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GLPG.AS - Galapagos NV & Gilead Sciences Inc Announce Global Partnership to Develop Filgotinib for the Treatment of Rheumatoid Arthritis and Other Inflammatory Diseases Call

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PRESENTATION

Operator

Good day, and welcome to the Galapagos webcast conference call. Today's conference is being recorded. At this time, I would like to turn the conference over to Elizabeth Goodwin. Please go ahead.

Elizabeth Goodwin - *Galapagos NV - VP IR & Corporate Communications*

Thank you very much, and welcome, all, to the audio webcast on the global partnership with Gilead, announced earlier today. I'm Elizabeth Goodwin, investor relations at Galapagos. This webcast is accessible via the Galapagos website homepage and will be archived for one year starting later today.

So that your questions can be included, we request that you call in to one of the telephone numbers given in today's press release. I'll give you the US number. That's 646-254-3361, and the code is 5852445.

I'd like to go on now to the disclaimer. We'd like to remind everyone that we'll be making forward-looking statements during today's audio conference. These forward-looking statements include remarks concerning future developments of the 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.

So, today's speakers will be Onno van de Stolpe, CEO, and Bart Filius, CFO of Galapagos. They'll go over the highlights of the deal with Gilead. You will see a PowerPoint presentation on screen, and we estimate this will take about 10 minutes. And this will be followed by a Q&A session with our executives. So, having said that, I'd like now to hand over to Onno to start off the presentation.

Onno van de Stolpe - *Galapagos NV - CEO*

Thank you, Elizabeth. It's a pleasure to present today the partnership with Gilead. We're clearly very excited that we have partnered filgotinib with such an esteemed pharma partner as Gilead. It's a deal that meets all the criteria that we said beforehand that we wanted to see in a partnership, and I would like to take you through that.

We're co-developing filgotinib in inflammatory diseases together with Gilead. We're contributing 20% of the R&D cost. But we also will be closely involved in -- we are closely involved in the development activities. So, we will continue in the development of filgotinib in other indications -- Phase Is, Phase IIs, outside RA and Crohn's. And that means that our involvement is much more than we would have in the situation that we had with our previous partner, AbbVie.

Clearly, Gilead is in the driver's seat. They are responsible the clinical, regulatory, manufacturing, and the marketing of the molecule and the product. But we have been able to secure substantial rights for Galapagos in the co-marketing of this molecule in the main markets in Europe as well as in the Benelux. This means that Galapagos is able to use filgotinib to build up a sales force, to build up an infrastructure, actually book the sales in the Benelux, and actually become a fully integrated Company.

When Galapagos started 17 years ago, we set up a platform -- a technology platform -- to identify multiple targets. From there, we went on to add the chemistry to make molecules against those targets; added development capabilities to bring these molecules into the clinic; and with filgotinib, we hope to learn from our partner, Gilead, to actually bring these products to patients and become a fully-integrated biotech outfit.

In the co-promotion territories, we will share all the profits 50/50. Outside those, we'll have a royalty arrangement where the royalties start at 20% and increase based on sales levels worldwide. We receive an upfront payment when the deal is closed, which we expect somewhere in January, of $725 million, that consists of an equity stake of $425 million and a license fee of $300 million.

On top of that, we'll get success-based milestones. Those milestones are a whole range of different milestones that range from starting of trials to filing, to registration, as well as to commercial milestones, totaling $1.35 billion.

So, a very valuable deal with a lot of financial numbers involved. What this really, though, boils down to, is that we've found a very strong partner that wants to develop this molecule towards patients together with Galapagos, and we believe that this is really the preferred partner to bring this product forward.

So, if we can go to the next slide, if we look at the clinical pipeline, just for those of you that are not as familiar with the Company, we now have partnered filgotinib, our JAK1 inhibitor, with Gilead.

The next steps there in the development are the start of the Phase III that is planned for the first half next year; and in Crohn's we have just released the 10 weeks data there, and we are expecting the 20 weeks in the first quarter of next year.

If we look at the rest of the pipeline, we have a new mode of action, GLPG1205, which is an inhibitor of target GPR84, that we're developing for ulcerative colitis, where we're expecting the Phase IIa results in the first quarter next year. We have an autotaxin inhibitor, GLPG1690, that we're developing for IPF -- idiopathic pulmonary fibrosis -- where the Phase IIa starts in the first half next year. We're very excited about that program as well.

And then a very large franchise around cystic fibrosis, where we're developing a triple combination therapy in collaboration with AbbVie. Triple combination -- you need three molecules to effectively address this disease -- a potentiator, corrector 1 and a corrector 2, and we're making a very nice progress in all three of those, with a lot of clinical data expected in 2016.

Recently we also brought a new partner molecule into the clinic together with our partner, Servier, where we're developing a new mode of action for osteoarthritis. That's currently in a Phase I study, and the results will be in the second quarter of next year.

So, if we go back to the subject of today's call, filgotinib -- just a brief overview of where we stand with this molecule before handing it over to Bart, our CFO, to talk about the deal specifics. Filgotinib has proven to be a very selective JAK1 inhibitor, JAK1 inhibitor being part of the family of JAKs, with the advantage of filgotinib that it really only works on JAK1.

We now have over 900 patient years of clinical experience, through the trials we have run in RA -- the DARWIN 1, the DARWIN 2, the DARWIN 3 trial, as well as the earlier trials, we have over 900 years of patients treated with the drug, which is a tremendous database with regard to efficacy and safety. It's an oral treatment where we can go with a once-a-day tablet. And we have shown efficacy in both RA as well as Crohn's disease in our DARWIN and FITZROY trials in 2015.

Not only is this molecule very efficacious in these diseases; it has shown, also, a very good safety profile, where it was very well tolerated. We had a very low dropout of patients. We saw an improvement in hemoglobin levels, which is important because many of these patients are anemic.

We also saw an improvement, both in the RA study as well as the Crohn's study, of the lipid profile, which was also very encouraging. No negative impact on any of the other lab parameters. So, that was also very encouraging.

And the studies have shown that there's a very low risk for interaction with other medication taken by these patients, which is important because medications might influence each other and have an impact on the efficacy.

So, all in all, the profile looks very attractive, both efficacy and safety, and that's clearly been recognized by Gilead, who decided to partner with us on this project.

So, with that, I would like to hand it over to Bart to give you an overview of the deal specifics.

Bart Filius - *Galapagos NV - CFO*

Thank you, Onno, and thanks, everyone, for listening in to this webcast this afternoon in Europe, and this morning in US. I'm going to say a few words about the split of roles between the two Companies, as well as some [technics] around the deal.

So, truly exciting. What is on this slide is that this is a partnership where Galapagos has the opportunity to really co-develop and co-commercialize filgotinib, which is really, as Onno was pointing out before, our opportunity to make a step into creating a commercially-based biotech company in Europe.

On the development side, Gilead has primary responsibility for development in inflammatory diseases, and Galapagos will be supporting by running further Phase I and Phase II trials that are necessary in the development program. Gilead will take on responsibility for regulatory, for manufacturing, and ultimate responsibility for global commercialization.

The exciting part on the commercial front is that we have the option to co-promote in the big five European countries -- Germany, UK, France, Italy, Spain -- and in the Benelux, our home territory. And in that same home territory, we will also be booking the sales if we exercise this co-promote option.

Then a couple of points on financial aspects around the transaction. So, first of all, the deal has been approved by the boards of both companies, but is subject to a closing condition, which is a review by the US antitrust authorities. We expect this not to take a very long period. It's an obligation under US law to do a filing for a transaction of this size. But under all normal circumstances, this should go rather quickly, and could potentially lead to a closing in January of 2016.

Upon clearance of the antitrust, we actually will start the closing process, which will be a subscription of shares by Gilead to a total amount of $425 million, which will approximate approximately 15% of the ownership of Galapagos after the share issuance. And we will also be receiving then the upfront payment of $300 million, bringing us to a cash position of north of $1 billion after the closing of that transaction.

And finally, important to note -- for those of you that are not familiar, in Belgium we benefit from a favorable tax regime called the patent income deduction regime. This will allow us to book income from milestones as well as the upfront license fee, as well as future royalties and profit share, under an 80% tax exemption. It's like a patent box.

This is not 100% sure. We will need to ask for a ruling from the Belgian tax authorities. But it is very likely that this will be treated this way, as it was also treated in our earlier arrangements in the alliance with AbbVie. So, all in all, a favorable position from a tax point of view as well.

Then maybe before we go into the Q&A, as a concluding slide, that some of you -- that the follower of the Company have seen before -- the outlook, on the Galapagos Islands there.

So, what are the key points for the Company? We will obviously now, together with our partner, Gilead, start preparing the next phase for RA and for Crohn's. We have got our CF program on track to deliver triple combo therapy. We have our proprietary target discovery platform to continuously feed the pipeline.

And, as a reminder, we have more than 20 programs that we're active on, beyond the programs that we saw on the clinical slides. We have fully-owned programs in ulcerative colitis and IPF that were shown before; and a very strong balance sheet to support innovation.

So, with that, Elizabeth, I give it back to you to organize the Q&A.

Elizabeth Goodwin - *Galapagos NV - VP IR & Corporate Communications*

Okay. Thanks very much, Bart and Onno. That does conclude the presentation part. I'd now like to ask our operator, Pascal, to connect us to any callers with questions for the Galapagos team.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions). Matt Roden, UBS.

Matt Roden - *UBS - Analyst*

Congrats on the partnership today. First question, on filgotinib -- it seems that, at ACR, some people were talking about dosing of filgotinib in Phase III maybe being a BID dose. I think you may have said something about transitioning then to a maintenance dose. Can you just clarify what the plans would be for a filgotinib dosing schedule?

And then, secondly, just on the deal, if you could just maybe go into a little bit more detail on the option to co-promote, what is the trigger? When does that expire? Do you have to pay into the partnership to take that option? Just, if you can put some parameters around what we should expect on that. Thanks very much.

Onno van de Stolpe - *Galapagos NV - CEO*

Matt, I'll answer the first question by actually answering that we cannot really disclose that at this point in time. We are submitting, and we have submitted, the first set of data to the FDA and EMA, and we will have the discussions regarding the clinical plans around Phase III with the regulatory authorities, and we will not discuss any of the details of those plans before we've had those discussion with the authorities.

So, the -- as the plans are made together with Gilead and submitted to the authorities, and then after we get a response from them in the meetings, we'll share that with you.

Bart Filius - *Galapagos NV - CFO*

And on the option to the co-promote, Matt, you would likely see us exercise that option in the course of 2017. I'm not giving an exact date, because actually what we're going to make it dependent on is what is needed for the product in terms of further commercialization. And we're actually going to be working together with Gilead on developing the plans for that, also for the European markets, very quickly after the closing of this transaction.

And as a function of that, we will be making a decision to opt in to those commercialization into those markets. There is no financial payment from Galapagos due for exercising that option. Obviously it's an option under the contract.

Matt Roden - *UBS - Analyst*

Okay. Great. Thanks for taking those. I guess one quick followup, if I may -- we see that you have pretty nice data in Crohn's disease that's moving forward. Is there a reason that this asset wouldn't be moved into ulcerative colitis as well? It seems like mechanistically there should be an opportunity there. Just wanted to get your thoughts on ulcerative colitis.

Onno van de Stolpe - *Galapagos NV - CEO*

Yes. It's clear that ulcerative colitis is the next one on the list, and we actually hope that we will move into UC in Phase III in 2016 as well. But, of course, that depends on the discussions with the authorities.

Matt Roden - *UBS - Analyst*

Yes. Great. Thanks again.

Operator

Matthew Harrison, Morgan Stanley.

Matthew Harrison - *Morgan Stanley - Analyst*

So, maybe two for me. So, first one -- can you just talk a little bit about -- obviously, you've said in the past you were engaged potentially with multiple companies around the partnership. How did you end up choosing Gilead? Obviously -- or, potentially you had choices with players who had an entrenched market share in the TNF category or in RA. So, just wondering how you think about commercialization and how you think about Gilead's capabilities, and what attracted you there.

And then, second, maybe if you could just talk a little bit about some of the items on the deal structure, and how you thought about those. Obviously, you could have maybe negotiated a deal structure where you didn't have to pay into development. Why do you -- why was that? Is that important to you? Did that -- what kind of rights does that give you, that was important to you?

And then maybe you could just discuss a little bit about how you view the opportunity specifically for some of the European countries that you pick to co-promote, and how you came to that list versus maybe a different list. Thanks.

Onno van de Stolpe - *Galapagos NV - CEO*

Thank you, Matthew. Good questions. We went in with a number of parties that met the criteria that we set beforehand, of a potential partner for these assets. And we entered into CVAs with these partners, and started discussions. Of course, a couple fell off very soon afterwards because of strategic or financial reasons; and with a number, we went in deeper, where we had presentations and due diligence.

I must say that, from day one, Gilead was our preferred partner for a number of reasons. We like the track record that Gilead has with bringing products to approval, to the market, to patients. They're unrivaled in that. Their speed of execution is phenomenal.

But what even -- was even more important, was that although they are number nine or ten in the pharma world, they have kept their biotech culture. That fits very well with Galapagos, and our team that interacted with the development team of Gilead was absolutely in favor of doing this transaction with them, because of the chemistry that happened when we had the meetings.

So, during the process it became clearer and clearer that Gilead was the party to do the deal with. Of course, we had some tough negotiations along the way. We actually, last night, more or less agreed on all the details, and it lasted until 7 o'clock this morning before we had the signatures on paper. But also, that process was done with remarkable execution quality of Gilead, so we've been very impressed with them all along. We believe they're a really good partner.

I could see your question with regard to an established player in the immunology field, or in the RA field, versus Gilead, who is just starting in that area. It -- there are pros and cons. If you have a company that has a TNF franchise, of course, the contacts with regulators, with payers, and the expertise in the fields with the KOLs, is there.

On the other hand, you're one of the products in their pipeline. You're going to cannibalize products that they have currently in their sales franchise.

A company like Gilead, or Gilead, will use filgotinib as the lead program in their inflammation franchise. We will have all the attention from the organization to bring this to the market, and with the execution power that Gilead has shown in HIV and HCV we believe that they are the best partner to secure the best [in-vote] of filgotinib in the very competitive RA field.

So, it's an -- it's been an interesting debate that we've had internally as well, for an established player versus, call it, the new kid on the block for inflammation. But we believe that Gilead clearly has the upper hand in that discussion, and therefore our first choice of Gilead to end up as a final partner, is really a dream come true for us.

Your second question on the deal structure -- we initially were going in, or had thoughts to do an AbbVie-like deal when we started the discussions. It would be a -- just a license deal, with royalties.

But we soon realized that if we really wanted to bring Galapagos to the next phase of its development, where we would build the infrastructure, that we needed co-promotion rights. And so, we asked all the partners at the table to include that in their offer where, for a large geographic area, we wanted to have these co-promotion rights and sales booking.

And so, in the discussions with Gilead it ended up to be in the major countries in Europe as well as in the Benelux. The fact that we can book the sales in the Benelux, enables us to build a complete commercial structure, and hopefully we can use that as a stepping stone for further products that we will develop and bring to the market.

In the discussion how these deals would be structured, we talked about upfront, of course. We talked about equity investment, because we thought it would be important for a partner to actually have an equity investment in Galapagos, to show their commitment but also secure potential -- to prevent the potential acquisition by another party; and, of course, milestones and royalty.

And I think with this deal with Gilead, we've found a very nice balance of upfront royalties, milestones, and equity. So, they really tailored the deal to our needs.

Then I would like to hand it over to Bart to talk about why we chose those countries in Europe.

Bart Filius - *Galapagos NV - CFO*

Yes. [I don't know that right now], Onno. I think it's -- in terms of the big five in Europe, those are the obvious countries, I think that -- to go for; and the Benelux obviously is a natural place for us to be, from where we're based and where we are originated.

Matthew Harrison - *Morgan Stanley - Analyst*

Bart, can I just ask one followup? Just specifically on the comment you made around the patent box tax rate structure, you said you weren't 100% sure that you could get the lower rate. What's the risk there, or what are the issues that have to be worked through?

Bart Filius - *Galapagos NV - CFO*

No, it's a small risk, Matthew. The only point is that officially we call for a ruling from the Belgian tax authority, and that's just a process that we need to go through. But there's enough legal description that this should fit the favorable tax regime.

Matthew Harrison - *Morgan Stanley - Analyst*

Thanks.

Operator

Jan De Kerpel, KBC Securities.

Jan De Kerpel - *KBC Securities N.V. - Analyst*

First of all, congratulations to the entire team. It is a very nice deal.

If you -- could you share, a little bit, your thoughts on what kind of patients you would like to start to envisage in the first clinical trials in RA and in Crohn's? What kind of subgroups would you focus on?

And then, to Bart, a small technical question -- how will you recognize the upfront payment? Will it be done in one go? Is that something for the 2015 figures? And could you give us some guidance on what kind of milestones -- sizes of milestones we could expect, let's say, in the next couple of -- 2 to 3 years going forward?

Finally, a more strategic question. Out of the filgotinib deal itself, you guys will have $1 billion of cash on the bank next year, that's largely sufficient to feed the co-development investments you need to do in filgotinib and other pipeline projects. So, the question here is, how will you put this money to work? What should we expect in 2016, and going forward from that? Thank you.

Onno van de Stolpe - *Galapagos NV - CEO*

Jan, thanks for the compliments. Let me start with the trial design. I'm not going to give a lot of details on it.

For Crohn's, it's really too early. We are awaiting the 20-week data, which has an induction maintenance arm in there. So, we're going to look at how that all plays out before we're even going to talk about a Phase III design.

For RA, it's more -- it's clearer, because of all the competitive trials that have been running, or are running. So, we clearly will have a TNF-alpha failure trial (inaudible) methotrexate and a naive trial going. How large and everything -- that's still -- that is subject to discussion with the authorities, so we're not going into any details there.

Bart Filius - *Galapagos NV - CFO*

Yes. On the -- Jan, on the upfront payment, first of all, it's not 2015, for sure, because the deal will not close until 2016. There will -- we will not recognize this in one go. This will probably be spread out over a couple of years. I hope to be a bit more precise when we talk about the annual figures in March. But it will be spread out over a couple of years because of the fact that we are going to be continuously involved in the development of this molecule.

Your question regarding milestones -- we cannot today give you more details on the timing of those milestones, and the actual split-out of those milestones. So, there, I need to refrain.

Onno, you want to take the last question on the -- how we will put our money to work?

Onno van de Stolpe - *Galapagos NV - CEO*

Yes. Jan, it's a little early to discuss that. It is important for a biotech company to have a sizeable amount of money in the bank to secure options regarding the use of those funds for the programs. Are we going to take a program all the way to the clinic ourselves? Are we going to partner at some point? Just the fact that we can make those choices without always having to think, can we finance that, will secure the best options at the best time.

We are also interested in potentially looking at acquisitions to strengthen the pipeline. We have the ambition to continue to grow as a Company, and really become a leader in the biotechnology field in Europe. And therefore, we will continue to be on the lookout of -- on attractive companies that have a pipeline that would complement what we currently have. Basically, the -- at this point, the plans are still very at the beginning. So, that is something for later -- for next year.

Jan De Kerpel - *KBC Securities N.V. - Analyst*

Okay. I see. If I may, a small followup question. Gilead indeed doesn't have late-stage products in inflammation, but they do have a few products in an early stage -- an antibody, if I'm not mistaken, and a Syk inhibitor. Do you see any possibilities of combination with those kind of molecules with filgotinib?

Onno van de Stolpe - *Galapagos NV - CEO*

That's a good question, Jan. And clearly, yes, Gilead is a combination therapy Company, as they have shown with HIV and HCV franchises. So, clearly, combination products have been discussed. And we also believe that the future of effective treatment in RA and IBD will be combination products to really lead to very high remission rates. Although filgotinib has a very good remission rate, there's always improvement possible.

So, I think, longer-term, combination products will be the way to go, and we believe that with Gilead we've got a very good partner that is keen on exploring that kind of combination program. So, we will at some point start combination products in Phase IIs.

Jan De Kerpel - *KBC Securities N.V. - Analyst*

Okay. Thank you very much. And once again, congratulations with the nice Christmas present.

Operator

(Operator Instructions) Marc Frahm, Cowen and Company.

Marc Frahm - *Cowen and Company - Analyst*

Congratulations on the deal. I'm just -- it sounds from your comments like you are planning in 2016 to start Phase III trials in RA, Crohn's and possible ulcerative colitis as well. And how are those -- the designs, especially of those latter two indications, going to be finalized? Is that going to quickly become purely Gilead's decision? Is there a committee between the two?

Onno van de Stolpe - *Galapagos NV - CEO*

Yes. Thanks. Well, clearly, there is a joint development committee in which these designs will be discussed, formalized and agreed, and then of course the discussion with the FDA EMA to get them okayed and implemented. So, there are all kinds of decision-making processes in these joint development process that have been -- that are part of the contract with Gilead.

At the moment, the -- for RA, the plans have been submitted by Galapagos because we were in charge of the first draft of the plans. They will be amended in the coming weeks and submitted as the final documentation for the FDA and EMA in January. So, Gilead will have its input on those plans.

For Crohn's, we have to await the 20-week data before we can go to the FDA with a relevant plan to discuss. And we hope that we can also initiate discussions regarding the design of the Crohn's -- of the ulcerative colitis Phase III study based on the Crohn's data.

Marc Frahm - *Cowen and Company - Analyst*

In that joint development committee, is it equal representation between the two companies, or something else?

Onno van de Stolpe - *Galapagos NV - CEO*

Yes. It's equal representation and -- but the ultimate decision power is with Gilead.

Marc Frahm - *Cowen and Company - Analyst*

Okay. And then as you -- in the last question was brought up potential combination therapies. How is that contemplated in the partnership in terms of economics, and who sets the price and the relative value of filgotinib versus whatever else might be combined with it?

Bart Filius - *Galapagos NV - CFO*

Yes. So, the combination product -- that would be at -- Gilead's call to make decisions on further developments on those. We will also not be contributing to the cost of development of combination products.

And there is an agreement between the parties, how the value of filgotinib as part of a combination product, will be treated. It will be treated fairly, so there will be revenues for Galapagos from the filgotinib contribution to any combination product that Gilead might develop.

Marc Frahm - *Cowen and Company - Analyst*

Okay. And then, with your GPR84 inhibitor, are you able to combine that with filgotinib still, or does that have to go through Gilead, and how can you weigh that combination versus whatever Gilead may want to contribute from their own pipeline?

Bart Filius - *Galapagos NV - CFO*

I think GPR84 is proprietary, and we will wait for the results to come in January.

Marc Frahm - *Cowen and Company - Analyst*

Okay. Thank you very much.

Operator

Hugo Solvet, Bryan, Garnier.

Hugo Solvet - *Bryan, Garnier & Co. - Analyst*

Congratulations for the deal. Can you give us just more color on this, because it's -- not sure of the deal, as Gilead is also working on JAKs in myelofibrosis and pancreatic cancer?

And, second one -- my understanding is that the 15% stake in Galapagos might imply strong interest from Gilead beyond just filgotinib. Do Gilead show the -- any interest for other assets in your pipeline? Thank you.

Onno van de Stolpe - *Galapagos NV - CEO*

We have kept the discussion solely on filgotinib to keep the discussion simple, as we wanted to get the deal done in a very short period of time. And so, we said, this is the asset that we want to partner, and that's it.

We have negotiated exclusivity on the JAKs for all diseases except for oncology. We keep all the JAKs that we have in-house -- the JAK molecules that we can develop for oncology. Gilead is also free to develop anything they want in oncology, independent of Galapagos.

We have excluded from the transaction one JAK molecule that we have as a candidate. It's actually a selective JAK1 PIK2 molecule that we will develop independently from Gilead, and Gilead has the first right to negotiate; not the first right of refusal, but the first right to negotiate after we conclude Phase I studies. So, that's the only thing that we discussed apart from filgotinib.

Marc Frahm - *Cowen and Company - Analyst*

Okay. Great. Thank you.

Operator

Keyur Parek, Goldman Sachs.

Tim Woodward - *Goldman Sachs - Analyst*

Hi, it's Tim Woodward, on for Keyur Parek. And first of all, congratulations on a great deal. I have a quick question on the 15% Gilead stake. What, if any, are the restrictions around that, both on whether they can sell it and whether or not they can add to it? Thank you.

Bart Filius - *Galapagos NV - CFO*

Thanks, Tim, for the congratulations. There is in the agreement both a standstill and a lockup, and we will not be disclosing any details on the timing of that. But there is provisions for that -- for both those directions.

Tim Woodward - *Goldman Sachs - Analyst*

Thank you.

Operator

(Operator Instructions) Vamil Divan, Credit Suisse.

Vamil Divan - *Credit Suisse - Analyst*

So, just -- (inaudible) the first one's a little -- a followup on some of your comments that you made prior, just around the timing of the deal, and the input that Gilead has, and what you've submitted so far to the regulators. It sounds like the deal just sort of finished coming together.

And then, just to clarify, [you tell me] you submitted -- so, what you've submitted so far, you've submitted on your own. And then you'll use their input more on the revisions to the draft. Is that the right way to think about it? Or, have they already -- do they already have a sense of what you've submitted, and then provide some input into that?

And then my second question, just -- if you can provide any more color around when you expect to have your meetings -- the upcoming meetings with the regulators. Thanks.

Onno van de Stolpe - *Galapagos NV - CEO*

Yes, Vamil. Thanks for the questions. We have given Gilead input on the dossier that we were preparing for the FDA and EMA, so they know exactly what's in there, and we have taken their suggestions in there. But clearly, up to the moment -- actually, up to this morning, we were on track to go for RA trials -- Phase III, ourselves. So, the trial design is basically just designed based on that option.

The possibility to -- it's a draft plan, so there's a possibility to revise, which we'll do over the next couple of weeks, together with the partner. And then we will submit the final plan with the input from Gilead in there. So, everything is on track and not delayed because of that. The meeting with the FDA and the EMA is in March, and that also is on track, as we had discussed previously with the investors.

Vamil Divan - *Credit Suisse - Analyst*

Okay. Thank you.

Operator

Sachin Soni, Kempen & Co.

Sachin Soni - *Kempen & Co. - Analyst*

Thank you for taking my question. I have one left. And again, congratulations from my side too. Since you have the freedom to bring any program forward in your preclinical and early clinical stage pipeline, if you were to rank that thing, what would be your most favorite program, bringing forward individually? Thank you.

Onno van de Stolpe - *Galapagos NV - CEO*

I don't think we have a preference. I think -- you mean between RA and Crohn's?

Sachin Soni - *Kempen & Co. - Analyst*

No. In your proprietary pipeline, which has not started yet.

Onno van de Stolpe - *Galapagos NV - CEO*

Oh, sorry. I think we are very excited about the 1690, the reason being that we can develop that for an orphan disease, IPF. And, as you know, we are interested in taking an orphan disease program all the way to the market on ourselves without a partner, so we can actually build an infrastructure around that product. So, from that point of view, we are extremely excited about that program.

Sachin Soni - *Kempen & Co. - Analyst*

Perfect. Thank you.

Operator

Mark Pospisilik, Kempen & Co.

Mark Pospisilik - *Kempen & Co. - Analyst*

Thanks for taking my questions, and congratulations from me as well. Maybe just one on the -- from all the partners that you were in discussions with, if you could sort of -- what the consensus view on positioning of JAKs as a class in RA?

I mean, are people primarily excited about, and is the focus going forward on putting these definitively in first line? Or, is there sort of still a first focus in sort of coming after TNFs?

And then, sort of a follow-on -- that question, more specific for filgotinib, any thoughts from potential partners on, say, unique features of filgotinib -- the hemoglobin benefit, and lipids -- how that might lead to positioning and strategy and development?

Onno van de Stolpe - *Galapagos NV - CEO*

Yes. To start with your first question, we are strong believers that ultimately the JAKs should be positioned as first-line therapies, and therapy that's shared by the partners, and the main reason being the fast onset of action. Where you have to wait a couple of months with the TNFs to see efficacy in most patients, with the JAKS you see a very good efficacy in 1 to 2 weeks. So, for the doctors to see if the drug works in a specific patient within 2 weeks is a big advantage.

Of course, on top of that, the oral, taking a pill a day versus injection or IV, is also a big advantage. So, I think longer-term, first line is the way to go. However, we don't need to have a lot of safety data to be able to convince doctors to change their view of not starting treatment with the TNFs.

Regarding the profile, with hemoglobin and the lipid profile, favoritism of filgotinib over the rest -- clearly, that is an important factor. It's the big differentiator versus baricitinib. And we believe that patients in both diseases, actually -- both in RA as well as in IBD -- are often anemic and would benefit from a treatment that actually raises the hemoglobin and helps prevent anemia.

The lipid profile is now consistently shown to improve by filgotinib, which is also a big benefit. We have seen it in DARWIN 1. We saw it to a lesser extent in the monotherapy DARWIN 2. But in the FITZROY Crohn's study we again saw a substantial improvement of the lipid profile, so we believe we got a very strong differentiating aspect in that regard as well.

Regarding efficacy, we'll have to show in the Phase III how it stands out compared to baricitinib. With regard to Crohn's, there's of course much less of a competition at this moment. There are very few effective treatments in Crohn's, so there, the field is still wide open.

Mark Pospisilik - *Kempen & Co. - Analyst*

All right. Thanks.

Operator

(Operator Instructions). Graham Tanaka, Tanaka Capital Management.

Graham Tanaka - *Tanaka Capital Management, Inc. - Analyst*

I just wanted -- you made a reference to a previous partner, AbbVie. I was just wondering what happened there. And then, if you could give us maybe a summary of what you've seen in terms of efficacy -- superior of efficacy in -- so far observed from Phase I and Phase II. Thanks.

Onno van de Stolpe - *Galapagos NV - CEO*

Well, I'll keep that short. AbbVie had an option on this program, and 2 months ago decided not to exercise the option, and made a choice for their internal-developed JAK molecule, ABT-494, to take that into Phase III. And by returning the option, or not exercising the option, the molecule -- the rights to the molecule reverted back to Galapagos.

Regarding what we have shown with filgotinib in RA and Crohn's, we have seen very good efficacy in a trial together with methotrexate as well as in the monotherapy, where we reached the highest efficacies shown to date. And recently we also published data on a study in Crohn's disease where we saw a very high remission rate in patients, especially in patients that were naive to treatment.

Graham Tanaka - *Tanaka Capital Management, Inc. - Analyst*

Has it been public, what those -- the efficacy rates were? The remission rates?

Onno van de Stolpe - *Galapagos NV - CEO*

Yes. You can easily find them on our website. There are press releases of the DARWIN studies; FITZROY studies. There are also a webcast like this one, that you can listen to and review all the data.

Graham Tanaka - *Tanaka Capital Management, Inc. - Analyst*

How close in mechanism of action or efficacy of side effects were the -- is the AbbVie compound?

Onno van de Stolpe - *Galapagos NV - CEO*

Well, that's not completely clear. They have just published a poster on the ACR conference, where they showed a profile very similar to a molecule that's currently on the market, tofacitinib, marketed as Xeljanz by Pfizer.

And we know from Pfizer molecule that it hits not only the JAK1 but also the JAK2 and JAK3. So, we believe that AbbVie's molecule is more what they call a pan-JAK selective molecule than a JAK1-selective molecule.

Operator

Thank you. There are no further questions waiting in the queue for the moment.

Elizabeth Goodwin - *Galapagos NV - VP IR & Corporate Communications*

All right. Thank you all very much. This now will then conclude the question-and-answer session.

I want to thank everyone who participated today, and I look forward to seeing you all and speaking with you all in the coming days and in the new year. So, happy holidays to you all, and a very successful 2016. Thank you, and goodbye.