to the speed at which we can get our epacadostat approved in that indication.

Tony Butler - *Guggenheim Securities - Analyst*

Thank you, Herve.

Operator

Thank you. Ladies and gentlemen, there are no further questions at this time. I will now turn the conference back over to Mr. Herve Hoppenot for closing remarks. Thank you.

Herve Hoppenot - *Incyte Corporation - President & CEO*

Okay. Thank you, thank you for your time today. Thank you for your questions. I know a lot of the questions were related to data that is not yet available. We look forward to seeing you at the SITC conferences where a lot of this data will be presented in the next few days. And I also want to remind you that the Lilly and us will have an investor call from 9am eastern in the morning of November 11 where Lilly specifically will be speaking about the data that has been presented for baricitinib. So thank you, and good-bye.

Operator

Thank you, this concludes today's conference. All parties may disconnect. Have a good day.