

**Transcript****Seasonal Influenza VLP Vaccine Phase II trial Conference Call - Novavax, Inc. []**

12/11/2008 11:00 (ET)

Operator: Good morning, ladies and gentlemen, and welcome to the Novavax Seasonal Influenza Top Line Results for its Phase IIa Study Conference Call. My name is Jonathan and I will be your coordinator for today.

At this time, all participants are in a listen-only mode. We will be facilitating a question-and-answer session towards the end of today's conference. [Operator Instructions]

Novavax, please proceed with your call.

**Tricia J. Richardson, Senior Manager, Investor Relations**

On today's call will be Dr. Rahul Singhvi, President and Chief Executive Officer; and Penny Heaton, Vice President of Clinical Development and Chief Medical Officer; other members of the senior management team are also available to answer questions.

We remind you that during this call, management will make forward-looking statements within the meaning of the Private Securities Litigation Reform Act, which involves risks and uncertainties inherent in our business. Actual results may differ materially from our expectations, and you should consider all of the cautionary statements made in our SEC filings and in this morning's press release.

This includes risks related to product development, clinical trials and results from clinical trials, and the company's ability to obtain adequate financing. For a complete statement of these risks, please see our SEC filings.

This conference call will be available for replay on the Novavax's website after the conclusion of this call.

Dr. Singhvi, please proceed with the call.

**Rahul Singhvi, President and Chief Executive Officer**

Thank you, Tricia, and good morning everyone. Welcome to the Novavax conference call on the top line results for our seasonal influenza Phase II study in healthy adults. This is a second VLP vaccine candidate this year for which we are reporting data from a Phase II trial.

We are very excited and proud to have brought both of our influenza candidates in Phase II development in the past 12 months. This is a tremendous accomplishment for Novavax, and I want to congratulate and thank the talented and dedicated employees at Novavax who have worked tirelessly to deliver on this aggressive plan for 2008.

During this call today, we will cover the following items with you, after which we will open the call for questions. First, an overview of the study design and objectives; next, a summary presentation of the immunogenicity and safety data from this study, and a path forward for our seasonal influenza vaccine program; next, the plan for subsequent seasonal influenza clinical trials, including a study in an elderly population; and finally, some summary comments.

Dr. Penny Heaton, our Chief Medical Officer, will share the information on the clinical trial in healthy adults as well as our plans for future trials for this program, and I will provide some closing remarks.

Now I will turn the call over to Dr. Heaton.

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**Penny M. Heaton, Vice President, Development and Chief Medical Officer**

Thank you, Rahul, and good morning everyone. For those of you who are following along on your slides, I'm now on slide two, and I will tell you as I progress from slide to slide throughout the presentation.

I'm very pleased this morning to share with you the top line data from a Phase IIa study of our seasonal influenza VLP vaccine.

Going onto slide three, the goals of our seasonal influenza virus-like particle or VLP vaccine program, are to develop a safe and effective vaccine against the influenza sub-types that are responsible for yearly epidemics. We believe that the influenza VLP vaccine has the potential to be differentiated from other influenza vaccines, because of the possibility of inducing broad immune responses with improved efficacy in older adults and cross-reactivity against drifted strains.

In addition, better efficacy maybe a benefit of our recombinant technology, because we can also more closely match our vaccine to strains that are circulating in humans without the need for egg adaptation.

Now let's turn to the study results. On slide four, before I share the data with you, please allow me to review the study design. This was the first clinical study of our trivalent seasonal influenza VLP vaccine in humans. This was a blinded, placebo-controlled study in healthy adults 18 to 49 years of age, designed to evaluate the safety and immunogenicity of the trivalent VLP vaccine when administered at different doses, including 5 micrograms, 15 micrograms, and 30 micrograms per strain.

Approximately 300 subjects were to be enrolled in the study with 50 subjects in each of the placebo in 5 microgram arm, and 100 subjects in the 15 and 30 microgram arm. The subjects were enrolled and received their vaccinations in September of this year. They've had their blood drawn for the evaluation of immunogenicity, and are now continuing to be monitored for safety outcomes for a full six months after vaccination.

Slide five, now we would like to review the top line safety and immunogenicity results of the study. The unblinded data from the current study show that the adverse events that were reported were similar to those observed with other influenza vaccines.

Non-serious adverse events such as fever, muscle aches, joint pain, headaches and fatigue were reported more frequently among vaccine recipients than placebo recipients. The severity of these non-serious events was not statistically different among vaccine and placebo recipients. There were no serious adverse events reported.

As you may recall, based on a review of blinded safety data early on in the study, we saw some different adverse events than those reported in the study of our pandemic H5N1 vaccine. However, as I just shared with you, when we saw the unblinded data, they were consistent with the types of adverse events observed with other licensed seasonal influenza vaccines.

Subjects will continue to be monitored for safety for a full six months after vaccination. We continue to improve our vaccine as we advance our process, formulation and clinical development to achieve the best safety profile possible for our final product.

Going on to slide six, the seasonal influenza VLP vaccine was also immunogenic, hemagglutination inhibition or HAI responses were measured approximately three weeks after vaccination against each of the three strains in the vaccine. For subjects we received out of the 15 microgram or 30 microgram doses, seroprotection rates, which we define as the percentage of subjects with HAI titers of 40 or greater, range from 95 to 97% for the H3N2 strain, 83 to 94% for the H1N1 strain, and 73 to 79% for the B strain.

For these same groups, seroconversion rates, which we define as a fourfold or greater rise in HAI titer, range from 90 to 100% for the H3N2 strain, 69 to 78% for the H1N1 strain, and 42 to 56% for the B strain, among those subjects who do not have antibodies to these strains before vaccination. The geometric mean HAI titers or GMT, were also robust and increased with dose.

Slide seven; we have also noted with great interest that the seasonal influenza VLP vaccine induced HAI antibody responses against drifted strains. For the 15 microgram and 30 microgram doses, seroprotection

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rates for a drifted H3N2 strain, A/Wisconsin were 96 to 97%, and for a drifted H1N1 strain, A/Solomon Islands were 78 to 92%.

Seroconversion rates for these vaccination groups were 92 to 100%, and 36 to 67% for the drifted H3N2 and H1N1 strains respectively, among subjects who do not have antibody to these strains before vaccination.

Again the GMTs were high, and they increased with increasing dose. Cross-protection was not observed with the different B strain.

You may be wondering how the immunogenicity of the VLP vaccine compares with that of approved seasonal influenza vaccine. While the only way to truly compare the attributes of different vaccines is to evaluate them in a head-to-head study, these HAI results appear to be similar to that reported for other licensed influenza vaccine. And it's important to remember that while from a regulatory perspective, HAI is important. Other immune responses may be important with regard to the efficacy of the vaccine as well, and I will discuss that more in a moment.

Going on to slide eight, let's once again review the progress that we have made on the goals for our seasonal influenza VLP vaccine program to develop a differentiated vaccine. First, we saw an HAI dose response in the clinical study. This is important because higher doses leading to higher geometric mean HAI titers maybe a pathway for a vaccine with improved efficacy, particularly in the elderly.

We also have data showing the breadth of the immune response. Most influenza vaccines are focused on responses to the surface HA protein. Our VLP vaccine not only contains HA but also contains neuraminidase, M1 protein, which maybe important for inducing further antibody and cell-mediated immune responses.

We have additional evidence for this from our pandemic study, which shows CD8/CTL responses in a subset of subjects, and also from our preclinical seasonal data, which have shown NAI response or neuraminidase inhibition antibody responses. And in addition, the current study has shown cross-reactivity against drifted strains.

Further, we can differentiate based on our manufacturing platform. The cloning process has been optimized allowing the VLPs for the 2008-2009 season to be made in six weeks, with the highest production yields that we have observed to-date. Further optimization of the manufacturing process is underway to ensure production of a vaccine with consistent high purity and yield. Taken together, these attributes support the potential differentiation of the seasonal influenza VLP vaccine from those already existing on the market.

So, going onto slide nine, what about our plans for moving forward with our seasonal vaccine program? In summary, the data from this study supports continued development of our seasonal influenza VLP vaccine to evaluate dosing, and further studies of safety and immunogenicity of the vaccine in healthy adults, and in adults over 65 years of age. The study in older adults is important for the company, because it will permit us to compare the safety and immunogenicity of our VLP vaccine candidate with those of a vaccine already licensed by FDA.

The real test of the VLP vaccine will be to conduct a head-to-head study with a licensed influenza vaccine. As most of you know, the immune response to vaccines currently available for the elderly population is modest, leaving older adults susceptible to influenza and its associated morbidity and mortality. CDC estimates that influenza is responsible for 36,000 deaths and 200,000 hospitalizations in the U.S. each year, the vast majority of which occur in the elderly.

As I've already shared with you, we have designed our VLP seasonal influenza vaccine candidate to induce a broad set of immune responses, which we hope will help address the need for better vaccines in the elderly population. We plan on moving ahead with another healthy adult study to optimize our dose selection, and we will use that for the elderly study in our late phase trials. This approach will improve our probability of success in subsequent studies, including the head-to-head study in the elderly, which will be done in the second half of next year, prior to the start of the flu season.

Now I'd like to turn the discussion back to Rahul for his summary comments.

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**Rahul Singhvi, President and Chief Executive Officer**

Thank you, Penny. I'd like to give you a brief summary of what you've just heard, and then turn the presentation over to questions.

In summary, we have a promising seasonal VLP vaccine candidate that has the potential to differentiate in the elderly population, and we plan to continue to develop this product in 2009 to collect data, to show exactly that. We will continue to improve our manufacturing process and quality of this vaccine candidate as we move forward in further human clinical studies. And third, we will continue to move forward on different fronts to establish commercial opportunities to leverage the value of this great program.

Before I turn over for questions, I'd like to remind everyone that preclinical data from our first RSV vaccine candidate was presented at the Vaccine Congress in Boston on Tuesday of this week by Dr. Trudy Morrison from the University of Massachusetts Medical School. A summary of these data maybe found on our website in our press release dated December 9, 2008, and we hope to post the data from the presentation on our website in the next few days.

This vaccine candidate along with our two influenza programs developed since 2005 illustrates the efficiency of our VLP platform and its great potential to address significant unmet medical needs. And we remain confident that we will have the technical capability and resources in 2009 to further develop these important product candidates in support of our overall corporate strategy.

This completes our prepared comments, and we will now like to turn over the call for questions.

**QUESTION AND ANSWER SECTION**

Operator: [Operator Instructions]. Our first question comes from Tom Schrader. Your question please.

**Q**

Good morning. Can you hear me?

**A – Rahul Singhvi**

Yes, we can, Tom.

**Q**

So, thanks for holding the call. The antibody data is certainly impressive. Can you talk about what else you are going to collect in this trial? I'm particularly interested in T cell responses, and your view of how important they will be, and how firm you think the data are; that those are the responses that maybe are required to make a flu vaccine that's going to be better in the elderly? Where are you sort of in your thinking on that kind of evolving paradigm? Are you going to collect data from this trial or is that something we'll see later?

**A – Penny Heaton**

Okay. So, let me start off by talking about what I think might be an ideal vaccine for the elderly. I really like to drop on a discussion that was held in a workshop about a year ago now, that was sponsored by FDA and WHO and CDC, where they all met to talk about the immune correlates of efficacy with influenza vaccines, and what might be needed in the elderly. And the recommendation there was really for a vaccine with a broad response.

We need the HAI titers and we need – if we can get higher HAI titers in the elderly, but it's also important we know that neuraminidase has been – the response against neuraminidase has been correlated with efficacy in the past. And certainly we also know that in the elderly there can be a waning of their cell-mediated immunity, so CTL responses are important as well.

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So, the call from the public health officials is to really develop a vaccine with the potential to induce a broad set of immune responses, so that helps them improving efficacy in the elderly.

So what we are doing now -- of course the first study was in the healthy adults, but we are actually looking at each prong, if you will, of the immune system or each arm of the immune system and looking at the responses. So what I reported today are the HAI responses. We are currently in the process of looking at the responses to neuraminidase as well. FDA has been helpful with the protocol on bad assays. We are working on that assay.

We are also working on -- we have collected peripheral blood mononuclear cells for an evaluation of cell-mediated immune responses in a subset of subjects from this study. And so these data will be rolling out over the next several months, and we will put the whole picture together, and we will have -- that will give us even greater confidence about our ability to differentiate in the elderly. But I can tell you based on the data we have so far, I mean we're really -- it's lining up to look very nice.

So we have good HAI responses. We know from our pandemic study, and this is a clinical study of human subjects that we had good CD4 and CD8 responses, CTL responses in a subset of subjects. We also know from our preclinical data that we are not only getting neuraminidase responses that we know that it's functional antibody, neuraminidase inhibition responses. So things are really lining up to look like that we are going to have the potential to differentiate in the elderly, with respect to several different aspects of the immune response.

**Q**

Okay, in terms of one quick kind of technical question. You like many other people see your best response for H3?

**A – Penny Heaton**

Yes.

**Q**

But that's the one that -- those are the variants that do all the real damage in the real world? Do you have the insight into that?

**A – Penny Heaton**

We don't, and in fact I've been talking with some consultants just earlier this week again about, why does H3N2 cause such severe disease, et cetera? And I certainly don't have any insights into that, and I think everyone is scratching their head about why that's the case.

**Q**

Okay. Okay, thank you very much.

Operator: Thank you. Our next question comes from Chris Walterhoff. Your question please.

**Q**

Hi, good morning guys. Thanks for taking my question. I'm just trying to get a sense of how the safety results we saw today maybe differed from your expectations and differ from the -- what we saw in the pandemic study, that kind of caused you to delay the study of it?

**A – Penny Heaton**

Yes, well, if you recall from our pandemic study, the safety data showed that essentially the rates of various adverse events were very similar in the vaccine and placebo groups, and we do not see fevers, muscle aches, headaches et cetera -- was extremely low rates and very few of these adverse events were

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reported.

In the seasonal study, what we did, we routinely review blinded safety data on an ongoing basis for our studies, and when we looked at the data at the end of the first week of vaccination, where patients fill out the diary cards for a week. We noticed that the overall rates just based on the blinded data at some of these events were higher in the vaccine as compared with the placebo group.

So what we wanted to do is really understand the pattern of the adverse events based on the dose response data, and we also wanted to look at them in an unblinded fashion before moving into the elderly population. And so, in fact that's what we did, we waited until we got the unblinded data, and once we got the unblinded data, what we saw is – as I've presented today, the type of events were very similar to what's been reported for other influenza vaccines, your typical fevers, muscle aches, headaches, myalgias.

The good news is there were no serious adverse events reported, and of course we are continuing to monitor the subjects for safety. So, we did just -- went to see what the safety profile was, and where we were with respect to immunogenicity on the dose curve before moving into the elderly, which is a more vulnerable population.

**Q**

Okay, I see, thanks. And then in terms of some of the AEs that we did see, did you see them higher – as an increased incidence I guess in the higher doses in the 30 and the 15 microgram doses?

**A – Penny Heaton**

There was some suggestion of that, actually it depended on the AE. They were in general higher among vaccine recipients as compared to placebo recipients, but for some there was a, it appears to possibly be a dose response, for others not. There isn't anything that's statistically significant, but of course this is a small study. And so we'll just continue to evaluate the safety in future studies.

**Q**

Okay, and in terms of the dose response, do you think we are sort of getting close to the top of the curve? Do you think we are going to go higher than 30 mgs in following studies?

**A – Penny Heaton**

Yes, if you look at our geometric mean titers, it still appears that we are on the very steep part of the dose response curve. So I would anticipate that we can push the dose even higher, and that's what we are going to be evaluating in these upcoming studies even with the healthy adults and the elderly.

If we can push this dose response higher and get higher HAI titers, and that's the real potential for differentiation, we know that when another flu company has done that, where they had pushed their dose up to 60 micrograms, got a nice dose response. And that was an egg-based vaccine.

We – based on our GMTs and where we see we are in the dose response curve, I feel like we can do the same thing and have the advantage of the much higher yields with our recombinant technology.

**Q**

Great, and maybe one last question, just on the pandemic study. Should we expect any final data maybe for the end of year or is that something that's going to come in 2009?

**A – Penny Heaton**

It will probably be in early 2009, we are running assays – actually even as we speak literally, and those data will be coming in early 2009.

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Q

Okay great, thanks a lot for taking my questions.

**A – Penny Heaton**

Thank you.

Operator: Thank you. [Operator Instructions] It looks like our next question is a follow-up question from Tom Schrader. Your question please.

Q

Hi, thanks for taking the follow-up. So, I'm just curious about how well -- whether you have a sense of whether all of your antigens were present at the same level or maybe your approach is better for some than other? I mean as I look at your data compared to other data, maybe like flu Rx or some of the recent data we have seen. Did the data for the B antigen, you seem to fall off more than they do, do you have insight into that? Is that a place where you think maybe you need more dose at this -- what's your thinking there?

**A – Penny Heaton**

Sure. So we did include each of the strains in the same concentration if you will, the same potency in the vaccine. And I think one thing we have to be cautious about is comparing the data head-to-head with that of other vaccines.

Q

Yes, sure.

**A – Penny Heaton**

Because the only way to do that is really in a head-to head study. The overall pattern of responses was similar to what's seen with other flu vaccines with the best response to H3, this next best...

Q

Right.

**A – Penny Heaton**

...to H1 and the lowest to B. I'm hesitant right now to do any direct comparisons; we want to do that, we're excited to do that, and we are going to be doing that next year where we could actually compare it or write in the study, so that we can show how we measure up to licensed vaccines. That's a very important point, very good point.

Q

Would that be an outcome trial or would that be an immunogenicity trial? At this point, is there any point in doing immunogenicity head-to-head?

**A – Penny Heaton**

It is very important to do immunogenicity head-to-head, and certainly we would do that before doing an outcomes trial, but the reason why it's important is because in previous studies they have shown, it has been shown that the HAI responses and the neuraminidase responses, both correlate with efficacy. And so it -- I think it will be important to evaluate from the immunogenicity perspective, and it will be very

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valuable from the immunogenicity perspective early on with the potential to look at outcomes later.

Q

Okay, fair enough. Okay, thanks again.

Operator: Thank you. There are no further questions in the queue at this time. I'd like to turn the program back to you.

Rahul Singhvi, President and Chief Executive Officer

Well, again, thanks for joining the call today, and again we feel very, very proud of getting the second clinical trial for the second candidate, and I want to thank you all for your support, and look forward to speaking to you in the next call.

Operator: Thank you ladies and gentlemen for your participation in today's conference. This does conclude the program. You may now disconnect. Good day.

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