Public release date: 9-Jun-2006 Contact: Janet Basu jbasu@pubaff.ucsf.edu 415-476-2557 University of California - San Francisco

Smokers invite to test vaccine against nicotine addiction

UCSF enrolls patients for phase II of "proof of principle" trial of nicotine blocking vaccine

UCSF's Habit Abatement Clinic is testing a vaccine that enlists help from the immune system to keep nicotine away from the brain. The vaccine is designed to help smokers quit and to limit the urge to start smoking again.

Called NicVax, the investigational vaccine is being developed by Nabi Biopharmaceuticals to prevent and treat nicotine addiction and to help people quit smoking. Normally when a smoker inhales, nicotine is carried by the bloodstream to the brain, where it triggers neuro-receptors to generate positive sensations that can lead to addiction. The vaccine stimulates the immune system to produce antibodies that recognize the small nicotine molecule. Bound to these antibodies, nicotine molecules no longer can cross the blood-brain barrier and enter the brain.

"With little or no nicotine reaching the brain, smoking is less rewarding. That gives the smoker a chance to change the behavioral and social factors that also influence smoking," said Victor Reus, MD, principal investigator for the study at UCSF.

Because immune antibodies remain in the body for some time, Reus said it is hoped that the vaccine also will prevent relapse. When a vaccinated smoker lights up months after quitting, the person should not experience the nicotine-triggered reward that tempts most people back into the habit.

Northern California smokers over 18 are invited to join a national study to determine whether NicVax can help people abstain from smoking and help them avoid relapsing within the next 12 months. Participation is free and requires a one-year commitment to come to San Francisco for injections and follow-up visits. The study also includes five behavioral counseling sessions. Participants will be paid for each visit and given validated parking at the clinic.

For information, interested persons should call the UCSF Habit Abatement Clinic at (415) 476-7453, visit www.ucsf.edu/nosmoke, or email rpilato@lppi.ucsf.edu.

UCSF is one of nine centers nationwide to participate in this phase II proof-of-principle clinical trial, which is sponsored by Nabi Biopharmaceuticals of Boca Raton, Florida, and the National Institute on Drug Abuse.

The FDA granted a "fast track" designation for the NicVax vaccine in March, to speed development and review of the drug if trial results are promising.

"Most people who smoke want to quit, and they now have a number of options to help them reduce nicotine dependence and quit smoking," said Sharon Hall, PhD, co- principal investigator and director of the UCSF Habit Abatement Clinic. "A vaccine that could prevent the addictive action of nicotine is a promising alternative option."

According to the Centers for Disease Control and Prevention, cigarette smoking contributes to 440,000 deaths each year ·one-fifth of all U.S. deaths. Quitting smoking has immediate as well as long-term benefits, improving overall health as well as reducing risk for diseases caused by smoking.

The mission of the UCSF Habit Abatement Clinic is to develop and evaluate innovative treatment strategies aimed at helping people quit smoking and stay quit. Funded by the National Institute on Drug Abuse and the National Cancer Institute, the Habit Abatement Clinic has been evaluating the effectiveness of smoking cessation treatment since 1980.

UCSF is a leading university that consistently defines health care worldwide by conducting advanced biomedical research, educating graduate students in the life sciences, and providing complex patient care.

###