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GLPG.AS - Galapagos NV Selective JAK1 Inhibitor Filgotinib Meets Key Efficacy Endpoints Call

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PRESENTATION

Operator

Good day and welcome to the Galapagos DARWIN 1 Final Results Conference Call. For your information, today's conference is being recorded. At this time, I would like to turn the conference over to Elizabeth Goodwin. Please go ahead, ma'am.

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

Hi. Thank you, everyone, and welcome to the audio webcast for our final results on the DARWIN 1 study with filgotinib. I'm Elizabeth Goodwin, Head of Investor Relations, and I'm going to talk you through our program today.

The webcast is accessible via the Galapagos Website homepage and will be archived for about a year starting later today. Also, if you're looking for a PDF copy of the slide deck, that will be available via the player after our webcast is over today.

So if you have any questions that you want to include at the end of the presentation, I request that you call into the telephone number given in the press release. I'm just going to give you one number now for your convenience. That's 32 -- for Belgium -- 2-789-2126 and there's an access code 6868513.

Now, I'd like to remind everyone that we will 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. I'd especially like to emphasize that later research results could differ materially from the final results of the DARWIN 1 study.

Today's speakers will be Onno van de Stolpe, Chief Executive Officer of Galapagos, and Dr. Piet Wigerinck, Chief Scientific Officer. Onno will give a few introductory words and then Piet will take you through the DARWIN 1 final results.

You will see a PowerPoint presentation on screen during this presentation. We estimated that the presentation will take about 30 minutes and this will be followed by a Q&A session with our executives.

I'd now like to hand over to Onno to kick off the discussion. Onno?

Onno van de Stolpe - *Galapagos NV - CEO*

Thank you, Elizabeth. It's a great pleasure to do the introduction of the DARWIN 1 final results. Before that, just a brief overview of Galapagos today, clearly, filgotinib, our flagship product looking forward in RA and other indications, but Galapagos is more than just filgotinib. We have a transformational cystic fibrosis therapy that we're developing that is moving forward according to plan and more news will come in the upcoming months.

We have two fully-owned Phase 2 programs, one in inflamed bowel disease and one in idiopathic pulmonary fibrosis, that we're moving forward and we're excited about. All generated through our own target discovery platform, the platform that continues to fill the pipeline with a number of discovery programs that are moving towards development. And this is all backed by strong financials and partnerships.

But today, will all be about filgotinib and RA. And of course, the RA market is very competitive, a large market, a lot of products already established in this market. So you can ask what patients are looking for in RA treatments. Clearly, we believe there are still huge market opportunities for novel drugs there, but they need to meet specific criteria.

First, it has to be oral. Oral administration is very important rather than intravenous or injection. It has to be highly efficacious on a number of the patient's relevant parameters. Rapid onset of action, a response within one or two weeks rather than months, and it needs to be safe and very well tolerated because it is a chronic drug that will be needed for the remainder of the lifetime.

So we believe that with filgotinib we have drug practice in house that can meet those criteria. The history of filgotinib goes back a long time. It was 10 years ago that Galapagos discovered JAK1 as a potential target for developing a drug against rheumatoid arthritis and other inflammatory diseases. We have worked very hard over the last 10 years to make molecules against the JAK1 and brought those into development.

In 2010, we started with Phase 1 with filgotinib at that time so-called 634. And over the years, we have showed in volunteers -- healthy volunteers that the molecule was safe, well tolerated, and then moved it into Phase 2 studies, and now, we're very pleased to view the final results of the DARWIN 1 study followed in a couple of weeks by the DARWIN 2 results.

The show is really for Piet to take the floor and discuss the data in detail with you. So I'm pleased to hand it over to Piet Wigerinck, our Chief Scientific Officer.

Piet Wigerinck - *Galapagos NV - Chief Scientific Officer*

Thank you, Onno. It's a pleasure to present today the scientific data on the final DARWIN 1 filgotinib data. This presentation will illustrate our introduction about this new and exciting data. The slides will show that filgotinib has increased efficacy of the more difficult RA and [constant] levels while maintaining its defensive and safety profile [first as JAK].

But when I talk about filgotinib, I often get the question, why do you think that the JAK1 [activity] is so important? Well, first of all, the data today will prove that selective inhibition of JAK1 is the way to get to unprecedented levels of efficacy. Secondly, the data will also show that [restraining] JAK2 will allow the patient to benefit optimally from the improvement of this disease by showing a positive impact on the hemoglobin within the first week of treatment. On the opposite side, which has been proven that blocking JAK2, there is a clear risk of generating anemia which with the selected JAK1 we don't need to worry about. And so, that's the basis why we years ago set -- we discovered JAK1 as a target and to go for this target (inaudible).

So before showing the [24] big data, let me start with repeating the conclusions at week 12, the primary endpoint of the study. So we and many people with us are very impressed by the clear dose response, the fast onset of action, and especially the high ACR70 and 50 responses observed. Also the safety data we're issuing, the low frequency of SAEs and AEs, the absence of any dose effect, and the [nine] differentiation from all the JAKs illustrated by increase in hemoglobin and a stronger increase in HDL compared to LDL.

So that was the data at the end of 12 weeks. So in 24 weeks, we have the question where we see further improvement on activity and can we maintain the safety profile? So when we looked at the 24-week data, what can we expect within the current competitive area? So in this slide, we have on the left, the [bucket list] of the [anti-kinase] of adalimumab of AbbVie; on the right, baricitinib Phase III by Eli Lilly; and the middle, tofacitinib on the market [sold] by Pfizer.

And let me start with adalimumab. As you can see, at week 24, the ACR20 is in the high 60s. ACR50 jumps above 50%. And ACR70 tries to approach 30%. Baracitinib is quite similar, a little bit higher ACR20 and a little bit lower ACR50 and ACR70. Tofacitinib in the middle is clearly less active than these two competitors. So let me draw your attention to the ACR70 where none of the competitors ever important data above 30%. So that's really the threshold of excellent activity.

So for those of you who did not attend the [first] DARWIN 1 call, DARWIN 1 is a 24 weeks study in which we include patients with active RA and which are on a stable background of methotrexate for at least six months. So there are a number of classic criteria to define active RA. What's important as well is that none of the patient had been exposed to [biologics] before. So they were methotrexate and numerous (inaudible) the biologics non response.

So DARWIN 1 is a -- wasn't quite complex for the upstart because we have seven different treatment groups between week 0 and 12. Also the primary endpoint at week 12, the story became even more complex. So we added four different groups in [blue]. So patients that did not reach 30% reduction in swelling in the joints are placebo and the low-dose groups were switched to the new groups in [blue].

So [30] of the placebo patients were changed to either 100 milligram daily or two times 50 milligrams. So this is important because for the rest of the present -- for the safety part of this presentation, the placebo group will consist of the 86 of -- the 86 patients (inaudible) placebo minus the 30 that was switched to the active treatment. So the placebo group will be 56 patients and those patients that were switched are not part of the frequently treated groups.

These four double groups are small and did not reveal any new information in terms of safety or efficacy and they won't be handled differently with the exception of a single slide to show their activity. So in the end, we have 11 groups for the safety important, we had to lump them all together because we were reading nothing between these [new] groups.

The slide as well is a repeat of what was shown in the webcast of 12 weeks and showed that we (inaudible) included patients with highly active disease measured as a [dossier pain] of higher than 6 and as well as the different groups were well spread. So patients at the different groups can be easily compared. So typically the criteria we get here are the ones we see, you know, the Phase 2b studies of this size.

DARWIN 1 was one of the biggest studies ever with almost 600 patients included. Typically, through the]competitors, they include about 300 to 400 patients. So with 600 patients at a global study, we had an excellent study.

Over to the data now. First of all, the overview of the early discontinuations, we showed here the comparison between placebo, the 56 patients as I explained, versus all the other patients. We decided not to split them by treatment group or dose as they are all really low and similar and there was really no dose trend observed of any of the endpoints.

So in total, 10% of patients that stopped early in the study is a low rate for 24-week study and is [center] to the Phase 2 study of baricitinib. Whether the patient discontinues for safety, efficacy or other reasons, there's no difference between placebo and active. And the fact that only 4% of patients dropped out in the active for safety is as well as a very good reason and show that there is hardly any safety [significance].

Thus far, we have looked up efficacy and we start with ACR 20, the lowest level of efficacy. We used the most conservative approach here. We intend to treat [NRI] methods. So these NRI methods we can keep the placebo group until the end of the treatment because the patient were switched or given a score of zero.

On the left of the slide, the data at week 12; on the right, the data at week 24. If you are typically reach a maximum between week six and eight in this patient group and that's what we see in the data as well being nicely confirmed with the highest [scores] we reached at week 12 are really

confirmed at week 24. This is the proof of the sustainability of the activity we saw in 12-week data of DARWIN 1. So more difficult hurdle for efficacy is ACR 50 and with respect for the patient's more (inaudible). Patients that reach ACR50 experienced a drop in signs or symptoms of at least 50%, a much more competitive hurdle of efficacy.

Filgotinib scored very high on ACR50 at week 12 with up to 55% of patients responding in the two times 100 milligram. On the second half of the study on the right, week 24, you'll see the q.d. doses catching up with the b.i.d. doses. So we see efficacy that is well approaching 50% or reaching 50% for two of the once a day dose groups. So of importance, the 55% as well is confirmed as the second sign of confirmation that we have sustained efficacy that we observed up to week 12.

Then move over ACR70, which is the most difficult hurdle, ACR70 really [based] the experience of 70% improvement of the signs and symptoms. We already had nice dose responses at week 12 and activity for all dose groups further increased by week 24. By week 24, all groups show statistical superior effect over the placebo group. Also, two great scores of both 30% of the hurdle in the competition at 24 weeks as I said did not reach. So with two groups over 30% and a top score of 39%, we really achieved here an impressive level of activity, which we did not expect to see in the study of 24 weeks.

So let me come back to this ACR70 score and put it in comparison to a number of our competitors. On the left we have tofacitinib, we have added [six] antibody in Phase III by (inaudible); sarilumab [is maintained], adalimumab and baricitinib. As you can see, none of them goes over 30%. And with our top score of 39% in the two times 100 milligram, we really explored here novel heights of efficacy, which is an impressive result.

Next to ACR70, we as well used the DAS28 system, which is a complimentary system of scoring in efficacy. We first come to the overview of all the ACR responses here. As you can see, very -- we see very nice dose responses for efficacy significance for all groups in ACR50 and ACR70 and as well as the confirmation of the primary endpoint [as well as] ACR20 and here as well we get efficacy significance for the once a day dose.

So let's now move to the DAS28 which is a complimentary way of measuring efficacy. DAS28 is a continuous course where you can see small increments of activity. This is of course for the b.i.d. groups. We have exactly the same curve for the [2D] groups. And in fact, they are textbook examples of dose responses in a clinical setting.

So first of all, let me -- let me remind you on the fast -- on the [facts] which you observed and which you see at [week one] already for the two times 100 milligram as well between week 12 and week 24 for all the active groups, not the placebo, we see further improvement of activity, which is highly statistical significance for all dose groups early on the study. And this is maintained over the 24 weeks. So a very nice picture of that 28CRP. And as we reported press release, the main change from baseline of score at 24 weeks which have been better for all groups competitor. I'll come back to this later for the active group.

But first a single slide on the activity we've observed in those four small [stage] groups. These are two groups that placebo patients sits to the mid dose, but also two groups who were patients in the low-dose groups of 50 milligrams daily but did not reach 20% of improvement on the (inaudible) who have had an increased dose.

So for the moment they switched in the middle of the study. You'll see a nice drop of DAS28. And so activity really kicks in as soon as the placebo patients to the mid-dose group and they're exactly the same of the mid-dose group the first one [fix]. Also important to see is the low dose patients in which we have doubled the dose amount really showed improved activity by increasing the dose. So the low dose we have in this trial was clearly the suboptimal dose. So DAS28 as well to measure patients have few or almost no symptoms anymore. And that's what we have reported in the press release earlier today.

Let me remind you that at the beginning of the study, this patient had a highly active disease with a mean score of higher than six. Let me guide you through this data. Let me start with the green bars which show how many patients achieved lowest level of disease at the end of the study with a DAS score below 2.6, the level defined for remission. In fact, this means these patients are almost symptom free. This is of course ranging between 20% for the low dose and up to 40% for the high dose. So this really affects patient population.

Filgotinib induces remission in up to 40% of the patients and impressive result again at 24 weeks. If we add the orange and the green bars together, we have all patients achieved a DAS score of below 3.2, or definition of low disease activity. For patient disease important threshold is quite good and also the regulators especially in Europe ask us to report it. Again all groups are statistically superior to placebo. And for the mid dose, we reached up to 50% response. For the top dose, response goes up to 64%, again, a very high impressive number. So almost two-thirds of the patients in two times 100 milligram achieved low disease activity.

And on this slide, we have compared recent data of some of the competitors. As some company choose a different [systems] comparative with all of the other compounds we typically use in our recent data for both baricitinib and sarilumab. As you can see, taken the low disease and remission together, they achieved a score that goes up to 50%. Really is more than 60% rate again explore here another levels of efficacy.

So now over to the safety endpoints, on the current slide, I will report the events over a full 24-week dosing period and placebo means all patients exposed to placebo during 24 weeks total number of 56. Filgotinib is the list of all patients taking filgotinib for 24 weeks and as well we have added those patients that has been exposed to filgotinib for 12 weeks, so kind of a worst case way of analyzing the data.

We decided not to split up by dose or treatment group as all the numbers are very similar. Let me start at the top view adverse events as serious infections and adverse events being the top. As you can see from the table adverse events, serious adverse events, serious infections, adverse events begin to stop were very similar or low frequency between the placebo exposed group and the filgotinib exposed group, so a good result. We did not observed any dose trends and decided for that reason to report in this way.

We did get one patient died in the study. She was in the two times 100 milligram dose group and she had a long history of RA, was 60 years old and lives in the Central American country. She died from pneumonia in a hospital not linked to the DARWIN study. As a consequence, there were no specific investigations performed. She was, as part of the DARWIN study, on a routine visit three weeks earlier. And during that period, all her white blood counts were normal. Thus far, this is the only case in the full filgotinib program. And then they [mean] the program including DARWIN 1, DARWIN 2, DARWIN 3 and the current study. Thanks to DARWIN 3 the total exposed to the high dose has accumulated the fact that six highest than exposed to the high dose in DARWIN 1 alone. So it remains a single study -- a single case up to now.

Let me come back now to the line in the table where it says [serious] infections. There are few cases with total frequency of less than 1% in the filgotinib exposed group which paints a very low number. The highest frequency of placebo group indicates that the number of serious infections in DARWIN 1 is in line with what we can expect in this disease population.

Then we have made a table of adverse events of special interest. These are mainly infections and MACE. Infection is of importance because we lower the immune system of the patients and infections is a real risk of that approach. You can here see this is slightly higher frequency of all infections. But again, we could not observe any dose response in here.

In the filgotinib exposed group, we observed a low number of serious infections as reported also on the previous slide and a few herpes zoster infections that's at least comparable to placebo. You'll see a slightly higher instance of urinary tract infections and upper respiratory tract infections. For the rest, we see a scatter of different kinds of reported cases, which made the full sum of 17.9% and 25.5%.

We also had two non fatal [SEs] of cardiovascular nature. One patient on the low dose suffers from a mild stroke recovered well and is currently still in the DARWIN 3 study. One patient of the mid-dose had myocardial infarction following progressive occlusion of a stent. Both cases were not directly related. Important as well is to note that we have no cases of opportunistic infection, tuberculosis, malignancies or lymphomas. So all in all, and [AE] profile we are happy with.

Let me now move to the lab findings. After showing at 12 weeks, we believe filgotinib is different there from our competitors. We again see here and confirm an increase of hemoglobin. Very important, we did not see any effect of filgotinib on lymphocytes. There is no safety seen on the liver and a small decrease in neutrophils bring those value back to the healthy normals. We see (inaudible) JAK inhibition a small increase in creatinine and a little drop of platelets again bring those [sizes] back to the mid of normal values.

We confirmed as well on the percentage, there is a highest increase of HDL, of LDL which is good and we also confirmed the increase of hemoglobin up to 4% which is welcome in this orientation. And I will show you the evolution overtime because it's nicely illustrated the importance of JAK1 selectivity. I'll wait until the graph is there.

Okay, so consistent with the blood sampling in any clinical study, we see a drop in hemoglobin during the first two weeks in the placebo and the low group. This was also reported by other companies. It takes about 12 weeks for full recovery in the placebo group.

To the high and the mid dose, we don't see them drop. Thanks to JAK1 selectivity, the body can compensate within the first week to drop in a blood (inaudible). Within four weeks, the patients have enough benefit and at increased levels compared to baseline. The JAK1 selective inhibitor filgotinib in contrast to nonselective inhibitors allows the patient to have a full benefit from the therapy from the first week onward.

So in no scientific term, in fact this means that the patient will get it. More bang for the buck using a selective JAK1 inhibitors compared to nonselective JAK1 inhibitors. The (inaudible) increase in hemoglobin and will report it at the scientific conferences will have impact on secondary endpoints like fatigue and other quality of life parameters which would be improved, thanks to these (inaudible).

So, this brings me to the conclusions of the DARWIN 1 study and let me start with efficacy. Filgotinib is an oral drug that shows very rapid onset of action. We've seen a clear dose response and we have sustained high levels of efficacy measures as the ACR20 and 50. During the second part of the study, we have elevated the efficacy on the more difficult endpoints like ACR70, remission and low disease activity and push these responses to noble and unexplored heights.

Let me as well conclude on safety. We are pleased with the safety profile as well. DARWIN 1 is one of the largest phase IIB studies ever. And we got a lot of comfort from the low drop out rate and most of the endpoints filgotinib score was comparable to placebo. The absence of any dose dependent side effects is adding additional comfort. We see the expected JAK-driven changes in neutrophils, platelets and creatinine. Finally, the differentiation we say at week 12 versus [other] JAK is now fully confirmed.

All right, thank you and all on the call, yes. Elizabeth?

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

Okay, now it's time for Onno to have -- provide some final remarks.

Onno van de Stolpe - *Galapagos NV - CEO*

Thank you, thank you Piet. Clearly, we are very pleased with the data. The future for filgotinib is bright which clearly brought in the benefit of patients hopefully when this drug might reach the markets early 2019.

So for me to give et a good overview on the outlook, again filgotinib moved forward both in RA as well as in Crohn's disease, the FITZROY study. We're moving forward with our triple combo cystic fibrosis program which is on track to deliver all components in the next couple of weeks. The rest of our pipeline as well as early stage discovery program and now the strong balance sheet after our NASDAQ listing to support the R&D efforts of the Company.

With that, we would like to conclude. I want to thank everybody who has worked so hard within the Company to get this data set ready and share with you in this webcast. And I think I'll hand it over to Elizabeth for questions.

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

All right, thanks everybody. I just want to say that concludes the presentation portion and now I would like to have Steffi, the operator, connect us to callers who have questions. Go ahead Steffi.

QUESTIONS AND ANSWERS

Operator

Thank you. (Operator Instructions.

We will now take our first question from Matthew Harrison from Morgan Stanley. Please go ahead.

Tyson Lusgard - *Morgan Stanley - Analyst*

Hi, this is [Tyson Lusgard], covering for Matthew. Can you explain the rationale of your current study and why in particular you think it's going to work?

Piet Wigerinck - *Galapagos NV - Chief Scientific Officer*

Okay. For the Crohn's study, they have shown and many people believe that (inaudible) what is wrong in Crohn's. JAK1 is heavily involved in a number of process that run in an excessive modes in Crohn's patients. So, we will show as well of the next -- of upcoming conference early August which we have shown there in patient sample that many of the JAK1-driven process in Crohn's patients really -- are in overdrive. And so a selective inhibition of JAK1 by filgotinib should [allow] these processes.

Secondly, Crohn's patients especially have low level of that blood cell because they frequently loose blood. And so having a JAK2 [sparing] regimen there as well will help and allow them to recover quickly.

Tyson Lusgard - *Morgan Stanley - Analyst*

Great, thank you.

Operator

Thank you. We will take now our next question from [Phil Nadel] from Cohen & Company. Please go ahead.

Phil Nadel - *Cohen & Company - Analyst*

Good morning. Congratulations on the data and thanks for taking my question. First question just on the death in Central America, how was that assessed by the investigator? I think in your prepared remarks you said it wasn't really to the study, it was just -- that was the formal -- the formal assessment given by the investigator.

Piet Wigerinck - *Galapagos NV - Chief Scientific Officer*

No, I don't think on the death I mentioned the relationship by the investigator. It was scored as being related to the direct medication. What I said was it happened in a different center, so the patient was brought to another hospital. And so, there is no possibility to do any extra investigations of patients of the (inaudible) responsible for the study locally was not informed during the case. He was only informed when the patient had died, and so there was no way of doing any extra measurements that could have given us more light on the cause or what was going wrong.

Phil Nadel - *Cohen & Company - Analyst*

Okay, that clarifies it.

Piet Wigerinck - *Galapagos NV - Chief Scientific Officer*

And when I talk about med case, the med cases were scored as being non-related. So, I guess the confusion is coming from there.

Phil Nadel - *Cohen & Company - Analyst*

Right, right, okay. And then second, in the past, you've disclosed that there is a mandatory hurdle where the -- if the data surpassed that hurdle, AbbVie is required to take on the filgotinib program. Can you disclose whether these data would surpass that hurdle or is that still not possible to assess until you see the DARWIN 2 data?

Onno van de Stolpe - *Galapagos NV - CEO*

That's clear, we need to see the DARWIN 2 data. This is Onno here but I said many times if AbbVie is not interested in the license, we will gladly waive the obligation even if it meets all the criteria because we would rather move forward with the molecule on our own, if AbbVie doesn't want to proceed this. So, it's not really a relevant point.

Phil Nadel - *Cohen & Company - Analyst*

Okay. Then just one last question and that's on the dose, should you move this order, or if it's at your discretion, which dose would you take forward based on the data you seen to date?

Piet Wigerinck - *Galapagos NV - Chief Scientific Officer*

[We want] to see DARWIN 2 coming out in a couple of weeks but currently any dose 100 to 200 will do fine. So if you look to the one on the 100 q.d. dose, the levels of efficacy was there, are excellent and competitive. Of course when we further increase the dose to the 2 times 100, we see it in higher activity but anything under 200 will do fine in phase III.

Phil Nadel - *Cohen & Company - Analyst*

Great, thanks for taking my questions.

Piet Wigerinck - *Galapagos NV - Chief Scientific Officer*

Thank you.

Operator

Thank you. We will now take our next question from Ian Somaiya from Nomura Securities. Please go ahead.

Unidentified Participant

Hi, this is [Dell] actually filling in for Ian. Thank you for taking my questions, great data. First, I don't have the slides in front of me but can you have the level of detail in there on the other types of infections that you saw among patients in the study?

Piet Wigerinck - *Galapagos NV - Chief Scientific Officer*

Well we have the data but we don't have them in front of us here and it's a scatter of everything. So really -- and mostly common infections, so I have not seen an infection there, very common infection but respiratory mainly and then urinary tract where the main process but mostly common infections.

Unidentified Participant

Okay. And how would you rate your confidence going forward with the higher dose in the male patients?

Piet Wigerinck - *Galapagos NV - Chief Scientific Officer*

Okay, so on the male patients on one of the slides, they did not pick well. We monitor -- we did monitor them intensively on the male hormones. They did not pick up any [safety] or death. So we were confident perhaps to start in phase II that this drug would be -- would work well and will be safe for males. We believed these data confirmed this, strengthens our belief.

Also now in DARWIN 3, we have a much higher exposure in number of male patients exposed to the high dose and also there we get comfort -- we are quite comfortable that both based on safety in the study as well as the additional pre clinical studies we have done. We will be able, moving forward, the 200 milligram into phase III.

Unidentified Participant

Great, thanks guys.

Piet Wigerinck - *Galapagos NV - Chief Scientific Officer*

Thank you.

Operator

Thank you. We will now take our next question from [Peter Wellsort] from Jefferies. Please go ahead.

Peter Wellsort - *Jefferies - Analyst*

Oh yes, thanks for taking my questions. Just with regard to the breakdown and of the sort of infections and any other [drop] out. I wonder if you could talk about -- was there any different in terms of the split of the types of infections. I appreciate that this is at the global level but there was no difference between those. Was there any sign of anything if you go down between the different types of infections by dose. And then second is, were there any incidences at all during the 24 weeks in any of the study arms of either malignancies or GI perforations recorded?

And then finally, just coming back to this death again just so I can understand this. I dropped off at one point, so the death was of a patient in pneumonia in the Central American Country in a hospital not linked to the study. But I think you've answered something about the white blood

cell counts being normal. Can I ask again when was -- when was that measured and how does that relate to -- was that weeks before or what sort of time point was that? Thank you.

Piet Wigerinck - *Galapagos NV - Chief Scientific Officer*

Yes, okay, let me start to the death patient, so indeed I mentioned I saw this happened, the patient was more than 12 weeks in the study. She had a routine visit three weeks before the pneumonia happened and at that moment all her white blood cell counts were normal. So, we did not have any concerns at that moment with that patient, so that's one.

On the malignancy in the JAK1 patients, we did not have any in the study, not in any. And then [tops] of infection and (inaudible) dose regimen, we spent day shifts starting with 11 groups with all types of infections. Bringing back to first six active groups at placebo not seeing anything, grouping them by dose b.i.d. and q.d., grouping every -- we did not see anything.

So, really we see a spread frequency, especially see that infection is low and what we see is an increase in respiratory infections like pharyngitis and in urinary tract infections and that (inaudible) and did see -- and did seen this not dose dependently. So, that's what -- what I think of but I hope I answered all of your questions or are there anything --

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Peter Wellsort - *Jefferies - Analyst*

That's great, thank you.

Piet Wigerinck - *Galapagos NV - Chief Scientific Officer*

Yes, thank you.

Operator

Thank you. (Operator Instructions). We will now take the next question from Vamil Divan from Credit Suisse. Please go ahead.

Unidentified Participant

Hi, this is actually [Anna Maria] in from Vamil. Thank you for taking our questions. So just to ask the question a little bit more on the dose or in your view what the right dose for phase III, do you think it will be once or twice daily?

And our second question, a little bit more in the safety, do you think the data from the study and presumably DARWIN 2 will be sufficient to allow for the high dose, the 200 milligram dose to be used in the male population in the US?

And then finally for the pneumonia case, do you have -- I know you said that it happened in a different hospital and the doctor was informed later on. Do you have any clarifications on the type of -- the [bug] that was involved or anything -- or any more color you can provide. Thank you.

Piet Wigerinck - *Galapagos NV - Chief Scientific Officer*

Okay, let me start q.d. and b.i.d., it was one of the slides that I don't think I mentioned during my presentation. We extensively compared b.i.d. and q.d. groups. We were happy to see that between 12 and 24 weeks in fact the q.d. groups catch up with the b.i.d. groups and we can't find any statistical difference between q.d. and b.i.d.

So moving forward into phase III, q.d. is a logic option I would say but okay we'll see who will takes the compound to phase III if AbbVie takes the option. I don't want to speak here for AbbVie but currently we have not see any difference or we can't find a difference between q.d. and b.i.d. and then according to me q.d. is the logic choice.

Toward [with the] males, your next question, I try to maybe answer better than previous time. So indeed, we have on the one hand side done an extra preclinical study which according to us gives us a high margin and the margin required to move the 200 milligram move forward on top of that. In the study DARWIN 1, we monitor intensively the male hormones and did not pick up any single death or something is going wrong.

So we did not see any signs; therefore, we think that as well to our comfort we already have, starting this phase II study but it's now up to us or AbbVie in the end of phase II process to convince everybody else as well with both [like subject] little data and what we see in the clinic that this is a safe dose to use as well in the US. On the pneumonia, it was [gone] pathogen E. coli which caused the infection.

Unidentified Participant

All right, thank you.

Operator

Thank you. We will now take a question from Mark Pospisilik from Kempen & Co., please.

Mark Pospisilik - *Kempen & Co. - Analyst*

Hi good afternoon. Thanks for taking my questions, just a few for me. If you can sort of help us understand, double check the math on the number of discontinuations and the rollover rate into DARWIN 3. So if I understand, there were 3.9% discontinuation for safety and we have a 98% rollover rate and that's probably patients who successfully completed the studies, so if you could just comment there.

And then the clarification on the timing for the AbbVie opt-in. My understanding was the clock started ticking from the DARWIN 2 data as well but there is a quote apparently in Belgian paper today that the AbbVie now has 60 days. So if you could just clarify or correct there.

And then on the baseline characteristics, so if you could just confirm that no statistical significance between any of the dose or placebo groups on baseline characteristics. It looks like the CRP was quite a bit lower in placebo.

Onno van de Stolpe - *Galapagos NV - CEO*

Hey Mark, it's Onno here with your question regarding AbbVie's opt-in period, so 60 days after the DARWIN 2 data sets which will be any day now to AbbVie. So basically, it's two months from now, yes.

Piet Wigerinck - *Galapagos NV - Chief Scientific Officer*

Okay, then on rollover rate to DARWIN 3, so if you report rollover rate of 98%, you always said 98% of the eligible patients, so the patients have discontinued and left the study prior to 24 weeks. They are not eligible to - [lots] of patients have to complete the 24 weeks study and then from that moment on could decide whether or not to stay.

So out of the total number of patients [I saw] here take off, obviously the ones that discontinued that's a 10%. And then on regional basis in some countries, we did not have approval time. So, this patient did not get a choice because we did not get the approval in time. So daily [flocks] a number of patients as well. And so -- but in general, from all the patients that quit rollover, 98% chose to stay into the program and went into DARWIN 3. I can confirm that number.

Then on the baseline, on the table we've -- the difference in placebo group with lower CRP, we honestly have not seen any impact of that. So, I think placebo group reacted as we expected. We of course hope for a somewhat lower placebo response of ACR20 but we are pleased with the placebo responses of ACR50 and 7. They are exactly in the normal range, so that's fair.

We don't believe -- I don't think we should have a lower CRP and the placebo has influence anywhere the efficacy. We see in fact the opposite in DARWIN 2 and that there is no impact either over CRP baseline on the efficacy.

[Were those] all your questions Mark or --

Mark Pospisilik - *Kempen & Co. - Analyst*

Yes, no that's great, thanks.

Piet Wigerinck - *Galapagos NV - Chief Scientific Officer*

Okay.

Operator

Thank you. As there are no further questions at this time, I would like to hand the call back to Ms. Elizabeth Goodwin for any additional or closing remarks. Thank you.

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

Thank you very much everyone. I like to close the call now with a remark that next week we got our interim financial results coming up and I just want to say that we're happy to report that we're going to finish up earlier with our reporting than we originally plan. So, it's going to be held on the 6th of August. Our webcast is actually next Thursday not next Friday, 6th of August. So, we hope that you can all make some time on that day to take a look at our results.

The webcast will be done by the CFO and myself as our CEO will be on vacation. So, we look forward to speaking with you then and I want to thank you all for participating today. If you have any questions, please feel free to pop me an e-mail or call me. My details are in the press release today and I look forward to engaging with you on these exciting results. Thank you very much, bye.
