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Galapagos NV & Gilead Sciences Inc to Announce New Commercialization and Development Agreement for Rheumatoid Arthritis Treatment Call

EVENT DATE/TIME: DECEMBER 16, 2020 / 1:00PM GMT

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PRESENTATION

Operator

Ladies and gentlemen, thank you for standing by, and welcome to the Galapagos webcast. (Operator Instructions) I'm must advise you that this conference is being recorded today, Wednesday, the 16th of December, 2020.

I would now like to hand the conference over to your speaker today, Elizabeth Goodwin. Please go ahead, madam.

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

Thank you all for joining us today to discuss the revised terms for filgotinib with Gilead. I'm Elizabeth Goodwin, Investor Relations. And this webcast is accessible via the Galapagos website homepage and will be available for replay later on today.

Sell-side analysts and professional investors will be invited to pose a question at the end of the call. And if you want to have your question included, you could dial in now on 32 for Belgium, 27933847, and the code is 7689939. You can also consult other numbers in our press release.

I'd like to remind everyone we'll be making forward-looking statements during today's webcast. These forward-looking statements include remarks concerning future developments of the pipeline, results of future or ongoing trials, future commercial and 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.

Today, we'll hear from Onno van de Stolpe, our CEO; and Michele Manto, our Chief Commercial Officer. During their presentation, you will see some slides progress on the screen, and this will be followed by a Q&A session with our management Board executives.

At this point, I'd like to hand over to Onno.

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

Thank you. Thank you all for calling in. I will give you an update on the news we received from the FDA in the consequences of that news for Gilead and for filgotinib. When we reported on the CRL earlier in the year, it became clear that there were 2 issues with regard to filgotinib getting to the market in RA. One was the MANTA study that needed to be completed which was a big surprise for us. Secondly, the fact that the FDA had an issue with the 200 milligram risk/benefit, which also was new to us. Following CRL, the normal path is to have a meeting with the FDA, the so-called Type A meeting, to discuss what needs to be done to resolve the issues of the CRL. That meeting took place last week. And based on the outcome of that meeting, the FDA -- Gilead has decided not to go forward with applying for registration of filgotinib in RA in the United States.

The reason is that the FDA has not changed its position with regard to the 200 milligram. They still believe that risk/benefit of that dose doesn't outweigh. It's not positive in view of the 100 milligram. The 100 milligram is also an active dose that's effective for treatment of the disease. And the FDA wants to stick to that dose. For Gilead, the 100 milligram is not an option because of the competitiveness in the RA market. So they decided to pass on the opportunity to launch this in the U.S.

As a consequence, the trials that were put on hold in the diseases that are associated to the RA disease segment in psoriatic arthritis, ankylosing spondylitis and uveitis, the decision has now also been made to not continue in those indications to -- in Phase III and to file for these results for approval. That doesn't mean that Galapagos has given up on these indications. We will come back to you in due time if and how we are going to continue with these trials for the European market and the Japanese market. But for the U.S., it doesn't make any sense to continue these large trials if there's no possibility to file for approval in those disease areas.

The second outcome of the Type A meeting was that with regard to the MANTA and MANTA-RAy studies, the FDA requires a follow-up of up to 52 weeks for any patient who does not recover fully by week-26, the data that become available in the first half of '21. So it could be that we have no extension of the trial review when there are no patients that have not recovered, it could also be that there is a continuation of the follow-up based on patients that have not fully recovered.

There are no new data in the MANTA and MANTA-RAy studies on which the FDA has based its decision. It's clear that they are very cautious with regard to the outcome of this trial.

Clearly, not good news for filgotinib for Gilead, Galapagos and for patients, but it's the reality we got to deal with. Clearly, the IBD opportunity in the U.S. remains. We had a positive Phase III readout in ulcerative colitis with the 200 milligram, and we are continuing the Phase III Crohn's disease trial, which data are expected in the first half of '22. So Gilead remains committed to that. We believe that even if the 200 milligram is not acceptable for RA, it could be possible -- it should be possible to apply for the 200 milligram in these indications. It's a different disease area with different medical needs. So we believe there is still a way forward for these indications. And it's a large indication as well. So we haven't given up on the U.S. for filgotinib. But for RA, the door is shut.

So the silver lining of this whole negative news is that we were able to negotiate and agree with Gilead on commercialization of filgotinib in Europe. With the new deal, Galapagos will become responsible for all commercial activities in all indications in Europe. So quite different from the current situation where Galapagos has only very limited geographical responsibility for diseases in Europe. We now will get the full European rights to Galapagos in every aspect of the commercialization.

So that will not happen from day 1 to day 2 because the commercialization is underway, the launch is underway in Germany, and we're at the brink of launching in a number of other countries. Galapagos has launched in the Netherlands. So we need to have a good transition of all these activities to Galapagos. We will get a -- welcome a lot of the Gilead's commercial team into Galapagos. And we anticipate that about 100 people will transfer from Gilead to Galapagos over the coming months. And we expect a full commercial organization to be in place and the complete handover completed by the end of '21.

So what does this mean for the economics? Well, the 50-50 P&L share that's currently in place for the European commercialization will remain in place until the end of '21. After that, Galapagos is responsible for the P&L.

All commercial economics will go to Galapagos as of January '22. And we have agreed on a royalty for Gilead between 8% and 15% starting in 2024. By that time, the commercial organize -- the commercial activities in Europe should be profitable. And therefore, we are willing to give Gilead the royalty at that point in time.

There will be no more EU milestones to Galapagos for filgotinib. So no approval milestone for Crohn's or UC. And as a balancing point, we will get the payments from Gilead of EUR 160 million. Gilead will retain commercial rights outside Europe. So nothing changes there. And all milestones and royalties outside Europe will remain intact.

So what is important to mention here is that the broader R&D collaboration that we signed with Gilead last year is not at all impacted by

this decision by Gilead not to launch RA filgotinib. They have confirmed their commitment to the inflammatory market and to Galapagos with its collaboration that they signed and for which they paid a lot of money to get an option right to all the programs that we're going to develop over the next 9 years. So we still see Gilead as a very important and strong partner. And it's unfortunate what has happened with filgotinib in the U.S. but we are ready to continue our collaboration and deliver new mode of actions to the patients.

So let's focus on Europe and our commercial vision there. We believe that having the European rights on filgotinib is value creative for us. Of course, the first years are money-losing as every launch of pharmaceutical product in Europe is, we have to build up commercial organization. We have to start the sales, which we're currently doing. Within a couple of years, the breakeven point will come and after that, we see a nice profitable market for filgotinib in Europe and that economic value, except for the royalty is payable to Gilead is done fully for Galapagos.

What this deal does? It accelerates our commercial presence across Europe, something we have told investors that was our plan in view of the launch, the future launch of ziritaxestat, our second drug in Phase III that is developed for IPF, idiopathic pulmonary fibrosis. And with this deal with Gilead, we can now build a commercial organization, as we speak, throughout Europe to be ready for our second product as well.

What also is important to note is that now with the deal with Gilead, we are completely aligned with the overall R&D collaboration that we have with Gilead. Filgotinib was an exception to the rule. All other molecules that we have in the pipeline and if Gilead takes an option, they will obtain the non-European rights, Galapagos will keep the European rights. And therefore, filgotinib is now aligned with that collaboration, which makes perfect sense from an operating model, which makes it all simpler and more effective and more agile.

So although the U.S. market of filgotinib being out is a big setback, this is clearly a very nice silver lining that we can now commercialize Jyseleca on the European market. So we're very excited about it. And I hope we can show the investors that is a great opportunity for Galapagos and to explain that in more detail, I'm happy to hand it over to Michele Manto, our Chief Commercial Officer. Michele?

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

Yes. Thank you, Onno, and good morning, good afternoon, everybody. So yes, there is a clear market opportunity for Jyseleca in Europe. The market size, as you see, is about 5 -- between EUR 5.5 billion and EUR 6 billion. This price is the big size of that, the big chunk of it comes from RA, of course, the largest indication with the IBD indication you see in Crohn's with a high dynamic there and growth in the market due to the higher unmet need and also the launch of new mode of actions. And the fact also that the JAK inhibitors are not established there yet, so we'll have also bigger role to play.

In this market, we have an ambition to reach EUR 0.5 billion peak sales in the second half of this decade. Reached through achieving a market share range of 8% to 12% across geographies and across indications, of course, reflecting the different potential and different market development in each of the European countries and also timing of reimbursement.

For Jyseleca itself, we see continuously a big opportunity to succeed in Europe. We are confident with the European label and also extended to Japan. That reflects the strength of our data. The data that differentiates -- helps differentiating towards the established biologic therapies with a fast onset of efficacy, the lasting activity, the monotherapy, also big demand from -- for RA patients. And of course, the convenience of being oral.

Also, there are elements that differentiate further in terms of safety profile, on the associated adverse events that are typically connected to JAK inhibitors, and also with 2 doses that we have approved in Europe and Japan. And last but not least, the rapid reduced responses that we have seen across the FINCH program.

So looking at how we can deploy this in Europe, Onno already alluded to that, that it is a transition path. It's not an overnight change. We'll start, of course, with a focus on the key markets. So the Benelux and the EU5, the core of Europe, where we already have our presence established and started with the deal we signed with Gilead last year. So we have legal entities in these countries. We have already launching in the Netherlands. We are preparing the reimbursement in other countries. And actually, we are now preparing for the intended transfer of the Gilead launching organization in Germany and U.K. for rheumatoid arthritis.

For the other countries, we intend to have a transfer later by year-end of '21 in the Alpine. So Switzerland and Austria, the Nordic country -- the Nordic countries and Ireland, there we will establish our legal entities and presence and then gradually transfer the organization in an efficient way reflecting also our lean approach to commercialization.

For the rest of Europe, highlighted here in green, we have a very pragmatic approach. We know direct presence. But really evaluating how we then make Jyseleca available as appropriate, but also considering third parties or other efficient opportunities. In that sense, we'll come to a full transition by the year-end of 2021.

So with that sense, looking at next year, for filgotinib, we have different highlights, of course, both commercially and with development, regulatory starting in the first half with the availability of the 26-week results for MANTA and MANTA-RAy. And then the U.S. -- UC submission in Japan, also expecting the CHMP opinion in Europe for UC paving the road then for the launch of UC in Europe, and then having activated the commercial transition. In the second half of the year, we'll then move to have, indeed, the approval and the launch of UC in Europe and then the conclusion of the commercial transition as I had lighted before.

Moving then towards 2022, we'll have the Crohn's topline from diversity. Also they're opening the next stage in the IBD commercialization. And then expecting the approval for UC in Japan, which then will move into 2022 second half with the potential submission for Crohn's disease in Europe and also in Japan.

And with that, I would pass back to Elizabeth.

QUESTIONS AND ANSWERS

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

Thank you very much. And that does conclude the presentation portion of the webcast today. We invite sell-side analysts and professional investors to pose their questions. (Operator Instructions)

The first caller will be Dane Leone from Raymond James.

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

Can you hear me?

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

Yes, I can hear you now. Go ahead.

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

Okay. Yes, sorry the operator is telling something there as well. Yes. So thanks for the update and giving the great detail on the go-to-market in the EU. The questions have been coming back to us last night and this morning are pretty directly related from investors around the verbiage within the press release and update for what the FDA is looking for, for the MANTA studies? So as your teams walked us through over the years around a potential T tox signal, everyone's been curious to understand when that will be resolved. I guess there's some concern that there might be a signal based on how the press release was written. So I just want to give your team an opportunity to clear that up and what you've seen with MANTA and what the real discussion is with the U.S. FDA?

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

Walid, can you answer the question please? Thank you.

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

Yes. Thanks Dane. This is Walid. Good afternoon, good morning, everybody. The MANTA and MANTA-RAy studies are both ongoing studies. Both of them are blinded. There's been no signal, as I mentioned before, those trials are monitored by data monitoring committee and that every chance that they reviewed the data, they told us to continue with no changes. So I have no reason to believe

that there's any signal and the FDA did not see any data that's different than what we have seen.

The -- it's very difficult for me to explain the position of the FDA and why it moved from June 2019 where we were told that we could submit without -- they could evaluate the risk/benefit of filgotinib 100 and 200 milligram without seeing the actual data from the MANTA program to requiring to see the data which would be normally the end of the 26-week double-blind, placebo-controlled portion of the study, which is designed in conjunction with the FDA and with every step of the way there, to now saying that they would want to see the full 1-year -- up to 1-year recovery period after the 26-week data. No reason has been given to us. No rationale has been given to us. It's very difficult for me to explain it. I'll be very honest with you. But I can tell you categorically, there's been no signal that we've seen, that they've seen that changed this. And the most informed people are the people on the Data Monitoring Committee whose job is to make sure that we monitor the safety of the trial, and these professionals have told us to continue the studies as designed.

So with that, as you know, we will have the topline data from the 26-week at the first half of the year. Maybe also I'll share this information with you. The FDA is keen that the team remains blinded. So there's going to be a very small unblinded team that will be working towards sharing the information with the regulatory authorities, particularly the EU and Japan, where we are actually selling our medicine, and we need to adequately inform on the risk/benefit to our patients who are actually prescribed this medicine. But also we will be sharing this with the FDA, and we'll talk with Gilead about the way to do that.

So that's the best information that I can give you, and I hope I addressed your question, Dane.

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

Great. Thank you. Our next question comes from Phil Nadeau from Cowen and Company.

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

My question is on the commercial ramp as you assume the responsibilities for filgotinib. Could you give us a little bit more detail about where Gilead was in building out its infrastructure in the EU5? And you mentioned that you'd take on maybe 100 or so people from Gilead. Do you think that's all you'll need to promote in Europe? And what other infrastructure will you need to build as you assume the responsibilities of filgotinib?

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

Michele?

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

Sure. Thank you for the question. So to recap with the previous agreement, Gilead was responsible for rheumatology in Germany and the U.K., and we would be -- we are responsible for rheumatology in France, Italy and Spain. So at the current moment, the Gilead team performed and is performing the launch in Germany with the actual promotion and for sales coming in and preparing the launch pending the nice reimbursement in the U.K. And so this is the bulk of the people that Onno alluded too, when mentioned the 100. And these are organizations that were effectively staffed and prepared to have a strong launch and impact in these 2 markets.

In the meantime, we have been preparing for the -- our launch in rheumatology in France, Italy and Spain. There, of course, the time line is slightly different because of the different reimbursement time lines with the 3 countries and expecting reimbursement in the first half of next year. And they're also ramping up in their activities. So that's how then we will integrate our forces. And yes, we see that the sizing and the quality of the people we got onboard are really strong, sizing adequate to the competition in the countries, and also the quality of the people coming with strong experience from biologics, rheumatology coming from the market leaders, companies then to either Gilead or Galapagos to make a strong launch with Jyseleca.

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

Just one clarification follow-up. Do you feel like you're in a position to launch in France, Italy and Spain in the first half of '21 as soon as reimbursement is secured?

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

Yes, this has been all the preparation we started a year ago with the 2019 deal with Gilead. So we established our entities there. We've been recruiting. We have been acting on reimbursement path. We have our organization there ready to go.

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

Okay. Our next question comes from Brian Abrahams at RBC.

Unidentified Analyst

This is Steve on for Brian. Could you remind us what the circumstances surrounding MANTA data would be to a patient review? And what could potentially lead to a delay in filing? And is it possible to run a post approval study? Or would the filing be delayed under that review?

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

So I think that's a question for me. I'm not sure I caught exactly your question. Which indication were you talking about? Is it an RA or...

Unidentified Analyst

Following the MANTA data for UC potentially?

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

For UC, right. So the FDA now is asking to look at the 52-week data. However, once we have the topline results from the 26-week, we will be discussing this with Gilead to see what is the best way to engage with the FDA. It's going to be a discussion that will be driven by data. And hopefully, we will be in a position to actually make a case to be able to move faster than the 52 weeks after the 26 weeks, I think. So...

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

Our next question comes from the line of Matthew Harrison from Morgan Stanley.

Okay. We'll move on. Next will be Jason Gerberry from Bank of America.

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

Just on the language in the press release about the different measures of -- sperm count measures for greater than 50% reduction. Is that just an endpoint measure? Or is there a specific reason why that threshold was mentioned in the PR? I just wanted to clarify on that.

And then just one quick question. Just on your market sizing for inflammation, roughly EUR 6 billion. It looks like that's on a list price basis. And I wonder with the impact of recent biosimilars, I think, with TNF, Humira having come down about 50% on price, what do you think that market may be on a net sales basis inclusive of the biosimilar impact of recent?

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

Jason, this is Walid. I'll take the first question before I pass it on to Michele. Yes, the 50% reduction in sperm count, that's the primary endpoint of the trial. This trial or both trials actually, have been designed based on the FDA White Paper where they essentially detail the design, the endpoint, the duration and the analysis. So this is a very well choreograph designed study based fully on a White Paper by the FDA. And actually, there are other studies that have been conducted that are similar to this. And that's the standard end point that should be used in that chunk.

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

Yes. So here's Michele. I'll take the second one on the market sizing. Of course, in Europe, we have different systems, different countries that apply prices also in a different way. So what you alluded to the biosimilar will not impact all the countries in same way. And also then JAK inhibitors as a class, are not necessarily linked to that -- to the pricing. So that's a more elaborate answer. But you could consider a range between 15% and 20% of differences between the list price and the net prices, but this really depends on the geographies.

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

Okay. Our next question comes from Peter Welford at Jefferies.

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

Yes. Can you hear me? Just one question actually, and a follow-up. The question actually is just with regards to the R&D. I wonder if you could give us any sort of idea as to the rough level of R&D spend we should be thinking about for filgotinib in 2021, given obviously -- you obviously have to take on some extra responsibilities? And if there are any sort of niche indications you could potentially consider? I know you mentioned that you disclosed future plans for these in current sort of rheumatoid arthritis type indications. But I guess is there anything else you potentially consider now that perhaps Gilead didn't before, given you're obviously in a slightly different situation now? And do you have the flexibility to do that? And then if I could just ask actually walid -- sorry, just going back to the point about MANTA, I know we're dwelling on this, but your point about the fact that the team remains blinded. Does that mean that from our perspective, we shouldn't expect potentially any visibility on MANTA until, I guess, we get a response from FDA, yes, no, if you like? Because it sounds as though potentially even management won't necessarily get any visibility on what's going on with MANTA.

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

Okay. Peter, let me take the first one. This is Bart speaking. Good morning, good afternoon everyone. R&D spend for 2021 for filgo, I'm going to give you an answer on the, let's say, spends before implementing all the effects of this transaction, and I'll explain that in a second in a bit more detail. But we anticipate under the existing construct where we pay 50% of the development cost that we would spend somewhere between EUR 80 million and EUR 100 million in the course of 2021 on filgotinib development. And most notably, that is going to the Crohn's study, which is the biggest study that is still alive. And the other studies, FINCH 4 long-term extension, DARWIN 3 long-term extension are also included in that package.

Now so that gives you that 50% cut on what the actual total expense of the program would be during that year. What you're going to see in our P&L is going to be a bit different at the end of the day because Gilead has under this arrangement agreed to pay us an upfront of in total EUR 160 million, which covers their 50% share of development costs for a couple of years on a selection of trials. And we will be recognizing that revenue also progressing the years and progressing the travel execution. So that's again, a bit of a complicated accounting method, but it gives you a bit of perspective on those expenses.

And with regard to the niche indications in MANTA, Walid, can I give that to you as a question?

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

Sure. Thanks, Bart. Yes. So the FDA would like to see the data of the 52 weeks monitoring phase or up to 52 weeks that Onno has described before, depends on whether there will be people who will be meeting the criteria that we talked about at the end of 26 weeks and how long they will last, but the maximum will be 52 weeks before they reverse.

They wanted the study to remain blinded so that they don't introduce any buyers. And as such, Gilead put together what we call a data integrity plan that's been reviewed and approved by the FDA, which posits that the team that's actually working on the study will remain blinded. And there's going to be a small team that will be unblinded, such that they will be able to communicate with the regulatory authorities on the group level results.

So indeed, I think in terms of the information that will be shared externally, this is something that we need to discuss with Gilead and align on. But to respect the data integrity plan, we cannot be sharing information about any details of this because otherwise, again, the team will become unblinded and biased. So we'll provide more clarity on this as we move forward. But the assumptions at this point is that we will not be sharing information detailing the results of MANTA. We'll be communicating directly with the regulatory authorities.

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

And on the niche indications -- and if I -- sorry, if I could just go back to Bart, just with regards to the cost then. Do we understand that in 2021, now you'll be booking the full cost, if you like, of the study, not your 50%, but that will be offset by the Gilead money in the revenue line, if you like. Is that the way we should think of it? You're paying for the studies now, but the 50% is offset by revenue rather than you booking half as you currently do?

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

Yes. It's -- that's almost correct, Peter. So there are 2 categories. Let me be -- and it's also drafted in the press release, but there's 2 categories of trials. One category where we continue to book 50% of the costs and Gilead will pay the other 50%. And then there's another category where we will book 100% of the cost and the 50% share of Gilead is actually affected through this prepayment. And indeed, that will be recognized then as those costs will be progressing through 2021 and 2022.

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

And Peter, what was the question regarding the niche indication? I missed it.

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

Yes, I guess I'm just thinking with regards to some other indications. I think it was mentioned at the start by Onno that there may be some -- you may consider future plans of things like -- so I said like -- so I guess I'm thinking what about other indications that were not previously part of the agreement? Do you have the flexibility to do that? And are there any other potential niche indications that may be Galapagos considered interesting, whereas obviously weren't perhaps under the broad collaboration that previously existed?

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

Yes. No, that's a fair question. So I think the easiest one are the indications that were being considered previously, I think the team is actively looking to see whether we can think of a development plan that would be appropriate for Europe and tailor-made for Europe. And of course, that requires discussion with the CHMP on that. But other niche indications as well are on the table. And again, we have the flexibility to do that. But it's premature right now because the team hasn't really had the chance to dig into this and figure out a path forward that would be viable, both scientifically and commercially for filgotinib for Europe on these. But we will communicate on those once we have clarity.

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

The next question will be from Lenny Van Steenhuyse from KBC Securities.

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

Two questions from my side, if I may, quickly. Do you anticipate any additional sales and marketing costs for 2021, considering the additional markets that you will be tackling with the revised agreement? And could you give us a sense of what those additional costs could be for that first year? And then secondly, could you please remind us of the time lines on the fistulizing and small bowel Crohn's disease trials that are ongoing? Gilead is, of course, in the lead in these trials. And in that sense, are these new elements that will be explicitly communicated when they arrive?

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

Yes, Lenny. Let me take the first one and then Walid, you can maybe take the questions on the other indications in Crohn's. So the ramp-up on the investment in sales and marketing in 2021 will indeed continue. Let me remind everyone that the costs, so the P&L results of filgotinib in 2021, will remain 50-50 shared between Galapagos and Gilead. But obviously, we were already under the old arrangements planning to ramp up the investments on both sides in both Gilead and Galapagos as we are launching in the various countries that Michele was describing. So yes, we will be seeing additional costs in the course of 2021, my current estimate -- but we will give more detailed guidance in February. But my current estimate is that this will be an additional roughly EUR 50 million for the year 2021 compared to 2020.

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

So regarding the study divergence. And I think 1 and 2, one is in the small intestine, Crohn's and the other one was in fistulizing Crohn's. Those were, as you know, small proof-of-concept study, exploratory study to some degree in that space to better understand the efficacy of filgotinib in these indications. Those studies are -- I believe we stopped them a bit earlier because, again, they were small, and it was very difficult to recruit and wanted to focus mostly on Crohn's disease considering also the corona situation. So we should be communicating on those. I think, sometime in the first half of next year, we should be in a position to share more information about that.

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

And our next question comes from Graig Suvannavejh from Goldman Sachs.

Graig Suvannavejh ***Goldman Sachs Group, Inc., Research Division - Executive Director & Senior Equity Research Analyst***

I've got 3 if I could. My first just has to do with, in terms of comments, maybe Onno told me earlier that you do expect I guess, breakeven for filgo from a P&L perspective. Is there a year or a time line that you're envisioning where filgotinib in Europe will become breakeven? And what might that be?

My second question just has to do with the launch that is underway in Germany and the Netherlands, and I'm wondering if you can provide any color or quantifiable metrics on how that launch is going? And if you do intend to provide some of that on a go-forward basis?

And then my last question just has to do with -- in Europe, how do you intend to message differentiation and/or the value proposition of Jyseleca in Europe to patients, physicians and payers, especially vis-à-vis the AbbVie JAK inhibitor that's already out there?

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

Okay. The second and third question for Michele. The first question, yes, we -- you can kind of read it in the press release where we agree with Gilead on a royalty starting from 2024. And we believe that, that is the year that filgotinib will be profitable in Europe. Michele?

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

Yes. So on the launches underway, yes, the first country is Germany in hands of the Gilead team in the Netherlands now. So it's early -- still early weeks to provide a full, say, volume or sales update there. What I can say is that we are tracking on a weekly base, very intensively, all the launch metrics that you will normally consider, right? The access, reimbursement, contracting is all going very intensively and very well. The other part is about the uptake and the adoption ladder, the input and the feedback is very strong as well in terms of appreciation of the differentiation features in efficacy and in safety and also confirming that the launch strategy is going in the right direction.

In terms of updates, we'll see next year to give regular updates on how the launch is going in different countries and then provide with some more clarity on these steps.

As of the messaging, well, we have -- as anticipated earlier in the presentation, we are very confident about the profile and the label. So we have 2 doses approved, which give the right flexibility for physicians to prescribe with the 200 milligram recommended dose for most of the patients, but also for the patients who might need a lower dose, we have that too. And yes, the part -- the key part will be the safety profile that we've been discussing for -- all along, the readout of the FINCH trials that really make us different and the typically JAK-associated adverse event. And that, again, on early feedback we get from advisory boards, the individual rheumatologist, et cetera, resonates very well.

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

All right. Our next question will be from Benoit Louage from Degroof Petercam.

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

I have 3 from my side, again, also a bit on the cost perspective for the upcoming years. I was just wondering whether you can give us certain level of guidance on -- could we -- should we expect a dramatic increase now in the cash burn versus the full year 2020 guidance? Or would this be more EUR 50 million increase, as was referred to in the expected increase in sales and marketing versus this year?

And then on the peak sales, an ambition of EUR 500 million, could you just confirm that this would imply for -- across all the indications of both RA and IBD? Or was this -- is this solely for RA that you mentioned this? And to finalize, I was just wondering whether you could give us your perspective on the recent Phase III results of AbbVie's RINVOQ on their induction data, which was, I think, a couple of weeks ago?

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

Yes, Benoit, let me take the first 2 questions, and then I'll give the floor to Walid for that perspective on the Phase III data. So in terms of guidance for 2021, again, this will come in all details in the beginning of next year. But as a reminder, as a company, this year, we've guided for a spend between EUR 490 million and EUR 520 million. That was a net spend, including the receipt of about EUR 100 million in approval milestones for filgotinib in Japan and Europe. So our actual underlying spend in 2020 is, let's say, roughly a bit north of EUR 600 million -- between 600 million and EUR 620 million. So that's the starting point. Indeed, we'll have an increase in sales and marketing costs as I was just describing. Otherwise, we try to keep our budget under control as much as we can. We want to obviously balance properly the R&D investments that we can make and that we need to make in our pipeline with the cash burn objectives that we have as a company. So we'll try to stabilize our expenses on R&D as much as possible but -- on sales and marketing indeed, and to a little extent also on G&A, you will find some increases, as I was describing earlier on in the call, of that base of a little north of EUR 600 million.

Then just to clarify the point, indeed, the peak sales ambition is across RA and IBD. Walid, on the Phase III program?

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

I'm sorry, I missed the question. Can you please repeat that? Benoit, what was your question on Phase III, please?

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

So maybe we've lost Benoit. He did not say which indication. So we don't have him on the line. Okay. I think we'll have -- yes.

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

Yes. Yes. Okay. Sorry.

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

Yes, I think we'll ask him to get back in the queue. No. Me neither. Okay. So our next question is going to come from Jason McCarthy at Maxim Group.

Michael Okunewitch ***Maxim Group LLC, Research Division - Equity Research Associate***

This is Michael Okunewitch on the line for Jason. Unless the -- I ask about the MANTA trial real quick and one follow-up after that. So I'd like to say just across your existing clinical data, have you observed any significant incidence of impact with same parameters that would indicate that whether or not you would have to continue for the 52 weeks?

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

So the only thing that we measured in any of our trials were looking at hormones, reproductive hormones, and we see no changes in those in our trials. We do not measure any semen parameters in our trials. These are notoriously highly variable, and that's why actually the agency is very prescriptive in the way a study to evaluate these parameters has to be designed. And actually, it's very technical. It has to be analyzed in a certain way in a very sort of sophisticated type of laboratory settings that's specializing in that. So no, we have not been measuring this.

And I think this links to a question that Dane asked earlier, there's no indication from any of our clinical trials, any new indication that would suggest that we need to be looking beyond this. That is not the rationale why the FDA is looking for the 52 data. So just to be clear on that point.

Michael Okunewitch ***Maxim Group LLC, Research Division - Equity Research Associate***

All right. And then the follow-up is, would an extension of the MANTA trial necessarily delay the filing for ulcerative colitis in the U.S.? Or is there a possibility that the Division of Gastroenterology and Inborn Errors accepts the 22-week data for filing?

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

No, the position of the FDA is similar. As a matter of fact, discussions on MANTA involve virtually all the divisions RA, GI and actually GU. The Urology division whose responsibility is specifically this organ system, so to speak. And so the default position is that the 52 weeks

will be needed before UC can be filed. Now as I mentioned before, once we see the 26-week data, we will have discussions with our partners to see whether there's an opportunity for us to reopen the discussion with the FDA based on those data to see if there's a path forward that will be -- allow us to file before the maximum of 52-week observation after the 26-week data.

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

Okay. Thanks Michael. Okay. We're going to go back to Matthew Harrison and open up the line for him.

Connor McGuinness Meehan ***Morgan Stanley, Research Division - Research Associate***

This is Connor on for Matthew. So we just had a question basically on what your expectations are for your base case in terms of IBD in the U.S.? And you mentioned that it sounds like you'll need the 52-week MANTA data. And then I guess, how comfortable are you with that being a possibility that you've moved forward? And I guess, what is your base case in the context of IBD in U.S.?

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

I'm assuming this is a question from a regulatory perspective, not a commercial perspective, right?

Connor McGuinness Meehan ***Morgan Stanley, Research Division - Research Associate***

Correct. And then I guess, how confident are you that it will be possible to move forward eventually with the commercial launch in IBD?

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

All right. So I'll take the first part, and then I'll let Michele tackle the commercial element. So we believe that we have a package that is very comprehensive, evaluating actually both doses in induction and maintenance. We've demonstrated that with the 200-milligram, we hit our primary endpoint and a number of secondary endpoints and the biologic naive, but also in the biologic IR, we hit the primary endpoint and nominally, a number of the secondary endpoint. And most importantly, in the maintenance trial, we saw very clinically meaningful effect in terms of maintenance of efficacy as well as steroids free remission in addition to the primary endpoint that we -- which is the EBS remission.

So we're quite confident in the efficacy profile of the 200 milligram. Now the safety as well, we've probably shown these data as UEGW, the safety and tolerability profile of filgotinib remained very good, and we believe the risk/benefit for that dose is positive, in our opinion.

Now the FDA is -- it's going to be difficult for the FDA to engage in earnest -- evaluating this before we resolve the MANTA situation, which remains open, as we talked about. So I think once we resolve that point, we will see what are the opportunities that would be possible in the U.S. But the default position today is that the 52-week data from MANTA will be needed. And it's not very clear to us to what degree we'll be able to convince the FDA otherwise once we see the 26-week data and we share with them. So that's my best guess at this point. Anything beyond that, I think I'm taking too much liberty at trying to interpret, and it might not be very valuable, to be honest with you. Michele?

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

Yes. Then to build on this, the key question indeed is about the regulatory situation there. So once this is clarified, the opportunity for -- in UC and IBD is big. It's big in Europe and by definition, even bigger in the U.S. So the unmet need there is clear -- is bigger than it is in rheumatoid arthritis. And we've seen that with a faster uptake that the new mode of action had in the UC indications -- in the IBD indications or with the (inaudible[AVN4]) for example, that is much stronger, much faster than you would see in RA. So also the question about access, et cetera, that are in RA are to be taken in a much lighter way, I would say, in IBD. They, of course, would depend on our label, on our situation, but the point that Walid highlighted with the search[AVN5] , the fast onset of action, the durability in a very -- tested in a very difficult-to-treat population as we had a selection, all point to a big opportunity, again, provided that the regulatory situation then supports that.

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

All right. And then I think probably our last question will come from the team at Kepler Cheuvreux.

Unidentified Analyst

I would like to know, could you give us more color about Jyseleca opportunity in RA outside Europe and mainly in Japan? What is Gilead position regarding this market? And maybe another very quick one about the opportunity in PsA on AS. Would you try to launch in Europe? Or does -- the market is too small to launch by your own?

Michele Manto *Galapagos NV - Chief Commercial Officer*

I'll take the first step on, give a first step up on the PsA, AS and then bring that back to Walid for the regulatory and studies there. So for Japan, Gilead, as announced, is cooperating with EISAI, it's a Japanese company that has a big presence in rheumatology. So that is indeed supporting the launch there and has all the elements connections and understanding of the rheumatology market to do that. So in Japan, rheumatology is a very diffused specialty. So we thought like we should meet with the physicians. And again, EISAI has all the connections and presence, and relationships to make that successful. And also, the label in Japan is, as it is in Europe, favorable with the 2 doses and reflecting the strength of the data from the FINCH program.

For PsA and AS, well, they are 2 very important indications. And then, of course, we would be glad to capture those opportunities, provided that the studies and the development, the regulatory environment supports that, given that, of course, we have to change the direction after the situation in the U.S. And Walid, if you can comment again on the point of how we could progress there?

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

Yes. No, I mean, I think we are in the midst of evaluating what type of studies we would need that would allow us to get an indication for ankylosing spondylitis and psoriatic arthritis in Europe. Once we put together a plan that would be doable, viable and sort of in line with the commercial opportunity, then we will go talk to the health authorities in Europe and see if that would be acceptable to them. And if that's the case, then we will embark on this. But we're not -- we haven't yet -- we're not there yet. So we're still looking at this and evaluating our options. I will communicate once we have a clearer idea about the next steps in those indications.

Elizabeth Goodwin *Galapagos NV - VP of IR*

All right. Thank you, everyone. That does conclude our Q&A session today. Please reach out to the IR team if you still have questions. We're also taking meetings at the January conference, where Onno will also be presenting via webcast.

Our next scheduled financial results call will be the full year 2020 results on the 19th of February, and we thank all callers for your participation today and wish you safe and healthy holidays. Thank you, and goodbye.

Operator

That does conclude our conference for today. Thank you for participating. You may all disconnect.

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[AVN2]19:01

[AVN3]30:13

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