AVANIR

Moderator: Brenna Mullen
November 1, 2010
7:15 a.m. CT

Operator: Good morning, my name is Teresa and I will be your conference operator today. At this time, I would like to welcome everyone to the Avanir Pharmaceutical NUEDEXTA™ FDA approval conference call. All lines have been placed on mute to prevent any background noise.

After the speakers' remarks, there will be a question and answer session. If you would like to ask a question at that time, simply press star then the number one your telephone keypad. If you would like to withdraw your question, press the pound key.

Thank you. Ms. Mullen, you may begin your conference.

Brenna Mullen: Thank you and good morning, everyone. Joining me on today's conference call is Keith Katkin, President and Chief Executive Officer, Dr. Randall Kaye, Chief Medical Officer and Christine Ocampo, Vice President of Finance.

I will begin the call by addressing our forward-looking statement. Following this, I'll turn the call over to Keith Katkin. As a reminder the statements made on this call represent our judgment as of today, November 1, 2010.

Our remarks and responses to questions during this conference call may constitute forward-looking statements, including plans, expectations and financial projections. All of which involve certain assumptions, risks and uncertainties that are beyond our control and could cause actual results to differ materially from the expected results expressed in our forward-looking statements.

These forward-looking statements include but are not limited to the anticipated timing of the commercial launch of NUEDEXTA, Avanir's ability to successfully market and sell NUEDEXTA in the United States, the safety and efficacy of NUEDEXTA and our financial ability to support the initial launch of NUEDEXTA.

We encourage you to take the time to review our recent filings with the Securities and Exchange Commission, which present these matters in more detail. As well as related with factors that could cause actual results to differ from the results anticipated by our forward-looking statements.

Avanir disclaims any intent to update any forward-looking statements made during this call. Now I will turn the call over to Keith Katkin to discuss the recent approval of NUEDEXTA for the treatment of pseudobulbar affect or PBA.

Keith Katkin: Thank you, Brenna. Good morning, everyone, thank you for joining us on our conference call to discuss the FDA approval of NUEDEXTA. We are absolutely thrilled that the FDA has approved NUEDEXTA as the first and only therapy to treat patients with PBA.

Friday marked a significant milestone for the many neurologic patients in the U.S. suffering from debilitating episodes of PBA. The last four years have been a pursuit of passion by the Avanir team with one goal, to make a therapy available for patients suffering from the debilitating condition of PBA.

As many of you are aware, PBA occurs secondary to a variety of neurologic conditions such as multiple sclerosis, ALS, stroke, traumatic brain injury and certain other neurologic conditions. The hallmark symptoms are involuntary, sudden and frequent episodes of laughing and/or crying.

PBA episodes may be out of proportion or even contrary to the patient's inner emotional state. Friday for the first time, these patients have a treatment option, NUEDEXTA. Laughing and crying are such common expressions that many of us take them for granted.

However, imagine if you had to live your life knowing that you're going to have four to five unexpected sudden episodes of laughing or crying lasting a few minutes each day. How would it impact your ability to function? How would it impact your ability to maintain social relationships? How would it impact your relationships with caregivers and loved ones?

Friday's approval of NUEDEXTA means something different for everyone affected by PBA. For me, it's a potential opportunity for a grandparent to spend time with their grandchildren. Last year I learned that one of our friend's mother's has multiple sclerosis and PBA.

The PBA episodes made it so the grandmother no longer feels that she can spend much time with her grandchildren because she has sudden and frequent PBA episodes. These crying episodes are disturbing and scary to her small grandchildren and have made it so that she cannot be around her grandchildren.

Until now, nothing was proved to treat PBA but now there is hope for these patients. NUEDEXTA is the first and only therapy that is FDA approved for the treatment of PBA. NUEDEXTA's a novel treatment option proven in clinical trials to significantly reduce the frequency and severity of PBA episodes.

Over the course of 12 weeks of treatment, patients taking NUEDEXTA experienced a 49 percent greater reduction in the number of PBA episodes than patients taking placebo. And over 1/2 of patients taking NUEDEXTA achieved symptom remissions as defined as no episodes at the end of the study.

We are very excited to make this first in class therapy available to patients living with PBA. With that, I would now like to turn the call over to Dr. Randall Kaye, who will review the labeling and important safety information for our newly approved medication, NUEDEXTA. Randall?

Randall Kaye: Thanks, Keith, good morning, everyone. Like you, I'm very excited with this news. I would like to start off by thanking all of the patients and investigators who have participated in our study as well as our dedicated employees, who

invested over 10 years of research and development to gain the approval of NUEDEXTA.

Over 1600 patients have been involved in Avanir sponsored clinical trials. These patients are truly the heroes of clinical research. They have opted to participate in research even when there is no guarantee that their efforts will benefit them directly.

Because of their efforts, we are now able to make NUEDEXTA available to patients living with PBA across the United States. In addition, our thanks go out to the many dedicated professionals at the FDA who worked so diligently over the many years in this program with us and spent untold hours after our NDA and complete response submissions to ensure that they would meet this PDUFA date.

In reviewing our prescribing information, we are pleased with the outcome. NUEDEXTA is indicated for the treatment of pseudobulbar affect or PBA. PBA occurs secondary to a variety of otherwise unrelated neurologic conditions and it is characterized by involuntary, sudden and frequent episodes of laughing and/or crying.

PBA episodes typically occur out of proportion or in congruent to the underlying emotional state. Studies to support the effectiveness of NUEDEXTA were performed in patients with amyotrophic lateral sclerosis or ALS and multiple sclerosis or MS.

NUEDEXTA has not been shown to be safe and effective in other types of emotional ability that can commonly occur, for example, in Alzheimer's disease and other dementias. The indication and usage section allows any patient with PBA to be a candidate for NUEDEXTA regardless of their underlying neurologic disease or injury.

In our final discussions, FDA did not require a REMS program, did not require mandatory safety monitoring except in patients with underlying cardiac risk factors and did not require a boxed warning.

We believe the label clearly communicates areas of risk that physicians need to consider before prescribing NUEDEXTA. Safety considerations such as drug-drug interactions and cardiovascular risk factors are clearly described, well characterized and we believe are manageable.

In summary we have a product label which enables access for any patient with PBA and helps physicians understand important safety information that needs to be considered prior to initiation of therapy. I would encourage everyone to visit the NUEDEXTA.com web site to see the full prescribing information.

Thanks for your and attention and with that I'd like to turn the call back to Keith.

Keith Katkin: Thanks, Randall. Before we conclude our prepared remarks, I would like to briefly discuss the next phase for Avanir, the commercialization of NUEDEXTA. Just as clinical and regulatory teams have been working hard to deliver results, so has our commercial team.

We have been laying the foundation for what we expect to be a successful launch of NUEDEXTA in the first quarter of 2011. We have been very busy recruiting to build our specialty sales force and this morning have started to reach out to the approximately 75 candidates that previously accepted conditional offers.

In addition, with approval in hand we are now moving forward with our plans for product packaging, distribution and marketing programs to increase awareness and receptivity in our targeted physician universe ahead of expected Q1 launch.

For example, later this week we will unveil the NUEDEXTA product booth at two important medical conferences, the American Academy of Physical Medicine and Rehabilitation meeting in Seattle as well as the American Society of Consultant Pharmacists meeting in Orlando.

In addition to our efforts with health care providers, we have been working closely with the various patient advocacy groups that represent populations at

risk of PBA to educate their clients and increase recognition, diagnosis and ultimately treatment of PBA.

We plan to be ready to launch NUEDEXTA with a fully functional commercial organization in the first calendar quarter of 2011. And are working hard to ensure that our commercial efforts build off of the great clinical and regulatory results we have delivered thus far.

As of September 30, 2010, our fiscal year end, total cash, cash equivalents and restricted investments were $39.4 million, which do not include proceeds from warrants exercised after the fiscal yearend totaling $3.9 million. We are very pleased that our current cash position provides us enough cash to fund the initial launch of NUEDEXTA.

In closing, I would like to take this opportunity to thank everyone that has been involved in getting NUEDEXTA approved by the FDA - patients, doctors, caregivers, investors and especially the Avanir employees and their families. Without their dedication, we would not be able to celebrate this tremendous accomplishment.

With that operator, I would now like to open up the call for questions.

Operator: At this time if you would like to ask a question, press star then the number one on your telephone keypad. Again that is star then the number one. We will pause for just a moment to compile the Q&A roster. And your first question comes from the line of Ritu Baral.

Ritu Baral: Good morning, guys, congratulations.

Keith Katkin: Thanks, Ritu.

Ritu Baral: Long – it's been a long path but this is great news for all of us and it's been a great strategy. Now asking about strategies going forward specifically Europe, do you plan on pursuing talks with the EMEA to sort of get the trials that you might need there in order. And also status of any partnership talks that you might have for a European partner.

Keith Katkin: Hi, Ritu, it's Keith, thanks very much for joining us this morning. Certainly as far as ex-U.S. plans go, that's an important strategic focus for us for the upcoming year. Our first part of that plan is to seek advice either with the EMEA or with the consultants from the EMEA so we can understand exactly where our clinical program is relative to what's needed to be filed there.

Certainly it is possible that our existing studies could be sufficient for filing but as you know, there's a lot of additional requirements in Europe, including pediatric requirements. So a very important focus for us in this upcoming year and as it relates to business development ex-U.S., certainly before approval there were a number of companies that were contacting us interested in as we've said before both U.S. and ex-U.S. partnerships.

So it's our expectation that given the great news on Friday, we would just expect to see that interest increase.

Ritu Baral: Got it. And since you guys run such a lean shop right now, do you expect to hire a senior level business development person to help you manage these inquiries and others?

Keith Katkin: We actually do have a dedicated and fantastic Vice President of Business Development, his name is Greg Flesher. And he's been with us here since the beginning. He's a scientist by background and also has commercial experience as well.

And he successfully led the sale of Fazaclo back about I guess it's three years ago now. Led the successful out licensing of our Xenerex antibody platforms and has really established himself in the business development community. So we have the utmost confidence in him and know that he will be able to deliver on our business development objectives for the upcoming year.

Ritu Baral: Great. Last question and then I'll jump back in the queue. What sort of marketing initiatives have you already pulled the trigger on? You did mention previously that you were doing pricing surveys. Do you have the price at this point or have you modified this sort of price range that you were thinking of? And could you give us a little more detail about what that pilot sales or pilot marketing force has been up to?

Keith Katkin: Yes, absolutely, so a number of questions embedded in that one, simple question. First I think in regards to pricing, obviously we are extraordinarily pleased with the package insert that we received from the FDA. And we think that's right in line with our expectations.

So we previously said that we expect the price of NUEDEXTA to be somewhere between $3,000 and $5,000 per year. We continue to believe that that is where we're going to price it. Over the next month to month and a half, we're going to refine our market research and our estimates and plan on putting out our final price here, probably late in the fourth quarter, so late November or maybe sometime mid-December.

The other question that you had, which was in regards to our – or what we like to call our advanced sales team or our A team, I'm not sure if everyone is aware but we did hire seven sales professionals about two months ago to start to educate health care practitioners on PBA.

And we did this in expectation of FDA approval. And the goal of that team was really to understand and be able to help educate the other 68 professionals that would be joining them on the sales force so we can have an even more effective product launch.

And what they have been finding is as we expect a high level of interest from clinicians in treating PBA. And we look forward to using the information and the market intelligence that they've gathered to ensure that when we have our full commercial launch in the first quarter of next year that we're able to absolutely hit the ground running, and demonstrate commercial success much like we've demonstrated clinical and regulatory success.

Ritu Baral: So what have they told you so far?

Keith Katkin: They, as I mentioned, the doctors as we have said are very aware of PBA, some of them refer to it by different names based on the clinical practice. But these uncontrolled episodes of laughing or crying secondary to neurologic disease or injury is something that they are all familiar with. They do not

believe that current therapies are very effective and that they are very interested in identifying a new therapeutic option for these patients.

Ritu Baral: Great, thanks, I'll hop back in the queue, congratulations again.

Keith Katkin: Thanks, Ritu.

Operator: And your next question comes from the line of Carol Werther.

Carol Werther: Thank you, congratulations. I have a few questions. My first is do you have an estimate for how much the launch is going to cost?

Randall Kaye: Yes, Carol, on our year end and fourth quarter earnings call, which will be sometime in late November or early December, we're going to put out all of our projections for our upcoming fiscal year. So we'll comment on that spend here I guess in just about a month.

Carol Werther: OK, do you think it's a drawback that there is not any pain data in the label?

Keith Katkin: No, not at all and actually we did not have any expectation that there would be pain data in the label. Our expectation all along was that the label would be focused on NUEDEXTA for the treatment of patients with PBA.

And there's such a tremendous market opportunity in PBA in the U.S. that I think we'll have plenty of time to focus on the pain indication and we'll talk about our strategic plans for what we plan on doing with pain in the future. But right now with the fantastic package insert that we received from the FDA, it really gives us everything that we need to be able to successfully commercialize NUEDEXTA for the treatment of PBA.

Carol Werther: And then do you think there's any liability since you have other publications in PBA with higher dosing that docs might want to try say even going up to a third pill a day?

Keith Katkin: I don't think so. The prescribing instructions clearly indicate that no more than two pills should be given per day. And we will certainly actively promote that. At the end of the day, ultimate prescribing decisions are at the discretion of the physician.

But given the – what we saw with the 20/10 dose in our clinical studies and the significant relief that these patients experienced both in terms of reduction in episodes, remission as well as a reduction in CNS Lability score, I think that they'll be well suited with the approved 20/10 dose.

Carol Werther: OK, thank you.

Keith Katkin: Thanks, Carol.

Operator: And your next question comes from the line of Mark Augustine.

Mark Augustine: Thank you, congratulations, Keith and team. I know that Randall touched on this, this label looks to be the broadest possible label. And while the MS and ALS populations are mentioned by name, I was hoping you could talk a bit about these additional on label populations and the implications for your detailing and marketing plans. Thank you.

Keith Katkin: Yes, thanks, Mark, great to hear from you. I should start out by saying that the label is in line with our expectations. And as we've said for a number of years, our in depth discussions with the FDA were that if we were able to study and demonstrate efficacy in two populations, here ALS and MS that we should qualify for a broad label.

So we're very pleased that the label shows that NUEDEXTA can be used for any patient suffering from PBA irrespective of their underlying neurologic disorder. So in terms of the patient populations, certainly ALS and MS patients are the most well known and well documented patients that have PBA as a co-morbid condition.

But what's not very well known is that when you look at some of the other populations, PBA is very prevalent in other populations. So for example in stroke, the National Stroke Association about two weeks ago put out a press release based on a survey that they did, and I'd encourage everyone to go to the National Stroke Association's Web site to look at that press release.

But it shows that PBA is highly prevalent in the stroke population and also that it's very impactful and has a serious burden for those patients. And we're working on similar programs with the other advocacy groups.

So beyond the stroke population, obviously the traumatic brain injury population is another one, which is well known to suffer from PBA as a co-morbidity. And certainly with all of our soldiers coming back, that's something that we want to be focused on and make sure that any potential relief that we can provide for those soldiers and other people suffering from traumatic brain injury can benefit from NUEDEXTA.

And beyond that if you look at the literature, there's certainly a number of other populations that suffer from PBA. And our goal is to ensure that clinicians make the correct diagnosis of PBA and that irrespective of underlying neurologic disease or injury that they are aware that there is now the first and only approved FDA treatment for PBA.

Mark Augustine: Thank you, Keith.

Keith Katkin: Thanks, Mark.

Operator: Once again if you would like to ask a question, press star then the number one on your telephone keypad. And your next question comes from the line of Matt Duffy.

Matt Duffy: Hey, good morning, thanks and congratulations. I just wondered if you could talk a little bit more about the specific physicians that your 75 reps are going to focus on at launch. And how many PBA patients you estimate that those physicians covered by your 75 reps actually treat.

Keith Katkin: Great, thanks, Matt. So what we are going to do with our sales force is at launch we're going to cast a very wide net. And we're going to give each of our sales representatives approximately a target list of 200 physicians, so about 15,000 physicians that we'll cover throughout the U.S.

And the way that we develop that target list of physicians was by using products that are typically used to treat the underlying conditions. So for

example, ALS you've got Rilutek, for multiple sclerosis you obviously have all of your interferons, for stroke you've got things like Plavix and Aggrenox. And then for dementia patients you have things like Aricept and Memantine.

So we believe that those prescriptions are a proxy for the doctors that are seeing the highest number of patients with these neurologic conditions. So if we go to those doctors that are seeing the highest number of patients, then our expectation is that they will have the highest number of patients that are suffering from PBA as well.

So if you look across the physician universe, that means that we're primarily focused on a neurologist, geriatric psychiatrist, geriatricians and then a physician class called physician PM&R and that's physical medicine and rehabilitation specialists. And those are the ones that typically work with stroke patients and traumatic brain injury patients after the acute injury.

And what we've seen so far from the advanced sales team that's been out there for about two months is that our targeting is good and that casting the wide net is the right approach. What the teams will do is they will actually reduce that list of about 200, somewhere between 125 and 150.

And then we plan on demonstrating commercial success and hopefully we'll grow the sales team sometime after launch from 75 to 100 or even more individuals. And that should give us the ability to – with 75 representatives target a majority of the patients in the U.S. that suffer from PBA.

Matt Duffy: OK, very good. Could you also talk a little bit about distribution on a couple levels? One, do you intend to sample the product? And number two, will you go through specialty pharmacy or sort of more broader retail?

Keith Katkin: As it relates to sampling, absolutely, we have an approved sample bottle, which will contain 13 capsules. And that was right in line with our dose titration that's in our package insert. That'll essentially give patients 10 days worth of therapy, so one pill a day for the first seven days and then three days of two pills each. And that should give them enough time to fill their prescription.

In regards to specialty distribution, typically in order to move to a specialty distribution channel, your price needs to be north of roughly $600 per month or about $7,200 per year. And given that we are expecting to price NUEDEXTA between $3,000 and $5,000 a year then that's not a price that's high enough to justify using specialty distribution.

And we think that's the right approach. There's so many patients in the U.S. that suffer from PBA. And they're spread out all throughout the U.S. that we think your traditional retail pharmacy approach is the right approach for NUEDEXTA.

Matt Duffy: OK, very good, thanks and congratulations.

Keith Katkin: Thanks very much.

Operator: Once again if you would like to ask a question, press star then the number one on your telephone keypad. And you have a follow up question from Ritu Baral.

Ritu Baral: Hi guys, thanks for taking my follow up. Can you comment on why the 20/10 dose was the only dose approved? And do you plan on pursuing the 30/10 dose at a future time? Do you think that it would add to the market opportunity?

Keith Katkin: Well we're certainly pleased Ritu, that NUEDEXTA is the first and only approved FDA treatment for PBA. And as a reminder, in the Phase III clinical STAR trial both doses achieved a primary efficacy endpoint of reduction of PBA episodes and also the first secondary endpoint, which was the CNS Lability Scale, a reduction in the CNS Lability Scale.

We do continue to believe the 30/10 dose does offer an incremental benefit. But I think you'll agree that when you receive a package insert that looks like the one that we received from the FDA there, you go ahead and you run with it, which is exactly what we did.

So we're going to evaluate our next steps in the program. It is certainly conceivable that we could file an SNDA and pursue the 30/10 dose. But we're

going to go back through all of the clinical information and see if we can put together a very compelling case for the 30/10, which we do think that we can.

But from a positioning and a lifecycle strategy, it actually – this 20/10 only approval gives us the greatest positioning. And what I mean by that is we found in our market research that doctors had a difficult time distinguishing between the benefits of the 20/10 and the 30/10. And they actually found it confusing and said they were going to start with a 20/10 dose only.

So with the approved package insert and with the 20/10 dose, we can really focus doctors on the appropriate diagnosis of PBA and then focus them on treatment with the one approved dose. And as we go back through our data and if we can build in our mind a compelling enough story for the 30/10, that would be a really nice lifecycle management component with the 30/10 being added to the label maybe 12 months out or so, which would do two things.

It'd give our sales force something new to talk about. And also would be a package insert modification, which would further increase our Hatch-Waxman activity.

Ritu Baral: OK, was there anything in the safety or tolerability profile between the two doses that FDA noted or scrutinized that sort of separated the two as far as review timelines or opinions?

Randall Kaye: Hi, Ritu, it's Randall. From a med reg standpoint, the 20/10 was the minimally effective dose. Both the 20/10 and the 30/10 hit the primary analysis, the primary endpoint with a very similar magnitude of effect.

The adverse event profile was a little bit higher in dizziness and I think that was the primary reason for the agency to focus on the minimally effective dose of the 20/10. But as Keith said, it gives us the option still of going back and having further discussions with FDA but certainly no specific unusual adverse event that was noted in the higher dose group.

Ritu Baral: Great, thanks, guys.

Operator: And your next question comes from the line of Carol Werther.

Carol Werther: Thanks for taking my follow up. So without the 30/10, you don't think that'll be disadvantaged. But with the 20/10 do – how will we – how will the doctors know to keep the patient on the drug? Will the caretakers keep a log or how do you go about that?

Keith Katkin: In terms of – could you restate the question there, Carol?

Carol Werther: I'm sorry. I was trying to figure out, so you start the patient on the sample dose. How does the doctor decide that the patient is responding and should stay on dose? Is there a time period that patients should be treated and then make a decision whether or not they're responding.

Randall Kaye: So Carol, it's Randall again. So what we've seen in our clinical trials is the response to therapy is readily observable. In some of our analyses we've seen that the – there's statistically significant and clinically meaningful improvement within the first week of dosing.

After that there is incremental benefit as patients go into the BID dosing. So we know that with a target being remission, 50 percent of patients had complete remission by the end of the study. And we know that – and we also know that by the end of the study, nearly – there was nearly 90 percent treatment effect or a 90 percent reduction overall at episode counts.

So it's going to come down to an individual assessment between the physician and a patient to determine if the patient has reached their target, whether that be complete remission or a substantial decrease in either the frequency or severity of the episodes.

Carol Werther: Thank you.

Operator: And there are no further questions at this time.

Keith Katkin: Great, well thank you, everyone for joining us. It certainly is a great day for patients suffering from PBA. We look forward to keeping you updated on our progress, including the planned commercial launch in the first quarter of 2011.

And we'll talk to you during our fourth quarter and year end conference call late in November or early December. Thanks very much.

Operator: And that concludes today's conference call. You may now disconnect.

END