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Federal Stimulus Grant Supports Crucial Study of Anti-Nicotine Vaccine

Efforts to develop a vaccine capable of preventing tobacco addiction got a \$10-million shot in the arm in the form of an American Recovery and Reinvestment Act grant. The award to Nabi Biopharmaceuticals of Rockville, Md., was funded by the National Institute on Drug Abuse (NIDA), part of the National Institutes of Health.

The Recovery Act funds will help pay for the first pivotal phase III trial of NicVAX, an injectable vaccine intended to help people quit smoking and prevent them from relapsing. The grant enables Nabi to retain its current staff as well as support 150 jobs at NicVAX research sites around the country.

Successful completion of the study will bring the vaccine closer to final approval. Already given fast track designation by the U.S. Food and Drug Administration, NicVAX passed initial regulatory hurdles showing the basic idea is sound. Patients in the trial get six monthly shots in the arm.

Earlier results show that smokers using the vaccine had higher rates of quitting and longer term cigarette abstinence than those given a placebo.

“Nicotine addiction causes nearly a half million deaths annually in the United States alone. Finding effective treatments that can help people stay off cigarettes has been a real challenge,” said NIH Director Dr. Francis Collins. “This Phase III trial of a nicotine vaccine offers tremendous hope towards solving this immense public health problem.”

Annually in the U.S., cigarette smoking costs more than \$193 billion (\$97 billion in lost productivity and \$96 billion in health care expenditures).

Like other vaccines, NicVAX works by boosting the immune system. In this case, the goal is to generate antibodies that bind to nicotine. Normally, nicotine is a small molecule that travels quickly through the lungs, then the bloodstream and into the brain. However, when nicotine is trapped by an antibody, it’s too large to get into the brain, subverting the rewarding effects of the drug.

“We know that once inside the brain, nicotine triggers the release of dopamine, a chemical linked to pleasure and to addiction. Once a person becomes addicted, it is extremely difficult to achieve and sustain abstinence. Withdrawal symptoms, environmental cues, and stress can all trigger relapse,” said NIDA Director Dr. Nora Volkow. “A vaccine that limits the ability of nicotine to enter the brain, and that is effective for six to 12 months following vaccination will give smokers a fighting chance to end the addiction/relapse cycle that plagues the great majority of smokers trying to quit.

“In the future, the anti-nicotine vaccine could also prove to be a powerful tool in smoking prevention,” says Volkow.

The award continues a public-private partnership between NIDA and NABI that started in 2001 with a grant to support the basic science that led to NicVAX. The effort continued in 2005 with a grant to help support early clinical trials to test the safety and efficacy of the vaccine.

“The Recovery Act grant enables NABI to take the next step in the development of NicVAX. We’re delighted that NIDA has chosen to support the NicVAX program, since we think it could ultimately benefit millions of smokers worldwide,” said Dr. Raafat Fahim, president and chief executive officer of Nabi Biopharmaceuticals.

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The National Institute on Drug Abuse is a component of the National Institutes of Health, U.S. Department of Health and Human Services. NIDA supports most of the world’s research on the health aspects of drug abuse and addiction. The Institute carries out a large variety of programs to inform policy and improve practice. Fact sheets on the health effects of drugs of abuse and information on NIDA research and other activities can be found on the NIDA home page at www.drugabuse.gov. To order publications in English or Spanish, call NIDA’s new DrugPubs research dissemination center at 1-877-NIDA-NIH or 240-645-0228 (TDD) or fax or email requests to 240-645-0227 or drugpubs@nida.nih.gov. Online ordering is available at <http://drugpubs.drugabuse.gov>. NIDA’s new media guide can be found at <http://drugabuse.gov/mediaguide>.

NIDA's National Drug Abuse Treatment Clinical Trials Network (CTN) is a multi-site research project of behavioral, pharmacological, and integrated treatment interventions to determine effectiveness across a broad range of community-based treatment settings and diversified patient populations. The CTN provides a foundation for conducting research with the primary goal of bridging the gap between the science of drug treatment and its practice through the study of scientifically based interventions in real world settings.

The National Institutes of Health (NIH) — *The Nation's Medical Research Agency* — includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. It is the primary Federal agency for conducting and supporting basic, clinical and translational medical research, and it investigates the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit www.nih.gov.

For information on the NIH's American Recovery and Reinvestment Act funding, visit <http://grants.nih.gov/recovery>. To track the progress of HHS activities funded through the recovery act, visit www.hhs.gov/recovery. To track all federal funds provided through the recovery act, visit www.recovery.gov.