

1) CAN YOU EXPLAIN THE ADDICTIVE RESPONSE YOU ARE TRYING TO PREVENT WITH NICVAX?

Nicotine is considered to be a highly addictive drug. After inhaling smoke from a cigarette, nicotine moves from the lungs into the bloodstream and across the blood brain barrier to nerve receptors in the brain. Nicotine is able to enter the brain because it is a very small molecule. When enough nicotine is clustered around these nerve receptors in the brain, called nicotinic receptors, it stimulates the release of a chemical called dopamine. This creates a pleasant feeling, what some smokers describe as a rush. This response occurs very rapidly after inhaling from a cigarette, often within one or two minutes. Based on the speed of this pleasurable response, nicotine is considered by many to be more addictive ounce for ounce than other drugs.

2) HOW DOES NICVAX® (NICOTINE CONJUGATE VACCINE) WORK TO TREAT THIS ADDICTION?

NicVAX has been developed to use the body's own defense mechanism, the immune system, to prevent nicotine molecules from entering into the brain. NicVAX is a conjugate vaccine designed to stimulate the immune system to produce antibodies that bind to nicotine. It is believed that these antibodies will act like a "sponge" soaking up nicotine as it circulates in the bloodstream. Nicotine when attached to antibodies will be too large to cross the blood brain barrier, thereby preventing nicotine from reaching the brain. The positive stimulus in the brain that is normally caused by nicotine is no longer present, thereby eliminating the addictive properties of nicotine and, consequently, helping people to quit.

Because the ability of the body's immune system to produce these antibodies is expected to be long lasting, it is believed that NicVAX will also be effective in preventing smoking relapse, a significant challenge with existing smoking cessation therapies. This is an important differentiator between NicVAX and current anti-smoking treatment therapies.

3) HOW WAS NICVAX DEVELOPED?

Nabi already had a well-developed conjugate vaccine program against *S. aureus* utilizing an efficient carrier protein (recombinant Exotoxin Protein A from *pseudomonas aeruginosa*; rEPA). Nabi's scientists worked hard to develop a chemical molecule that is a nicotine derivative and then conjugated it to rEPA. After several attempts, our scientists were able to optimize the structure, synthesis and purification of the nicotine-like molecule. Animal studies were then conducted in collaboration with external researchers. These studies demonstrated the effectiveness of the prototype vaccine in preventing nicotine from reaching the brain and the resulting behavioral and physiological effects of nicotine. After completing toxicology studies, human clinical studies were initiated.

4) WHAT SUPPORT IS THERE FOR THE EFFICACY OF NICVAX?

Clinical data indicates that NicVAX, if approved, could potentially be one of the most efficacious smoking cessation products available. In an earlier Phase II clinical trial, NicVAX achieved a 33 to 40 percent quit rate in smokers who received the highest dose level versus nine percent in the placebo group. These results represented a vaccine-only effect, as patients were not given any supplemental treatments, behavioral support or counseling. It is expected that the response rate would be further improved as behavioral support and counseling are built into the program.

In the Phase II study, scientists observed that nicotine antibodies increased in all nicotine vaccine groups. More patients who received the highest dose of vaccine achieved 30-day abstinence, and in a shorter amount of time, than those who received the other doses or placebo. Moreover, scientists found no evidence of withdrawal symptoms such as craving, irritability, or compensatory smoking (smoking more of a cigarette or puffing more often to increase nicotine intake). More than 90 percent of reported side effects were of mild or moderate severity. The most frequently reported events were upper respiratory tract infection, headache, cough, and inflammation of the nasal passages and throat. There were no observed differences in the frequency of these events among the four treatment groups.

5) WHAT DID THE OUTSIDE SCIENTIFIC INVESTIGATORS CONCLUDE FROM THE TRIAL RESULTS?

Based on their analysis of the data, these scientists concluded that study participants who received the vaccine experienced none of the typical withdrawal symptoms commonly experienced by smokers. The results support that this nicotine vaccine may offer a promising new treatment alternative for smokers seeking to quit. The data warrants additional clinical research to maximize the vaccine's ability to diminish nicotine's effects in humans. Dr. Dorothy Hatsukami, an investigator in the Phase II study, and her colleagues published the results from the Phase II study in the November 2005 issue of *Clinical Pharmacology and Therapeutics*.

6) WHAT HAPPENED AFTER THE PHASE II CLINICAL STUDY?

The human immune system is naïve to nicotine. Because it is a very small molecule it passes through our bloodstream undetected. In order to create high levels of antibodies we use an adjuvant, alum, to boost the immune system's response to the vaccine. Adverse reactions to vaccines are often associated with adjuvants.

After the Phase II trial demonstrated that the antibodies produced with NicVAX could be effective in treating nicotine addiction, we worked to optimize the formulation of the vaccine. The manufacturing process allowed us to double the antigen content and halve the adjuvant content of the vaccine. This optimized formulation was developed to further enhance the safety profile for NicVAX, a vaccine which could be dosed in hundreds of millions of smokers around the world.

In 2005 we completed an open label Phase II study in which the reformulated vaccine was shown to stimulate antibodies to levels equivalent to the vaccine with higher adjuvant content used in the previous Phase II trial. Based on this result we are now comparing the efficacy of both formulations of NicVAX in a larger blinded, placebo controlled proof-of-concept Phase II clinical trial, initiated in May 2006.

7) CAN YOU DESCRIBE THE RATIONALE FOR THE PHASE IIB TRIAL?

A Phase IIB “proof-of-concept” study for NicVAX was initiated in May 2006. This study was designed in collaboration with an advisory panel comprised of outside scientists and clinicians with expertise in the areas of vaccines, immunology and addiction. The study will evaluate the effectiveness of an optimized formulation of the vaccine manufactured at commercial scale in our vaccine plant in Boca Raton, Florida. It follows the protocol we expect to use in Phase III efficacy studies based on consultations with regulators in the United States and Europe. It is sized to show the effect of NicVAX with significance. This study also incorporates other core elements of smoking cessation programs including behavioral modification and counseling. It is expected that these elements will increase the success rate observed in the earlier Phase II trial which was designed to measure a ‘vaccine-only’ effect on smoking cessation.

8) CAN YOU DESCRIBE THE PROTOCOL AND ENDPOINTS OF THE PHASE IIB STUDY?

The study is a double-blinded, placebo-controlled dose ranging study comprised of approximately 300 patients, a large enough sample size to establish both proof-of-concept and optimal dose identification. The primary endpoint of the study is the abstinence rate at six months. Abstinence will be evaluated by several measures including reported cigarette consumption, chemical markers of nicotine in the bloodstream, and behavioral assessment. Secondary endpoints include the abstinence rate at 12 months, total cigarette consumption, titer levels, safety and nicotine dependency. The study protocol is based on the consultations we had with U.S. and EU regulators with respect to the design and endpoints for NicVAX’s Phase III efficacy studies.

9) WHERE IS THIS STUDY BEING CONDUCTED?

The study is being conducted at approximately 10 sites that are experienced in smoking cessation throughout the United States.

10) WHEN WILL DATA FROM THE PHASE IIB STUDY BE AVAILABLE AND WHAT ARE THE NEXT STEPS?

Results from the study are expected to be announced in mid-2007. With positive results, we expect to initiate Phase III efficacy studies in the second half of 2007.

11) WHY DID YOU CHOOSE TO CONDUCT AN ADDITIONAL PHASE II STUDY RATHER THAN PROCEEDING DIRECTLY TO A PHASE III STUDY?

We believe that the results from this study will be important in affirming that we are optimally positioned to demonstrate the vaccine’s efficacy in Phase III clinical studies. To that end, the Phase IIB trial was designed in close consultation with the company’s external scientific and clinical experts, it is following a design similar to what is anticipated for the Phase III trials and we are utilizing an optimized formulation of the vaccine manufactured at our plant at a scale capable of supporting commercial launch. In addition to that, the Phase IIB study will help establish the optimal dose and dosing regimen for the Phase III trials.

12) WHAT MAKES NICVAX DIFFERENT FROM CURRENTLY MARKETED PRODUCTS?

We believe that the vaccine approach inherent to NicVAX will provide significant advantages compared to currently marketed products. First, unlike current approaches, NicVAX is designed to work by empowering the human immune system to make antibodies that bind to nicotine in the bloodstream and prevent it from entering the brain, eliminating the need for nicotine or chemicals to enter the brain. Second, unlike currently marketed treatments which the patient can stop taking at any time, the antibodies created by NicVAX are expected to last 12 months or longer. During this period of time, the effect of NicVAX cannot, we believe, be overcome. This is important because studies have shown that if the subject can remain abstinent for 6 to 12 months, they are very likely to remain abstinent. This is critically important given the high rate of relapse that smokers experience.

It is important to note that in March 2006, Nabi Biopharmaceuticals announced that NicVAX had received Fast Track Designation from the U.S. Food and Drug Administration (FDA), which facilitates the development of products that treat serious diseases where an unmet medical need exists. This designation affirms that the FDA regards smoking as a significant unmet medical need.

13) WHAT IS THE IMPACT OF THE RECENT APPROVAL OF PFIZER’S ANTI-SMOKING PRODUCT CHANTIX™ (VARENICLINE)?

We consider Chantix’s approval to be very positive for NicVAX. First, it is a validation of the mechanism of action of NicVAX, as both NicVAX and Chantix work by blocking nicotine from reaching receptors inside the brain and thus eliminating the pleasurable and addictive response to smoking. Chantix works by using chemicals to block the receptors in the brain, preventing nicotine on the brain from causing the addictive pleasurable response. NicVAX works outside the brain, by absorbing nicotine in the bloodstream.

But in addition, we believe that NicVAX could offer additional and significant advantages over Chantix in areas such as duration of response and prevention of relapse. While you will eventually stop taking pills and be able to resume your addictive habit, antibodies to nicotine are expected to be long-lasting, up to twelve months or longer. Booster doses of the vaccine could also extend the protective antibody response for periods beyond one year. We also believe that the fact that NicVAX works within the bloodstream rather than in the brain could prove to be an important distinguishing factor.

14) ARE THERE OTHER COMPETITIVE ANTI-SMOKING PRODUCTS UNDER DEVELOPMENT?

There are other nicotine therapies under development, including vaccines. However, we are the only company ready to employ commercial-scale manufacturing of an optimally formulated product used in clinical studies. This is believed to provide a significant competitive advantage. NicVAX has also shown a superior safety profile compared to other vaccines in development. In addition we have an intellectual property portfolio for technology related to NicVAX that includes both issued and pending patents in the U.S. The company also holds granted patents in 18 European countries, plus patents and pending patent applications in numerous other countries around the world.

15) WHAT INDICATION WILL YOU SEEK FOR NICVAX?

The clinical trials for NicVAX are designed to support two different indications: Smoking cessation and prevention of relapse.

16) HOW PROTECTED IS NICVAX'S PATENT POSITION?

We possess a strong global intellectual property position for NicVAX and its manufacture that protects the value of this important asset. We have an intellectual property portfolio for technology related to NicVAX that includes both issued and pending patents in the U.S. The company also holds granted patents in 18 European countries, plus patents and pending patent applications in numerous other countries around the world.

17) HOW WILL NICVAX BE MANUFACTURED DURING COMMERCIALIZATION?

We plan to manufacture NicVAX at our vaccine plant in Boca Raton, Florida. In fact, the vaccine being utilized in the current Phase IIB study was manufactured at commercial scale in an optimized formulation at this facility.

18) WHAT IS USUALLY REQUIRED TO DEMONSTRATE EFFICACY FOR SMOKING CESSATION PRODUCTS?

Typically, one would have to demonstrate that the quit rate (which is defined as 30 consecutive days without smoking) is significantly greater on active treatment than on placebo. For example, for Zyban, an already marketed drug, the quit rate was 36% at the highest dose versus 17% in the placebo group.

19) HOW ARE YOU FUNDING THE DEVELOPMENT OF NICVAX?

We have secured significant funding for NicVAX from external sources. In September 2005, we announced a \$4.1 million grant by the U.S. National Institute on Drug Abuse (NIDA), part of the National Institutes of Health, which is expected to fully offset the external costs of the Phase IIB proof-of-concept clinical study. NIDA has also contributed significant scientific and clinical expertise to the program and has funded the costs for toxicology testing and earlier clinical trials in the U.S. We would expect to continue to secure outside funding to support the cost of Phase III efficacy studies.

20) ARE YOU GIVING UP RIGHTS TO THE PRODUCT AS A RESULT OF THIS NIH FUNDING?

There have been no requirements to give up product rights or to commit to royalty payments connected with this NIH funding.

21) WHAT IS THE COMMERCIALIZATION STRATEGY FOR NICVAX?

It is our intent to seek a commercialization partner for NicVAX. We believe that the marketing of this product will be conducted primarily to primary care physicians and thus, a partner with an existing sales infrastructure targeting these physicians would be ideal. Within future partnering relationships, there may also be opportunities for us to market this product candidate within hospital settings, which would take advantage of our existing commercial strength.

22) WHEN DO YOU EXPECT NICVAX TO REACH THE MARKET?

We do not comment on that as we cannot predict the length of the regulatory review process. What we can say is that we anticipate to file our BLA in 2009. Also, in March 2006, we announced we have received fast track designation for NicVAX from the FDA. As a result, we would anticipate to be granted priority review, which would mandate the FDA to provide an opinion on our license application in a 6 month period.

23) HOW BIG IS THE MARKET SIZE FOR NICVAX?

It is too early for us to make projections on the size of the market for NicVAX. However, given that an estimated 70 percent of the 45 million adult smokers in the U.S. want to quit and that there are more than 1.3 billion smokers worldwide, we believe the market for NicVAX is considerable.

24) DO THE STAPHVAX PHASE III RESULTS HAVE ANY IMPLICATIONS FOR FUTURE NICVAX CLINICAL STUDIES? DID YOU MAKE CHANGES TO THE NICVAX DEVELOPMENT PROGRAM?

We are following a well constructed plan to advance the development of NicVAX. We have used an outside advisory panel in the design and evaluation of the scientific and clinical programs for NicVAX. The Phase IIB trial initiated in May 2006 uses vaccine manufactured at commercial scale in our own manufacturing facility, which is capable of supporting the commercial launch of NicVAX. The Phase IIB trial is following the expected Phase III trial protocol and was defined based on our work to reach consensus with regulators in the United States and Europe. The vaccine is being dosed in smokers who are expected to respond better to a vaccine than immune-compromised dialysis patients.

Next with regard to the vaccine itself, the carrier protein used in StaphVAX and NicVAX is the same. That means we will benefit from the significant immune response and the safety profile demonstrated with StaphVAX in two large Phase III clinical trials. Different from StaphVAX however, the carrier protein is conjugated to a synthetic small molecule when we produce NicVAX. This means that we are not dealing with the variability of a biological antigen. This means that we have seen strong evidence of consistency in both the quality and affinity of antibodies produced by stimulating the human immune system with NicVAX.

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