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INCY - Q3 2016 Incyte Corp Earnings Call

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OVERVIEW:

INCY reported 3Q16 revenues of $269m and net income of $37m, or $0.20 per share basic and $0.19 per share diluted.

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CORPORATE PARTICIPANTS

Mike Booth *Incyte Corporation - VP of IR*

Herve Hoppenot *Incyte Corporation - President and CEO*

Barry Flannelly *Incyte Corporation - EVP and General Manager*

Steven Stein *Incyte Corporation - SVP and Chief Medical Officer*

David Gryska *Incyte Corporation - EVP and CFO*

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

CONFERENCE CALL PARTICIPANTS

Salveen Richter *Goldman Sachs - Analyst*

Cory Kasimov *JPMorgan - Analyst*

Michael Schmidt *Leerink Partners - Analyst*

Josh Schimmer *Piper Jaffray & Co. - Analyst*

Ying Huang *Bank of America Merrill Lynch - Analyst*

Ian Somaiya *BMO Capital Markets - Analyst*

Simos Simeonidis *RBC Capital Markets - Analyst*

Evan Seigerman *Barclays Capital - Analyst*

Eric Schmidt *Cowen and Company - Analyst*

Liisa Bayko *JMP Securities - Analyst*

Brian Abrahams *Jefferies LLC - Analyst*

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

Peter Lawson *SunTrust Robinson Humphrey - Analyst*

Alethia Young *Credit Suisse - Analyst*

PRESENTATION

Operator

Greetings and welcome to the Incyte Corp's third-quarter financial results earnings conference call.

(Operator Instructions)

It is now my pleasure to introduce your host Mike Booth Vice President of Investor Relations for Incyte. Thank you may begin.

Mike Booth - *Incyte Corporation - VP of IR*

Thank you Diego. Good morning and welcome to Incyte's third-quarter 2016 earnings conference call and webcast.

The slides used today are available for download on the investors section of www.Incyte.com. Speaking on today's call will be Herve Hoppenot, our CEO, who will begin with some high level comments in our objectives and priorities here at Incyte.

Herve will then pass to Barry Flannelly who leads our US organization, and who will provide an update of Jakafi sales and prescription trends during Q3, as well as touch on Jakafi's recent inclusion in the NCCN Guidelines.

Steven Stein, Incyte's Chief Medical Officer will briefly review the updated ECHO-202 data of epacadostat plus pembrolizumab as presented at ESMO, and provide some background on our decision to initiate a Phase 2 trial of our FGFR inhibitor 54828 for the treatment of patients with Cholangiocarcinoma.

Dave Gryska our CFO will summarize our third-quarter financial results before opening the call for Q&A, for which we will be joined by Reid Huber our Chief Scientific 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 2016 guidance, the commercialization of our products, 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-Q for the quarter ended June 30, 2016 and from time to time in our other SEC documents.

I would now like to pass the call to Herve for some introductory remarks.

Herve Hoppenot - *Incyte Corporation - President and CEO*

Thank you Mike and good morning everyone.

We have made excellent progress during the third quarter, both on the top line, as well as within our portfolio. Before we dig into the details I would like to begin our discussion today by taking a step back and talking briefly about what we are trying to build here at Incyte.

Cancer is one of the biggest challenges facing our society today. It certainly has a significant impact on the well-being of millions of cancer patients, as well as their loved ones, but it also has a substantial economic impact both through lost productivity and the effect on the healthcare system.

The need for more effective treatments is clear and advances are being made.

As shown in the chart on the left side of slide 6, since 2010 the number of new Hematology and Oncology approvals by the FDA has been on an upward trend, and the chart on the right illustrates how patient outcomes in melanoma, depicted as improvement in progression-free survival, have improved with different therapeutic regimens from chemotherapy through BRAF and MEK inhibitors, to Immuno-Oncology doublets.

Many of us felt a sense of excitement at the ESMO conference last month, given the wealth of data presented and a number of innovative therapies being discussed. It also provided us with further evidence that the scientific community, where Incyte is an active participant, is in the process of transforming the treatment of cancer.

Incyte is a company built on innovation and we strive to bring first or best in class therapies to patients in need. Our portfolio now contains 15 different candidates across 11 different targets and we employ around 1,000 people in the US and across Europe. With total revenue in Q3 that grew 44% over the same period last year we are in a position to reinvest our resources in multiple therapeutic opportunities.

Sales of Jakafi continue to show robust growth as we approach the five-year anniversary of its initial US approval, and combining Jakafi sales in the US, Iclusig sales in Europe, and Jakafi royalties from Novartis provides us with dynamic revenue growth. We also have an additional potential source of revenue from Baricitinib being developed by our partner Eli Lilly, which is currently under global regulatory review for the treatment of patients with rheumatoid arthritis.

With our financial resources and dynamic top line growth we can reinvest in a virtuous cycle of product development to bring additional innovative therapies to patients. We have a diverse portfolio of products and are building medical and commercial footprints in major markets around the

globe. Having global development expertise in-house is already enabling us to develop our products more effectively and we will also seek to use in-house commercial teams to successfully launch our products upon approval.

I will now pass the call to Barry for an update on Jakafi.

Barry Flannelly - *Incyte Corporation - EVP and General Manager*

Thank you Herve and good morning everyone.

Sales of Jakafi continue to perform well. In the third quarter net product revenue from Jakafi was $224 million, a 39% increase over the third quarter of 2015 and 8% increase over the previous quarter. In view of this strong growth we are increasing our 2016 Jakafi net product revenue guidance to a range of $850 million to $855 million from the previous range of $825 million to $835 million.

We are pleased that nearly five years after its first approval we now have approximately 9,000 patients currently being treated with Jakafi and that number continues to grow. Growth comes from our position education efforts, especially detailing on the long-term benefits that Jakafi treatment provides.

The chart on the right side of slide 10 illustrates the strong year-on-year demand growth that we are experiencing with both of Jakafi's approved indications. In September we announced that Jakafi has been included as a recommended treatment for appropriate patients with myelofibrosis in the latest NCCN guidelines. Inclusion in the guidelines will help inform healthcare providers' treatment decisions for patients with myelofibrosis and we believe that inclusion in the NCCN guidelines also underscores the important and long-term clinical benefits seen in patients treated with Jakafi.

We are also looking forward to the ASH conference in December, where a pooled analysis of the five-year overall survival data from both COMFORT-1 and COMFORT-2 studies of Jakafi in patients with myelofibrosis will be presented.

I would now like to pass the call along to Steven for a clinical update.

Steven Stein - *Incyte Corporation - SVP and Chief Medical Officer*

Thanks Barry.

We've made good progress within our development portfolio since our last quarterly conference call, and today I would like to concentrate on the recent epacadostat data update at the recent European Society for Medical Oncology meeting, and on our 54828 our FGFR inhibitor, for which we've recently opened a second Phase 2 trial.

Last month updated Phase 1 data from the ECHO-202 trial of epacadostat plus pembrolizumab in patients with advanced melanoma and select solid tumors were presented at the ESMO Annual Congress in Copenhagen.

I would like to start my brief overview of the data with patient safety data. Now with 56 weeks median follow-up for responders, and that's much greater drug exposure than our last presentation at SITC in November 2015, the combination of epacadostat plus pembrolizumab continues to be well-tolerated. There were no treatment-related deaths, and the maximum tolerated dose of epacadostat has not been reached. 19% of patients in the trial experience grade three or four treatment-related adverse events and five patients, or 8%, experienced treatment-related adverse events that led to discontinuation.

The next slide shows the waterfall and spider plots of the patients with Treatment-naive melanoma. The overall response rate in this population was 58% and the disease control rate was 74% by RECIST. For responders, the median follow-up was greater than 56 weeks, with a range of 46 to 90 weeks, importantly at this presentation all responders remained in response at the time of the data cut.

Slide 15 shows progression-free survival. The median progression-free survival has not been reached. The six-month progression-free survival rate is 74%, and the 12-month progression-free survival rate is 57%.

With all the necessary caveats of cross trial comparisons we believe our data compared favorably to establish benchmarks. Recall that progression-free survival is one of the two jeweled primary endpoints in the ongoing ECHO-301 Phase 3 trial of epacadostat plus pembrolizumab for the first-line treatment of patients with advanced or metastatic melanoma.

Let's move onto our FGFR development program on slide 16. We announced in our second quarter update that we were initiating a Phase 2 trial of 54828 in patients with bladder cancer. This study is now open for recruitment.

In addition we have also been to Phase 2 study of 54828 in patients with Cholangiocarcinoma, a type of biliary track cancer. While treatment of this type of cancer can be curative, if found early enough for surgical resection, most cases are diagnosed in the later stages, where resection is not a possibility.

Cholangiocarcinoma is rare, with incidence in the US and Western Europe of around 1.6 cases per 100,000 population. The rates are significantly higher in Asia. In Japan, for example, the incidence is 3.2 cases per 100,000 population, while incidence and other Southeast Asia countries is higher still. Between 6% and 13% of all cholangiocarcinoma patients have FGFR2 translocations, and an additional 5% have other FGF or FGFR alterations. We are not aware of differential geneotypic rates by geography.

The primary endpoint of the Phase 2 cholangiocarcinoma study will be overall response rate in patients with FGFR2 translocations. Secondary endpoints will include overall response rate in patients with other FGFR alterations.

Slide 17 summarizes the whole portfolio, which now includes 15 development candidates against 11 different molecular targets. The portfolio graphic now includes 57643 which is our second BRD inhibitor and which is currently in a dose escalation study. As we have done with many of our programs, we have elected to progress two distinct BRD inhibitors into development. These compounds allow us an opportunity to evaluate different pharmacokinetic and pharmacodynamic profiles, thereby increasing our optionality around decision-making and what is becoming an exciting therapeutic class.

I will finish on our news flow slide. There are multiple potential value drivers for Incyte over the next 12 months. We are finalizing our plans to initiate the pivotal program for ruxolitinib in graft versus host disease, and we also expect to provide you with proof of concept data from our JAK-1 program in graft versus host disease at the American Society of Hematology Conference in early December.

We remain on track to initiate the 39110 plus osimertinib study in lung cancer by the end of the year, and we also look forward to providing you with initial clinical data from the FGFR and BRD programs next year as the data become available.

In immuno-oncology and beginning in the first half of next year we look forward to sharing data from some of the Phase 2 cohorts of the ECHO trial of epacadostat in combination with PD-1 and PDL-1 inhibitors. We also remain on track to initiate a proof of concept study for our anti-OX40 agonist antibody 1949 in the fourth quarter of 2016. Data from Incyte's Phase 2 trial of topical ruxolitinib for the treatment of patients with alopecia areata have been accepted for presentation at the 2016 Alopecia Areata Research Summit, which is taking place in New York City on November 14th and 15th. Last but not least, we are looking forward to the first regulatory decisions on baricitinib.

With that I will pass the call to Dave for the financials.

David Gryska - *Incyte Corporation - EVP and CFO*

Thanks Steven and good morning everyone.

In the third quarter we recorded $269 million of total revenue. This was comprised of $224 million in Jakafi net product revenue, $13 million in Iclusig net product revenue, $29 million and Jakafi royalties from Novartis, and $3 million in contract revenue. Jakafi's net product revenue of $224

million represents 39% growth over the same period last year. Based on Jakafi's performance year-to-date, we are increasing our full-year Jakafi net product revenue guidance to a range of $850 million-$855 million.

Our gross net adjustment for the third quarter was approximately 12%. We expect that gross and adjustment for the full year to be approximately 12%.

Our cost of product revenue for the quarter was $20 million. This includes the cost of goods sold for Jakafi and Iclusig, the payment of royalties from Novartis on US Jakafi net sales, and $5 million for the amortization of acquired product rights related to the Iclusig product acquisition.

Our R&D expense for the quarter was $143 million, including $16 million in non-cash stock compensation. Looking at projected R&D expense for the full year we are updating our current guidance to a range of $570 million-$580 million.

The reduction in projected R&D expense for the previous guidance for 2016 is in large part due to slower than forecasted headcount growth and phasing of certain expenses from various programs in our development pipeline into next year. We will provide a range of next year's R&D expense in our fourth-quarter call in February, and given the breadth of opportunities in our current portfolio we expect a substantial increase in R&D expense in 2017.

Our SG&A expense for the quarter was $76 million, including $10 million in non-cash stock compensation. We are on track to end the full year with our existing guidance in the range of $285 million to $310 million. We recorded $8 million in expenses related to the change in fair market value of the contingent consideration for the Iclusig royalty liability and we expect the full-year amount to be approximately $17 million.

Turning now to net income and earnings-per-share for the third quarter, we reported $37 million in net income or $0.20 per share basic and $0.19 per share diluted. We now expect 2016 net income to be in a range of $100 million to $110 million. This range also reflects the quarter-to-date decline in the market value of a long-term investment.

Looking at our balance sheet, we ended the third quarter with $717 million in cash and cash equivalents. We expect positive cash flow for the remainder of the year and expect to end the year with over $750 million in cash and cash equivalents.

As noted in our press release, Novartis achieved pricing approval for Jakafi in polycythmia vera in the third major European country in October, which triggered a $40 million milestone. We will record this $40 million milestone in the fourth quarter.

To summarize, we are very pleased with Incyte's performance in the third quarter. Jakafi delivered strong revenue growth. We have fully integrated our new business unit in Europe. We grew our cash position and continue to make significant investments in our clinical development programs.

Incyte is well-positioned from a cash and operating income perspective to execute on our strategies for growth, which we are confident will deliver significant long-term shareholder value. Operator that concludes our prepared remarks please give your instructions and open up the call for Q&A.

Thank you.

QUESTIONS AND ANSWERS

Operator

Thank you.

(Operator instructions)

Salveen Richter, Goldman Sachs.

Salveen Richter - *Goldman Sachs - Analyst*

Thanks for taking my question.

Just given the milestones from Novartis in the lead for the next three quarters and base business growth, it would appear that you will be EPS GAAP profitable going forward. Is that a fair assumption? Then a second question on the bromodomain program, can you give us a little more clarity in the difference between 54329 and the new molecule? Will you be moving into different indications and when should we expect initial data from both?

Thanks.

David Gryska - *Incyte Corporation - EVP and CFO*

Salveen I will answer the first question. Yes we will be EPS positive for this year, as I mentioned, the range is between $100 million to $110 million. Obviously we have not given guidance out for next year and we'll be doing that in our February conference call.

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

Salveen this is Reid, thanks for the question on BRD. As we've done for many of our programs we often will progress more than one molecule in the clinic when it's appropriate to evaluate different pharmacokinetic and pharmacodynamic profiles in Phase 1. Bromodomain inhibitions is an excited therapeutic opportunity. I think were still at the early stages of that, and we think we're best positioned by evaluating both 54329 and the follow-on compound 57643.

It's really about evaluating different PK profiles and potentially different pharmadynamic profiles and seeing how that may affect efficacy and safety. We look forward to seeing those data merge over the next few quarters and certainly will share them with you as we are ready.

Salveen Richter - *Goldman Sachs - Analyst*

Thank you.

Operator

Corey Kasimov, JPMorgan.

Cory Kasimov - *JPMorgan - Analyst*

Great thank you good morning guys. I appreciate you taking the questions and nice quarter.

So two of them for you. First of all can you talk about the potential significance of the recent NCCN treatment guidelines for Jakafi and how that might drive use above and beyond how it is positioned in the market today? Do you know if there's a plan to publish guidelines for PV as well?

Then my follow-up question was just clarification. I was wondering if you could just talk about what you mean in your press release where you say enrollment was suspended in the Phase 1/2 trial for your PD-1. I guess that term suspended can mean a number of different things.

Thanks.

Barry Flannelly - *Incyte Corporation - EVP and General Manager*

So Cory, this is Barry, I will answer the first couple of questions about the NCCN guidelines. The easier one is they've indicated that they'll release sometime in 2017, maybe over the next first six months of 2017, guidelines for polycythemia vera and essential thrombocythemia.

The first question about whether -- we're just very positive about the NCCN, their approach in myelofibrosis and it reinforces our clinical data. We already have approval in patients who have intermediate one to high risk patients and there's really very few patients in the low risk category, maybe 10% of the patients. Their recommendation was symptomatic patients that have low risk so we think that represents a small patient population.

Steven Stein - *Incyte Corporation - SVP and Chief Medical Officer*

Cory hi, it's Steven Stein. Thanks for your question related to 1210.

The www.clinicaltrials.gov listing actually says active not recruiting. As of October 21 of this year we notified investigators that enrollment of new subjects to the Phase 1 trial of 1210 had been placed on hold in order to perform a thorough assessment of the compounds profile. I'm not going to be able today to give you any more details on this as we are in the midst of that review of that compounds profile.

Cory Kasimov - *JPMorgan - Analyst*

Okay. Thank you.

Operator

Michael Schmidt, Leerink Partners.

Michael Schmidt - *Leerink Partners - Analyst*

Good morning and thanks for taking my questions.

I had two on Jakafi: a commercial question in terms of sequential growth could you breakout inventory versus price versus volume growth? Then the second question is as we are waiting results from Gilead's momelotinib trials in MF later this quarter, can you give us a sense of how you think about your competitive position in MF, in particular in patients that have anemia at base-line or are transfusion dependent and how Jakafi used in those patients for example.

Thank you.

Barry Flannelly - *Incyte Corporation - EVP and General Manager*

For your first question -- there was no pricing in Q2 versus Q3. It was the same wholesale acquisition price and in fact there was very little inventory movement one way or the other so the 8% growth quarter-over-quarter was most entirely demand.

Your second question related to momelotinib: we think the clinical profile of Jakafi stands up very well to any compound in the treatment of myelofibrosis. Remember they are only going after an indication in myelofibrosis, they have no polycythemia vera indication.

In terms of anemia we will see when their data reports out but we know from further analysis of our COMFORT trials that patients that came in with anemia or experienced anemia while on Jakafi in fact still benefited from the drug and still had an improved survival advantage versus patients who did not receive Jakafi. We think it's a compelling clinical profile for the drug and we'll see what happens when they report out their data sometime in the future.

Michael Schmidt - *Leerink Partners - Analyst*

Great. Thank you.

Operator

Josh Schimmer, Piper Jaffray.

Josh Schimmer - *Piper Jaffray & Co. - Analyst*

Thanks for taking my question. First, you indicated a substantial increase in R&D next year, I'm wondered if there's any way to quantify that ahead of your guidance? As well as you think about advancing epacadostat into additional Phase 3 solid tumors settings, when do you think you will have adequate data to inform those decisions? And what kind of bandwidth do expect to have in the R&D budget to accommodate multiple simultaneous Phase 3 programs.

Thanks.

David Gryska - *Incyte Corporation - EVP and CFO*

Okay so I will answer the first part of your question. In terms of the R&D for next year we are not going to quantify what substantial means. Rest assured that it will go up from where it is today because of some phasing in some shifting from this year into next year into the R&D. And Herve is going to answer the second part of your question.

Herve Hoppenot - *Incyte Corporation - President and CEO*

The reason why we spoke about increase for next year is because, as you saw in Q3, there were a number of expenses that we were planning to see happening during the next few months that have been moved into next year. We wanted to make sure everybody understood that, in fact the intensity of the development program is not slowing down at all. We have multiple projects that are starting.

And in the case of epacadostat, as I have to said, we would be open to multiple Phase 3 studies when the data is available and we have the resources to do that and we would not slow down in any way the program for epacadostat based on budget impact. We are able now with the strength of our top line growth coming from multiple sources to sustain and afford for multiple Phase 3 over a period of years. That's really the picture we have.

And the comment about next year was just to make sure that people understood that the way the Q3 R&D budget has been evolving is not something that you can trend for the next quarters. It will probably go through a rebound over the next few quarters.

Josh Schimmer - *Piper Jaffray & Co. - Analyst*

Does that mean that you are not looking at this point to manage the business for bottom-line growth but more for R&D investment and capital allocation, or how do you think of that.

Herve Hoppenot - *Incyte Corporation - President and CEO*

That's what I was trying to say in my introduction. I think it's fundamentally important that we are watching the cash flow very carefully. That is something that is truly important that we can finance our own investments in our own research by ourselves. And then we are looking at every opportunity to create value through drug product development.

If we see opportunities that are reasonable we will do them even if it has an impact on the short-term profitability over the next few quarters because it's absolutely clear to us that it's the best interest of all our investors. We are in the phase of cancer discovery and cancer development where we can see that opportunities are available today and maybe they will not be there tomorrow. We will be looking at a case-by-case on the quality of the assets that we have in our pipeline and when we see opportunity to develop then we will do that.

Josh Schimmer - *Piper Jaffray & Co. - Analyst*

Thank you.

Operator

Ying Huang, Bank of America Merrill Lynch.

Ying Huang - *Bank of America Merrill Lynch - Analyst*

Good morning thanks for taking my questions.

My first one is regarding to the PD-1 enrollment suspension. Hypothetically, if you have to discontinue the PD-1 I wonder what you could do with the GITR and OX40 program? Do you need to seek another PD-1 to combine with those I-O assets.

Then secondly, I want to ask about a potential event strategy for non-small cell lung cancer.

We have seen that the PD-1 antibodies are quickly becoming a first-line therapy in non small cell lung cancer, and we know that from your Phase 1 data epacadostat as, I believe, it does not have activity in experienced patients who have already had PD-1 treatments. In that case how would you develop an I-O inhibitor in non small cell lung cancer?

Thank you.

Steven Stein - *Incyte Corporation - SVP and Chief Medical Officer*

Ying hi, it's Steven Stein. Thanks for your questions.

Firstly as regards PD-1 1210 that is an enrollment hold on new patients as we perform an assessment of the compounds profile in totality. We've made no further decisions related to the compound. I take it your question was a hypothetical, but going forward across programs including GITR, OX40 etc. We are looking at multiple potential partners in terms of PD-1 and PDL-1's.

In terms of non-small cell lung cancer your right, it is a dynamic field that changes rapidly and certainly in the first-line setting testing for a biomarker and levels of expression look to be important for PD-1 therapies and then the chemotherapy combinations, as well. In terms of our own data in lung cancer that we're busy gathering data at the moment across our collaborations.

We will have patients, and many patients, who have not experienced any immunotherapy yet. We are positioned to be able to answer the question of whether or not we add to PD-1 activity in those settings. We are perfectly positioned to answer that question, actually.

Ying Huang - *Bank of America Merrill Lynch - Analyst*

Thank you Steve.

Operator

Ian Somaiya, BMO Capital.

Ian Somaiya - *BMO Capital Markets - Analyst*

Thanks. Just had a couple of questions.

The first one on Jakafi. I guess after having five years of the myelofibrosis market all to yourself, just try to get a better understanding of what the future growth opportunity is within that indication, and how we should think about momelotinib if the Phase 1/2 data is reflective of the drugs commercial profile.

Then separately on IDO, Steven or Reid maybe you can just speak to how predictive melanoma data has been when considering success in solid tumors. I know you can't speak to your own data but maybe just the I-O field overall, whether it's marketed drugs or other drugs in development, that would just guide us to how to think about other drugs success in melanoma and whether they were specific tumor types that tended to respond similarly?

Barry Flannelly - *Incyte Corporation - EVP and General Manager*

Hi it's Barry.

To answer your first question about Jakafi's growth, well the way we look at it is that we really only penetrated myelofibrosis about one third of the prevalence patient population, so we think we have an upside there.

In terms of if momelotinib comes to market there's a couple of different scenarios one is that they in fact have a second line indication after Jakafi and we really don't think that this is going to have an impact on us. If they come to market in the front-line setting where Jakafi's currently approved, the way I think about it is that we have long-term data with long-term spleen response, we have improved symptoms, and we have an overall survival advantage and we don't cause neurotoxicity.

I think our competitor profile again, will match up very well with Jakafi. And we continue to see not only are we adding more patients every single quarter, just like we did this quarter in myelofibrosis, but in fact those patients continue to benefit for a long time on Jakafi.

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

This is Reid I will take your second question.

I think as a field we've come to appreciate that melanoma is a very attractive proving ground to test immune-based therapies and that's true across all classes. It is a more inflamed tumor type, so there's an active component of T-cells. It certainly has a high mutational burden and all those things lend itself to being perhaps a lower bar, if you will, for immune-based therapies.

Exactly how that predicts response across other tumor types, or whether it does, is probably a class specific question. It's certainly has shed new light, I think, from the field to understand which other tumor types may also harbor some of those characteristics of an inflamed phenotype and we can think about tumor types like bladder, lung, head and neck, renal cell, all in a new light because of the groundbreaking work that's happened in melanoma.

As we look at the emerging IDO data, certainly the signal that we reported at ESMO that formed the basis of our Phase 3 ECHO-301 program are important, I think, to having a derisking of the program. How or whether that translates to other tumor types is all going to be dependent on the data that we are generating. But I would say it increases our confidence; it doesn't decrease our confidence certainly, and coupled with the safety profile if we think about the emerging doublets landscape and some of the other tumor types, an attractive safety profile is going to be more not less important as the therapies move into early line in front-line settings.

So, I think we're encouraged based on those data. We are excited by the program. But we still have to generate the data that speaks precisely to what the opportunity may be outside of melanoma.

Operator

Thank you. Simos Simeonidis, RBC Capital Markets.

Simos Simeonidis - *RBC Capital Markets - Analyst*

Good morning guys thanks for taking my question.

Just to clarify in terms of news flow what can we expect for epacadostat announcements? You mentioned that we're going to see additional proof of concept data sometime first half of next year. But is it still the case that we may see an announcement or announcements about your plans, which tumor types you may go into Phase 3 earlier than that?

Secondly could it be the case where you can have multiple announcements? For example, you can say going to go into lung, and then a month later you say we're going into this other tumor types, or will it all be one announcement for your Phase 3 plans?

Herve Hoppenot - *Incyte Corporation - President and CEO*

Herve here, let me try to take that I mean we have tried to describe it in the past and we are precisely where -- the way we described it, which is a obviously a disclosure of the data at conferences is not entirely under our control because the dates of the conferences are set with larger intervals in between. If we are the point of making a decision to go to Phase 3 we think we think it's an advance that should be disclosed. So we would at this time announce it as we have done -- I think I remember waiting to get of the melanoma study, and that's really what's driving the process.

I don't think we would be in a position where all the data from all the Phase 2 are going to be available at the same time. In fact we are just starting some new indications in some of these combinations, so you cannot expect that all of these studies are going to close at one point and then boom the whole set of data will be available. I think it will be more in batches as we are progressing through the first half of next year and that's really the situation we are facing here.

Simos Simeonidis - *RBC Capital Markets - Analyst*

Okay perfect and finally, has there been any impact in your Phase 2 trials by the durvalumab partial hold?

Steven Stein - *Incyte Corporation - SVP and Chief Medical Officer*

Hello it's Steven Stein, so in terms of head and neck cancer and what happened there, it is something we were aware of. We obviously have a clinical collaboration with AstraZeneca. The impact on the protocols will involve wording changes for people to exercise appropriate cautions for things like, for example, if the tumor is close to a major vessel. In addition if there's an underlying bleeding disorder.

In terms of our actual protocols and program, that continues unabated. It's just learnings from their experience and then an avoidance to try and have that toxicity not happen on our programs.

Simos Simeonidis - *RBC Capital Markets - Analyst*

Great thank you.

Operator

Geoff Meacham, Barclays.

Evan Seigerman - *Barclays Capital - Analyst*

Hey all this is Evan Seigerman on for Geoff. Thanks for taking my question.

Just a follow-up on kind of the IDO timelines in lung. I believe last week Merck mentioned that it would be in a position to make the go notice -- go decision on Phase 3 by mid-2017. Is this still in line with your assumptions and how often and how much do you look at the data on an ongoing basis to help you make this choice? Thank you.

Herve Hoppenot - *Incyte Corporation - President and CEO*

As we said I would think -- as we said the ability to make a decision is not just based on the response rate data, it's based on the duration of response. It's based on the biomarkers specifically in lung cancer, where as you know things have changed a little bit of a past few months with new emerging data from PD-1 as a single agent. I think Merck comments about mid-2017, and we speak about the first half of 2017, so that's probably very much overlapping from that standpoint.

We don't know exactly when it would be, because as I said this is data that is emerging. The database that will be populated to make the decision with the partner is not yet populated. So we don't have access to that data with the full set of biomarker, duration of response, and response rates yet and when we have it is really where we will be able to move to the next step.

Evan Seigerman - *Barclays Capital - Analyst*

Great. Thanks for taking the questions appreciate it.

Operator

Eric Schmidt, Cowen and Company.

Eric Schmidt - *Cowen and Company - Analyst*

Good morning, another question on epacadostat for Herve.

From the time you would make a go decision on a pivotal study, how long would it take to actually start such a trial, and would that change if you were doing it with or without a partner? I ask because I think it took a good six to nine months in melanoma and I'm wondering if you could shorten that timeline?

Herve Hoppenot - *Incyte Corporation - President and CEO*

I think the decision to work with a partner on that is really something that we are looking at this in a natural way that we tend to like to work with a partner; it has a small financial impact on the cost of the study. But it's also a way to learn and benefit from their own scientific understanding of their own product.

It's not just a financial benefit of working with a partner, there is a little bit of a shared scientific information. If for any reason a partner would rather not be part of the study, which could happen for budget reasons or for any other external reason, we are always open to do the study by ourselves.

In terms of the timing I think last time the announcement was made at the point where we were in the planning stage, so maybe took a little bit of time to go through the entire planning, protocol writing, and then execution. In general what we tend to see the window between the decision to do a Phase 3 and the first patient in the Phase 3 to be less than six months.

That would be an industry-standard.

Eric Schmidt - *Cowen and Company - Analyst*

Thank you.

Operator

Liisa Bayko, JMP Securities.

Liisa Bayko - *JMP Securities - Analyst*

Hello, there. I was wondering if you talk a little bit about R&D. I know you've increased how much are going to be spending this year. Just curious where you're spending where you hadn't accounted before where you're placing more dollars?

Thank you.

Herve Hoppenot - *Incyte Corporation - President and CEO*

The importance of the R&D spending -- we are a company that is fully integrated, so we have a relatively large team working in chemistry and biology and doing discovery every day, in fact. That's a piece of it.

I don't know if we have given details on the split between the different cost structure. But you can imagine that that part is mostly internal costs. So there basically head counts that are working on our projects. And then on the D side, the Development side, Steven Stein's group, we have a mix of internal costs. So we have a team of people that has been increased fairly substantially over the past three years and we have obviously a number of costs that are study-related. So they are directly attached to the number of patients that we are accruing in our studies.

That's sort of the way it works. The way it gives us is some flexibility understanding depending on the cycle of study. So as we discussed earlier, if we were initiating a number of Phase 3 studies, we could do it. We have the infrastructure to do it. And that would increase the external cost

attached to this Phase 3 studies. If we have less commitment to studies ongoing at some point in time, then the external costs can go down and we have created in our systems the flexibility to do that.

The growth of our current R&D budget is mostly driven by the external costs related to the studies, as we have now built the team that is of a good-size to be able to manage this project. I guess that's what I can say about the confidence of the R&D budget.

Liisa Bayko - *JMP Securities - Analyst*

Great and then just kind of two programs that don't get as much attention. But the GVHD and alopecia; can you just remind us of dosing and briefly what are you looking for in the data to show that there's a strong signal.

Thanks.

Steven Stein - *Incyte Corporation - SVP and Chief Medical Officer*

Yes hi, Steven Stein answering your question.

On graft versus host disease there are a few entities there. There's acute graft versus host disease and chronic graft versus host disease, and then there is steroid refractory components, and then there's a first-line entity in acute that's not yet steroid refractory. So you just have to be careful about the entities you're talking about and the clinical manifestations in each of those can be different. And because of acuity of disease and needing to control it early that can also mean slightly different things.

We have not yet disclosed the dosing we use in any of these programs yet, but when they started starts and go up on www.clinicaltrials.gov more information will be available. But they are not -- they are in keeping with what we know about ruxolitinib's profile and what it can do. For alopecia areata, just reminded of the topical ruxolitinib formulation, a cream and would need going forward potentially more dose range and work to work out exactly the dose to deliver there.

Liisa Bayko - *JMP Securities - Analyst*

Okay. And then just final question, any inside you can give us on baricitinib, obviously it's a large market opportunity and I think the ranges out there are pretty broad. Has Lilly provided any guidance on how they're thinking of competing in that market? Is it going to be a priced to take share strategy or more of a premium pricing? How should we think about where it falls into the regimens available?

Herve Hoppenot - *Incyte Corporation - President and CEO*

Thanks for the question. It's difficult to answer, because our partner Lilly is really driving a lot of the strategy for the launch and they have not been communicating, obviously, all the details of their strategy. So it will not be appropriate for me to speak about it.

What we see is that the profile of baricitinib from the multiple Phase 3 studies that have been performed is it certainly very good when compared to the TNFs. So that certainly something that would be core to the strategy of the product. Because that's where the medical profile is driving a lot of the decisions that will be made there. We know the review process is ongoing and the target dates that have been discussed is early next year. So that's really what we can say on baricitinib.

Liisa Bayko - *JMP Securities - Analyst*

Okay. Thanks a lot for the questions.

Operator

Brian Abrahams, Jefferies.

Brian Abrahams - *Jefferies LLC - Analyst*

Hello. Thanks for taking my question and congrats on the strong quarter. On the fourth-quarter -- on 2016 Jakafi growth, I wonder if you could talk about the drivers for fourth-quarter growth. I think based on the midpoint of your guidance it looks like you're expecting both absolute and percentage quarter-over-quarter increase to be less than fourth-quarter or third quarter, as compared to third quarter over second quarter despite a price increase that you took at the end of the third quarter. It sounds like there weren't any one-time factors that contributed to third-quarter growth. I'm just wondering if you are expecting maybe lesser price in pull through, perhaps a slight waning of demand growth, or maybe you're just being conservative?

Then separately on the development side, where do you foresee epacadostat potentially fitting into relative to checkpoint plus chemo combos, just wondering if you could potentially move straight into any Phase 3's on top of chemo in a PD-1, if you wanted to go that route? Or would you need additional Phase 2 work before you took that step?

Thanks.

Barry Flannelly - *Incyte Corporation - EVP and General Manager*

Thanks, Brian. This is Barry, I'll answer the first question.

We think it's prudent to our guidance going forward $850 million represents a 5% quarter-over-quarter growth and goes up to 7% quarter-over-quarter growth at $855 million, so we think that's good. Mostly the fourth quarter is one of those quarters that you don't know exactly what's going to happen, lots of vacation days and time off for healthcare professionals and for our staff in November and December.

Historically Jakafi has had very good fourth quarters and some soft fourth quarters. So that's why were putting out guidance like that. But we still have lots of enthusiasm for continued growth in both MF and PV.

Steven Stein - *Incyte Corporation - SVP and Chief Medical Officer*

Brian hi, it's Steven Stein.

In related to the chemotherapy question both in combination with checkpoint inhibitors, there are at least two questions that we will answer in our clinical program going forward. One is does a PD-1 or PDL-1 plus IDO perform similarly or better to a PD-1 or PDL-1 combo plus chemo?

Then the other one we are very interested in answering and we will begin clinical work shortly is adding IDO to a chemotherapy combination in multiple different histologies and multiple different chemotherapy combinations. There is a lot of good science there around what chemotherapy can potentially do in terms of neo-antigen release etc. But those -- that latter question, we still need more clinical work to answer to get to meet your question.

In terms of a tolerability profile, that is something else which we will obviously carefully examine, because the PD-1 plus IDO combo as you know, and we just presented updated data at ESMO very well-tolerated. And then the different tolerance for a chemotherapy combination; so to be continued and to be answered over the ensuing year.

Brian Abrahams - *Jefferies LLC - Analyst*

Thanks very helpful.

Operator

Ren Benjamin, Raymond James.

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

Hello good morning thanks for taking my questions and congratulations on the great quarter.

Maybe just going back to epacadostat, can you give us a sense as to what studies we might see first, and is it as easy as kind of going back and looking at when these studies have started, or are there different enrollment challenges that are taking place with a variety of studies?

The other question is again, related to the PD-1 inhibitor, Steve did enrollment complete, and now you are assessing the efficacy of the drug or was there some signal that forced you to stop mid-enrollment?

Just a high level question for Herve, just given the current climate regarding price increases, can you maybe talk a little bit about how you are planning to, or handling this going forward, and are there any rumblings from payors? Or does that really just happen once there's a competitor on the market? Thanks.

Steven Stein - *Incyte Corporation - SVP and Chief Medical Officer*

Ren, hi it's Steven Stein I will take your first two questions then hand it over to Herve.

The first one I'm not going to answer satisfactory for you because it depends on histology and when they come in in terms of the data sets. We will, and we've said repeatedly, across our collaborations, we studied more than a dozen tumors. We will enroll north of 600 patients this year and have very healthy cohorts for each of those to analyze.

Some areas are more competitive than others. These are known areas like lung cancer can be more competitive than other histologies. I'm not going to comment as to what data sets will come in first before others, and as Herve said earlier we'll present them appropriately.

In terms of your question related to our PD-1 1210 inhibitor the dose escalation phase completed and we have information to make decisions on what to go forward in terms of dose expansion. And that's what we're looking at the totality of the profile at the moment.

I will hand it to Herve.

Herve Hoppenot - *Incyte Corporation - President and CEO*

In the question about the climate on price, I think -- again, I mean back to what I said at the beginning of the quarter. I think our view is that innovation is what creates value, it creates value for society it creates value for patients, obviously, first, by where we can help and you see that now.

You see a number of tumor types where physically a diagnosis just of years ago people were looking at palliative ways to treat these patients, and where there are now there are option is to potentially have some curative or very long-term responses, and that's really what's driving most all of our efforts in bringing these new drugs to market. What it does to society is an incredible amount of savings on the cost of treating cancer. And

that's really where the economics work really well, is that today most of the cost of treating cancer -- 80% of it in the US and around the same number in Europe, are not coming from medicines. They're coming from the rest of the cost in surgery and palliative care, radiation therapy etc.

So the model we are pursuing is the model that will be over time obviously building for us an importance source of new revenues through innovative products and at the same time being able to make it in such a way where the healthcare system will benefit from this innovation, and we see that. I know there is a lot of noise about the way people look at some of the cost issues. But the reality is that we see already that when products are truly effective they are in fact cost savings for the healthcare system.

In the case of Jakafi in myelofibrosis, it's a situation where we are in a position where the coverage in the US is very broad and we don't see a lot of hurdles there. Obviously it's based on what Barry was describing where the symptomatic benefits and now the survival benefit is well established for this product.

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

Thank you.

Operator

Peter Lawson, SunTrust Robinson Humphrey.

Peter Lawson - *SunTrust Robinson Humphrey - Analyst*

A question for Barry or Steven just around the ASH data. What could we see -- it looks like what Jakafi five-year data GVHD, any color around that data?

Steven Stein - *Incyte Corporation - SVP and Chief Medical Officer*

Hello, Peter. It's Steven Stein.

As you know, the American Society of Hematology abstract published in the next 24 to 48 hours, and I'm embargoed until then. So I can't give you color around the data, other than to point to what we said in the actual presentation, which is the pooled analysis of COMFORT-1 and -2 overall survival data in myelofibrosis will be presented as part of our numerous presentations at ASH.

Then additionally 39110 our selective JAK-1 inhibitor proof of concept study in graft versus host disease will also be presented there. So as soon as the abstracts are live you can look at the data set in the actual presentations. I can't provide more color at this point.

Peter Lawson - *SunTrust Robinson Humphrey - Analyst*

Just in the earlier I-O pipeline, GITR and OX40, when can we see data around those molecules?

Steven Stein - *Incyte Corporation - SVP and Chief Medical Officer*

Steven again.

The GITR program dosed early in the second half of this year and OX40 is about to dose, so we will be conducting those studies as efficiently as possible. But you are looking a year plus ahead to see data related to the Phase 1 experience for those compounds.

Peter Lawson - *SunTrust Robinson Humphrey - Analyst*

Thanks.

Operator

Alethia Young, Credit Suisse.

Alethia Young - *Credit Suisse - Analyst*

Hey guys. Thanks for squeezing me in. Congrats on the quarter.

This is probably for Barry. As it relates for Jakafi, with the broader guidelines is it a matter of finding the patients, or is it educating the doctors who are reviewing the charts around that opportunity?

Barry Flannelly - *Incyte Corporation - EVP and General Manager*

Sure so for myelofibrosis it is sometimes difficult. Myelofibrosis patients obviously are seen by hematologist, oncologist in the community and they may not see them as frequently as they do some metastatic lung cancer patients for example.

So to recognize that these patients -- that patients that they might call low risk, let's say, but are actually high risk and they need to be treated right away, sometimes that's very difficult for them to assess. Our educational efforts -- some of our educational efforts are focused on that, to make sure that physicians who are treating patients with myelofibrosis are appropriately assessing the risk that these patients are under and the NCCN guidelines reinforce that.

Alethia Young - *Credit Suisse - Analyst*

Then, just on momelotinib and looking at your longer-term data in COMFORT, do you think that the long-term data is something that is important to doctors? Meaning that, let's say, a bear case scenario comes out from momelotinib where the data looks like it supports a first-line therapy. Do you think that having that longer-term data is something that's very important and relevant and momelotinib would have to be held to the same standards?

Barry Flannelly - *Incyte Corporation - EVP and General Manager*

Yes exactly. That's why keep on saying our clinical profile matches up very well. We have long-term spleen response data, long-term safety data. We improved symptoms to a great degree for these patients, and in fact we have a 30% reduction in the risk of death. And there is no endpoint in the momelotinib studies, either Simplify one or Simplify two for overall survival. So we think we are in good shape.

Alethia Young - *Credit Suisse - Analyst*

Great. Thanks.

Operator

Michael Schmidt, Leerink Partners.

Michael Schmidt - *Leerink Partners - Analyst*

Hey guys. Thanks for taking the follow-up.

I had a couple additional questions, one on duration of therapy in MF in clinical practice. Has that been similar to what's been seen in long-term follow-up of the COMFORT trials?

Barry Flannelly - *Incyte Corporation - EVP and General Manager*

For myelofibrosis in the COMFORT trials, what you are talking about is that patients -- 50% of patients stayed on it for three years. While in the everyday setting, not in the clinical trial setting it's less than that. But it's hard to predict.

Patients stay on therapy for a long time. We have some percentage of patients who stay on therapy for a very long time and benefit greatly from it. So we've never really talked about the true persistency. But it's more than 12 months.

Michael Schmidt - *Leerink Partners - Analyst*

Great. Thanks.

Then one of the FGFR inhibitor, the question there is whether the Phase 2 studies that you have initiated there, whether those could be registration enabling.

Steven Stein - *Incyte Corporation - SVP and Chief Medical Officer*

Michael, hi. It's Steven Stein responding. There are robust large Phase 2 studies of approximately 100 patients each. They will capture response rates along with duration of response. There are multiple precedents both in the United States and in Europe for approvals with good high response rates that are durable.

In the US it would be on the accelerated approval conditions, in Europe under conditional approval conditions, for which you would then have to do confirmatory studies. So it's a review issue based on the efficacy data we see. But there is potential.

Michael Schmidt - *Leerink Partners - Analyst*

Okay. And one on capmatinib, the MET inhibitor with Novartis where it looks like they are expecting filing in 2018. I was wondering whether it's known which specific indication that could be in? Is that a monotherapy approach in MET selected lung cancer patients, or potentially in combination with each of our inhibitors? Thank you.

Herve Hoppenot - *Incyte Corporation - President and CEO*

Herve here, I think our understanding that it would be in lung cancer.

Michael Schmidt - *Leerink Partners - Analyst*

Any more color on the royalties and potential milestones from that program?

Herve Hoppenot - *Incyte Corporation - President and CEO*

I think what we have said on the royalties is that there would be in the teens -- low teens, So 12% to 14%. And that's a milestone attached to different events like approval, et cetera, that we have not disclosed yet.

Michael Schmidt - *Leerink Partners - Analyst*

Perfect. Thank you and congrats again on the quarter.

Herve Hoppenot - *Incyte Corporation - President and CEO*

Okay.

Operator

Thank you. I will now turn the floor back to Mr. Herve Hoppenot for closing remarks thank you.

Herve Hoppenot - *Incyte Corporation - President and CEO*

Okay. Thank you for your time today and for your questions. We look forward to seeing some of you at the ASH conference next month. But for now we thank you again for your participation in the call today. Thank you and goodbye.

Operator

This concludes today's call. All parties may disconnect have a great day.
