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GLPG.AS - Galapagos NV Filgotinib Meets Primary Endpoint in Phase 2 Study in Patients with Moderate to Severe Crohn's Disease Call

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PRESENTATION

Elizabeth Goodwin - *Galapagos NV - Head of Corporate Communications & IR*

Hello, everyone, and welcome to the audio webcast of Galapagos's FITZROY week 10 results with filgotinibin in Crohn's disease.

I'm Elizabeth Goodwin, Investor Relations at Galapagos. And this webcast will be accessible via the Galapagos website home page and will be archived for about one year starting later today. We'll also post a transcript of the call today a little bit later on.

So that your questions can be included, we request that you call in to the telephone number given in today's press release. I'll give you one right now. That's 1 for the US, 646-254-3373, and the access code is 4725658.

Moving on to the disclaimer slide, I'd like to remind everyone that we will be making forward-looking statements during today's audio conference. We would especially like to point out that future results with filgotinibin may differ materially from the interim week 10 analysis presented today.

Today's speakers will be Onno van de Stolpe, CEO, and Piet Wigerinck, CSO, of Galapagos. They will go over the week 10 results with filgotinibin in Crohn's disease. You will see a PowerPoint presentation on screen during this presentation. We estimate that it will take about 25 minutes and will be followed by a Q&A session with our executives.

So, at this time I'd like to hand over to Onno to start the presentation. Onno?

Onno van de Stolpe - *Galapagos NV - CEO*

Thank you, Elizabeth. It's with great pleasure that I give an introduction to today's results; exciting times. After very successful DARWIN results in RA, we are now presenting the FITZROY results with filgotinibin in Crohn's disease. This is exciting as the first JAK that actually gives efficacy in this disease.

Filgotinibin more and more shows to be a very safe, effective oral for autoimmune diseases, not only for RA and IBD, but we also believe that there are opportunities in other disease areas as well in the future.

But, clearly Galapagos is more than only filgotinibin. We have a very large cystic fibrosis program in collaboration with AbbVie that is moving forward. We have fully owned programs in other disease indications in the clinic as well as in our pipeline.

We have a platform, a discovery platform where we are constantly generating new targets that are moving into drug discovery. And we have a very solid balance sheet with EUR334 million in cash. So, we are really a biotech company that can move forward on its own independently to the next phase of its development.

If we go to the next slide and look at the pipeline, the two top programs there is filgotinibin in RA and Crohn's. You see that we are expecting more milestones coming up.

We are on track to start Phase 3 in filgotinibin in RA by the end of the first quarter next year. And for IBD the next -- and Crohn's the next milestone moment will be the publication of the 20 week data in the first half next year.

But, more data are coming up, a new mode of action in ulcerative colitis, GPR84, which we are expecting in the first quarter next year, a Phase 2A study. We are planning to start a Phase 2 in an -- on a new mode of action, autotaxin in idiopathic pulmonary fibrosis. That will start first half next year.

And then, a lot of activities around our CF portfolio. With cystic fibrosis we are going for a triple combo therapy where we are combining a potentiator with two different correctors, corrector 1 and corrector 2; different modes of action there. And that triple combination therapy should go into patients in the first half 2017.

Very exciting program; we are doing that in collaboration with AbbVie, the partner that we value for cystic fibrosis and where the relationship actually is very good if there are any questions in that regard. We're all committed to move this forward and show that we've got the best combination therapy for that patient population.

We recently announced the entry into the clinic of a new mode of action in osteoarthritis. Osteoarthritis is a very large disease area with a very high unmet medical need. We are doing this in an alliance together with Servier, a French pharma company. And we have started Phase 1.

Interesting in that alliance is that, if it is successful in Phase 2, we have the unencumbered US marketing rights so we can partner or move that forward ourselves in the United States. So, exciting programs in the clinic. Today is not the moment to discuss our discovery pipeline, but also there we are making very nice progress.

So, all in all, Galapagos is in very good shape. But, that's not why you are calling in at the moment on this webcast. You want to hear about the Crohn's data, so I am going to hand it over to Piet Wigerinck, our Chief Scientific Officer. Piet, the floor is yours.

Piet Wigerinck - *Galapagos NV - Chief Science Officer*

Thank you, Onno. On behalf of the whole filgotinibin team, I also want to welcome all of you to this call.

It is the fifth time this year that I can present novel Phase 2 data on filgotinibin, and again they are excellent. Today I will present the 10 week interim data in Crohn's disease. I will share more details on the baselines, the observed safety and efficacy, and I also will report efficacy for the naive and the anti-TNF failing subgroups of the population.

So, by the end of this presentation, you will understand how solid the efficacy data for Crohn's disease are, but let me start by asking why did we test filgotinibin in Crohn's disease. We had three good reasons to do so.

First of all, we thought there was a strong scientific rationale to evaluate a truly selective JAK1 inhibitor for autoimmune diseases of the GI tract. Secondly, Crohn's is a more difficult hurdle to take. We all know the stories about compounds that were positive in UC, but it never reached the primary endpoint in Crohn's. So, showing activity in Crohn's is really a big step forward.

And finally, most importantly, there is a high unmet medical need for patients with Crohn's. They only have few option treatments. At the bottom of the treatment scheme, you see there are the steroids, very old drugs, very good for short term benefits for the symptoms but never a cure for the disease.

After steroids, there are a number of relatively old and nonselective drugs like the thiopurines. And then, if you can't control disease with these first line drugs, we have to go to the anti-TNFs. I will illustrate their limited level of efficacy during this talk as well.

So, after the anti-TNFs and some new other injectables, for the patient unfortunately the final step in treatment is the removal of part of the colon. And that's what we all want to avoid. So, that's the reason why in the industry there is a large effort on going to find better treatments for Crohn's disease patients.

So, how do we measure the disease activity in the Crohn's patients? We use a score named the CDAI score. It's a complex score that is where the patient is measuring every day the number of stools, how much pain he experiences, and other symptoms like general feeling.

The maximum score is 600. So, the goal of the new treatment, and that's indicated by the arrow, is to put patients below a level of 150, when we consider them to be in remission.

For clinical trials, we typically include moderate to severe patients with a score between 220 and 450. A second clinical measurement point is a drop of 100 points of CDAI score. That's what we call a clinical response.

Let's now have a look to the FITZROY study design. FITZROY is a 20 week study with the primary endpoint after 10 weeks, and that's the one we report today. And as it's a primary endpoint, we make it public.

The first 10 weeks is a relatively simple design. Patients receive either placebo, either 200 milligrams of filgotinibin in a ratio 1 to 4. The second part of the trial is more complex and won't be discussed today.

The study is still ongoing. The last patients are completing their treatment over the coming weeks. And as the study is still ongoing, we receive the blinded information only. So, full data disclosure and unblinding will happen after all patients have concluded all their visits.

The FITZROY study had an 80% power to show a 20% difference between active and placebo. One really needs 180 patients to make that point. So, what type of patients did we include?

So, we were looking for patients with active Crohn's disease. We find on the one hand side by a CDAI score between 220 and 450, but as well we needed independent endoscopic confirmation of active disease and ulceration. So, this is a very strict entry criteria.

And this is over time how the field has learned to do studies, that if you want to do a good study, if you want to come to conclusions, you really need do an endoscopy at baseline in a blinded fashion. So, that's a very important difference with many other studies.

What did we learn in terms of other medications? Well, we only allowed a stable dose of oral steroids or the salazines. None of the other immune modulators were allowed in the study. So as well, patients that had been on anti-TNFs could enter the study but had to stop that eight weeks prior to baseline.

So, finding the right patients for Crohn's trials is not easy. There's a lot of competition and our exclusion criteria was quite strict. So, we had to screen more than 300 patients to finally randomize 175 patients, of which 174 were exposed.

So, 44 went into the placebo arm, 130 in the active arm, and you can see that both arms had an early discontinuation rate of around 15%, which is normal for these type of trials. The main reason to discontinue early was a worsening of disease, illustrating that we really included patients that were very sick.

About 100 patients had been treated and had failed at least one TNF prior to inclusion in the study. 73 patients were TNF naive patients, as we call them.

They came from a spread of countries. So, the anti-TNF experienced patients and the TNF failing patients in fact were recruited in Belgium, Germany, France, and UK. The naive patients mainly came from Hungary, Poland, Russia, and other countries.

So, a very good mix of countries, and a mix that allows to exclude a country effect as well. So, by the mix of Eastern and Western European countries, we could come to an almost 50/50 mix of TNF naives and TNF experienced patients.

Let's have a look on how sick the patients were at baseline, because that's also important to judge efficacy. And as you can see, Crohn's patients, they are young patients. On average, they had -- the mean age was 37, and they had been sick for over eight years. There's a slight difference there between placebo and active.

The mean CDAI score at baseline was 293, which is exactly the target we had set forward. You can see as well about 50% of the patients were taking oral corticosteroids. But all over, the trial was well balanced and there are no real differences between placebo and active here.

So, what was for us the key question to be answered with this study? We wanted to see whether filgotinibin would jump over the high hurdle of clinical remission. We did choose this endpoint because it's, for the patient, a significant improvement of their disease.

As you can see, filgotinibin did excellent, almost 50% of patients reaching remission in 10 weeks in a mixed population of experienced and TNF naives, compared to 23% for the placebo only.

The delta between the two groups is good as well, a 25% difference between delta and active in a Crohn's design. That is what everybody would like to obtain. So, these data are in short a fantastic start for a broad development in inflammatory diseases of the GI tract, which we'll show some more detail on the coming slides.

Let's go and have a look over the response over time. You see in orange the active group, in gray the placebo group, and you can see that from week two onwards both groups separated nicely. And over time, there was really an almost always growing difference between active and placebo.

Timing endpoint as well, the graph indicates that 10 weeks might not be the maximum yet. So, we expect, over the second part of the study, we will watch it carefully whether we see a further increase of activity with the 200 milligrams.

Next to the CDAI score we also measure how much of the patients reach the stage of clinical improvement. That's measured as a 100 point drop. So, on the left you see the data for the clinical remission, on the right the 100 point CDAI drop.

You can see, as expected, this a lower hurdle so the efficacy rates are higher and are excellent as well. 60% is really a high rate of patients that reach in 10 weeks a clinical response of 100 points.

Next slide? The CDAI scoring system focuses a lot on GI systems. Next to those systems, we also gathered additional info on the quality of life of our Crohn's patients in the study. These types of questionnaires are becoming very important to obtain approval for novel drugs.

As you can see, filgotinibin outperformed placebo on the overall score and on every separate component of the questionnaire. So, all in all, at every level here we obtained a very strong P value showing that the activity as we measured it is really a consistent and true improvement of the quality of life of these patients.

We also looked and separated the anti-TNF naives from the anti-TNF experienced. Let us be clear. The trial was not designed to show a statistical difference. And this is an interim analysis, all the data remain blinded and we can't calculate P values, so you won't get them today.

Filgotinibin is really doing excellent here. In the naive subgroup with 73 patients, we obtained 61% of patients reaching clinical response within 10 weeks. Comparing to placebo becomes tricky, as the placebo groups really become very small. These are less than 20 patients.

Looking to the right column, also the number of patients reaching clinical improvement is high. So, these 61% of patients that reached clinical remission we want to put into context of other studies. So, these are studies we did discover of a number of approved drugs for Crohn's, Cimzia, Entyvio, Humira, and a number of drugs in late stage development.

As you can see, the 61% really outperforms any of those studies ever published for these combos. So, in the anti-TNF naive, we are really setting another mark here.

Let's now go to the TNF experienced patients. This is about a 100 patient big group. As expected, the efficacy levels are lower as this is more difficult to treat population. Again, we see consistent activity across the clinical endpoints, a very strong performance here in terms of a 100 CDAI drop.

Of note, of course, is the high placebo rate. But, again, these is a very small group and we have only 25% patients here. So, every patient adds for 4%, and making a comparison there becomes difficult.

Do notice in this small placebo group we had more patients at baseline with really a low CDAI start value. So, we need to wait for unblinding whether it is this small group that is driving the high placebo group -- the high placebo rate in this subgroup.

Comparing to other published studies is on this slide. There are less studies in this population, but you can see the level of efficacy we see is good and is better than what every other compound has reported recently. So, typically 30% has been the max observed in this patient population.

So, TNF failures, it takes more -- it takes longer to drive them down to remission. We are very happy with the observed 37% efficacy rate we saw with filgotinibin.

Okay, let's go to safety now. Safety is a kind of boring study because we are going to repeat exactly what we saw with DARWIN. We don't see, in fact, a difference between active and placebo in terms of AEs, serious AEs, severe AEs, and AEs leading to stop. So, very well balanced between placebo and active, and no difference at all.

Next slide? So, also in terms of the most frequently reported adverse events, we have therefore both groups' infections and infestations, GI disorders typical for the disease, and nervous system disorders, mainly headaches, in this group have been reported and, again, as frequently in placebo and in active.

I have one special slide only left, and that is the LDL and HDL. So, we were very -- it was a good surprise to see that in this FITZROY study the effect will repeat what we've observed in the DARWIN 1 data. So, no difference from placebo in terms of LDL increase and a nice 20% increase of the HDL, the so-called good lipids only. So, this stronger increase in HDL compared to LDL also makes the atherogenic index is moving into the right direction.

Finally on safety labs, I have shown the most important parameters that changed. So, we saw an increase in hemoglobin similar to placebo. Different to the RA class, we almost see no drop of neutrophils. We mean that in the RA class we really decreased the disease level.

Lymphocytes, again, a confirmation of the fact that they don't change, as well as liver enzymes. Again, a confirmation that filgotinibin does not increase liver enzymes.

The kidney parameter of clearance is increased both in the active group and the placebo. And on finally lipids, we have discussed on the previous slide. So, only the 200 milligram filgotinibin showed an LDL increase.

Next that brings me to the conclusions of the study. So, we are very proud of filgotinibin. It's the first JAK inhibitor that shows efficacy in Crohn's patients.

Bringing an easy to take oral and a highly efficacious and safe drug to the market will have a major impact for the life of many patients. On top, filgotinibin clearly has an important positive impact as well on the quality of life of these patients.

I believe everybody is impressed with the high efficacy in TNF naive patients. As expected, the remission rates are lower in the more difficult to treat TNF experienced patients, but also there filgotinibin takes a very good start.

The FITZROY study fully confirms the growing confidence we have in the safety of this novel drug. So, our Company we are gearing up to drive forward the development of filgotinibin in multiple GI indications.

That's it.

Onno van de Stolpe - *Galapagos NV - CEO*

Thank you, Piet. Let me conclude our official presentation by talking about the outlook, especially around filgotinibin.

As everybody is aware, we have initiated discussions to find a development and marketing partner for filgotinibin for all indications, RA, Crohn's, other IBD and other autoimmune indications.

We said after AbbVie decided not to exercise their option that we anticipated to be able to sign on a partner before the end of the year. We're still on track with that timing.

I have to say that of course you never know if that will be realized. These are complex discussions, negotiations, and contracting. We are discussing with multiple partners in parallel as we speak. But, we remain positive that we can sign on a new partner before the end of the year.

It's clear that, to explore the full potential of filgotinibin in all these disease indications, we need a partner, a strong partner that can contribute financially as well as operational. These are very large studies and in multiple indications.

We want to start as soon as possible with studies definitely in ulcerative colitis, but also other disease indications. So, to explore that, a going alone scenario is not ideal.

Having said that, as we said previously, we have worked very hard to get all the filing documents for the Phase 3 ready. And we're on track to start the RA trial with filgotinibin at the end of the first quarter, if everything goes according to plan.

We would like to have a partner on board before the end of the year to give them input on the final -- with the final discussions with the FDA and the EMA regarding the design of the trials. But, if we don't conclude a deal before year-end, we will have those discussions by ourselves, which is also a possibility.

Very exciting times; a lot still has to be done between now and the end of the year, but the feeling is very positive. And clearly the Crohn's data will help in those discussions to reach a result that is favorable for Galapagos and for filgotinibin.

With that, I would like to hand it back to Elizabeth.

Elizabeth Goodwin - *Galapagos NV - Head of Corporate Communications & IR*

Okay. Thanks, Onno and Piet.

This concludes the presentation portion of the conference call right now. I'd like to ask our operator, [Pia], to connect us to callers who have questions for our executives.

QUESTIONS AND ANSWERS

Operator

Yes, thank you. (Operator instructions.) Phil Nadeau, Cowen and Co.

Phil Nadeau - *Cowen and Co. - Analyst*

Good morning. Thanks for taking my questions, just two for me. First, in the past you've suggested that you had term sheets for the partnership in front of you, and that those term sheets assumed positive data from the Crohn's trial. So, are the data that were presented today kind of consistent with what was thought when those terms sheets were drawn up?

And then my second question is on the safety side. Did you measure male hormones for signs of testicular toxicity? And if so, what did you find?

Onno van de Stolpe - *Galapagos NV - CEO*

Yes, Phil, I'll take the first question. Piet can answer the second.

As I said, we asked the partners to assume a positive outcome of this trial. And, yes, the outcome is in line with what these partners had hoped for and expected. So, we continue the discussions based on the term sheet that we had negotiated.

Piet?

Piet Wigerinck - *Galapagos NV - Chief Science Officer*

Okay, then the question on the male hormones. In all our Phase 2 studies, we have extensively tested male hormones. So, especially this study is an important one, as we have young males in here included as well.

And again, we have not seen any changes in those male hormones that we did not want to see. So, efficacy changes because the disease improves and that's it.

Phil Nadeau - *Cowen and Co. - Analyst*

Okay, great. Thanks for taking my questions. Congratulations on the data.

Piet Wigerinck - *Galapagos NV - Chief Science Officer*

Thank you.

Onno van de Stolpe - *Galapagos NV - CEO*

Thank you.

Operator

(Operator instructions.) Matthew Harrison, Morgan Stanley.

Unidentified Analyst - *Morgan Stanley - Analyst*

Hi. Thanks. This is Vikram on for Matthew. Just had a question on baseline characteristics. Could you provide any detail around kind of baseline CRP levels? And also, could you provide any detail around the baseline versus 10 week endoscopy details beyond what was already mentioned in the presentation?

Piet Wigerinck - *Galapagos NV - Chief Science Officer*

Okay. Thank you for the questions. I will take those.

Baseline CRP values, they were in the range of 15 milligrams per liter. So, we will report as well later at a scientific conference whether or not this impacted on the activity of filgotinibin.

Then you had a question as well on the endoscopy at 10 weeks. So, we did indeed perform endoscopy an independent way at baseline. We've also performed endoscopy at 10 weeks. These data, as well as the biomarkers data, they fully support what we see in terms of efficacy here.

So, both the biomarker data and endoscopy data, they fully go into the same line of the difference between active and placebo in that we see improvements. But, again, these data will be as well presented at an upcoming medical conference.

Unidentified Analyst - *Morgan Stanley - Analyst*

Okay. That's helpful. Thank you.

Piet Wigerinck - *Galapagos NV - Chief Science Officer*

Yes.

Operator

Peter Welford, Jefferies. Peter Welford, your line is now open.

Okay. Sachin Soni, Kempen & Co.

Sachin Soni - *Kempen & Co. - Analyst*

Good morning, everyone, and congratulations on the data. Two questions. Where do you think the drug would fit in the treatment paradigm for Crohn's as it stands? And how do you think that's going to influence your studies for future and future design, if you could say something on that?

And second question on partnering. Onno, you have mentioned in the past that your bias is to go for co-share co-development. Is that still the case, or would you -- or that has changed in terms of the term sheet that you have been negotiating currently? Thanks a lot.

Piet Wigerinck - *Galapagos NV - Chief Science Officer*

Onno, you will start?

Onno van de Stolpe - *Galapagos NV - CEO*

Please, Piet.

Piet Wigerinck - *Galapagos NV - Chief Science Officer*

I start? Okay. First of all, thanks for the question again.

So, this is an oral drug. What we've seen in terms of efficacy in the naive is so great that we really believe that this drug should be used prior to anti-TNF use.

What we see as well, in those patients that have failed an anti-TNF with 39% of efficacy, if we can confirm that in a bigger trial later as well there it could rescue patients that have failed one or more anti-TNFs.

So, we think this drug could be used broadly. But, the level of efficacy we see in the naives really demands that we develop it as well for early treatment and for later after that, so as well prior to -- after anti-TNF treatment.

Onno van de Stolpe - *Galapagos NV - CEO*

Sachin, thank you for the question regarding our ambition to, in a new deal, retain certain co-promotion rights. Yes, that is, in the discussions that we're currently having, still the case.

We want to use filgotinibin to make the next steps for Galapagos to develop a fully integrated biotech pharma company. And that means that we want to establish an infrastructure with a sales force in certain geographic areas. And the partners that we are discussing with are open for that structure.

So, we hope to learn from these partners and use their expertise to make Galapagos ready for introducing new products by ourselves in the future. It's a big step for us and we don't have a commercial infrastructure at the moment. But, we believe filgotinibin is the molecule that should lead us to that infrastructure.

Sachin Soni - *Kempen & Co. - Analyst*

Thanks a lot.

Operator

Hugo Solvet, Bryan Garnier.

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

Hello. Thank you for taking my questions; two if I may. First one, if you do not manage to get a partner on board before the end of the year or end of the Phase 2 meeting, would you need to recruit a team? Did you already have the expertise at Galapagos to handle the Phase 3 study on your own?

And second question, you mentioned several times that you've learned from the AbbVie deal, especially on the exclusivity of deals when inked. What should we think about the rights you gained back on some JAK inhibitors from GSK? Their development will be discontinued? Did any of the pharma you're in talks with express any interest? I would appreciate your view on this. Thanks.

Onno van de Stolpe - *Galapagos NV - CEO*

Hi, Hugo. Let me start with the last question. I am not going to give you much details on that. Clearly, this is part of the discussion about the new partnership regarding exclusivity.

Currently, all the JAKs that we have developed, so that are molecules that have various selectivities for JAK1, JAK2, JAK3, and [TIK2], are in the hands of Galapagos, no obligations to anybody else. But, you can imagine that a new partner wants to make sure that Galapagos will not develop independently an inflammation molecule out of these JAKs that could compete with filgotinibin outside the alliance.

So, it's a fine balance with what we want to retain and what will be part of the deal. We have said previously that we would like to retain rights in oncology to move molecules forward. And that is as far as I can go in answering that question.

It is part of the discussions, and we like to retain as much rights. But, we also understand that a partner wants to be assured that we are not going to compete internally with development of other molecules that could compete with filgotinibin.

Regarding the first question, how much we would have to expand if we are going to go on our own, I'd like to hand it over to Piet to answer that.

Piet Wigerinck - *Galapagos NV - Chief Science Officer*

Thank you, Onno. So, we have been working since the beginning of the summer, in fact, to have a plan in case we would get filgotinibin back. So, first thing is that we have gathered all the people who have faced the experience in the company that were present at that moment into a Phase 3 team.

And we further will expand that team. So, that effort is ongoing as we speak. And there we do it in two phases. We have a first phase of expansion we want to do anyway whether we find a partner or not. And if we don't find a partner, we will have a second wave of hiring so that in total there will be a team of about 60 people that we believe we need to do a focused Phase 3 program for filgotinibin.

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

Okay. Thank you.

Operator

There are no further questions in the queue.

Elizabeth Goodwin - *Galapagos NV - Head of Corporate Communications & IR*

All right. Well, thank you all very much. I think we'll wrap up now. Again, there'll be an archive version of the webcast plus the slides and a transcript available via our home page a little bit later today.

I want to thank everyone for all the support and participation today, and I hope to speak with all of you soon. Thank you very much. Goodbye.