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INCY - Q1 2016 Incyte Corp Earnings Call

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OVERVIEW:

Co. reported 1Q16 revenues of $264m, net income of $24m, basic EPS of $0.13 and diluted EPS of $0.12.

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Barry Flannelly *Incyte Corporation - US General Manager*

Steven Stein *Incyte Corporation - Chief Medical Officer*

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PRESENTATION

Operator

Greetings and welcome to the Incyte Corporation first-quarter financial results conference call.

(Operator Instructions)

As a reminder, this conference is being recorded. I would now like to turn the conference over to your host, Mike Booth, Vice President of Investor Relations. Thank you, you may begin.

Mike Booth - *Incyte Corporation - VP of IR*

Thank you, Diego. Good morning and welcome to the Incyte's first-quarter earnings conference call and webcast. The slides used today are available on the investor section of Incyte.com.

Speaking on today's call will be Herve Hoppenot, our CEO, will begin with a strategic review and provide further detail on our acquisition of ARIAD's European business announced this morning. Barry Flannelly, who leads our US organization, will provide some detail on Jakafi sales during Q1. Steven Stein, Incyte's Chief Medical Officer, will give a brief update on our clinical portfolio; and David Gryska, our CFO, will summarize our first-quarter financial results, the impact of the ARIAD transaction as well as our upcoming news flow for 2016. We'll then open the call up for Q&A, for which we'll be joined by Reid Huber, our Chief Scientific Officer.

We'd like to remind you that some of the statements made during the call today are forward-looking statements, including statements regarding our expectations for 2016 guidance, our expectations regarding the planned acquisition of ARIAD's European operations, the commercialization of Jakafi and our development plans for the 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-K for the year ended December 31, 2015 and from time to time in our other SEC documents. I'd now like to pass the call to Herve for some introductory remarks.

Herve Hoppenot - *Incyte Corporation - CEO*

Thank you, Mike, and good morning. Moving to slide 5 let me start with a reminder that Incyte has a very unique profile within the biopharmaceutical industry, as we have a fast-growing pipeline, we have been cash-flow positive for each of the last four quarters and we have the potential for a second important source of revenue should baricitinib be approved in 2017.

So we have a very strong start to 2016.

Financially, Jakafi's growth continued, increasing by 59% year over year and we are raising Jakafi net product revenue guidance for 2016. The peak potential of the Jakafi brand may also be increased should we be able to successfully develop Jakafi for GVHD.

The latest output from our discovery and development teams was presented at AACR, positioning Incyte for future success. We now have a portfolio of 14 clinical candidates. We have just dosed the first patient in our LSD1 program and we expect a clinical trial for our GITR program to begin in the next few weeks.

Our later-stage portfolio is also progressing well, and we expect to launch two pivotal programs in the coming months, ECHO-301, the Phase three trial studying in epacadostat in combination with Merck's pembrolizumab in first-line melanoma patients will begin shortly. And in the second half of 2016 we look forward to initiating a registration program for ruxolitinib for the treatment of GVHD.

Moving to slide 6. With this perspective in mind we were pleased to announce this morning an agreement to acquire ARIAD's European business. As you know, Incyte has a diversified portfolio of exciting European projects which represents one of the largest hematology-oncology pipelines in the industry. We also have a fully-integrated US business that is very successful as evidenced by the continued strong growth in Jakafi.

Our strategy is to do the same in Europe, and we faced a tactical choice of whether to build the European business or to buy one as we seek to maximize the chances of launch success of our products in Europe. Last year we established our European headquarters in Switzerland which is now home to a growing European clinical development team. And upon closing of the ARIAD transaction, which we expect to occur on June 1, Incyte will immediately have a fully-integrated European operation of 125 FTEs with medical and commercial teams in place across the continent.

The addition of the ARIAD team in Europe will not only accelerate the establishment of Incyte in Europe, it will do so in a manner that is financially efficient because revenue generated by sales of Iclusig will offset our European operating costs. If further compounds from our portfolio are approved in Europe, the ability to leverage our fully-integrated European operation should allow us to maximize the chances of European launch success, mirroring our operations in the US.

Slide 7 summarizing the Iclusig profile. You know Iclusig is approved in Europe for the treatment of patient with CML and Ph-positive ALL that are resistant or intolerant to dasatinib or nilotinib - Sprycel and Tasigna. Iclusig is also approved for all patients with T315i mutation and the activity against the T315i mutation is important and is very unique to Iclusig among all the BCR-ABL inhibitors.

Moving to next slide, slide 8, some of the financial components of the transaction. Upon closing, which now is planned at the end of the month, Incyte will pay $140 million cash up front to ARIAD and will pay additional considerations for tiered double-digit royalty on inside sales of Iclusig in Europe. We also expect to make two development cost-sharing payments to ARIAD of $7 million, one in 2016 and one in 2017. Additional potential milestone payments may also become due, but only if additional indications for Iclusig are approved in Europe. We forecast that the acquisition of ARIAD's European operation will be earnings accretive to Incyte beginning in 2018. With that, I'd like to turn the call over to Barry Flannelly for an update on our Jakafi franchise.

Barry Flannelly - *Incyte Corporation - US General Manager*

Thank you, Herve, and good morning, everyone. We continue to see strong growth in Jakafi sales in the first quarter. Net product revenue for the quarter was $183 million, an increase of 59% over the first quarter of 2015. As a result of this performance and the strong underlying demand for Jakafi, we are increasing our full-year net Jakafi product revenue guidance for 2016 from $800 million to $815 million to a new range of $815 million to $830 million.

Slide 11 shows the sales bridge for Jakafi in Q1 versus Q4 last year. Volume growth in Q1 was robust, at 7% over Q4 2015, but this was offset by the typical increase in gross to net in the first quarter of each year. This is mostly driven by the 50% discount we make to the coverage gap, also called the doughnut hole, for Medicare Part D patients. As patients move out of the doughnut hole, the gross to net stabilizes for the remainder of the year.

Jakafi is standard of care for the treatment of intermediate and high-risk myelofibrosis patients in the US, and the beneficial effect for patients is highlighted by the five-year survival data published at ASH last year from the COMFORT-II pivotal trial. Five-year data from the COMFORT-I trial is going to be presented at ASCO in June.

The launch of PV is going well, as evidenced by the strong flow of new patients beginning treatment with Jakafi. The 80-week analysis of the response trial recently published in Haemotologica demonstrated that patients have durable control of hematocrit and spleen volume and which is now included in the Jakafi label. As we have said previously, we are confident in reaching our long-term sales Jakafi target of $1.5 billion in MF and PV alone.

Patients who experience graft versus host disease represent a significant unmet medical need in the US. If ruxolitinib is successfully developed and approved by the FDA, it could provide us with a new indication for Jakafi and provide yet further growth to the brand. With that, I'd like to pass the call over to Steven for a brief clinical update.

Steven Stein - *Incyte Corporation - Chief Medical Officer*

Thanks, Barry. As you have already heard, our overall portfolio continues to progress well, including the first patient dosed in our LSD1 inhibitor program. In my remarks today, however, I will focus on our two new pivotal programs, ruxolitinib in graft versus host disease, GVHD, and epacadostat in first-line melanoma.

There is a clear unmet medical need for patients with graft versus host disease, long-term survival rates in patients with corticosteroid-refreactory GVHD are between 5% and 30%. A multi-center survey published in Leukemia last year and encored at the American Society of Hematology showed that treatment with ruxolitinib generated a greater than 80% response in patients with GVHD. And of those responders, the relapse rate was less than 10%. We believe these are impressive results, and we look forward to the initiation of our pivotal program of in ruxolitinib in GVHD patients later this year.

Slide 15 summarizes some key trials within the epacadostat clinical development in hematology and oncology development program, which continues to progress well, the ECHO program. We expect about 600 patients to be enrolled into the phase 2 expansion cohorts by the end of the year. And we expect data to become available from some of these cohorts in the second half of 2016.

ECHO-301, the phase 3 trial of epacadostat in combination with pembrolizumab for the first-line treatment of patients with advanced or metastatic melanoma, is expected to begin enrolling in the coming weeks. The clinical trial of record is now available to view. The trial will have co-primary endpoints of progression-free survival and overall survival and is planned to enroll 600 patients randomized one-to-one into two cohorts of pembrolizumab plus-minus epacadostat. We anticipate initial data from ECHO-301 in 2018.

I'll finish my segment with a portfolio slide which illustrates Incyte's balanced and diverse portfolio of small and large molecules across various development stages. The quality of our drug discovery work was demonstrated at the AACR meeting last month, where Incyte candidates were featured in ten abstracts in both mono and combination therapy set-ins. With that I'll pass the call to Dave for the financials.

David Gryska - *Incyte Corporation - CFO*

Thanks, Steven, and good morning, everyone. I'd like to start by covering the details of the acquisition of ARIAD's European business, and then turn to Incyte's first-quarter performance. The planned acquisition of ARIAD's European business is an important step in executing our strategy of expanding outside of the US. We already have a nucleus of a Europe organization and this transaction accelerates a planned European expansion while adding a commercialized product to offset future operating expenses.

We anticipate the transaction closing on June 1, 2016, at which time we'll begin to record revenue for Iclusig in Europe and recognize expenses related to the European business. To provide financial guidance on the ARIAD European business for the remainder of 2016 post-closing, we expect net product revenue for Iclusig to be in the range of $25 million to $30 million. This assumes that the transaction closes on June 1 as planned and that ARIAD records the outstanding deferred revenue relating to Iclusig sales in France.

We expect 2016 R&D expenses to be in the range of $15 million to $20 million. This includes the first of two $7 million payments to ARIAD relating to the development of Iclusig. The second payment will be in 2017.

And lastly, we expect SG&A expenses to be in the range of $30 million to $35 million. This guidance includes operating expenses for the operations in Europe and a non-cash purchase accounting expense of approximately $10 million.

Since this transaction will be considered the purchase of a business, we'll value the product rights of Iclusig as an asset on the balance sheet at June 1 and amortize the product rights over the life of the patent. For the remainder of 2016, the product rights amortization is estimated to be approximately $10 million. This will be recorded as cost of product revenue. Looking further ahead, we will seek to strategically invest in our expanded European organization and expect the acquisition to be accretive to our earnings on a GAAP basis in 2018.

Now turning to the first quarter. We continued to deliver strong financial performance while increasing investments in our long-term growth. We recorded $264 million in first-quarter revenue. This comprised of $183 million of Jakafi net product revenue, $22 million in Jakavi royalties from Novartis and $59 million in contract revenue, including two milestones paid by Lilly related to the FDA and EMA submissions seeking approval for baricitinib in rheumatoid arthritis.

Jakafi net product revenue of $183 million represents 59% growth over the same period last year. Based on Jakafi's performance, we are increasing our full-year Jakafi net revenue guidance to a range of $815 million to $830 million. As with similar oral oncology drugs, our gross-to-net adjustment is higher in the first quarter of the year than the rest of the year, primarily because of our share of the doughnut hole for Medicare Part D patients. We expect that our gross-to-net adjustments for the full-year to be approximately 12%.

Our cost of product revenue for the quarter was $6 million. This includes the payment of royalties to Novartis on Jakafi sales. Our R&D expense for the quarter was $157 million. This includes the $35 million milestone to Lilly in payment for the rights to develop ruxolitinib in GVHD and $12 million in non-stock compensation.

Looking at our projected R&D expense for the full year, we are updating our current guidance to a range of $635 million to $660 million. This includes the addition of the ARIAD European business and several changes to components of R&D expense forecasts related to our existing portfolio.

Specifically, we have added the $35 million milestone payment to Lilly for the rights to develop ruxolitinib in GVHD to our forecast. This increase is offset by increased projected savings related to the discontinuation of ruxolitinib in solid tumors and by the removal from our 2016 forecast of development of baricitinib in diabetic nephropathy.

Our SG&A expense for the quarter was $65 million. This includes $8 million in non-cash stock compensation and an increase in our donations to independent charitable foundations, which are typically higher in the first quarter and lower as the year progresses. As far as our projected SG&A expense for the full year, we are updating our guidance to a range of $285 million to $310 million. This includes the addition of the ARIAD European business previously mentioned.

Turning now to net income and earnings per share for the first quarter. We delivered $24 million in net income, or $0.13 per share basic and $0.12 per share diluted. For the full year, and driven primarily by our increased revenue guidance for Jakafi, we expect net income to be in the range of $10 million to $20 million.

Looking at our balance sheet, we end the first quarter with $811 million in cash and cash equivalents. During the first quarter we experienced strong positive cash flow from operations and milestone payments from Lilly. We expect positive operating cash flow from operations to continue through 2016, but expect it to be offset by an upfront payment to acquire the ARIAD European business as previously discussed and planned capital spending on our Delaware campus.

We expect to end the year with over $600 million in cash and cash equivalents. With our current cash balance and multiple sources of cash flow, we are in an excellent position to continue to make important investments in our long-term growth.

I'll end our prepared remarks with a news flow slide. We have just dosed the first patient in our LSD1 program. In the next several weeks we expect to initiate a clinical trial for the GITR program and dose the first patient in the pivotal phase 3 trial of epacadostat in first-line melanoma.

Later in 2016, we expect additional proof-of-concept data from the ongoing phase 1, phase 2 trials of epacadostat in combination with PD-1 and PD-L1 antibodies to become available, as well as initial clinical results from our FGFR and BRD programs. The initiation of the OX40 agonist clinical trials are slated for the second half of 2016 as is the initiation of the registration program for ruxolitinib in GVHD.

In summary, we are well-positioned with a robust and diversified product portfolio. We have the financial resources to enable us to build a global biopharmaceutical company and create long-term shareholder value. Operator, that concludes our prepared remarks, please give your instructions and open the call for Q&A. Thank you.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Brian Abrahams, Jefferies.

Brian Abrahams - *Jefferies LLC - Analyst*

Hey, guys, thanks for taking my question and congrats on all the progress. My question would be in terms of timing. What prompted you to seek to expand the European infrastructure at this time versus in a couple of years once some of those phase 3s for epacadostat and the other programs are a little bit more advanced?

And I'm curious if you have any other plans for Iclusig development other than the cost-sharing that you suggested. Then lastly on that front, as we look towards future investment, you mentioned the potential to expand out that infrastructure. What's the right way to be thinking about the potential SG&A impact going forward?

I know ARIAD has mentioned that they plan to save $65 million in expenses next year. Should we be thinking about an additional $65 million, an exact offset? Or are there potential synergies or conversely, additional investments that you might make that might increase the impact to SG&A beyond that? Thanks.

Herve Hoppenot - *Incyte Corporation - CEO*

Okay, thank you, Brian. Let me try to take it through your question. I think the timing is a very important question, and thank you for asking that. The way we look at our maturation of the portfolio is obviously the initiation of the phase 3 study with 30 with the epacadostat is an important milestone.

But we're also looking at the advancement of many of our own projects, including our JAK1 selective inhibitor 39110 in multiple indications, as you know. We also -- and you saw some of the data at the AACR moving our PI3K delta. And our FGFR inhibitor is soon now reaching in the phase 1 stage where we are looking at the next steps. So it's not just one but I think there are a number of ways where we will be in the mode where we need to be more active in Europe to maximize the potential of these launches, any of these if they make it through the entire process.

We are now in mid 2016. We are obviously looking for some of these projects at somewhere around 2019, maybe. I think it's the right time to be ready, not only to prepare the launch like the commercial aspect, but as you know there is also involvement of European centers. So part of the ARIAD acquisition includes medical teams that I think will be very important to maximize our activities in Europe. Obviously the market access and all the work that needs to be done to be able to go through the reimbursement process very quickly.

The way we think about it is that we are now at this stage where we will have a team in place. As you have heard -- I will answer your question about the SG&A, but what we are looking at is that the Iclusig potential -- it's a product that is growing relatively fast -- will allow us to be in a position where in fact the team is self-funded for this time. We have between now and whenever the next product is coming.

In terms of the plans for new indications for Iclusig, the current situation is obviously we have a base plan based on the current indication. You know there is an effort ongoing and we would be participating to that of doing two things. One is to try to optimize the dose. As you know, the dose of Iclusig is something that is still under review.

And there is a study ongoing to try to see if a different dose would have a better opportunity window. And there is a study to compare it to nilotinib in second-line CML. Both of these are ongoing and obviously based on the results, we would be including this data in our European label. For other indications there is no specific plan that we are pursuing at all.

For the $65 million, the way you have to think about it, we had in fact, in our plans for 2016, expenses that we were anticipating at Incyte to try to stop to have infrastructure in some of the European countries to do what I was just describing, which is help the epacadostat, delta JAK1 and FGFR programs work locally with the academic center of the trial. All of that costs that we are planning to have starting in 2016 and in 2017, is obviously not going now to be happening in addition to the ARIAD team. In fact, the ARIAD group, the medical group, will take some of that workload based on the current infrastructure.

So you have two things happening, is that you have an offset of costs that would have happened if we had not done the transaction. And you have obviously the management of the costs going forward between the Iclusig-dedicated team and the team that would be walking on those other projects. As we said, we see this to be completely balanced starting -- or in fact accretive to our business starting in 2018.

Now, we have no plans of very short-term to expand the infrastructure that we are requiring from ARIAD. So you should not think of another wave of new SG&A coming from Europe because we think the size is in fact exactly what we are shooting for if we had to do it by ourselves. I think that answers most the questions you were asking, right?

Brian Abrahams - *Jefferies LLC - Analyst*

Thanks, Herve, that's really helpful. Appreciate it.

Operator

Salveen Richter, Goldman Sachs.

Salveen Richter - *Goldman Sachs - Analyst*

Thanks for taking my question. Sorry, just want to follow up on the earlier question regarding the ARIAD transaction. We should assume at this point you're comfortable in the size of investment in the European operations? Could you also give us some color on the $135 million in milestones and what the breakdown is and the threshold levels here? And I have a question on the pipeline to follow up with.

Herve Hoppenot - *Incyte Corporation - CEO*

Yes, I'll take these two. Starting with the milestones, the way all the milestones that we have attached to new indications, some of them are related to the second-line potential indication based on the study against nolitinib. Some of them are attached to potential new indications that could be in oncology or outside of oncology. So it's a very broad field.

Obviously we don't know yet if there is or will be any effort in any of these indications. That's really -- except for the second-line test that we discussed. I don't think we will be disclosing exactly the details by indication, so that gives you the perspective, which for us is basically that we have a base case based on the current indication that works for us. We see everything that is coming in addition to that as a upside from that base case.

In terms of the size of the infrastructure in Europe which was your first question, we are very comfortable with what it is. It's well spread across a number of countries where we want to be able to actively develop our products. And that will be the core of the launch program for our new products in Europe. And it's the usual Italy, Spain, France, Germany and UK. It gives us the right footprint that we would have created by ourselves if we didn't do this transaction.

Salveen Richter - *Goldman Sachs - Analyst*

Thanks, Herve. Then with regard to the IDO program that's going to read out in the second half, can you help us understand which tumor types would read out first? And with the Keytruda plus IDO and melanoma study, the ECHO 202, the phase 2 portion of that study, will we see more patient data over the data seen at SITC or is it just going to be more scans?

And then just one question on Jakafi guidance. Is the increase really driven here by PV upside or expectations of future MS upside? Thank you.

Steven Stein - *Incyte Corporation - Chief Medical Officer*

Salveen, thanks, it's Steven. As you know, we presented at SITC and SMR in the fourth quarter of 2015 on the initial data sets which we now have additional scans on those patients which has reinforced our confidence in the epacadostat-pembrolizumab combination in first-line melanoma and our decision to initiate the phase 3 program. However, there's not enough new data to justify a presentation at this time.

To get the meat of your question, if you look across the four PD, PD-L1 combinations, as we said on the call, we'll enroll about 600 patients across 13 tumor types. It's too early to say what tumor types will have available data when. But we will be getting data over the course of the year. And that is the most I can say about it at this point in time.

Barry Flannelly - *Incyte Corporation - US General Manager*

And your question about Jakafi guidance is it's driven both by MF and PV. In fact, we continue to add new patients in both PV and MF. And the other part of it is, many of these patients are staying on drug for a long period of time, so that's where our guidance comes from. Thank you.

Salveen Richter - *Goldman Sachs - Analyst*

Thank you.

Operator

Michael Schmidt, Leerink Partners.

Michael Schmidt - *Leerink Partners - Analyst*

Hey, good morning, thanks for taking my questions. Herve, I had a follow-up on the ARIAD transaction. Given that there is still some time, as you mentioned, until you're in-house-developed products could come online in Europe. How do you think about adding additional commercial or new commercial products to that existing infrastructure via business development?

Herve Hoppenot - *Incyte Corporation - CEO*

Yes, thanks, Michael, you're right. It's something we don't predict because, as you know, every BD&L is always an adventure on the anniversary of the result. It has been the case that when we were looking at opportunities in the past, just having a footprint in the US only was, in fact, a problem for the partners who were looking for somebody to commercialize that product on a broader basis. So it was a little bit of a catch 22, where you don't have the team, you don't get the product, and if you don't have the product, you don't have the team.

What we have now is very efficient way to have a high-quality group of people, an interesting product that is growing. And obviously it will open new opportunities. As we have always said, we look at different options and if something seems to make sense from a strategic and financial standpoint, we will do it, but we don't need to do it.

The way we are now deployed in Europe and the US, we have teams that, obviously in the US, generating a lot of income from Jakafi. And in Europe we have a team with a growing pipeline, an interesting product and covering most of the costs from that Iclusig business. If we can have something else, it would be in addition some upside on that scenario. But the base scenario now is very good, and I think will help us maximize our launches when they come.

Michael Schmidt - *Leerink Partners - Analyst*

Okay, thanks. And then a question on the GVHD opportunity. You had some information there on incidence and prevalence. Could you share some more information on the size of that opportunity? Especially, is there a chronic type of therapy, a paradigm? Or is it a one-time treatment? And then also what duration of phase 3 development do you foresee for that product?

Barry Flannelly - *Incyte Corporation - US General Manager*

This is Barry. Maybe I'll hand it over to Steven for more information, but in terms of the opportunities, there's 21,000 stem cell transplants in the United States alone. About half of those are autologous and the other half are allogeneic.

It's the allogeneic that end up having the GVHD. Fewer patients have acute GVHD and then more patients have chronic GVHD. The way it generally breaks down is that then those patients who have acute GVHD might have a shorter duration of therapy and chronic GVHD might have a longer duration of therapy.

We think it's an exciting opportunity and we hope to help a lot more patients with GVHD as we hopefully successfully develop this drug. And I'll hand it over to Steven to answer the question about phase 3 development.

Steven Stein - *Incyte Corporation - Chief Medical Officer*

Yes, thanks Barry. In terms of the question, one of our slides in the presentation alluded to an incidence in the US of new patients of 7,000, about half acute and half chronic. And then in terms of prevalence, about 10,000 patients with chronic GVHD.

In terms of development plans, obviously as Herve said, we have an ongoing study with our JAK1 inhibitor, 39110, which is in phase 1 safety tolerability at the moment in GVHD. Now with the acquisition of the ruxolitinib rights and already having achieved, if you will, a proof of concept with external data, we're developing registration plans.

The ruxolitinib proof of concept data is in steroid-refractory acute and chronic graft versus host disease, so that's the likely area of development there. And then we will discuss our own 39110 development plans because there are other entities to consider. There is still first-line acute GVHD and there's still potential for prophylaxis in the setting. Those are the areas we're considering at the moment.

Michael Schmidt - *Leerink Partners - Analyst*

Okay, great. Thanks very much.

Operator

Cory Kasimov, JPMorgan.

Morgan Haller - *JP Morgan - Analyst*

Hey, good morning, guys, this is Morgan on for Cory. I had a quick question on the further development of Iclusig. How does that fit into with the rest of everything you have going on with the pipeline, with the bandwidth you have? And then I have a follow-up.

Steven Stein - *Incyte Corporation - Chief Medical Officer*

Yes, it's Steven answering you, Morgan. In terms of Iclusig, as Herve said, there is ongoing work to do -- in the actual indication -- within chronic myeloid leukemia. There is reasonable amount of safety evidence that a dose range in work may alleviate some of the toxicity as regards arterial occlusive disease. Executing that study will be very important across three dose ranges.

And then there's ongoing effort, as Herve said as well, in second-line chronic myeloid leukemia head to head against nilotinib. In terms of further development it's a relatively promiscuous agent in terms of different kinases that it does hit. And with the now setup of a joint development committee with ARIAD, we'll have to discuss those opportunities going forward, whether they're areas of interest to explore or not. But it's really too early to say more about that at the moment.

Herve Hoppenot - *Incyte Corporation - CEO*

To complement that in terms of how does it fit with the rest of the portfolio, there is no overlap. There's two studies already ongoing and it's not going to compete with the rest of the portfolio. It's a project that would be managed in a separate manner from the rest.

Morgan Haller - *JP Morgan - Analyst*

Okay, great. Then I wanted to confirm that the guidance of $25 million to $30 million is for post-close on? Is that correct?

Herve Hoppenot - *Incyte Corporation - CEO*

Yes.

Morgan Haller - *JP Morgan - Analyst*

Okay, great, thanks a lot. Appreciate it.

Operator

Geoff Meacham, Barclays.

Carter Gould - *Barclays Capital - Analyst*

Hey, good morning, guys, this is Carter on for Geoff, thanks for taking our questions. I got one on strategy. I appreciate the cost efficiency in today's deal but in the optionality it gives you in terms of involving use sites and maximizing the launches, was there any sense given to how this maybe changes prioritization of certain indications? I'm thinking specifically on IDO.

And then on the GVHD opportunity, could you speak about the strategy of moving forward with both 110 and ruxolitinib, given your motivations on the economics and the partnership with Novartis? Thank you.

Herve Hoppenot - *Incyte Corporation - CEO*

Maybe I'll go first on the first one. No, it has absolutely no impact. It has absolutely no impact on rethinking the IDO indication between hematology and oncology. These are completely separate. I think there is obviously a lot of our pipeline that is in hematology. There are a number of indications where we are looking at it and Iclusig is not changing any of the balance between oncology and hematology in our pipeline. And if you can speak about the GVHD development.

Steven Stein - *Incyte Corporation - Chief Medical Officer*

Sure, it's Steven again, thanks, Herve. So just to reiterate and maybe go a bit slower, in terms of graft versus host disease, there's at least four entities. There's steroid-refractory. Steroids, particularly prednisone, is first-line treatment. But you get steroid-refractory acute graft versus host disease. And after about 100 days of this devastating medical condition, you can get what's called chronic graft versus host disease which is also steroid-refractory. Those are two separate entities.

And then there's also first-line acute graft versus host disease when patients are treated for the first time before they become refractory to steroids. Then there's a fourth potential entity where you can actually think about prophylaxis for the condition in people post-allogeneic bone marrow transplant who are at high risk to develop graft versus host disease.

All four of those have been considered. What I said in my earlier comments with ruxolitinib that the data published last year in Leukemia and presented at ASH, they have presented, if you will, proof of concept data for ruxolitinib in both of the first two entities, steroid-refractory acute and steroid-refractory chronic graft versus host disease. Those are the likely areas of development for ruxolitinib.

Then for 39110, we would be considering the other entities. That's where we are at the moment. I think that answers your question.

Carter Gould - *Barclays Capital - Analyst*

Just a quick follow-up. Did the Novartis deal preclude you from moving forward with 110 in those earlier settings? Thank you.

Steven Stein - *Incyte Corporation - Chief Medical Officer*

No, it does not.

Carter Gould - *Barclays Capital - Analyst*

Thank you.

Operator

Ying Huang, Bank of America Merrill Lynch.

Ying Huang - *BofA Merrill Lynch - Analyst*

Good morning, thanks for taking my questions. I have one for housekeeping question. Does your Jakafi revised guidance for 2016 include any pricing increase for the rest of the year? And then secondly, how important is the second-line CML indication for Iclusig in Europe for you in terms of decision-making in licensing the rights? Thanks.

Barry Flannelly - *Incyte Corporation - US General Manager*

This is Barry. Obviously we took price increase on April 1, and we don't really discuss our pricing strategy going forward after that.

Herve Hoppenot - *Incyte Corporation - CEO*

So let me take that one on the second-line indication. The way our deal is constructed, in fact, makes it such that it works with and without the second-line indication. It works differently with the current indication that we have. And you know Iclusig is growing relatively fast in Europe. It's still in the launch or pre-launch mode in many of the countries as it is being reimbursed. Assuming there is no second-line indication, it would give us enough resources to cover the cost of the infrastructure.

If we get the second-line indication, it's going to trigger milestone payments, as we have discussed. And it's going to obviously increase the potential top line and it would be an upside to the base case. But both base case and the upside case are reaching our strategic objective, which is to get the team in Europe to be self-funded in some way.

Ying Huang - *BofA Merrill Lynch - Analyst*

Thanks, Herve. And then finally one follow-up on the data release. It doesn't sound like you guys have any significant update at ASCO. Should we assume a meaningful update for epacadostat at ESMO?

Steven Stein - *Incyte Corporation - Chief Medical Officer*

Yes, it's Steven. You're right in that we're leading to the second half. We can't comment on what will be at ESMO until the abstracts are released. The second half of the year is where we target and present in more data.

Ying Huang - *BofA Merrill Lynch - Analyst*

Thank you for the color.

Operator

Ian Somaiya, BMO Capital Markets.

Nate Smith - *BMO Capital Markets - Analyst*

Hi this is Nate on for Ian. Thanks for taking my questions. Starting off with the ARIAD deal, how should we think about the buy-back contingency plan within the deal? And then, could you comment on any tax implications of the deal and whether you may be able to see any tax advantages from an EU operations perspective? And then I have a question on the pipeline.

Herve Hoppenot - *Incyte Corporation - CEO*

I'll take the buy-back, obviously you can -- you'll realize and I think it's very rational -- that it was very important to ARIAD because in their overall strategy approach to their company, which is basically regroup resources in the US territory made sense to have this transaction about the European business done because it's where reduced spending. And it just happened that it's also a very good deal from our side for all the reasons that we have discussed. So I think it's a case of complementary idea.

And came this issue of what if somebody is willing to acquire ARIAD. So it's based on the control of ARIAD and is interested in the European business. So we came up with this buy-back option that is part of our agreement. And the buy-back option is obviously responding to their needs and it's built in such a way where there is timing so it can happen basically between three and six years after signature of the deal.

So it gives us a certain amount of time to get prepared so that in case it were to happen. And it's based on financial terms that have been discussed where there would be all the milestones that have been paid plus additional milestones based on the past 12 months of sales, plus forward royalties of 20% to 25%. So in some way it was meeting everybody's needs where there is a delay of a number of years.

It's still allowing a potential buyer of ARIAD to have access to Iclusig, and it's giving us financial conditions that would be certainly somewhat favorable. So that's how it was built, and I think it's meeting everybody's needs in this transaction.

David Gryska - *Incyte Corporation - CFO*

On your second question -- it's Dave -- on the tax, there will be some tax efficiency because ARIAD does have some net operating losses that we will carry forward to us in the acquisition of the entity. And to the extent that the profits that this enterprise creates in the future are enough to

offset the NOLs, we do have some NOLs in our entity that we started in Switzerland. So there is some tax efficiency that we'll benefit from by this acquisition.

Nate Smith - *BMO Capital Markets - Analyst*

Great. And then on the pipeline, can you help us understand how your early-stage oncology portfolio fits together? And how you plan to develop these drugs? And what data you have generated so far that could help direct development of combinations within the pipeline? Thank you.

Reid Huber - *Incyte Corporation - Chief Scientific Officer*

Yes, this is Reid, thanks for the question. As we've brought forward discovery programs and now into early development programs over the last four to five years, there's been a concerted effort by the team to build and nucleate around certain aspects of the portfolio. One of those is really around JAK inhibition where we've had, I think, a long-standing leadership position, beginning with ruxolitinib and baricitinib and JAK1, JAK2 inhibition, but now more recently into more evolved profiles like JAK1 selective inhibition.

Those agents with, I think, clear opportunity in hematologic malignancies offer us the opportunity to build around them and bring forward other agents which are very interesting in their own right, and have their own potential development programs but also leverage the JAK inhibitor space. One example of that is PI3K delta.

We've presented over the years a lot of the pre-clinical data and even some clinical data last year at ASCO that helps to reinforce the interest in that particular doublet. That will be one that we continue to explore in the clinical setting.

Beyond JAK1 and delta, it's also given us the opportunity to bring forward mechanisms like PIM inhibition which really works as a correlate to delta inhibition. They're active on the exact same pathway and are reciprocally regulated. And so a PIM inhibitor in our portfolio makes a lot of sense and would allow us to do interesting things in the combination space, again, much of which we've presented over the years publicly.

And finally, LSD1 and BRD, two epigenetic mechanisms, both with a potentially important role in leukemias and potentially also in lymphoma for BRD, again, build around that portfolio philosophy quite well. And the exact same thing is happening on the immuno-oncology side. Again, they are nucleated around IDO inhibition where we now have brought forward out first GITR agonist, soon and OX40 agonist and also end-licensed a PD1 inhibitor. And from the small molecule side, begun to explore some very novel biology around JAK and PI3 kinase delta inhibition on modulating the local inflammatory environment to provoke immune cell function.

So I think that you can look at our portfolio and hopefully see that around targeted therapies and immuno-therapies there's actually a very strong effort to bring forward mechanisms which not only have their own potential mono-therapy approaches but also very much leverage the adjacent molecules in the portfolio. And the idea frankly, is to create a portfolio where the value and the totality is much greater than the simple sum of the parts.

Nate Smith - *BMO Capital Markets - Analyst*

Great, thanks for the color and congrats on the deal.

Operator

Eric Schmidt, Cowen and Company.

Eric Schmidt - *Cowen and Company - Analyst*

Thanks, good morning. Just a quick clarification question for Barry on the volume growth of Jakafi in the quarter. I think the slide says 13% growth. You audibled in your script 7% quarter-on-quarter growth. Was there also some inventory stocking going on?

Barry Flannelly - *Incyte Corporation - US General Manager*

No, the slide's referring to millions of dollars, so it's $13 million one way, $12 million the other way.

Eric Schmidt - *Cowen and Company - Analyst*

My bad, thank you.

Barry Flannelly - *Incyte Corporation - US General Manager*

So it's 7% demand growth, as you said -- as I said in the script.

Eric Schmidt - *Cowen and Company - Analyst*

Got it. Is then for Steven, as you think about making a go-no go decision on something like lung cancer for epacadostat, I think you've committed doing that before year end, do you need to see the data from the ongoing PD1 studies and first-line lung cancer given the dynamic nature of that tumor type?

Steven Stein - *Incyte Corporation - Chief Medical Officer*

Eric, it's Steven, thanks for your question. Again, 600 patients, 13 histologies, we'll have data availability across the second half of this year. Lung is one of those histologies where we'll be looking closely and making decisions based on data.

In terms of your question will we need to see in our first-line data to make decisions, to be honest here, it would be helpful, but I think we have enough historical controls and enough data already across many, many agents that I think we have to be able to make rational comparisons using things like response rate. So it's not an absolute.

Eric Schmidt - *Cowen and Company - Analyst*

Thank you.

Operator

Liisa Bayko, JMP Securities.

Liisa Bayko - *JMP Securities - Analyst*

Hi there. Strategically, I was wondering if you could compare-contrast the idea of acquiring ARIAD versus perhaps doing an acquisition like this. And might this be part of a longer-term strategy with respect to acquiring ARIAD? And any tax implications, too, would be helpful. Thank you.

Herve Hoppenot - *Incyte Corporation - CEO*

I think you have to put it from our needs standpoint. I mean we have already a very large portfolio of projects in our pipeline. I think we have a strong discovery team for small molecule. It has been very productive over a number of years. So our discussions were very much about what we need and we don't have, which is an organized European platform with infrastructure, with medical teams across the different countries, commercial teams and market access.

I think it just happened that it was strategically something that ARIAD was interested in discussing for the reason I was explaining. And I think for the reasons I have also communicated this morning that they are trying to concentrate their resources in the US to be ready to not only grow Iclusig but also some of the pipeline products that may be coming soon. That's where the discussion was centered, in fact. I see it as a deal that has a lot of win-win qualities for both organizations and where we get really what we were looking for which is related to our European infrastructure on being able to maximize our products there.

Liisa Bayko - *JMP Securities - Analyst*

Okay, thank you, that's helpful. And then a technical question. You mentioned amortizing the product rights for Iclusig. What period of time should we think about that over?

David Gryska - *Incyte Corporation - CFO*

That will be over -- it's Dave speaking, Liisa -- it will be over the life of the patent and it will be straight line.

Liisa Bayko - *JMP Securities - Analyst*

And when do the patents end? Can you remind us what your assumptions are there?

David Gryska - *Incyte Corporation - CFO*

The patents end in 2026.

Liisa Bayko - *JMP Securities - Analyst*

Okay, thank you. And then if you could comment at all on -- I know Concert put forward this oral JAK molecule that's dueterated for alopecia. Can you comment on any IP and plus-minus benefits on topical versus oral for the alopecia indication? And that's my final question, thank you.

Reid Huber - *Incyte Corporation - Chief Scientific Officer*

This is Reid. On the IP side, our patent applications for ruxolitinib do disclose an embodiment that includes all isotopes of atoms occurring in the compounds for the invention. That, specifically, includes isotopes of hydrogen, such as tritium and deuterium. We're very confident in the patent estate we have around ruxolitinib and we'll clearly look to protect that if it makes sense.

In terms of the oral versus topical, we're doing a study right now with topical ruxolitinib. So we'll answer that question clinically in terms of how that formulation looks and that method of delivery relative to oral therapy.

Obviously any oral therapy, particularly in a condition like this one, has to be particularly cautious around safety implications in this sort of a disease. And that's really what drove our interest in the topical formulation. And there's a considerable proportion of the patient population where a topical

formulation could address a significant on unmet need. Obviously an oral therapy could be more appropriate for much more widespread disease and may be effective there but it has to be balanced with the safety risks that come from oral JAK inhibition in those types of patients.

Liisa Bayko - *JMP Securities - Analyst*

Thank you.

Operator

Reni Benjamin, Raymond James.

Reni Benjamin - *Raymond James & Associates, Inc. - Analyst*

Good morning, guys, thanks for taking the questions. Just one for me regarding the ECHO 301 study. Can you talk a little bit about the co-primary endpoints? Do both need to hit for an application or is there a potential strategy for if you get the PFS first and an application going in and waiting for the OF? Or how are you thinking about it?

Steven Stein - *Incyte Corporation - Chief Medical Officer*

Reni, it's Steven, the ECHO 301, the phrase 3 in first-line melanoma does have co-primary endpoints of progression-free survival and overall survival. It doesn't have to be both. We could file with a benefit in either. So that's why we estimate data availability in 2018 and obviously that's based on the PFS endpoint.

Reni Benjamin - *Raymond James & Associates, Inc. - Analyst*

Got it. Then going back to the ARIAD deal real quick, how many countries is Iclusig approved in? And is part of the strategy to either expand further in terms of building sales forces in individual countries?

Herve Hoppenot - *Incyte Corporation - CEO*

I can speak with the territory that we have organized this transaction around. It's approved at the European Union level, so that's where the technical authority is taking place. Then there's a reimbursement that is done country by country.

So in terms of the European Union, the reimbursement is obtained now in some of the large countries like Germany. But it's still work in Italy which is obviously a very fast-growing country for Iclusig. But it's still not fully obtained.

As you know, in France there is a situation where you can have an ATU. You can basically sell the product before it is fully reimbursed but there is a claw-back that is taking place at the time of reimbursement. It's anticipated to be happening relatively soon. Some of the other countries are still in the process of getting reimbursement inside the EU.

And then in our agreement there are countries outside of the European Union, like Russia is one of them, where we would have to find a partner, which is probably what we would be doing to go through the entire process of approval and reimbursement.

Reni Benjamin - *Raymond James & Associates, Inc. - Analyst*

Great. Thank you, guys.

Operator

Andrew Berens, Morgan Stanley.

Andrew Berens - *Morgan Stanley - Analyst*

Hi, thanks, good morning, guys. Two questions, one on epacadostat and then one on Iclusig. As we prepare for the PFS data in melanoma later this year, the first part of next year, how should we think about the benchmark commercially for the combination therapy? Not just versus Keytruda, but also some of the other data that are out there for combination IO therapy.

Steven Stein - *Incyte Corporation - Chief Medical Officer*

Hi, Andrew, it's Steven. Just to be clear, the ECHO 301 PFS data will be most likely 2018. Later this year, as I said earlier, we hope to be able to update our phase 1 data that we presented at SMR last year. We'll have enough additional scan data to update that.

In terms of the benchmarks, obviously there's regulatory and then there's the clinical benchmark, and you alluded to the latter. a regulatory point of view, we'll have to beat the label pembrolizumab mono-therapy PFS of around six months. But the NIVO IPI clinical benchmark in the same setting is around 11.5 months. So those are the sort of numbers we're thinking of.

And then there's a bunch of new answers around PDL1 positivity, et cetera, which can come in. You just have to be really careful that you're comparing an apple to an apple in terms of the data sets and the staining that you're using. We think about it mostly in terms of those two numbers I just alluded to.

Andrew Berens - *Morgan Stanley - Analyst*

Okay. And we're not going to get any of the PFS data from the phase 1, phase 2 trial? I had thought that we were expecting that at the end of this year maybe.

Steven Stein - *Incyte Corporation - Chief Medical Officer*

You are correct. We will have updates on the scans available to us in appreciable amounts sometime in the second half of this year. And we hope to be able to present it to you. That is our intent.

Andrew Berens - *Morgan Stanley - Analyst*

Okay. So we will see PFS from that trial?

Steven Stein - *Incyte Corporation - Chief Medical Officer*

Yes.

Andrew Berens - *Morgan Stanley - Analyst*

Okay, great. Then in terms of Iclusig, as those of us who don't cover ARIAD think about modeling the EU opportunity, have they experienced any reference pricing in Germany yet? And what's the status in the UK when these -- and the assessment?

Herve Hoppenot - *Incyte Corporation - CEO*

I can take care of some of that. In Germany the price went through the entire review, and is a price that is approved by the government. In the UK most of the usage is funded through the cancer fund. It's not a NICE reviewed kind of situation, it's a cancer fund.

Remember, it's a relatively rare form of CML because the product is approved for two groups of patients, the ones who are resistant to or refractory to nilotinib or Sprycel, and a group of patients with 315I mutation. The 315I mutation is relatively rare in the first-line setting but the incidence of 315I mutations is increasing with the lines of treatment that you are receiving. So it becomes more and more frequent on the smaller number of patients as the patients are going from first-line to second-line to third-line.

In the UK it's going through the cancer fund. In Germany it went through the entire process. It's ongoing in France, and we are anticipating -- or ARIAD is anticipating the resolution of the negotiation in France. It's already approved and reimbursed in Italy and the other countries still in the reimbursement process now.

Andrew Berens - *Morgan Stanley - Analyst*

Great, thanks for the color, appreciate it.

Operator

Ladies and gentlemen, we are out of time for questions. I will now turn the conference back over to Mr. Hoppenot for closing remarks. Thank you.

Herve Hoppenot - *Incyte Corporation - CEO*

Yes, thank you, thank you all for your time today and for your questions. I think it's a day today where we show that we have made three big steps. One is you see the growth of Jakafi in the US because it's important to see that now we are a year after the launch in PV and we are still growing very dynamically, both in PV and in MF.

We spoke about the several big steps which is the progress of our pipeline. We are planning to initiate two pivotal studies soon or over the next few months with epacadostat in first-line melanoma and with ruxolitinib in GVHD. I think it's really important that you see the third big step was now establishing Incyte firmly as a trans-Atlantic Company with an organization in Europe.

As I said at the beginning, our goal with that organization is really to mirror the powerful and successful organizations that we have in the US we've established now five or six years ago, and be able to make sure that we maximize our launches when our products are maturing. And also grow Iclusig, that has a lot of potential to grow, as it's still in a phase of the launch that is relatively early. I think it was a very exciting few weeks and months for us in the beginning of the year. I'm looking forward to sharing our progress with you later this year with the Q2 call by mid-year. Thank you.

Operator

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