



CHANTIX® (varenicline) Demonstrates Efficacy in Smokers Who Previously Attempted to Quit Smoking with CHANTIX

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New Positive Top-line Results in Adult Smokers Re-treated With CHANTIX

"These new data show that, for some adult smokers who had previously taken CHANTIX but either did not quit smoking or relapsed after quitting, another quit attempt with CHANTIX may be fruitful."

(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) announced today that a post-marketing study assessing the efficacy and safety of varenicline (CHANTIX®/CHAMPIX®) in a population of smokers who had made a previous attempt to quit smoking with CHANTIX, and either did not succeed in quitting or relapsed after treatment, met its primary endpoint.

CHANTIX significantly increased continuous abstinence rates compared to placebo at weeks nine to 12, the last four weeks of treatment (primary endpoint). The efficacy rates were consistent with findings seen in other CHANTIX clinical trials in smokers who had not been previously treated with CHANTIX. The safety and tolerability profile of CHANTIX in this study was also consistent with previous studies. The most commonly reported treatment-emergent adverse events were nausea, abnormal dreams and headache, with incidence rates similar to previous CHANTIX studies.

"Smoking is considered a chronic, relapsing medical condition. The availability of pharmacological treatments has led to a large and growing population of smokers who have made previous quit attempts but were ultimately unsuccessful," said Steven J. Romano, M.D., senior vice president and medicines development group head, Primary

Care Business Unit, Pfizer Inc. "These new data show that, for some adult smokers who had previously taken CHANTIX but either did not quit smoking or relapsed after quitting, another quit attempt with CHANTIX may be fruitful."

Study Background

This study was a Phase 4, 12-week, randomized, double-blind, placebo-controlled, multi-center study, which evaluated the efficacy and safety of varenicline tartrate 1 mg BID for smoking cessation in adult subjects, who had made a previous attempt to quit smoking with CHANTIX and either did not succeed in quitting or relapsed after treatment. Patients included in this study had taken CHANTIX for a smoking-cessation attempt in the past (for a total treatment duration of a minimum of two weeks), and at least three months prior to study entry, and had been smoking for at least four weeks.

About CHANTIX

CHANTIX was approved by the FDA in May 2006 as an aid to smoking cessation treatment in adults 18 and older. CHANTIX has been shown to increase the likelihood of abstinence from smoking for as long as one year compared to treatment with placebo. 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 CHANTIX. If patients slip up, they can stay on CHANTIX and keep trying to quit.

Important CHANTIX (varenicline) Safety Information

Some people have had changes in behavior, hostility, agitation, depressed mood, suicidal thoughts or actions while using CHANTIX to help them quit smoking. Some people had these symptoms when they began taking CHANTIX, and others developed them after several weeks of treatment or after stopping CHANTIX. If the CHANTIX patient, their family or caregiver notice any of these symptoms or behaviors, they should stop taking CHANTIX and call their doctor right away. They should tell their doctor about any history of depression or other mental health problems, which could get worse while taking CHANTIX.

Patients should not take CHANTIX if they've had a serious allergic or skin reaction to it. If they develop serious allergic or skin reactions, including swelling of the face, mouth, throat, or a rash, they should stop taking CHANTIX and see their doctor right away as some of these can be life-threatening.

Patients should tell their doctor if they have a history of heart or blood vessel problems or have any new or worse symptoms during treatment with CHANTIX. Patients should get emergency medical help right away if they have any symptoms of a heart attack or stroke.

Dosing may be different for patients who have kidney problems. Until the patient knows how CHANTIX affects them, they should use caution when driving or operation machinery. Common side effects include nausea, trouble sleeping and unusual dreams. CHANTIX should not be taken with other quit-smoking products. Patients should tell their doctor which medicines they are taking as these medicines may work differently when quitting smoking.

Full prescribing information and Medication Guide are available at www.pfizer.com.

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Varenicline is known as CHANTIX® in the U.S. and CHAMPIX® outside the U.S.

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