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Q3 2020 Galapagos NV Earnings Call

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PRESENTATION

Operator

Ladies and gentlemen, thank you for standing by, and welcome to the Q3 2020 results conference call. I would now like to hand over the conference to your first speaker today, Elizabeth Goodwin. Please go ahead.

Elizabeth Goodwin *Galapagos NV - VP of IR*

Hi, and thank you all for joining us today for our third quarter results call. I'm Elizabeth Goodwin, Investor Relations, also representing our financial reporting team to bring you this information today. This recorded audio webcast is accessible via the Galapagos website homepage and will be available for replay later on today.

Sell-side analysts and professional investors are invited to pose a question at the end of our call and can dial in using a series of numbers in our press release from last night. Here's one for Belgium, that's 3-227-933-847. The code is 8542327, and I'll repeat that right before the Q&A starts.

I'd like to move now to our forward-looking statements and remind everyone that we will be making forward-looking statements during today's webcast. These statements include remarks concerning future developments of the pipeline, future financial results, growth of our company and possible changes in the industry and competitive environment. Because these forward-looking statements involve risks and uncertainties, Galapagos' actual results may differ materially from the results expressed or implied in these statements.

Outside of filgotinib in rheumatoid arthritis in Europe and Japan, none of our drug candidates are approved by any regulatory authority.

Today's call will be like our other quarterly calls, our CEO, Onno van de Stolpe, will cover operational highlights for the third quarter; Chief Business Officer, Andre Hoekema, will present our deal with OncoArendi announced last night; and Chief Operating and Financial Officer, Bart Filius, will highlight our financial results and close with the outlook for the coming months.

During their presentation, you'll see the slides progress on screen, and this will be followed by a Q&A session with the executives at the end.

And at this point, I'd now like to hand over to Onno to talk about the third quarter operations. Go ahead.

Onno van de Stolpe ***Galapagos NV - Co-Founder, CEO***

Thank you, Elizabeth, and welcome, everybody. Good afternoon, good morning. We would like to start with the operational highlights. Clearly, the highlight of the year for us is the approval of Jyseleca, so that's filgotinib, in rheumatoid arthritis in the EU and Japan, which, of course, is a hallmark moment for Galapagos. This was overshadowed by the complete response letter we received from the FDA for the U.S. approval. In the CRL, they listed 2 reasons: one, the MANTA and MANTA-RAy results that they are awaiting before making a decision on the approval, which is the testicular tox study that we're executing with Gilead. And they expressed their concerns, the risk/benefits of the 200 milligrams. A very disappointing CRL, very unexpected, but a reality we got to face with.

And thirdly, for Jyseleca, we were pleased last week to announce the filing of Jyseleca in the EU for ulcerative colitis, the second indication for this drug that we are going to go for. Very nice to announce that the first shipments were made both in Germany and the Netherlands. Germany started 2 weeks ago, and Netherlands actually started on Monday and Tuesday, the first shipment was out that's the order coming in on Monday. So we are off, and now we got to get off to a good start in the various countries. The other European countries are going to follow shortly.

If we look at the rest of the pipeline, clearly, we had a number of other news items. We presented the full SELECTION data of ulcerative colitis, the filgotinib trial, at the conference. That cost them the front pages there because the very good data that filgotinib showed in that trial.

We also had a positive top line result of ziritaxestat, so that's '1690 in systemic sclerosis, the NOVESA trial. We are pleased with that data set, and we're discussing how to proceed with ziritaxestat in that indication.

And then we had a very disappointing outcome of the '1972 molecule in the ROCCELLA study in osteoarthritis, a year-long treatment where we didn't see any difference between placebo and the drug, which means that '1972 for osteoarthritis is -- development is ended. We are bringing '1972 back to the lab to see if we can find other indications, but we're not proceeding this in osteoarthritis, very disappointing.

Last week, we did an extended science seminar on Toledo, where we disclosed the targets, the SIK that we are focusing on. I think it was a very good signs and development update for Toledo. The whole package is very convincing. The identification of the target in the assay, the literature evidence of the mechanism of this SIK targets, all the preclinical data that we have in the various diseases that are extremely convincing and the very positive Phase I data that we saw a nice target engagement of -- but also a proof of principle because of the effect of IL-10 and TNF in that trial. So we clearly have a confirmation in human that we have a dual mode of action, which is very, very reassuring. And we also, from Phase I, saw that we have a very nice window with regard to safety, which is, of course, important in the further development.

We are now moving this forward in a number of different Phase II trials as we discussed at the seminar. And that will lead to quite some news flow in '21 and '22. So the first readout of the PoCs, 3 in '21 with '3970. Also our second molecule for Toledo targeting the SIK will move into the clinic in and give a readout in '21. And then in '22, we'll get a number of different readouts. And hopefully, we get the first Phase IIb readout in '22 so we can prepare for Phase III already in '22.

Well, clearly, we have a development plan set up to bring this innovation, this program with a lot of potential to patients as fast as possible. I think that is very important for the patients but also for Galapagos. We believe that this is a once-in-a-lifetime opportunity that we're progressing. And we're extremely excited about the targets, the mechanism as well as the first results that we have with '3970 and '4399. So let's hope that the good data will continue to come in this program. And you will hear much more about it in '21 and '22.

With that, I would like to hand it over to Andre Hoekema, our Chief Business Officer, to talk about the deal that we announced at OncoArendi late last night. Andre?

Andre Hoekema ***Galapagos NV - Chief Business Officer***

Thank you, Onno. Good afternoon, everybody. In our presentations, we often speak about our internal pipeline. And here, I would actually like to highlight how we also add external assets. And there's actually 2 reasons to do that. First of all, we have a very strong balance

sheet, and we really want to use that, not only to grow our internal pipeline and accelerate programs through the clinic, but actually also add external assets to our R&D engine. And talking about that engine, both in discovery and in clinical, we have a lot of expertise that that engine really fire from all cylinders. So in our view, it really makes a lot of sense to not only use it for internal molecules, but also add molecules from third parties that we think really makes sense.

Of course, in that effort, we really focused on inflammation and fibrosis, the core indication areas of the company. And it will not surprise you that when we talk about criteria, we really look for molecules that really fit Galapagos, that means novel modes of action, high-risk, high reward, and in that way, they should strengthen our pipeline.

On the next slide, you actually see the deals that we have signed this year. We've done a number of deals with molecules that hit all those criteria, Fibrocor and Scipher, both from North America, Canada and Boston. Just a few words about it. Fibrocor has come up with novel targets in fibrosis based on patient samples, very complementary to what we do. And we have moved to the first program that we licensed from Fibrocor to a candidate drug. So very pleased with that.

And Scipher has a somewhat similar complementary technology operating from Boston. They identified targets based on the molecular signature in patients, and we think that also fits very well with our own internal programs.

Ryvu identified a novel inflammation target that we really liked. The company's located in Kraków, Poland. We've also seen a deal.

Today, I'm really pleased to say a few words about the first clinical stake assets that we licensed from a company also in Poland in Warsaw in fibrosis. So let me first say a few words about the business deal.

It's a collaboration on a really novel class of fibrosis targets. OncoArendi did really some breakthrough work in this target class, chitinase. Chitinases play a role in fibrotic diseases, mostly in lung so that really fits with our interest. We have a fibrosis franchise underway with ziritaxestat and '1205 and earlier programs, and we really think there's a very nice niche where we can add another program, so we decided to work with OncoArendi.

You've seen the deal structure, an upfront of EUR 25 million. Development, regulatory and sales milestones for a total of EUR 320 million plus royalties. And we've also negotiated the right to get access to their other chitinase programs in case those hit candidate as well.

So let me say a few words about this novel target class. Chitinases are known to play a role in lung fibrosis. It is a very novel class but at the same time, we like it because there's quite a bit of validation. In knockout mice, you see that mice lines that missed those chitinases show a very reduced disease burden in the IPF models. And moreover, the molecule that OncoArendi has in development OATD-01, [when those 2] mice the same, they really reduce the disease burden. So the target class are 2 chitinases, as I said, very well-validated. We are not aware of any competition. So typically Galapagos first-in-class potential. We think there is really a lot of room to bring this into IPF and possibly in other fibrotic disorders. And at this point, Piet and Walid, are preparing a Phase IIb study to bring this molecule forward.

So if I can have the next slide, just a bit of detail on this validation that I just mentioned. Here, you see some data that show what bleomycin, which is the standard animal model for IPF. Thus, on the left, the control, you see healthy mice on bleomycin treatment. You get a formation of lesions in the lung expressed by Ashcroft score. And as you can see, the molecule from OncoArendi really reduces that effect similar to Pirfenidone. So this is one of the validations that I talked about. And we're really excited about it because a clinical asset that fits in right behind ziritaxestat, which is in a large Phase III study as we all know in '1205, where we will report the Phase II data shortly. So in summary, very happy to be adding this asset to our pipeline.

And with that, let me hand over to Bart to get you the Q3 financial data. Bart?

Bart Filius ***Galapagos NV - COO & CFO***

Thanks, Andre. And good morning, everyone, in the U.S., good afternoon in Europe. Happy to say a few words about the financial results for the quarter. And I'll finish off with an overview of, let's say, the short-term outlook in terms of events. But first on the financials.

As you can see here on the slide, starting off with our cash position. Healthy cash balance of EUR 5.3 billion at the end of September 2020, which brings our cash burn for the first 9 months of the year to EUR 433 million. As usual, we exclude 2 particular categories of cash flows, both income and expense. On the cash income side, we are excluding EUR 25 million that we received over the first 9 months due to increases in capital as a result of warrant exercises. And we also had a quarter which was, and this is 9 months total. But we had a quarter where the U.S. dollar weakened significantly compared to the euros. And as we report in euros, we are incurring a translation effect. So this is not realized but it's a translation effect of our dollar position that we have on our balance sheet, which is roughly 20% to 25% of our overall cash balance. That, obviously, in one quarter, goes up, in the other quarter, it goes down. It's not included in our cash burn, nor is it in our guidance. So EUR 433 million is the first 9 months of cash burn in total. We retain our full year guidance of between EUR 490 million and EUR 520 million. And for those of you that are doing the math, EUR 433 million for 9 months, if you divide by 3, multiplied by 4, you get up higher than the EUR 520 million. The key thing that's happening in terms of cash in the fourth quarter is also the receipt of the milestones for the approval of filgotinib from Gilead, which, by the way, meanwhile, have been received in the month of October, which were $105 million, hence, our, let's say, cash run rate to get from EUR 433 million to a max of EUR 520 million is a bit lower in the fourth quarter than it has been in the first 9 months.

Then on the P&L itself, let me highlight 3 categories. Revenues, first of all, and EUR 370 million of revenues is to a large extent, driven by accounting revenues for previous events, and those are related to our deferred income position on filgotinib. And our deferred income position on what we call the access rights to our platform. Both of which are a consequence of the transactions that we've signed with Gilead as we recognize those receipts over time and those are in one shot to the largest extent. So hence, we have now recognized a big chunk of our total top line in terms of accounting revenues here.

In terms of costs, a bit over EUR 500 million of operating expenses. That's an increase compared to the first 9 months of last year, and that's driven on one hand by the R&D investments that we're taking in filgotinib, in Toledo and in our earlier programs. But it's also driven by increases in staff and most notably in the commercial area, where we're ramping up clearly for the launch of filgotinib in Europe, and we're building out our infrastructure in the key European countries.

Then finally, net results. There is between operating results and net results. There is a gap that is driven by financial expenses. I've already highlighted the currency effect, which you can find there. But there's also a bit of accounting to be done on these Gilead warrants that are outstanding, which, depending on the volatility of the share, can be a positive or negative from one quarter to the next. But here, you see the numbers that are in those line items.

Then if I conclude this part of the prepared comments and the presentation, let me say a few words about the outlook and in 2 categories. First of all, on filgotinib. And I'm sure we'll discuss that in a bit more detail in the Q&A as well, but we are still anticipating a type A meeting with the FDA in the fourth quarter of this year. We are on filgotinib, also anticipating after the filing that we've done in Europe in Q4. We anticipate the filing in Japan in the first half of next year. And also the first half of next year, we should get a -- get the MANTA and MANTA-RAy data and get a better understanding of what those are telling us.

And then on the other programs still to come for the fourth quarter are the results of '1205, our PINTA program. We have first dosing in a study with a molecule called '3667. We've not yet disclosed the targets of that molecule but we're doing the study in psoriasis. And we anticipate first dosing in the fourth quarter. And then on Toledo, as you know, we have already dosed in a couple of PoCs last month as we were discussing in the webinar. But we are also anticipating in the beginning of next year to those 2 further indications, lupus and Sjögren's.

And then finally, for the first half of next year, a big milestone, obviously, is also the futility analysis on ISABELA. So quite a lot of news

flow in the, let's say, next 6 to 9 months coming up.

Let me conclude there. And Elizabeth, if you can take over for the Q&A, please.

QUESTIONS AND ANSWERS

Elizabeth Goodwin ***Galapagos NV - VP of IR***

Thank you. That does conclude the presentation. Today, we invite sell-side analysts and professional investors again to pose their questions. Here's the dial-in number for Belgium, country code 32-27-933-847, and the code is 8542327. (Operator Instructions)

Our first question comes from Lenny Van Steenhuyse from KBC Securities.

Lenny Van Steenhuyse ***KBC Securities NV, Research Division - Financial Analyst***

Congrats on the interesting OncoArendi deal. You're looking to further position this one in IPF clinical trials mentioning a Phase IIb trial. I was wondering if you could give some additional color on what we should expect in terms of clinical trial design as you're mentioning a Phase IIb, and in that sense, we might not expect the PINTA-like trial, but perhaps something more extended. Could you perhaps elaborate a bit on that?

And as a second question, the 3Q report also mentions the JAK1 inhibitor, GLPG0555 entering Phase I study again. I believe this compound also went through some safety studies quite some years ago. So I was wondering a bit what triggered the revival of this compound. And what's the strategy indication-wise for this one.

Andre Hoekema ***Galapagos NV - Chief Business Officer***

Thank you. Onno is not on the call, Walid go ahead.

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer***

Thank you. This is Walid. I'll take the question on the OncoArendi, otherwise known as '4716 now. It's been baptized today, actually. So our plan is to do a study where we test multiple doses. So that's why we are calling it Phase IIb. And we're still early in the design of the trial, but it will be a larger trial than PINTA. The duration probably will be about the same. We're talking about a trial, probably about 200 patients total so significantly larger than PINTA looking at patients with IPF with no background therapy and also on top of background therapy. So that is the current plans, but we will come back with more details as we get closer to starting the study. And I'll turn it over to Piet to talk about '0555.

Piet Wigerinck ***Galapagos NV - Chief Scientific Officer***

Okay. Walid, thank you. So '0555, for those of you who follow us for a long time, in fact, this was the fast molecule, that GSK took on board. And then after a while GSK gave them back to us. But that came with a very interesting data package where they evaluated '0555 in OA explants and a whole tox package with its showing effect that compared to other JAK inhibitors '0555 really did something special on the cartilage of OA patients. And so we've taken a package, and we've now started intra-articular because that was the whole game doing intra-articular injection, which would be done injection once every 6 months in the end to see whether we can pick up on signals in OA patients. Thank you.

Elizabeth Goodwin ***Galapagos NV - VP of IR***

Okay. Thank you very much for that. Our next question comes from Laura Sutcliffe from UBS.

Laura Sutcliffe ***UBS Investment Bank, Research Division - Equity Research Analyst***

I'd just like to pursue the OncoArendi deal a little bit more. The -- so you've now got 4 IPF on once at least. I think if we include the mention that IPF got in your Toledo presentation. Could you just sort of outline how all of these things fit together for us in a little more detail? That would be great. And I just want to check one thing on your ISABELA trials, if that's okay, please. Are those trials stratified by background therapy? If not, should we be concerned about whether or not you can get a useful result from them.

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer***

Thank you. So let's start from your first question. We at Galapagos have been saying that we have been quite interested in building a franchise in fibrosis. And IPF is our lead indication that we are -- we have a number of compounds in development there. And as you know, IPF is a very serious disease with a very poor prognosis. And essentially, these patients after diagnosis, the median survival is about 2 to 5 years. As such, there is huge unmet medical need there to essentially stop the progression of the disease. And consequently, when you develop medicines to treat it, the idea is to develop combination therapy, particularly when you have molecules with very good safety and tolerability profile, and you combine them together with the ambition to stop the progression of the disease. And hopefully, patients with this illness will no longer have to worry about dying from IPF but actually living with a disease that's not going to progress anymore. That is our ambition. It's a tall ambition. But that's our ambition.

And for that, we need multiple shots on goal. And it's beyond the scope of our discussion today, but we look to target multiple approaches, looking at a variety of cellular mechanism biologic mechanism from fibrosis to inflammation to be able to have complementary efficacy in these programs.

And our plan is to advance these molecules. And as they show efficacy if they lend themselves to be combined with each other from biological mechanisms, as I mentioned, and also from safety and tolerability, our plan will be to combine altogether with it.

Going to the develop program. In the develop program, we stratify between the treatment arms, placebo and the 2 doses of ziritaxestat plan and you stratify based on background therapy, either on no background therapy on nintedanib or on pirfenidone. So we do stratification on those trials.

And just to remind you, based on our discussions with the FDA, these studies have been reviewed with them and also in Europe, specifically the FDA. This type of design will allow us to get an indication from the treatment of IPF. So I hope I addressed your question here.

Elizabeth Goodwin ***Galapagos NV - VP of IR***

Our next question comes from Emily Field from Barclays.

Emily Field ***Barclays Bank PLC, Research Division - Research Analyst***

On Gilead's recent call, they seem to indicate that -- at least that they expect that they could learn something somewhat definitive from this type A meeting regarding the path forward for filgotinib in RA. It seemed to indicate that perhaps there could be some indication of whether there remains a path forward for 200 milligram. I was just wondering if you could give any thoughts on that, when we would expect that meaning to occur. And then just what exactly will be communicated to investors.

Then also, if you have any insights into when the decision was made to pause the other trials for PSA, AS and uveitis. And when we could expect -- or what the bar will be to get those trials restarted?

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer***

Okay. Thank you. I hope you guys can hear me better now. I was told that the voice before was not as great. Okay. So the -- I'm not sure I'm going to be able to add much more color than what Gilead actually had been sharing. It's essentially the type A meeting will take place as Bart said a few minutes ago still this year, before the end of the year, that's our expectation. And in terms of what we'll be getting out of it, that could be a number of potential ways forward. And that's, I think, Merdad, the CMO at Gilead talked about a few days ago. There's going to be an effort to see clarity about the path forward for the CRL to address the concerns that the agency has on the risk benefit of the 200 milligram and also specifically the exact data that would be -- that would have to be shared about the MANTA program.

And I think based on that, coming out of the meeting, I think Gilead will have a sense about the prospects of filgotinib. And as a result, whether or not the trials that were paused will be able to resume. And I think they will guide right after that meeting based on the outcome of the meeting.

Emily Field ***Barclays Bank PLC, Research Division - Research Analyst***

But the meeting is expected to occur before the end of the year?

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer***

That's correct.

Elizabeth Goodwin ***Galapagos NV - VP of IR***

And our next question comes from Nick Nieland from Citi.

Nicholas Peter Russell Nieland ***Citigroup Inc., Research Division - VP & Analyst***

So just a quick one. Does Gilead have opt-in rights for the OncoArendi asset? Secondly, for Bart, a few directional questions on the breakdown of your R&D spend, please. So firstly, do you expect your filgotinib spend in '21 to be lower than 2020? Secondly, you've spent less on ziritaxestat in '20 than you did in '19. I was wondering why that was, and will that be more in 2021. Toledo spend looks like it will nearly double this year. What growth can we expect for that in 2021. And then can you just describe what's within the other programs that's nearly halved of your spend and which is growing at over 50% so far this year. And then just a very quick question on the accounting question on the $105 million milestones, over what period these will be recognized in your revenue?

Andre Hoekema ***Galapagos NV - Chief Business Officer***

Bart, will you take those?

Bart Filius ***Galapagos NV - COO & CFO***

Yes. I'll take those questions. I was just keeping notes to make sure I get track on all the points that you raised, Nick. So first of all, does Gilead have an opt-in right on the OncoArendi asset, and the answer is yes. So as with all our compounds, both in-licensed and self-developed. At the end of Phase IIb, there is an opt-in moment for Gilead, and they pay us a milestone of EUR 150 million, following which they will share the rest of the R&D expenses 50-50, and they get the rights for ex Europe against the royalty of 20% to 24%. So this follows the normal economic structure of all compounds.

Then on the R&D breakdown, a couple of points that you raised. First of all, if we go 2021. It's a bit difficult to assess at the moment, as Walid was just expressing the question mark around PSA, AS and uveitis, that's going to be obviously a driving factor in the expenses for 2021 as well depending on whether that's resumed or paused. So that's an answer that I cannot really give you today. On ziri, it's less, but that's only mechanical because last year before the collaboration, we were taking 100% of the costs on ziritaxestat. Then we started to share this 50-50 on the end of September 2019. So if you look at the comparison of the first 9 months this year against last year, you see a decline, but it's effectively an underlying increase in the actual expense when it's shared with Gilead.

And to a certain extent, that happens on filgotinib, but in the other direction there, the costs are increasing, but that's also reflecting that we are spending 20% of those costs in 2019, at least on the first 6 months. And then 50% in the remainder of the year.

Toledo growth, correct. That indeed -- growing significantly this year compared to last year. We do anticipate some further growth as those proof-of-concept studies are getting online as we speak, and we'll be continuing to run throughout 2021. So indeed, for Toledo, you should expect some further increases.

Then finally, the other portfolio. That's really the whole portfolio that's in development, both in preclinical development and in the clinic. And so those include the molecules that we referred to earlier in the call, such as '3667, '0555 as Piet was highlighting. And then at the moment, I think we have in PCC and Phase I status not mistaken, somewhere between 5 and 10 different programs that we're running. So that's explaining why this other category is meaningful and is also growing.

Then lastly, your question on the accounting treatment for the milestone. It's actually treated together with all the other filgotinib income that we have received in the past, and we will receive in the future. We are basically lumping them all together and then spreading them out over the period of the development program of filgotinib. And that basically is currently estimated to be -- and then I mean, the regulatory development program for the next 3 to 4 years still to go. So it's a bit of a complicated accounting treatment but we don't

recognize everything out of the $105 million immediately, but we actually are spreading that out over the period. I hope I have answered your questions, Nick.

Elizabeth Goodwin ***Galapagos NV - VP of IR***

And so our next question will come from Peter Welford from Jefferies.

Peter James Welford ***Jefferies LLC, Research Division - Senior Equity Analyst & European Pharmaceuticals Analyst***

I've got 2. Firstly, just returning to Gilead, if we can, just with the comments they made on psoriatic arthritis and AS, just curious here how this works as far as obviously, this is now a 50-50 cost share. But obviously, Gilead does understand that we have a focus on the U.S. But clearly, for these indications as well, those trials are essential for other geographies as well. So I guess curious to understand the thinking behind pausing these studies, given this is an FDA-specific problem and how Galapagos thinks about this. And what we can sort of think of a path forward given obviously the potential challenges that there could be within the U.S., but equally the significant opportunity there is elsewhere?

And then secondly, on chitinase inhibitors, just curious if you can ask, is this a target that you have tried addressing with your internal drug discovery platform efforts? And if so, I guess, curious why you think this particular asset is differentiated or perhaps why they've done something that you couldn't do, if it's the case or why you haven't pursued it, I guess, internally?

And then just a quick one for Bart. Is the EUR 27 million that you're paying to OncoArendi, I presume that's within the cash burn guidance for this year. But could you just clarify that, that is right.

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer***

Let me take the first question on the Gilead. Well, look, I think these programs on psoriasis and closing spondylitis and uveitis, were designed with the idea to have -- to address the global regulatory sort of situation. And as the U.S. situation is less clear, Gilead decided to pause these in consultation with us, and we were aligned with that because we need to have clarity as to what's happening in the U.S. and what is the future plan there before we can decide whether the studies, the way they are designed, they could go and they would address the geographies where we're interested in and where we're going to have a way forward. And so it seems like a sensible way to go forward to have this much more informed by the discussion with the FDA, there needs to be some changes made. And that's why it's stopped. And then we'll see where we go from there after we have that meeting, and we can adjust accordingly. And we will be talking much more with much more clarity at that point. After we...

Elizabeth Goodwin ***Galapagos NV - VP of IR***

This is Elizabeth. Walid, I just think it might be helpful to add that it's a pause in enrollment only. Is that correct? It's a pause in enrollment? (inaudible)

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer***

That is -- yes. That's correct. Yes.

Elizabeth Goodwin ***Galapagos NV - VP of IR***

Thank you. And we had a question on the chitinase inhibitors, why they're differentiated?

Andre Hoekema ***Galapagos NV - Chief Business Officer***

Piet, you take that one.

Piet Wigerinck ***Galapagos NV - Chief Scientific Officer***

Okay. Thank you, Peter. Did we just finally target ourselves? The answer is no. And that's for a very simple reason is that this target is expressed only in active macrophages. And we never did that type of target screens -- or we never did the target screen in that type of cells for fibrosis. So in that sense, as we didn't screen macrophages for fibrosis. We didn't set up ourselves to file it. We were impressed with the data. It's a complete novel target, makes sense in the disease. And both the compound data and the knockout data for IPF make great sense. And we believe it nicely complements our internal IPF portfolio. That's why we did the deal. Was there a third question on there, Bart?

Bart Filius ***Galapagos NV - COO & CFO***

Yes. That's mine. So Peter, I can confirm your question. So the EUR 27 million that is paid to OncoArendi as part of this transaction is part of our cash burn forecast of between EUR 490 million and EUR 520 million.

Elizabeth Goodwin ***Galapagos NV - VP of IR***

Our next question will be coming from Rushee Jolly at Bernstein.

Rushee Singh Jolly ***Sanford C. Bernstein & Co., LLC., Research Division - Research Analyst***

Rushee Jolly, Bernstein. My question is on the small molecule '4059 that entered the clinic in the quarter. For the last year of your R&D update, we showed preclinical data on the asset demonstrating an impact on triglycerides weight in blood. And those who are either taking it combined with metformin. So I appreciate the mechanism is undisclosed at present, and it's very early. But can you talk a little about any aspects of the molecules that you feel may be particularly differentiated? And that's given that we have several old diabetes drugs on the market would affect the stretch beyond weight and blood sugar. And then tied to that SIK as well also seems to be an interesting target for diabetes and obesity. Do you have any plans to push any of the Toledo assets into these diseases as well?

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer***

Okay. I'll take both questions. Let us start on SIK and metabolics, that's an easy one. We are aware of those publications, and we follow up with every molecule in every animal model, whether or not we see something that points us into that direction as a potential application for the Toledo platform. And if we decide at the spur of the moment that indeed, this is a path forward you'll hear from us. But it's well known, and it's on our radar. On '4059, so that compound moved to Phase I. It's a complete novel target. And in that sense on its own or already working in a complete different way than older and more recent drugs. So we want to see what it does in Type 2 diabetes, we believe it has a position on its own. We've compared heavily to older and newer drugs and with the profile, we see it is different from what is out there. So the moment we move into Phase II, we will update you more fully on how we see this drug fitting in the total field there. Thank you.

Elizabeth Goodwin ***Galapagos NV - VP of IR***

All right. Our next question comes from Evan Seigerman at Crédit Suisse.

Evan David Seigerman ***Crédit Suisse AG, Research Division - VP & Senior Equity Research Analyst***

So one for Bart, I would -- can you expand on some of the differences that EMA and FDA see between the JAK class. I think in the U.S., we don't realize how more open the European regulators are to JAKs. And I think that might help put into context the launch that you're starting with filgotinib.

Andre Hoekema ***Galapagos NV - Chief Business Officer***

Yes. Let me transfer that question, Evan, to Michele, our Chief Commercial Officer, who is also on the line. And I think he's happy to take it.

Michele Manto ***Galapagos NV - Chief Commercial Officer***

This is Michele Manto. So we've seen also a difference in the uptake of the molecule. So if you look -- of the class, if you look at Europe, we see that the class is really going strong. So we've seen that before only with Luminex in the market, they achieved a 15% share. And we also seen Rinvoq also came into the market earlier so in Germany. This went up to 20%. So the class keeps growing and also not cannibalizing between the molecules, which is also leaving a good base for our ongoing launch. Also what we are seeing is that the in the dynamic markets, the advance plan so like Germany, you see 20% of the bio naive really going on JAK inhibitors and 1/3 of these patients going on JAK inhibitors. So you see also a different base of use. And of course, at the same time Rinvoq is growing strongly as well in the U.S., indicating that the demand is there. For the rest, of course, difference in the regulatory scene between FDA and EMA is something Toledo already addressed. And the next news will come with the type A meeting outlook, as already indicated. I hope this answers your question.

Evan David Seigerman ***Crédit Suisse AG, Research Division - VP & Senior Equity Research Analyst***

No, that is helpful. I mean, just, I guess, one more thing to follow up there. Do they look at the risk-benefit of JAKs differently in Europe? It seems that FDA is a little more conservative when you look at baricitinib and now filgotinib, whereas you have approvals in Europe.

Michele Manto ***Galapagos NV - Chief Commercial Officer***

Walid, do you like to take that on the regulatory side?

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer***

Yes, sure. I mean, I think that's a fair assessment. I mean, if you compare the situation with baricitinib between Europe and the U.S., it pointed to that direction. Yes, I'm not sure what more to add to it, honestly. I think these agencies form their own opinion based on the review of the same data. Sometimes they talk to each other but in the end, their opinions could be different. And I think in this case, you see Europe going in 1 direction and the U.S. a different direction. So let's hope filgotinib will prove that theory wrong, and we'll get it approved with both doses in the U.S. and see which way we go forward from there.

Elizabeth Goodwin ***Galapagos NV - VP of IR***

Thanks, Evan. We now turn to Brian Abrahams at RBC.

Brian Corey Abrahams ***RBC Capital Markets, Research Division - Senior Biotechnology Analyst***

On filgotinib, I guess 2 questions for me. First off, can you talk about the potential for approval of the 200-milligram dose for a more narrow, say, TNF refractory RA population. Is this something that's planned for discussions at a Type A meeting? And would you want to potentially commercialize it in RA in the U.S. with that kind of label if your partner Gilead does not wish to? And then secondly, can you frame for us your expectations on, I guess, specifically on the possible durations of follow-up necessary for the MANTA and MANTA-RAy studies and how that might shape you and your partner's go-forward decisions on filgotinib?

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer***

Yes. Let me take the clinical question, the regulatory questions, and then I'll ask Michele to answer the hypothetical commercial question. Look, I think the Type A meeting is meant to engage with the FDA to see what potential avenues we can have going forward. The FDA, as we've said before, and Gilead actually said, raised questions about the risk/benefit of the 200-milligram and target indication. And therefore, there could be potentially a way forward when you look at patients where the risk/benefit is a bit more different essentially people who have -- who are biologic incomplete responders, where the difference between 100 and 200 on efficacy is a bit more prominent, and those are patients usually are in need of new medicines. So that's a potential way forward, and it's something that will be discussed. Whether that will be a way forward or not, whether Gilead would be excited about it, all of these are part of the myriad of potential outcomes of the Type A meeting, and it would be very difficult to speculate on this.

Regarding MANTA, I think those studies have been designed with a clear collaboration with the FDA and actually to great extent dictated by them as they described those studies in a white paper. There is a similar study that was done in healthy subjects with a compound by Pfizer called Pregabalin. So those are studies are well-designed and are standards. So again, the primary end point of the study will be at week 13, although the double-blind portion of the study is 26 weeks of treatment, as we talked about.

Now as any of those studies, we do follow the patients afterwards for those who might have a reduction in sperm count. We follow them for a period of a year after we -- after the end of the 26 weeks or until they reverse, and then we do stop following them. That's how the studies are designed. And I think those are also explained on clinicaltrials.gov. And for the commercial question, I'll turn it over to Michele.

Michele Manto ***Galapagos NV - Chief Commercial Officer***

Yes. Thank you, Walid. So on the [bio IR], is that's a growing segment also and also in the U.S., causing the number of therapies, and we see also the JAK inhibitor is also taking good place there. On top of that, we've seen in Phase II, so the 200-milligram has a very strong profile for filgotinib. Then from this to the commercial scenario and opportunities, this highly depends on the actual outcome in a different combination that would come out of the label and the type of a meeting. So it's not the moment to have a straightforward answer here, and we'll need to see what the type a and the outcome of the discussion with the FDA will bring us.

Elizabeth Goodwin ***Galapagos NV - VP of IR***

Our next question comes from Matthew Harrison at Morgan Stanley.

Matthew Kelsey Harrison ***Morgan Stanley, Research Division - Executive Director***

I guess 2 things for me. One, can you just remind us of sort of the steps for commercialization in Japan and pricing there relative to some of the other geographies. And then secondly, I guess, any updates or any clear thoughts on when we could see the futility analysis for ISABELA. I remember there was a piece around further enrollment that influenced that.

Michele Manto ***Galapagos NV - Chief Commercial Officer***

Okay. I'll take the first one on the commercialization in Japan. There is this territory that Gilead owns and where they act. So pricing as well will be a decision that they take. They, in Japan, Gilead operates also in collaboration with the local companies with Eisai to maximize the operations there. And that also is an indication of the opportunity to maximize the market there with the presence that Eisai has in the hematology market. I'll pass it to...

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer***

Thanks, Michele. Essentially, for the futility for ISABELA. I think currently, we are still planning for having the futility in the first half of next year. With the big caveat of the uncertainty around corona right now, as a matter of fact, that applies for all of our pipeline, just like any other company right now. So we'll see how that's going to evolve. But so far, we are sticking with that plan, and we will be guiding in the future if we have any change in these. Thank you.

Elizabeth Goodwin ***Galapagos NV - VP of IR***

And now next up is Phil Nadeau from Cowen.

Philip M. Nadeau ***Cowen and Company, LLC, Research Division - MD & Senior Research Analyst***

My question's actually on the Toledo Phase II trials. Through reviewing the designs, the structure's a bit small. It looks like in each of the trials in RA, psoriasis and UC, only about 15 to 20 patients will actually get '3970. When we compare that to the Phase II proof-of-concept studies for filgotinib, those trials were more like somewhere between 100 and 150 participants. So what's the rationale for the smaller patient numbers in the Toledo program. And do you think those trials are each large enough to give you a clear signal for efficacy and safety in the different indications.

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer***

Piet, do you want me to take that?

Piet Wigerinck ***Galapagos NV - Chief Scientific Officer***

You can go ahead. Yes.

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer***

Okay. Thank you. So thanks for the question. Great question. Look, this is our approach. Galapagos, the way we develop our medicines in general, we try to take -- we cast a wide net. And in the case of Toledo, we really want to learn from the lead compound to inform the whole platform and bring -- build the bridge from the preclinical data to the Phase I pharmacodynamic data that we shared with you to the proof-of-concept data that we see and see whether our story as we build it based on the biology preclinically on the models are holding out when we go to the clinic. If you want to do larger studies, then it will be a significant investment and as such, you need to choose. And we think then that you lose the ability to explore the wide array of potential diseases that could benefit from it from adaptive to innate immunity as we shared with you also a week ago or so.

So as such, we do a smaller study, where you can have 1 of 3 outcomes, either you see nothing. And therefore, it's not worthwhile continuing to fish in that pond for that particular disease. Or do you see something that's, wow, very impressive that will allow you to take a very decisive next step and then go straight into larger trials or you get something that gives you a signal that is worthwhile pursuing, maybe changing of the type of the patients, maybe go in a subpopulation, maybe change the end point that you look for and learn from it. That's kind of the approach that we take there with the 5 proof-of-concepts that we see across psoriasis, you see RA, Sjögren's and

lupus. However, as we talk the other day, and I'm putting the plug for it, again, in the case of psoriatic arthritis, because of the mechanism of action because it sits to benefit from both innate and adaptive immunity model based on what we understand of the biology, we decided to take a bet there and go straight into dose-range finding study in psoriasis -- psoriatic arthritis I should say, because that is the chance that we get to bring this particular class of medicine fastest to patients by jumping straight in a dose range finding study.

Elizabeth Goodwin ***Galapagos NV - VP of IR***

So our next question comes from Dane Leone from Raymond James.

Dane Vincent Leone ***Raymond James & Associates, Inc., Research Division - Research Analyst***

I'll just keep mine, I guess, kind of brief and targeted. So before year-end, you're expecting the top line results of the PINTA '1205 study in IPF. Two just points of interest on that one. Based on clintrials.gov, that study completed in August. Just wanted some color in terms of now being November, what analysis is being done or kind of the context that you're putting in from that study to then deliver the top line results?

And then secondly, and I'm not sure how much you can get into it, but there have been questions around the PK profile of '1205 from the IBD studies or the healthy volunteer studies maybe that were dose ascending, there was accumulation of the drug given the long half-life. Could you just comment in terms of how that might be different in terms of the dosing strategy, whether you just need to use lower doses in IPF relative to IBD that had been explored.

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer***

Okay. I'll take the PINTA questions. In the PINTA, it's 26 weeks study, 30 IPF patients with the 3 different backgrounds. And we will report out on SEC and FRI. So FRI on its own, it's a massive data set. And so we are making our way through that and we will understand it fully at the moment that we present those data. So that's the analysis ongoing. But FRI is huge, I can tell you, and we want to be 100% sure that we have everything ready when we come out.

The PK profile of '1205 indeed a compound gets to a steady state level. We did PINTA, a tox study where we took a single dose. We can go lower -- based on target coverage, we can go lower if that's needed later. We did not anticipate or we do not anticipate that there's a difference between IBD patients and IPF patients. But the data will need to show that. Anything else?

Elizabeth Goodwin ***Galapagos NV - VP of IR***

Our next question comes from Jason Gerberry from Bank of America.

Jason Matthew Gerberry ***BofA Merrill Lynch, Research Division - MD in US Equity Research***

I guess first one for me. One of the hypotheticals that Gilead talked about on their call was a potential path forward or moving forward with UC but not RA. So I just want to make sure I understand that correctly because that would presume that you have an approval for 200 mg for UC, but not perhaps RA. And is there a rationale there? Is it potentially that you need to push dose with UC or maybe an inherent predisposition of RA patients to blood clots that presuppose that scenario.

And then my second question is just the European launch and realizing that there's probably a lot of nuance at the country level, but how do you guys think about order of entry effectively kind of third amongst the next-generation JAKs. Do you look at the Olumiant launch? Do you think that as later entrants come into the market, are there any price negotiation considerations that come into play? Just wanted to know if you can kind of clarify some of the order of entry considerations with the broader EU launch.

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer***

Thanks, Jason. I'll take your first question. Indeed, actually, in -- we've seen, and we know from the biology and from prior molecules that in UC, you often need a higher dose than what you have in RA. Also, I want to be very clear. The FDA never said that the 200-milligram in RA is not approvable because of the specific safety concern with that dose. What the FDA has said, and we've been very clear on this, is that they believe that the risk/benefit of the 200-milligram compared to the 100-milligram, and they have concerns about that. So in other words, the 100 milligrams is very good. So in their opinion, it's not warranted to use the 200-milligram in that indication, and they

specifically said in that indication.

So I think it's a different scenario in UC. Also the population is different. And you've seen recently when we shared the data from SELECTION at UEGW, you've seen the more color on efficacy but also on safety. And you see the profile that 200 milligram continues to look very good as well in this patient population. So I think the agency will have to make that determination on its own. Of course, they're not going to completely ignore all the data that they have from other indications. But I don't think the read-through is 100% because they need to evaluate the risk and benefit of the 200-milligram in the IBD population. And I'll pass it on to Michele.

Michele Manto ***Galapagos NV - Chief Commercial Officer***

Yes. Thank you, Walid. So on the European loans, of course, there are differences in the different countries on the health care system reimbursement and et cetera. So the first thing is that we really started after the EU approval with all the procedures to really be on speed and yet they're converted and accessible as soon as possible. In terms of pricing, well, without getting too much details, of course, we have systems in different countries which are now readily prepared for the negotiation and discussion for JAK inhibitors, and that's a good one because we can navigate those systems without adding any complexities or new things, which, again, can play on timing, on helping us accelerate the reimbursement and at the same time without really getting on price and on different levels than what we've seen before in the market.

In terms of order of entry, there is no special considerations here that we would consider and now that I think, and that's what we are aiming at.

Elizabeth Goodwin ***Galapagos NV - VP of IR***

We've got one more question from Benoit Louage at Degroof Petercam.

Benoit Louage ***Banque Degroof Petercam S.A., Research Division - Research Analyst***

I have 2 related to the IPF franchise, more specifically for '1205. I was just wondering now awaiting the PINTA trial readout, if this trial would be positive on which time frame approximately could we expect you communicating on the next steps going forward with these compounds in IPF and actually as well in systemic sclerosis. And as a follow-up on that, I was just wondering what your view and Gilead's view would be in the speed of trying to evaluate '1205 and ziritaxestat and as kind of a combination therapy setting in Phase III. Would that be something for within the very near future to look into and to initiate or would you await maybe some monotherapy evaluation in Phase III first before taking or getting into such strategies?

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer***

Thank you, Benoit, this is Walid. I'll take those questions. So I think we've talked a little bit about our plans for the OncoArendi program to evaluate this in dose range finding in a Phase II program. I think the idea would be, depending on the results of PINTA, we can -- if the results are fantastic, we can jump straight into an ISABELA program Phase III. If they are somewhere in the middle, we can propose something like the OncoArendi for the '4716 program going forward.

Regarding the question on -- and I'm sorry, regarding the time line for it, again, it's really hard to predict these ahead of time. We scenario play for all these. We prepare. But then until you see the data, it's very hard to predict. If it's straight forward, then we can -- the delay will be very short because we usually plan for these things ahead of time. If the data required us to crush our head, that might take a little bit longer for us to come up with a clear path forward as to what we want to do.

Regarding combination '1690, that's always been an option. But again, these things, as you can imagine, is -- you have 2 experimental drugs, and you don't know the dose for neither 1 of them, then doing these factorial design type of trials become prohibitive. So I think we must think cleverly about it and do some combination work that will enable us to figure out which dose we would use going forward. So there's a little bit of thinking already on that, and we're starting to do some work preclinically to allow us to do so, but we don't have any clear clinical plan that I can share with you right now. But it's definitely something that is on our radar screen and something we are certainly interested in across all of our IPF franchise and candidate compounds, as I said before. Thank you.

Elizabeth Goodwin ***Galapagos NV - VP of IR***

All right. Thank you very much for that. We're going to wrap up today. Please reach out to the IR team, Sofie Van Gijsel or myself if you have any questions. Looking ahead, we'll be webcasting executive presentations at the Jefferies Healthcare Conference later this month and at the JPMorgan Healthcare Conference in January. Our next scheduled financial results call will be for the full year 2020 results on the 19th of February 2021.

We thank all callers for participating today, and please stay safe and well. Thank you. Bye-bye.