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INCY - Q2 2015 Incyte Corp Earnings Call

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OVERVIEW:

Co. reported 2Q15 total revenue of $163m.

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PRESENTATION

Operator

Greetings, and welcome to the Incyte second-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 our host, Michael Booth, Vice President of Investor Relations. Please go ahead.

Michael Booth - *Incyte Corporation - VP of IR*

Thank you, Diego. Good morning, and welcome to Incyte's second-quarter 2015 results conference call and webcast. The slides in today's presentation will be made available for download on the Investor section of Incyte.com after the call concludes.

Herve Hoppenot, our CEO, will begin with a few words summarizing the quarter, and then Barry Flannelly, who leads our US Organization, will provide a commercial update on Jakafi. Rich Levy, who is in charge of Incyte's drug development activities, will update you on our clinical portfolio, and Dave Gryska, our CFO, will describe our second-quarter financial results. Then we will open up the call for Q&A, for which we will be joined by Reid Huber, our Chief Scientific Officer, and Kevin Harris, VP Global Product Strategy.

On the call today, we will be discussing Jakafi, which is FDA approved for patients with intermediate or high-risk myelofibrosis, and for patients who have polycythemia vera who have had an inadequate response to, or are intolerant of, hydroxyurea.

In addition, we would like to remind you that some of the statements made during the call today are forward-looking statements, including statements regarding our expectations for 2015 guidance, the commercialization of Jakafi, our development plans for Jakafi and other indications, and for other compounds in our pipeline. These forward-looking statements are subject to a number of risks and uncertainties that may cause our actual results to differ materially, including those described in our 10-Q for the quarter ended March 31, 2015, and from time to time in our other SEC documents.

With that, I would now like to pass the call to Herve for some opening remarks.

Herve Hoppenot - *Incyte Corporation - CEO*

Thank you, Mike. Good morning, everyone. We have had a very successful quarter on both the commercial and the clinical development side; and as promised, today we are very pleased to include a more detailed review of the Jakafi launch to date in polycythemia vera.

So, the commercialization of Jakafi continues with significant momentum, and the launch in PV has added to Jakafi's growth. Today we reported Q2 sales growth of 69% year over year, and we have raised full-year 2015 net product revenue guidance for Jakafi to a range of $560 million to $575 million from the $525 million to $565 million previously communicated.

During Q2, we have also progressed as planned on the clinical front. We continue to recruit patients into the phase III Janus program and into the other solid tumor studies for both ruxolitinib and our JAK1 INCB039110.

The PD-1 / PD-L1 combination trials with epacadostat, our IDO1 inhibitor, are all recruiting well, and the FGFR and BRD inhibitor programs are also recruiting patients. Phase III data from baricitinib was presented at the EULAR conference in June, and we also provided updates from the RESPONSE study of ruxolitinib in PV and data from the novel-novel combination of JAK1 plus PI3 Kinase Delta at ASCO.

Before I close this short introduction, I want to emphasize how important and successful we believe this quarter was for Incyte. We expect the launch of Jakafi in PV to provide us with a new growth driver for the future, as our research and development team continues to rapidly broaden our product portfolio. And we also expect that our financial discipline and strength will continue to allow flexibility in our resource allocation process.

I would now like to pass to Barry to give us details of our commercial performance in the quarter, as well as some greater insight into the progress of the launch of Jakafi in PV.

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

Thank you, Herve. Good morning, everyone. I am looking forward to getting to know all of you better in the coming months, and I am also excited to begin my new role within Incyte leading our US Organization.

The sales of Jakafi accelerated in the second quarter, driven by uptake of Jakafi in the treatment of patients with uncontrolled polycythemia vera, and continued growth in myelofibrosis. In the second quarter, we achieved $142 million in net sales of Jakafi. This represents a 69% increase over the same period last year, and a 23% increase over the first quarter. Demand grew by 19% quarter over quarter, and inventory remained stable.

On the next few slides, we will review some of the key elements of the launch in polycythemia vera. This graph plots the total number of prescribers that are new to Jakafi in the last two years. In the first half of 2015, we can see that the PV launch has led to a jump in the number of prescribers who are new to Jakafi compared to previous periods. We have been consistently adding new prescribers for the MF indication through 2014; and since the launch in PV, this analysis reveals that the breadth of prescribers has increased. This is consistent with our expectations, because we expanded our targeting efforts to seek prescribers with high PV potential who may not be actively treating patients with myelofibrosis.

On slide 9, we see a second piece of evidence that the Jakafi launch in polycythemia vera may have changed prescriber behavior. The PV launch has driven a shift in utilization of 10-milligram tablets as the starting dose. The use of 10 milligrams as the starting dose has increased from approximately 25% during 2014, which represented use in MF only, up to approximately 43% during the first half of 2015, illustrating the impact of the PV launch. As you know, there are five strengths of Jakafi tablets available, and the recommended starting dose of Jakafi for patients with polycythemia vera is 10 milligrams twice daily.

Recent market research is shown in the chart on slide 10, which shows the primary reasons that physicians gave for initiating therapy with Jakafi in patients with polycythemia vera. As you can see, 80% of patients are switching from hydroxyurea to Jakafi, based on an inadequate response to hydroxyurea, which might be needed to better control hematocrit, enlarged spleen or PV-related symptoms. The remainder of patients who have initiated Jakafi are either intolerant to hydroxyurea or who have specifically requested a change to Jakafi.

Patient identification has been a key area of focus for our launch efforts, as we seek to educate healthcare professionals about the subset of patients who lack full disease control. As we stated on our Q1 call, the initial wave of PV patients taking Jakafi may have had, for example, elevated hematocrit and enlarged spleen and PV-related symptoms. Our challenge, and also our opportunity, is to help educate physicians about the need to also treat those patients who have elevated hematocrit or enlarged spleen or PV-related symptoms for whom hydroxyurea was inadequate.

Moving now to a measure of physician satisfaction with Jakafi, we asked physicians who have used Jakafi for their measure of satisfaction with the drug, using a scale of 1 to 7, where 1 was not satisfied at all, and 7 was extremely satisfied. As you can see, the results of our recent market research are very positive, and are reflective of the feedback we are receiving directly from both physicians and patients.

We continue to focus our efforts on educating healthcare professionals on the importance of maintaining hematocrit consistently at or below 45%, and the consequences of the lack of disease control. While most physicians are aware of 45% as a target level for hematocrit, the majority of physicians interviewed are willing to tolerate levels well above 45%, as shown in the chart on the right side of slide 12. This is a key educational opportunity as we move forward. We expect to build steady and consistent momentum within the PV indication over time, as we execute our launch plan, aiming to close educational gaps, clearly position Jakafi for patients with uncontrolled polycythemia vera, increase the breadth and depth of prescribing, and reinforce positive experiences with Jakafi.

Slide 13 shows data that we have shared with you before, but with our indications for MF and PV combined. We have penetrated just over one-third of addressable myelofibrosis patients within our label, and we are just starting to serve the approximately 25,000 uncontrolled polycythemia vera patients that we continue to believe are addressable within our PV indication. We expect that Jakafi has a long life cycle ahead. Recall that we have a composition-of-matter patent on ruxolitinib until 2027.

We are still at the beginning of our commercialization of Jakafi, and we believe that steady and consistent growth of Jakafi in PV, combined with continued successful growth in MF, has the potential to represent a significant long-term commercial opportunity for Incyte. We are confident, even with the expected level of future commercial competition, that this long-term opportunity may result in net product revenue reaching $1.5 billion for the US Jakafi franchise in MPNs alone.

In summary, the ongoing launch of Jakafi in PV has accelerated our top line by adding significantly to ongoing growth from our MF indication. I will now hand the call over to Rich to give us a brief update on clinical progress in the quarter.

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

Thanks, Barry.

Beginning with our PV data from ASCO in June, we presented follow-up results from the pivotal RESPONSE trial of ruxolitinib in patients with uncontrolled polycythemia vera. The table on the left shows that 83% of the patients were still receiving ruxolitinib at a median exposure of 111 weeks. And the right panel highlights the probability of maintaining the primary response in the ruxolitinib arm for at least 80 weeks, starting from the time of initial response, was 92%.

The second key data set we presented at ASCO were the initial results of the combination of '39110, our JAK1 selective inhibitor, plus '40093, our PI3K Delta inhibitor, in patients with B-cell malignancies. Slide 16 highlights aspects of the data from the Hodgkin's lymphoma cohort, which shows both deep, as displayed on the left, and durable, as displayed on the right, responses to the combination. I'd like to emphasize that this trial was run in heavily pre-treated patients. For example, 70% of these Hodgkin's lymphoma patients had received five or more prior lines of therapy. We're in the process of deciding on next steps for the combination, and we will provide more details when our plans are finalized.

Moving now to baricitinib, our JAK1/JAK2 inhibitor that's partnered with Lilly: Results of the first two Phase III studies in patients with rheumatoid arthritis were presented at the recent EULAR conference. The BEACON trial was a study of baricitinib versus placebo on a background of traditional DMARDs, including Methotrexate, in patients who had already failed one or more TNF inhibitor-based regimens. The BUILD trial was a similar design in patients with RA who had failed prior DMARDs, but had not received TNF inhibitor-based therapy. Both BEACON and BUILD met their primary end points; and as an illustration, three of the BUILD slides from Lilly's webcast from EULAR are reproduced here.

In terms of efficacy in the BUILD study, a significant effect of baricitinib versus placebo was seen across ACR20, 50 and 70 scores at both 12 and 24 weeks, and in the structural end points at 24 weeks. The BUILD study, although not powered for a structural end point, did include analysis of structure, and the results were sufficiently robust that the 4-milligram dose of baricitinib showed statistically positive effects on the modified total Sharp score, as well as to each of its two components: the erosion score and the joint narrowing score. The lower panel reviews the adverse events, and shows that the incidence of adverse events, including serious infections, with baricitinib was similar to placebo.

Before the end of 2015, we and Lilly look forward to sharing data from the additional two Phase III studies of baricitinib in rheumatoid arthritis, including patients with early stage disease in the BEGIN trial, as well as the 1,300-patient BEAM study. BEAM includes a fully powered comparison to Humira, the market leading therapy for RA.

Slide 18 summarizes our current portfolio, and I will just briefly touch on a couple of aspects. The Phase III Janus studies of ruxolitinib in pancreatic cancer are recruiting, and the results of Janus I are expected next year. We also have several proof-of-concept trials running for both ruxolitinib and our JAK1 inhibitor '39110. In the first quarter, we began dosing patients with our FGFR inhibitor; and in the second quarter, we began dosing patients with our BRD inhibitor, and both programs are making good progress. Additionally, all four of our epacadostat studies in combination with either anti PD-1 or anti PD-L1 are progressing very well.

I will now turn the call over to Dave to give us the financial highlights of the quarter. Dave?

Dave Gryska - *Incyte Corporation - EVP & CFO*

Thanks, Rich. Good morning, everybody.

We recorded $142 million of second-quarter net product revenues and $17 million of Jakavi royalties from Novartis for sales outside the United States. Our total revenue grew at 64% in the second quarter of 2015 over the second quarter of 2014, and reached $163 million.

For the second quarter of 2015, R&D expense was $112 million, and SG&A expense was $52 million. We recorded an unrealized gain of $27 million from our investment in Agenus. We ended the quarter with $627 million of cash and cash equivalents on our balance sheet.

Slide 21 shows our updated financial guidance for 2015. Given the strong performance of Jakafi in the first six months of the year, we are raising net product revenue guidance to a range of $560 million to $575 million. The previous range was $525 million to $565 million.

As Rich detailed, our research and development activities are moving along as planned; and accordingly, we are tightening our R&D guidance, lifting the bottom end of the range to give a revised range of $475 million to $500 million for the full-year 2015. We are increasing our full-year SG&A guidance to a new range of $195 million to $210 million. This increase primarily reflects additional investments we are making in the commercialization of Jakafi.

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

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Our first question today comes from Matt Roden with UBS. Please state your question.

Matt Roden - *UBS - Analyst*

Great. Thanks very much for taking the question and congrats on all the progress here.

I wanted to -- in the spirit of your now $1.5 billion peak sales estimate in the MPNs alone, I wanted to think about this year. And if I just apply trends from prior years to your current first-half sales, I can get to numbers north of $600 million for this year. Just wondering as you think about your guidance and the scenario analyses and sensitivities to your numbers, if there is something that you are seeing that should rule out that type of possibility.

And then related, just wanted to know if you could talk about maybe the real world experience of PV vis-a-vis the clinical trial experience particularly with discontinuations. One of the remarkable points in our opinion of the Phase III PV study was the very low discontinuation rate. I am just wondering if you are seeing the same thing in the real world. Thanks very much.

Herve Hoppenot - *Incyte Corporation - CEO*

Thanks for the question. On the first part of your question, I think the way you can look at the guidance is looking at the year-to-year growth rate that we are speaking about here which is in the high 50%s to 60% growth from 2014 to 2015.

It's an acceleration of the growth, and I think it is reflecting the success of Jakafi in PV. Concerning the rate of discontinuation, maybe Barry if you want to speak to it.

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

Sure. As the best data that we have as Rich just pointed out is from the 80-week RESPONSE data, looking at 83% of the patients still receiving therapy at 111 weeks.

Now of course, we only have six months really of experience with the launch of PV indication, and we do see, begin to see, a separation just a little bit between the persistence on MF and PV, but you would expect that. We will have to see a lot more data, a lot more patients on Jakafi for PV to get a real understanding of the long-term persistence, but the clinical trial data gives us confidence.

Matt Roden - *UBS - Analyst*

Great. Thanks very much, and congrats on the progress.

Operator

Our next question comes from Eric Schmidt with Cowen & Company. Please state your question.

Eric Schmidt - *Cowen and Company - Analyst*

Thanks for taking my question and congrats also on the progress. Maybe another one for Barry. I think in the past Incyte's been fairly explicit that it expects the PV launch to be more gradual than that in MF, given I guess less urgency to treat.

Is that still your view with the good trajectory you are seeing? And in terms of the long-term guidance, the $1.5 billion, maybe you can provide a target year for that guidance and a rough peak split between the two indications? I assume over time you think PV might be larger than MF?

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

Yes, thanks, Eric. We are very excited about the launch in polycythemia vera. We've gotten great uptake we think from our physicians who have patients who have PV, who have prior hydroxyurea therapy, but I think as we pointed out in the past, it is patient by patient, physician by physician.

One of the things I've learned from a meeting we had with a group of physicians recently who treat PV patients is they really only see their patients about six times per year, and that's to their office. So in fact, the physician may only see their patients a couple times a year, and mid-level providers are seeing patients the other time.

So really they have to see the patient and then identify that they have symptoms or they're uncontrolled on their current therapy in order to make a treatment decision to switch that therapy. So it is gradual, but it's consistent and we are really excited about what we've accomplished so far.

Herve Hoppenot - *Incyte Corporation - CEO*

On the second part of the question for splitting sales between MF and PV, frankly we don't intend to do that. There are a number of reasons for it. One of them is that it is not absolutely clear that for some patients, if they have an actual diagnosis of MF or PV, because there are a number of cases where it is not easy to see.

What we believe over the long term is the guidance we are giving of $1.5 billion is peak sales guidance. It's something that you should look at in the longer term in the life of the product.

Eric Schmidt - *Cowen and Company - Analyst*

Thank you.

Operator

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

Cory Kasimov - *JPMorgan - Analyst*

Hey, good morning guys. Thanks for taking the question and also add my congrats on the good quarter.

Similar to what Matt asked, I wanted to also go into the potential differences in the real world experience for PV from a duration standpoint. Obviously it is way too soon to say where this will ultimately settle out given how robust the duration data was in the Phase III. So I realize this isn't apples to apples, but can you remind us how Jakafi's real world duration in MF has compared with clinical trials and then I have a follow up pipeline question.

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

So we've never been particularly quantitative about what the actual median duration of treatment is in the marketplace in MF, but it clearly was shorter than we saw in the clinical trials where the median duration of treatment was about three years. So I wouldn't be surprised personally if in the marketplace PV is a little bit less or somewhat less than it is in the clinical trials, but I would also think that the relative duration of treatment in the clinical trials of PV to MF would likely be borne out in clinical practice as well. But I can't really get quantitative about it.

Cory Kasimov - *JPMorgan - Analyst*

Okay. Understand. Then for baricitinib, is there anything you can say as opposed to just deferring to Lilly on the potential next steps for the diabetic nephropathy indication?

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

So they're in the process of trying to finalize plans for a potential registration study that includes discussions with outside experts as well as regulators, and until such time as their decisions are made, then they will propose that to us as to whether or not we want to participate. We really can't say anything in specific other than the data from the phase II was unexpectedly strong and we believe that Lilly will go forward in some manner.

Cory Kasimov - *JPMorgan - Analyst*

Okay. Great. Thanks for taking the questions.

Operator

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

Michael Schmidt - *Leerink Partners - Analyst*

Good morning. Thanks for taking my questions. I had another one on the PV launch. To what degree has your copay assistance program affected the gross to net adjustment? And a second question, on the pipeline, how should we think about news flow from the epacadostat PD-L1/PD-1 combination trial? Thank you.

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

So for the first question, the biggest part of our gross to net is really Medicare rebates, Medicaid rebates, VA, Department of Defense, and 340B. So the copay is really a minor part of it. The biggest ones are really the government rebates.

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

So on epacadostat, our IDO1 inhibitor - all four of the trials are moving along well, and we're in discussions with each of our partners about the appropriate timing of potential abstract submissions to medical meetings as well as if the data are robust enough to move forward into registration trials. So we can't be specific. We have said in the past that certainly the latest we would have data in the public domain would be sometime next year.

Michael Schmidt - *Leerink Partners - Analyst*

Great. Thank you.

Operator

Thank you. Our next question comes from Ying Huang with Bank of America Merrill Lynch. Please state your question.

Ying Huang - *BofA Merrill Lynch - Analyst*

Good morning guys. Thanks for taking my questions. First one on PV here and in terms of the new prescribers that use it for PV, are you also seeing a spillover effect from the doctors who may also use more ruxolitinib in MF?

And then secondly on the run rate for MF, are you seeing more new patients or a plateau of new patients getting onto therapy for MF in this quarter? Thank you.

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

Sure. In terms of prescribers, as you can imagine, the vast majority of prescribers for both MF and PV are the same docs. It just so happens that we found a group of prescribers who hadn't experienced the use of Jakafi in MF. And once they start using the drug in PV, they may in fact have MF patients that they then prescribe for. The second question was --

Ying Huang - *BofA Merrill Lynch - Analyst*

Oh, in terms of quarterly new patient additions.

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

Sorry. We continue to have a steady growth, a steady consistent growth in MF patients. We think the growth in MF is going to contribute well to the sales, full-year sales this year, and both MF and PV new patients continue to grow.

Ying Huang - *BofA Merrill Lynch - Analyst*

Thanks.

Operator

Thank you. Our next question comes from Ian Somaiya with Nomura. Please state your question.

Ian Somaiya - *Nomura Securities - Analyst*

Thanks and congratulations on a great quarter. One question on the market dynamics. I was wondering if you can speak to the payer mix as you launch into PV. And a question on IDO, is there a scenario where you would have enough data in house to be confident enough to announce the start of pivotal studies prior to the data presentation at ASCO next year?

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

Sure. So I will take the first question. In terms of payer mix specifically for PV, we think it's a slightly younger population. So you might see a little bit less Medicare patients, but it is pretty much consistently the same. In the terms of commercial payers, it's exactly the same and coverage really hasn't been an issue for PV.

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

So on IDO progress, I mean, we have certain meetings that come up and they control the timing of when there is detailed presentations of the data, but that doesn't drive the timing around our decisions to move into registration trials. So if the data are sufficiently robust before then, we would not be waiting for ASCO to announce something. It could happen sooner.

Ian Somaiya - *Nomura Securities - Analyst*

Is it possible for you to give us some sense of timing, when you would have in essence enough data to make that decision?

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

Not really. I mean there is quantity of data and then there is direction of data, and they're both important to being able to make those decisions. I really don't want to get into prognosticating when that might be.

Ian Somaiya - *Nomura Securities - Analyst*

Okay. Thank you.

Operator

Thank you. Our next question comes from Chris Marai with Oppenheimer. Please state your question.

Michelle Gilson - *Oppenheimer - Analyst*

Hi guys. This is actually Michelle on for Chris. We were wondering how you look at your partnerships? We recall a competitor had said on their call, Roche actually, that their molecule had characteristics - this is in regards to the IDO inhibitor -- that their molecule has characteristics that are similar to and they feel pharmacologically superior to they specifically cited your molecule.

Reid Huber - *Incyte Corporation - Chief Scientific Officer*

So I think we're not going to comment on the preclinical profile of the compound. I think most relevant is to see the emerging clinical profile and then we will have something that is better relatable to the emerging epacadostat profile.

I will say that we continue to be very pleased with potency, safety, pharmacokinetics of epacadostat in the ongoing program and see little opportunity for another compound that's also an IDO of one selective inhibitor to significantly differentiate. So our focus now is on trying to maintain the competitive gap we have. We think that's a very important asset to the portfolio.

Michelle Gilson - *Oppenheimer - Analyst*

All right. Great. Just a follow up to that. I guess are you guys looking towards spending maybe a little bit more to speed up the clinical development of your IDO and maybe your BRD too, the ones that are in very competitive spaces, to provide that competitive advantage? Just when we are thinking about the profitability and balance sheet going forward?

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

So the amount of money that we're spending is not what is controlling the time lines at this point. So first of all, if you look at the IDO studies that are being done with PD-1 inhibitors, you need to start at a relatively low dose and you need to wait certain amounts of time before you can go to the next dose level. And then you want to generate enough data within any particular tumor type to make a decision as to whether or not you are going to go forward or not.

Each of those things are progressing as quickly as we had hoped. Throwing more money at it would not make it go any faster. What we are committed to is should data be robust enough, we are going to make a fast and large commitment to registration studies and remain well ahead of our closest competitors.

Michelle Gilson - *Oppenheimer - Analyst*

All right. Great. Thank you, guys.

Operator

Our next question comes from Matt Roden with UBS. Please state your question.

Matt Roden - *UBS - Analyst*

Great. Thanks for taking the follow up. As it relates to baricitinib, can you address the competitive landscape in rheumatoid arthritis, particularly any thoughts, Rich or Reid, you may have on the recent filgotinib data, anything that is worth pointing out from a compare or contrast perspective. And then related, what are your expectations for the BEAM study in terms of the comparison to Humira? Thanks.

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

Okay. So with respect to the JAK1 selective inhibitor where there is Phase II data out there. I mean, first of all we believe that the Phase II data are quite acceptable, but Phase III is really going to be key and let me tell you a couple of reasons why.

So first of all, we have seen with our own JAK1 inhibitor and now it is confirmed also with the JAK1 inhibitor from Galapagos that in order to see the top range of efficacy, you really need to get to high levels of JAK1 inhibition compared to the levels of JAK1 and JAK2 inhibition that you need with balanced inhibitors. And that level of inhibition is quite high, and it's not to say there is a problem with that. It's just not been tested over the long term yet.

So we need to see the Phase III safety data as much as anything else to see whether those levels of JAK1 inhibition are going to give you the type of safety profile that's needed to be successful in a drug program in arthritis. Other things that we would say are that even after you correct for trying to take out what the placebo response is, you are still in danger to trying to compare across studies, head to head are the gold standard of course.

And then finally assuming that they are going to start Phase III studies approximately the beginning of 2016, that would put them a full three years behind where baricitinib started Phase III and we would expect a full three years behind in terms of time to launch. You had another question?

Matt Roden - *UBS - Analyst*

Yes. I was going to ask about your expectations for the BEAM comparison to Humira.

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

Sure. So one of the big upside positives coming out of the data that's already been presented was the structure data coming out of a study that was about half the size of the BEAM trial. So I would expect that given the designs of this trial, that that would be fine.

With respect to the expectations against Humira, again with the difficulty of comparing across trials, I think our results have been as good as, or numerically slightly better than, historical data with Humira. The study is adequately powered that it has the potential to show superiority if the results are consistent with some of the data that we've seen. But simply having noninferiority to Humira across the board for a drug that's an oral once a day treatment, we think would lead to a very attractive profile.

Matt Roden - *UBS - Analyst*

What are the metrics we should be looking at? Is it the ACR scores or the DAS28 is it the structural data?

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

So the way that it works and I can't get into all the details. First you look at superiority to negative control arm. Then you look at structure. And then you look at noninferiority to Humira I believe based on ACR20, but I am not 100% sure.

Then you start to look at potential for superiority both based on DAS and ACR scores, and I just can't recall exactly what the order in which that is done. But certainly we expect to be able to get to those analyses while still preserving alpha to make a statistical comparison on efficacy.

Matt Roden - *UBS - Analyst*

Super helpful. Thanks, Rich.

Operator

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

Herve Hoppenot - *Incyte Corporation - CEO*

Okay. Thank you for your time today and for your questions. After a very successful Q2, we are looking forward to a series of very important and exciting events over the next several months and we look forward to talking to you again at our third-quarter conference call in early November. So thank you and good-bye.

Operator

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