

FINAL TRANSCRIPT

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ADXN.S - ADDEX PHARMACEUTICALS SA - ADX10059 Studies 104 & 105 Clinical Results - Conference Call

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PRESENTATION

Operator

Good morning and good afternoon. This is the Chorus Call conference operator. Welcome to the Addex Pharmaceuticals Conference Call. As a reminder, all participants are in listen-only mode and the conference is being recorded. After the presentation, there will be an opportunity for you to ask questions. (OPERATOR INSTRUCTIONS).

At this time, I would like to turn the conference over to Chris Maggos, Head of IR and Communications of Addex Pharmaceuticals, accompanied by Vincent Mutel, Chief Executive Officer, and Charlotte Keywood, Chief Medical Officer. Please go ahead.

Chris Maggos - *Addex Pharmaceuticals - Head of IR & Communications*

Thank you, operator, and thanks to those of you listening today for taking the time to learn more about Addex. Today, Charlotte Keywood, our Chief Medical Officer, will review the clinical data from the press release issued this morning. And then, Vincent Mutel, our CEO, will give you an overview of our pipeline and near term milestones prior to opening the call for your questions. Charlotte?

Charlotte Keywood - *Addex Pharmaceuticals - Chief Medical Officer*

Thank you very much, Chris. Yes, it gives me pleasure to update you on the latest progress in the developments of 10059 following our recent Phase I program completion. You're aware that in the past, we -- in the Phase I program and the successful Phase IIa studies last year, we have used unformulated simple drug powder in a capsule and although we saw efficacy and there were no safety problems some of the side effects that we saw in the study, which include some mild transient dizziness and drunk feeling were not judged to be commensurate with going forward into longer term clinical trials or a commercial profile. And the reason that these CNS-type side effects occurred was because the unformulated API was very rapidly absorbed into the blood stream following oral administration and hence entering into the brain very rapidly.

So, following from those data, we decided to develop a formulation that would slow the rate of absorption of 10059 into the body to avoid the occurrence of these side effects. And we went through a formulation exercise. And in order to test the pharmacokinetics, safety, tolerability and also to get pharmacodynamic information in the indication of GERD, we undertook two Phase I studies. Firstly, to select and then test the new formulation. And then, also to look at the new formulation in

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combination with food and proton pump inhibitors, which of course are going to be used as background therapy in the Phase II program in GERD.

The first study we did was called ADX10059-104 and the study comprised two parts. The first part was a single-dose crossover to select the new formulation that would go forward into further testing. It was a three-way crossover of the old API simple powder-filled capsule with two new potential modified release formulations. As I say, the objectives were to look at the safety, tolerability and kinetics and select the most appropriate formulation to take forward.

The second part of this study was done using the selected formulation - a modified release formulation -- and was a multiple ascending-dose placebo-controlled study of three different dose levels using the modified release formulation. Again, the primary objective of that was to look at PK and safety and tolerability, but, in addition, we looked at pharmacodynamics effects on reflux parameters. And I'll give a little bit more detail on that a little bit further on.

Just to summarize results of part one of ADX10059-104, we found that when both new formulations were tested, in fact, the compound was absorbed at a slower rate, had a lower peak exposure and maintained -- very importantly, maintained overall plasma exposure through 24 hours. We didn't see any adverse events with the formulation that we selected to go forward into the second part of the study.

And that was on the background of seeing adverse events -- sort of typical adverse events of dizziness, drunk feeling and flushing -- in 7 out of 12 of the subjects when they took the old powder-filled capsule. So, the new formulation was very much better tolerated than the old powder-filled capsule. So, really, we achieved the objectives for the selection of the formulation.

And if you have a look at the graph, this just shows you how the modified release formulation did its job, if you like. You can see the old powder-filled capsule has got this very rapid spike -- this early spike. This was what was causing these adverse effects.

As you can see, in fact, with both the formulations -- the one we selected is actually the pink line you want to be looking at, but, as you can see, with both the new formulations, the modified release reduced that rate of absorption into the blood stream. And also, you want to look out beyond the sort of 10-hour time point, you can see that the plasma exposure is maintained as well. And this helps us go with our twice daily dosing, which is also another important objective that we've achieved.

As I say, the pink line -- that formulation was the one that was selected. And the reason for that really is the kinetic characteristics are slightly more favorable than the formulation that's represented by the green line, whose numbers or kinetic parameters are a little bit more safe with that formulation. So, that one was taken forward into part two.

And in part two, the principal objective of part two was really to look at the kinetics and then the safety and tolerability of repeat dosing with three different dose levels of the compound. And what we found was the kinetics of the repeat dosing were very favorable and very much compatible with twice daily dosing going forward. And additionally, we got safety and tolerability data, which again support the long-term use in -- or longer term use, I should say, that we plan to do in the Phase II program.

Now, additionally, as I've mentioned, we wanted to look at the pharmacodynamics and their effects on GERD reflux -- esophageal reflux parameters and we used a healthy subject model of GERD, which is very predictive of reflux events in GERD patients. And this is known as a sort of reflux provocation test. And what you do is you give healthy people a big, high fat meal. We sort of nickname it, the "Big Mac Meal." It's a high volume, high fat meal that has to be eaten within 15 minutes. And then, reflux events are measured by means of a probe going down the nose, down the esophagus, into the stomach that measures both impedance, that's electrical resistance in the esophagus, as well as pH.

And this is advantageous, because it means we can pick up all types of reflux events, not just acid reflux events, which we previously looked at in our GERD patients. We can pick up all types of reflux events -- weakly acidic, non-acidic as well as just purely acid reflux events. It's a more sensitive detector of anti-reflux activity.

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And when we did the test, what we saw was that in -- we saw a dose dependent treatment effects on reflux events in the subjects taking ADX-10059. I say, they were -- it was placebo-controlled, so the results are all compared to placebo. We saw a positive treatment effect on the percentage of total acid exposure that was statistically significant. And also, on the post-prandial number of weakly acidic reflux episodes as well. Again, that was statistically significant for the 10059 treatment.

And when we looked at doses individually, we saw a number of statistically significant effects on important reflux parameters. For example, overall, impedance measured reflux, so that's all types of reflux events, the weakly acidic reflux events, the time in which the esophagus was exposed to acid, so the percentage of acid exposure time, and also bolus exposure, and that talks about liquid volume going up and down the esophagus. So, you've got a good profile of activity of all types of reflux events there.

Likewise, with the 250 mg dose, we saw statistically significant results for a number of the reflux physiological parameters that we measured there. And, in fact, when we looked to the 50 mg dose, we didn't see any statistical significant results, but there definitely appear to be trends and possible numerical reductions in reflux events compared to placebo in the 50 mg dose group.

So, if we move on to Study 105 and that -- because in the Phase II program, where, as you know, we're looking at patients who are partial responders to PPI. We're looking to treat patients who have breakthrough symptoms with PPIs. We studied the interaction of 10059 with concomitant use of PPIs. And also to help us determine the dosing for Phase II, we also looked at the possible interaction with food. And, in fact, we did a three-way crossover in the same subjects in the three different states -- fasted, with food or with PPI.

And we found that neither food nor PPI significantly effected their plasma exposure following dosing with 10059. So, that sort of makes things easier moving forward into Phase II. And, yes, as we previously reported, we are planning to start Phase IIb in quarter four this year. Everything is in preparation for that at the moment. Phase IIb in GERD is going to comprise two studies.

We're going to look at the effects of 10059, first of all, as a monotherapy, in other words, not given with any other treatment. We're going to select patients who are known to be responders to PPIs, who are not on PPIs or other acid reducing therapy for the duration of the study. It's a multi-center study taking place in Europe. We're going to look at the effects of a single dose compared to placebo in controlling GERD symptoms in these patients. They have a baseline evaluation period, followed by a two-week drug administration period in which we evaluate GERD symptoms. So, we'll be looking at comparing the reporting of GERD symptoms in the active treatment period compared to baseline.

And in this study, in a subset of patients, we're actually going to again look further at the mechanism of action of the compound. We've looked at reflux events by means of resistance monitoring -- impedance monitoring the esophagus. We also want to look very specifically at esophageal sphincter function. So, in this study, as well as doing some more impedance monitoring looking at reflux events, we're actually going to look at esophageal sphincter function with pressure monitoring, which is called manometry. And that will take place in a subset of the patients -- of the 90 patients in this study to get further information. That study is due to report in the second half of next year.

The other study we're planning to do in GERD is a dose-range finding study in patients who are on PPIs, but still have breakthrough symptoms of GERD, so PPI partial responders. This study is going to take place in the United States and in Europe. Again, really, we're looking at symptom control in patients with GERD. So, two week baseline symptom evaluation period. And then, a full week treatment period. The effect on GERD symptoms will be compared for the different treatment groups with placebo. There'll be three active doses evaluated and one placebo group in this study. And, again, that is commencing in quarter four this year and is due to report as in second half of 2009.

And finally, the final part of the Phase IIb evaluation program is the other indication, of course, which is migraine prevention. As you know, we've got meaningful efficacy data in the migraine model last year. We're going to look at dose ranging, efficacy, tolerability. Again, three doses compared to placebo in a parallel group looking at the frequency and severity of migraine attacks

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in a 12-week treatment period compared to baseline. And that study is going to take place in the EU and is due to report in the second half of 2009.

So, that's the updates on the clinicals for the time being. I should like to hand over to Vincent to give you an update on the rest of our activities.

Vincent Mutel - Addex Pharmaceuticals - CEO

Thank you, Charlotte. So, as you can infer, we are quite pleased by the outcome of the Phase I study. It has changed our perception of the commercial value of its demand. And we hope very much that it's going to change the perception of the commercial value as well for our potential partner, who will be included in development of this molecule. So, 59 is moving ahead in its development as Charlotte said now in multiple Phase IIb trials.

At the same time, we are going to move 48621, which is another mGluR5 negative allosteric modulator, in L-DOPA induced dyskinesia in Parkinson's disease. You have seen in the press releases that we are talking about this indication as well for 59, but we'll come back on the rationale which is behind, because there is an emerging number of news about the use of an mGluR5 negative allosteric modulator for this indication and there's a clear interest from the pharma for the development of such drug into this indication.

63365 has moved, as you've seen, now toward actually co-development and as well as the mGluR2 PAM-- and thus we have two positive allosteric modulators that we have partner with Merck & J&J moving forward and that actually achieved new progress compared to the previous disclosure of our pipeline.

In terms of business activity and business development activity for the pipeline, we have, as you know, been engaging in partnership discussions for 59. It's quite extensive and very clearly the new results, in our opinion, on this molecule will, we hope, boost very much our discussions with potential partners.

We are having discussions, as you know, on the partnership of 71943. We indicated already in the past that if the conditions are interesting and satisfying, we will be considering partnership for this compound. There's a very large interest for this mechanism of action, because of the potential of such molecule in inflammatory pain in particular.

Regarding our pre-clinical discovery pipeline, we have also, as we have indicated, partnering discussions, which have been initiated on a number of these programs. In particular, we have added an A3 antagonist program for the treatment of glaucoma. The mGluR7 negative allosteric modulator program for, in particular, the post-traumatic stress and also depression is subject to discussions. The mGluR2 negative allosteric modulator as well. We are considering establishing partnership or co-development of these programs as soon as possible.

Let me spend some time on the rationale behind the use of mGluR5 negative allosteric modulator for L-DOPA induced dyskinesia. In fact, there have seen recent publications of results, in particular by Novartis, with their molecule which is called AFQ056.

Recently, after Parkinson's Disease in primates showing results with AFQ056, which are extremely encouraging, because their molecule shows a clear increase of efficacy when combined with L-DOPA to lowering the consideration that this molecule could be active to increase the efficacy of L-DOPA and as well was shown in the pain study to reduce dramatically the dyskinesia associated with the use of this product and of L-DOPA at the same time.

So, it's possible to consider that mGluR5 negative allosteric modulators actually will be used to prevent dyskinesia caused by L-DOPA as an add-on therapy, and might also be used as an L-DOPA sparing agent, which is a very important objective for the pharma and has raised then the interest of the overall pharma for the potential use of this mechanism of action in this indication.

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It is a very straight-forward development, as you know, and very accessible for Addex, at least the L-DOPA induced dyskinesia indication, which we are engaging and already on course for the development of 48621. The trials are short; very clearly shorter than symptom control in Parkinson's Disease. The end points are very clear. And we can, we have the means to and we can afford to do the development in Phase II or even Phase III. And last but not least, this type of approach can qualify for FDA fast-track status. So, we will very much explore the potential of 48621 into this indication, but we are also considering the potential use of 59 for the very same indication.

And I will finish on the near term clinical milestone. As you've seen, we have completed the Phase I quite successfully and reported today. The next milestone for the clinical development is the start of Phase IIb of ADX10059 in two indications -- the GERD symptom control and migraine prevention. And this is going to start in the fourth quarter of this year with reporting of the results on the second half of 2009.

At the same time, we will move forward 48621 in Phase I for completing the study, which had been started already with a formulation of the compound, which was the active pharmaceutical ingredient in capsule. So, we developed a new formulation for this molecule and we will complete now the Phase I study starting very soon. And we hope to be able on the back of this to move 48621 in Phase IIa in L-DOPA induced dyskinesia and Parkinson's Disease patients. And this is going to occur at the beginning of 2009.

And on this, I will open now the conference call for question and answer and wait for your questions.

QUESTIONS AND ANSWERS

Operator

Excuse me, this is the Chorus Call conference operator. We will now begin the question-and-answer session. (OPERATOR INSTRUCTIONS).

First question is from Philippa Gardner, Lehman Brothers. Please go ahead, madam.

Philippa Gardner - Lehman Brothers - Analyst

Hello, there. I have two questions, if I could. Firstly, this is probably for Vincent, just in terms of the partnering of 59. Now that obviously we've got an improved tolerability profile, do you think that -- is this going to be something that happens post all the data coming in the second half of '09? Or is this something that might happen sooner with a partner?

And then, maybe just a question for Charlotte as well. I just wanted to try and understand why in the GERD studies in the monotherapy and the PPI partial responders, why you've got different treatment durations with 59 in those? Thank you.

Vincent Mutel - Addex Pharmaceuticals - CEO

Okay. So, regarding the partnering strategy that we have, as you remember, we have announced that we would like to partner the molecule post-Phase IIb results. We believe that it is now starting to be probably more important to secure partnership for the development of this compound sooner than later due to the complexity to have an extent of the, let's say, during Phase IIb and launch and commercialization of the product.

Also, through some discussion we had with various partners -- potential partners, we expect to a certain extent, their need to be involved sooner rather than later in the development of the drug. Now, to tell you when this partnership is going to appear

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and when the deal will be signed, as we have said always in the past, we are working very much on that, but I cannot give you more guidelines and information about the timing for this.

Philippa Gardner - *Lehman Brothers - Analyst*

But you don't think it's contingent on getting the next sort of data in the second half of next year?

Vincent Mutel - *Addex Pharmaceuticals - CEO*

At least we don't work in this direction.

Philippa Gardner - *Lehman Brothers - Analyst*

Okay.

Charlotte Keywood - *Addex Pharmaceuticals - Chief Medical Officer*

Philippa, yes, in answer to your question about the differing lengths of dosing duration. In the monotherapy study, it's shorter than the add-on therapy study, because the add-on therapy study, you do have this background of PPI therapy.

In order for us to get an accurate evaluation of the drug effects or the add-on drug effects, we feel we need a four week treatment duration, so we can adequately distinguish whether the compound is having an effect. In the monotherapy study, the effects would be more immediately obvious, because there is no background treatment effect of the concomitant therapy. So, that's the difference in these studies. One is a different treatment duration.

Philippa Gardner - *Lehman Brothers - Analyst*

Okay. I thought it was something like that. I just wanted to check.

Charlotte Keywood - *Addex Pharmaceuticals - Chief Medical Officer*

Yes.

Philippa Gardner - *Lehman Brothers - Analyst*

All right. Thank you.

Chris Maggos - *Addex Pharmaceuticals - Head of IR & Communications*

Next question, please?

Operator

The next question is from Mr. Michael Aitkenhead, Piper Jaffray. Please go ahead, sir.

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Michael Aitkenhead - Piper Jaffray - Analyst

Good afternoon and congratulations on today's results. I just have a couple questions about the second part of study 104. Specifically, whether you saw any dose dependent side effects in that part of the study? And, secondly, I know you allude to efficacy data for the 125 and the 250 dose. Are we to reason to that the 250 dose was in fact more efficacious? Or do we not have sufficient information?

Charlotte Keyword - Addex Pharmaceuticals - Chief Medical Officer

No, I can tell you that -- so, the -- in fact, the answer to the first part of your question, we saw some minor adverse events, but we've previously seen with ADX10059, but the incidence is far lower than we saw with the API capsule, for example, in the repeat dose study with that. So, that again is re-supporting this good tolerability of the new formulation. And then, the second answer to your -- asked your second question is in fact 250, 125 -- 250 didn't have more efficacy than 125. So, we saw the dose dependency between the 50 and the 125 and then 250 mg didn't confer any additional efficacy over and above what we saw for the 125.

Michael Aitkenhead - Piper Jaffray - Analyst

Okay, so just following on to that then, can you tell us what the minor adverse events were? And what their incidence was?

Charlotte Keyword - Addex Pharmaceuticals - Chief Medical Officer

What I view -- I don't know if you're interested in the -- we have one person who had dizziness with 250mg. So, in the entire Phase I, those two Phase I studies, and then things like fatigue and headache and the usual kind of things you often get in a Phase I unit, to be honest with you as well.

Michael Aitkenhead - Piper Jaffray - Analyst

And then just very finally following on to that, can you tell us what dosage you're likely to take forward for the Phase IIb in either indication?

Charlotte Keyword - Addex Pharmaceuticals - Chief Medical Officer

Yes, so, I mean, I think, having got this very strong efficacy data around the 125 mg dose, what we want to do is treat -- the purpose of Phase IIb dose range finding is to look at the minimally effective dose. So, we're going to bracket the 125 mg dose and then also go down to 50 mg. So, we're going to explore doses in the range to 50 mg to 150 mg. There was some signal of possible effect in the 104 study of the 50 mg dose on reflux parameters. We want to see whether that is going to translate into any clinical benefit. So, we are looking in the range of 50 to 150 for the Phase IIb program.

Michael Aitkenhead - Piper Jaffray - Analyst

That's brilliant. Thank you.

Charlotte Keyword - Addex Pharmaceuticals - Chief Medical Officer

Okay.

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Operator

(OPERATOR INSTRUCTIONS).

Chris Maggos - *Addex Pharmaceuticals - Head of IR & Communications*

Operator, I think we can wrap up.

Operator

Yes, sir, there are no more questions at this time.

Chris Maggos - *Addex Pharmaceuticals - Head of IR & Communications*

Okay. Well, thanks very much for joining us today. Charlotte, Vincent and myself will be available for your questions if you think of anything else. We're at your disposition. We look forward to talking to you in the near future. Bye-bye.

Vincent Mutel - *Addex Pharmaceuticals - CEO*

Thank you. Bye.

Operator

Ladies and gentlemen, the conference call is now over and you may disconnect your telephones. Thank you very much for joining. Goodbye.

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