



# Significantly More Patients With Cardiovascular Disease Quit Smoking Using Chantix/Champix(®) (Varenicline) Compared With Placebo

Monday, March 30, 2009 - 07:30pm

Findings from First Study of Varenicline in Heart Disease Patients Presented at ACC

(BUSINESS WIRE)--Pfizer Inc today announced the results of a study that found that 47 percent of smokers with a history of cardiovascular disease who took CHANTIX/CHAMPIX® (varenicline) were able to quit smoking and remain abstinent during the last four weeks of treatment (weeks 9-12) compared with just 13.9 percent of those given placebo. These findings were presented today at the American College of Cardiology 58th Annual Scientific Session in Orlando, Fla.

“These data are consistent with the findings from the pivotal varenicline trials, which showed that varenicline was more effective than placebo among smokers who were generally healthy,” said Dr. Nancy A. Rigotti, professor of medicine at Harvard Medical School, director of the Tobacco Research and Treatment Center at Massachusetts General Hospital, and lead study investigator. “This study demonstrates that varenicline is effective in helping smokers with cardiovascular disease quit smoking. The safety profile of varenicline in this study also resembles that of the pivotal studies. The results are encouraging because the participants were at greater risk for death given their advanced ages, durations of smoking and histories of cardiovascular disease.”

Cigarette smoking is a well-established risk for cardiovascular disease. In the United States, approximately 130,000 adults die each year from smoking-related cardiovascular disease. This figure is approximately one-third of all smoking-related deaths among adults age 35 and older. Studies have shown that quitting smoking reduces the risk of death by 36 percent for smokers who have coronary heart disease, a type of cardiovascular disease.

“Patients are always encouraged to quit smoking after experiencing a cardiac event, such as a heart attack or stroke, but many eventually start smoking again, putting themselves at serious risk for a second event,” said Dr. Robert A. Kloner, director of research at the Heart Institute of Good Samaritan Hospital and professor of medicine at the Keck School of Medicine at the University of Southern California in Los Angeles. “It’s important that every smoker, and particularly those with heart disease, work with a health care professional to develop a quit plan.”

### About the Study

The multicenter, double-blind, placebo-controlled trial included 714 adult patients (ages 35-75 years) who had smoked an average of 10 or more cigarettes daily in the year before enrollment. All patients wanted to quit smoking but had not tried to in the past three months, and had stable, documented cardiovascular disease that had been diagnosed more than two months prior. Eligible cardiovascular disease diagnoses included history of heart attack, a certain type of heart surgery, chest pain, peripheral arterial vascular disease, and stroke or transient ischemic attack.

Patients were randomized to twelve weeks of treatment with either varenicline (n=355) or placebo (n=359) and were followed to week 52 in a blinded post-treatment phase. All patients received smoking cessation counseling throughout the study. The primary study endpoint was continuous abstinence rate during the last four weeks of treatment (weeks 9-12). The key secondary endpoint was continuous abstinence rate from the last four weeks of treatment through the post-treatment phase (weeks 9-52).

At the end of 52 weeks, 19.2 percent of patients who were randomized to take varenicline during the treatment phase remained abstinent, compared with 7.2 percent of patients randomized to take placebo.

Varenicline was generally well-tolerated. In the varenicline group, 7.4 percent of patients experienced cardiovascular events vs. 6.6 percent in the placebo group (difference 0.8, 95 percent CI: -3.0 to 4.6). Serious adverse events occurred in 6.5 percent patients treated with varenicline compared with 6.0 percent of those given placebo. None of the

serious adverse events involved depression, suicidality, or abnormal behavior.

The most common adverse events reported in the study were nausea (29.5 percent for varenicline vs. 8.6 percent for placebo), headache (12.7 percent vs. 11.1 percent), insomnia (11.9 percent vs. 6.6 percent), vomiting (8.2 percent vs. 1.1 percent), abnormal dreams (7.9 percent vs. 1.7 percent), fatigue (7.1 percent vs. 4.0 percent), nasopharyngitis (6.5 percent vs. 8.6 percent), constipation (6.5 percent vs. 2.0 percent), diarrhea (6.2 percent vs. 5.1 percent), dizziness (6.2 percent vs. 4.6 percent), and dyspepsia (5.4 percent vs. 3.4 percent).

This trial was funded by Pfizer Inc and was conducted in 15 countries.

## IMPORTANT SAFETY INFORMATION

CHANTIX/CHAMPIX® (varenicline) is a prescription medicine to help adults 18 and over stop smoking. Adults who smoke may benefit from quit smoking support programs and/or counseling during their quit attempt. It's possible that patients might slip up and smoke while taking varenicline. If patients slip up, they can stay on varenicline and keep trying to quit.

Some patients have had changes in behavior, agitation, depressed mood, suicidal thoughts or actions when attempting to quit smoking while taking varenicline, or after stopping varenicline. If patients, their families or caregivers notice agitation, depressed mood or changes in behavior that are not typical for the patients, or if patients develop suicidal ideation or suicidal behavior, they should stop taking varenicline and tell their doctor right away. Patients should also tell their doctor about history of depression or other mental health problems before taking varenicline, as these symptoms may worsen while taking varenicline.

The most common side effects include nausea (30 percent), sleep problems, constipation, gas, and/or vomiting. Side effects that are bothersome or don't go away should be reported to a doctor.

Patients may have trouble sleeping, vivid, unusual or strange dreams while taking varenicline. Patients should be advised to use caution driving or operating machinery until they know how quitting smoking with varenicline may affect them.

Varenicline should not be taken with other quit smoking products. A lower dose of varenicline may be necessary in patients with kidney problems or who get dialysis. -5-

Before starting varenicline, patients should tell their doctors if they are pregnant, plan to become pregnant, or if they take insulin, asthma medicines, or blood thinners. Medicines like these may work differently when patients quit smoking.

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## About Pfizer

Founded in 1849, Pfizer is the world's largest research-based pharmaceutical company taking new approaches to better health. We discover, develop, manufacture and deliver quality, safe and effective prescription medicines to treat and help prevent disease for both people and animals. We also partner with health care providers, governments and local communities around the world to expand access to our medicines and to provide better quality health care and health system support. At Pfizer, more than 80,000 colleagues in more than 90 countries work every day to help people stay happier and healthier longer and to reduce the human and economic burden of disease worldwide.

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