

# FINAL TRANSCRIPT

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## **ADXN.S - ADDEX PHARMACEUTICALS SA - ADX10061 Phase IIa Smoking Cessation Data - Conference Call**

**Event Date/Time: Oct. 01. 2007 / 11:00AM ET**

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## CORPORATE PARTICIPANTS

**Chris Maggos**

*Addex Pharmaceuticals - IR*

**Vincent Mutel**

*Addex Pharmaceuticals - CEO*

**Charlotte Keyword**

*Addex Pharmaceuticals - Chief Medical Officer*

## CONFERENCE CALL PARTICIPANTS

**Peter Welford**

*Lehman Brothers - Analyst*

**Tracy West**

*Jefferies & Co. - Analyst*

## PRESENTATION

**Operator**

Good morning and good afternoon. This is the Chorus Call conference operator. Welcome and thank you for joining the Addex ADX10061 smoking cessation data conference call.

As a reminder, all participants are in a listen-only mode and the conference is being recorded. After the presentation, there will be an opportunity for you to start -- to ask questions.

(OPERATOR INSTRUCTIONS)

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

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**Chris Maggos** - *Addex Pharmaceuticals - IR*

Hello, everyone. Thanks for taking the time to join us. During the call today, Vincent Mutel will provide you with some background about ADX10061 and our reasons for pursuing it.

Charlotte will then remind you of the protocol and reiterate what we know about the data. Then Vincent will briefly review the status of the rest of the pipeline and open the call to your questions. Vincent?

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**Vincent Mutel** - *Addex Pharmaceuticals - CEO*

Thank you, Chris. Good morning and good afternoon. So I will briefly summarize the overview on 61 and the reason why we have moved this compound forward. ADX10061 is a potent selective competitive dopamine D1 receptor antagonist, so it's not an allosteric modulator, which was discovered and developed by Novo Nordisk for schizophrenia. The compound shows activity in schizophrenia, but not better than the classical D2 receptor antagonists. And for this reason, it's development in this indication was terminated.

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CeNes took the molecule further and looked at its potential in sleep and, in particular, looking at its effect on sleep architecture and demonstrated an effect of the drug at a 10-milligram dose. It's interesting because this is [also] the choice of the dose that we made in the smoking cessation trial.

The rationale behind the use of this compound for this indication is -- was very strong. We have seen that the D1 receptors are involved in the cue-induced craving, which has been demonstrated in animals to be a very effective mechanism, and D1 antagonists were objectively seen in several animal models to decrease nicotine self-administration in various models.

We in-licensed ADX10061 from CeNes in 2002, so it's a compound that we have entered in our portfolio and we have done quite large development around this molecule. The compound had an excellent safety package and good tolerability]. That's what we got from Novo. And we spent time and effort to reposition it on smoking cessation, finally succeeding to have an IND for a smoking cessation trial, which is going to be explained to you by Charlotte.

So, Charlotte, if you want to take over.

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**Charlotte Keywood** - *Addex Pharmaceuticals - Chief Medical Officer*

Okay, yes, thank you very much, Vincent. Just to reiterate the study design, we used a gold-standard study design for studying smoking cessation. It was a double-blind, placebo-controlled study, seven weeks treatment duration, comparing the dose of ADX10061, 10 milligrams, four times daily, with placebo in just under 150 patients.

As I say, we used the same sort of study design and the same primary end point that's been used for evaluating the efficacy of bupropion and varenicline, both of which, as you know, are licensed for smoking cessation.

The primary efficacy endpoint was continuous smoking abstinence for four weeks, starting from the beginning of week four. We used this same primary endpoint as has been used in other studies, so that we could have some validation of our findings in comparison with other drugs that are on the market and known to be efficacious.

The study was conducted at key opinion leader sites in the United States and the investigators that took part in these studies have all previously been involved in the development of bupropion, varenicline, and rimonabant, so they were highly experienced investigational centers.

I think Vincent alluded to the choice of the dose. The 10 milligrams four times daily dose really was chosen based upon previous clinical data where we had demonstrated that 10 milligrams had a pharmacological effect in sleep architecture, but also based on plasma concentrations, given optimum dopamine receptor occupancy, and that was based on previous studies using positron emission tomography. So we feel we had a clinically relevant dose in this study.

Going now onto the efficacy outcome, we saw that for the primary endpoint and also major secondary endpoints there was no separation of active drug activity from placebo, either numerically or statistically. So that the portion of patients with continuous abstinence over four weeks was not greater in the active treatment group than in the placebo group. And, likewise, for a number of secondary efficacy parameters that we have just analyzed, there is no separation of active drug from placebo.

So, to that end, we are not going to go forward any further with smoking cessation with this compound. I'll now hand back now to Vincent Mutel to give you a further update.

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**Vincent Mutel** - *Addex Pharmaceuticals* - CEO

Thanks, Charlotte. So I think it's quite clear regarding the potential of this product in smoking cessation. 61 demonstrates efficacy on sleep architecture, which is something we are keeping in mind for potential further development. We are considering other indications for this compound. We will very rapidly come to a conclusion regarding its development.

I want again to reiterate that ADX10061 is a classical orthosteric competitive molecule which is not belonging to our platform of development, which is focused on allosteric modulators. We strongly believe that the allosteric modulation is a very good proposition and we have in fact moved in our pipeline a substantial amount of compounds which are allosteric modulators, including the most advanced drug candidate, ADX10059, which is a negative allosteric modulator of the mGluR5 receptor.

This compound demonstrates clinical efficacy in two separate Phase III trials in gastroesophageal reflux disease and in migraine. We are currently moving this product according to our development into now Phase IIb, and there's a good progress made with 59 so far.

The second compound that we have moved out of the allosteric modulation platform is ADX48621. This is a compound which is also an mGluR5 negative allosteric modulator, but for larger indications, like depression and anxiety. The rest of the portfolio we have is comprising a number of allosteric modulators for various indications -- schizophrenia, anxiety, spasticity, contraception, Diabetes Type Two. We believe that those products will be first in class and very promising molecules.

I would like to draw your attention on some progress we made recently, ADX63365, it is an mGluR5 positive allosteric modulator that we have moved into schizophrenia which is entering now in Phase zero and will be in Phase I testing in 2008 and ADX71441, which is a positive allosteric modulator of the GABAB receptor, a very interesting mechanism of action for the treatment of spasticity, gastroesophageal reflux disease and anxiety. Again, that's clinically validated for a certain number of these indications and a completely differential mechanism of action with an allosteric modulation here.

Our project with J&J is moving quite well. The mGluR2 positive allosteric modulator has been moving very rapidly towards the qualification in Phase I. I think recently people have seen the interest of the mGluR2 receptor activation through the publication by Eli Lilly of a Nature Medicine paper demonstrating activity in schizophrenia.

This is opening up even more possibilities for a compound which is on a validated target for anxiety, which then is now also validated for the second indication, schizophrenia. So we are extremely confident in the potential of the allosteric modulation platform, which is leading me now to the clinical milestone that we will have for the time to come.

So 59 is going to complete the Phase IIa trial in anxiety by the end of this year. It's perfectly on time. We have good progress into the development of this molecule. We will start the Phase IIb trial in gastroesophageal reflux disease and in migraine prevention by mid-2008, in accordance to the timelines that we set up before.

The compound has been through galenic development and we have been successful. We have been able to complete the formulation of the molecule, and so we are going now to go forward with the development of the compound.

ADX48621 will enter in the second part of the Phase I, also after having galenic formulation development. And, finally, the two molecules I was talking about, the 63365 and 71441, will both enter in Phase I programs in 2008-2009.

So on that note I would like to thank you for your attention and open the conference for questions.

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## QUESTIONS AND ANSWERS

### Operator

(OPERATOR INSTRUCTIONS)

The first question is from Mr. Peter Welford from Lehman Brothers. Please go ahead, sir.

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### Peter Welford - Lehman Brothers - Analyst

Hello, just a couple of questions. Firstly, can you give us -- on the 59, I know you said the galenic formulation has been completed. Could you possibly give us a guideline on when we may see any data that you may have I guess comparing that and the potential dosing and the sort of PK profile of that to the prior formulation?

Then, secondly, does the 61 decision to discontinue development, can you give us some idea about what costs may have been factored in for, I guess, putting together a package for partnering or other things that may well have gone on over the next sort of few months or so, and so potentially what impact this could have, if any, on your sort of financial assumptions.

And I guess the only other question I have, which you may not be able to answer, is can you give us any comments on partnering discussions for the early stage pipeline and perhaps which ones you see as being more important to potentially partner in the near term. Thank you.

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### Vincent Mutel - Addex Pharmaceuticals - CEO

Yes, thanks, Peter. So regarding 59, as I said, we have, as we announced, moved forward in the galenic formulation of the molecule. We have obtained a number of tablet forms, which are interesting and moving forward. We will complete PK experiments in dogs very soon to see which one would be the most promising one, and then move them in a new Phase I trial to explore the potential PK profile and adverse events that we can observe with this new formulation.

So in terms of timeline, I think we are more or less in the time we said or we announced before. I do expect that we will complete this activity in terms of PK dogs quite happily, quite soon, and move to the Phase I as soon as we will have the product available for the testing, I think around the end of this year.

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### Peter Welford - Lehman Brothers - Analyst

Okay.

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### Vincent Mutel - Addex Pharmaceuticals - CEO

Regarding 61 decision for partnership and costs incurred, we have -- it's a very good question, thanks that you asked for that. We have been spending some money to improve the synthesis and also to re-patent, as you know, the compound. We wanted to have a better position regarding the patenting of 61. This activity we are going certainly to complete what we started, but the cost is very, very small for this.

We didn't want to do more than that. We put the formulation on hold, as well, because we wanted to have confirmation of the activity in smoking cessation because, as you remember, we wanted to have a formulation which is suitable for this indication.

Now we have to change our view. There are, as I said, potential other indications for this compound. We have seen the effect on sleep. I should stress that in sleep there is an interesting turn to the story, as we have a use pattern on sleep for this compound,

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which is quite substantial and which is very, very good, very solid, so that could be maybe a way to move forward and to look for a partner for development.

I think we are not going to invest a lot in this direction anymore, or at least to minimize the investment, because I think what we have cooking into the pipeline of the Company is certainly fine for us to move forward.

And now regarding your question about the partnering discussion, this has been clear. I think we always said that and I can reiterate with you the strategy around partnership. We have considered a number of projects to partner already, as soon as possible, at the stage they are. And this includes ADX63365 for schizophrenia.

It includes also the GPCR PAM for Parkinson's. We are discussing actively with potential partners for this program, and as you can believe we are having already some activity around that. It's a story which is lasting for a year, at least.

59 is an interesting situation, because we have been announcing that we will partner this molecule post Phase II. This doesn't preclude us to talk to people, which we have done, and I think we have opened more and more the book about this component, because I think it's the right time also to check the water around the interest of this [product], molecule, but also the development pathway that the pharma would consider for it. So we have also business development activity ongoing around 59, as you would expect.

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**Peter Welford** - *Lehman Brothers - Analyst*

Thank you very much.

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**Vincent Mutel** - *Addex Pharmaceuticals - CEO*

Thank you for your question.

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**Operator**

The next question is from Mrs. [Tracy West] from Jefferies. Please go ahead, madam.

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**Tracy West** - *Jefferies & Co. - Analyst*

Hi there, thank you. I just wanted to ask, and you've already talked about this a little bit, and can you tell us a bit more with regards to 159, what's actually involved once you have selected your formulation between sort of that selection and starting the Phase IIb, just to get a little bit of clarity on what actually you have to do in terms of clinical studies and then animal work.

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**Vincent Mutel** - *Addex Pharmaceuticals - CEO*

So, Charlotte, would you like to take this one?

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**Charlotte Keyword** - *Addex Pharmaceuticals - Chief Medical Officer*

Yes, yes, I can do that. So what we have to do is, from a regulation perspective, once we've selected a promising formulation, we have to do a comparison with the previous formulation, which we will do, as both a single dose, and then we will go on to do a repeat dose, pharmacokinetic profile with the preferred formulation and we're also planning to do some additional drug interaction work before going on into Phase IIb.

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Once we have those Phase I data we are -- at the same time, actually, we're in parallel preparing regulatory filings for both the EU and the United States so that we can conduct our further Phase IIb development in both continents. We see the importance in opening an IND with the compound.

So that's all going to take place between now and the middle of -- well, it is all taking place and ongoing now between now and the middle of next year.

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**Tracy West** - *Jefferies & Co. - Analyst*

Okay, and you believe that you'll be in that sort of Phase I stage around the end of the year. That would be --?

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**Charlotte Keyword** - *Addex Pharmaceuticals - Chief Medical Officer*

That's correct.

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**Tracy West** - *Jefferies & Co. - Analyst*

And my other question was just sort of a bit more on licensing. And I was wondering whether you've explored any opportunities to do any licensing deals on a sort of platform basis. Obviously you've got a great technology platform and I wondered whether you were looking at sort of generating any value from that by setting up some early-stage collaborations with anyone and trying to generate some revenue from that opportunity.

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**Vincent Mutel** - *Addex Pharmaceuticals - CEO*

Well, as usual, it's a question that has to be asked because of the nature of our platform. What can I say? We have discussion on specific programs, very clearly. We have been entertaining some discussion with people who have specific interests for specific receptors, families of receptor that have been the objective discussion already for four years, because people understood the value of the technology and there are some GPCR, but also outside of the GPCR field, there have been recurrent discussions with companies about that.

I think it's very fashionable today, the type of [broad] deal that you are talking about. What can I say? We have -- our door is open, and Addex as a company, which is having very good relationships with the pharma. We have been systematically talking to them, opening the doors and continue discussion since the beginning and this is something which is, as you can believe, leading to questions of this nature.

But we have not really -- I mean, we have priorities regarding -- and proactively pursuing some outlicensing, in particular, for the two projects I was talking about, and 59, as you can believe. This is taking a lot of time. It's a lot of activity, as you can imagine. And we are continuing to have discussion about other parts of our portfolio.

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**Tracy West** - *Jefferies & Co. - Analyst*

Okay, that's great. Thank you.

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**Vincent Mutel** - *Addex Pharmaceuticals - CEO*

You're welcome.

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**Operator**

(OPERATOR INSTRUCTIONS). Mrs. Keywood, gentlemen, there are no more questions at the moment.

**Chris Maggos - Addex Pharmaceuticals - IR**

Okay, everyone, well thanks for listening in and we look forward to talking to you when we have better news.

**Vincent Mutel - Addex Pharmaceuticals - CEO**

Thank you, goodbye.

**Chris Maggos - Addex Pharmaceuticals - IR**

Bye-bye.

**Charlotte Keywood - Addex Pharmaceuticals - Chief Medical Officer**

Bye-bye.

**Operator**

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

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