



Significantly More Smokers With Mild-To-Moderate COPD Quit Smoking Using CHANTIX/CHAMPIX® (Varenicline) Compared With Placebo

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Findings from Pfizer-Sponsored Study Presented as Late-Breaker at American College of Chest Physicians Annual Meeting

(BUSINESS WIRE)--New study results showed that 42.3 percent of smokers with mild-to-moderate chronic obstructive pulmonary disease (COPD) 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 8.8 percent of those given placebo ($p < 0.0001$). These findings were presented by investigators at CHEST 2009, the 75th annual international scientific assembly of the American College of Chest Physicians (ACCP).

“Quitting smoking is of paramount importance for all smokers, particularly those with a smoking-related illness, such as COPD,” said Dr. Donald Tashkin, study investigator, emeritus professor of medicine at University of California, Los Angeles. “This study shows that varenicline is an effective means of smoking cessation for a highly nicotine-dependent, difficult-to-treat group of patients. The safety profile of varenicline in this study was consistent with its pre-approval clinical trials.”

Up to one-half of all people who smoke may eventually develop COPD, a serious illness that includes both chronic bronchitis and emphysema.^{1,2} More than 12 million people in the United States are diagnosed with COPD, and 80 to 90 percent of them are

smokers.^{3,4} Further, approximately 24 million U.S. adults have evidence of impaired lung function, suggesting that many people who smoke may have COPD and not yet realize it.⁵ Worldwide, COPD currently affects 210 million people and is expected to become the world's third leading cause of death by 2030.⁶

"We at Pfizer want to help people quit smoking," said Dr. Briggs W. Morrison, senior vice president, Primary Care Medicines Development Group at Pfizer. "We sponsored this trial to offer healthcare providers additional information on smokers who are at risk for or diagnosed with COPD, who might especially benefit from quitting. This is just one of several planned and ongoing studies of varenicline that we hope will enhance the medical community's understanding of this important medicine."

According to international treatment guidelines from the Global Initiative for Chronic Obstructive Lung Disease (GOLD), quitting smoking is the single most effective--and cost-effective--intervention to prevent COPD and slow its progression.⁷ The guidelines recommend that all smokers, including those who may be at risk for COPD and those who already have the disease, be offered the most intensive smoking cessation intervention feasible, such as medication and support.⁷

About the Study

The multicenter, double-blind, placebo-controlled trial included 499 adults (at least 35 years of age) who had smoked an average of 10 cigarettes or more per day in the year before enrollment. Study participants had mild-to-moderate COPD and smoked for an average of 41 years. Participants had a high level of nicotine dependence as indicated by the average Fagerström Test for Nicotine Dependence score of 6.1 (on a 10-point scale).

Study participants were randomized to twelve weeks of treatment with either varenicline (n=248) or placebo (n=251) and were followed to week 52 in a blinded post-treatment phase. All participants received smoking cessation counseling throughout the study. The primary efficacy objective was to compare 12 weeks of treatment with varenicline (1 mg twice daily) to placebo for smoking cessation in smokers with mild-to-moderate COPD, and to evaluate abstinence from smoking for the 40 weeks after the treatment period. The safety objective was to gather safety data for 12 weeks of treatment with varenicline or placebo in smokers with mild-to-moderate COPD.

During the last four weeks of treatment (weeks 9-12), 42.3 percent of study participants with mild-to-moderate COPD who were randomized to take varenicline remained abstinent compared with 8.8 percent of those given placebo ($p<0.0001$). At the end of 52 weeks, 18.6 percent of participants who took varenicline remained abstinent, compared

with 5.6 percent of participants randomized to take placebo ($p < 0.0001$).

Varenicline was generally well-tolerated in the study. Treatment-emergent serious adverse events occurred in 2.8 percent of study participants treated with varenicline compared with 4.4 percent of those given placebo.

Certain COPD patients were excluded from this study, including those with serious medical conditions, such as mental illness. There was one suicidal ideation event for placebo and no such event for varenicline. Incidences of other psychiatric adverse events were low and similar between varenicline and placebo.

The most common adverse events reported in the study were nausea (27.0 percent for varenicline vs. 8.0 percent for placebo), abnormal dreams (10.9 percent vs. 2.8 percent), upper respiratory tract infection (9.7 percent vs. 8.4 percent), insomnia (9.7 percent vs. 6.0 percent), headache (8.1 percent vs. 8.0 percent), flatulence (7.3 percent vs. 5.2 percent), and vomiting (6.5 percent vs. 2.4 percent).

This trial was sponsored by Pfizer Inc.

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.

IMPORTANT SAFETY INFORMATION

Some people have had changes in behavior, hostility, agitation, depressed mood, suicidal thoughts or actions while using varenicline to help them quit smoking. Some people had these symptoms when they began taking varenicline, and others developed them after several weeks of treatment or after stopping varenicline. If you, your family or caregiver notice agitation, hostility, depression or changes in behavior, thinking, or mood that are not typical for you, or you develop suicidal thoughts or actions, anxiety, panic, aggression, anger, mania, abnormal sensations, hallucinations, paranoia or confusion, stop taking varenicline and call your doctor right away. Also tell your doctor about any history of depression or other mental health problems before taking varenicline, as these symptoms may worsen while taking varenicline.

Some people can have serious skin reactions while taking varenicline, some of which can become life-threatening. These can include rash, swelling, redness, and peeling of the

skin. Some people can have allergic reactions to varenicline, some of which can be life-threatening and include: swelling of the face, mouth, and throat that can cause trouble breathing. If you have these symptoms or have a rash with peeling skin or blisters in your mouth, stop taking varenicline and get medical attention right away.

The most common side effects include nausea (30%), 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 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.

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.

Please click [here](#) for Full Prescribing Information and Medication Guide.

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Donald P. Tashkin, M.D., Primary Study Investigator, Emeritus Professor of Medicine at UCLA; If embedding or linking to these sound bites, please do so in their entirety, including Important Safety Information. For Full Prescribing Information and Medication Guide, please go to the following links: http://www.pfizer.com/files/products/uspi_chantix.pdf and http://www.pfizer.com/files/products/ppi_chantix.pdf, respectively.

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