CHANTIX®/CHAMPIX® (varenicline) Demonstrates Smoking- Cessation Efficacy In Smokers Unwilling or Unable To Quit Abruptly

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New Positive Top-line CHANTIX/CHAMPIX Study Results

Pfizer Inc. (NYSE: PFE) announced today that a new smoking-cessation clinical study assessing the efficacy and safety of varenicline (CHANTIX®/CHAMPIX®) met its primary and secondary endpoints. This is the first study of varenicline using the approach of reducing smoking prior to quitting. Smokers in this study were unwilling or unable to abruptly quit smoking within four weeks, but were willing to reduce smoking over a period of 12 weeks, with the goal of quitting by the end of that period. Smokers in the study were treated for a 12-week reduction phase followed by a 12-week abstinence phase (for a total of 24 weeks of treatment).

“Setting a fixed quit date can be daunting to smokers, which is why reducing the number of cigarettes smoked is a commonly-used approach to quitting,” said Steven J. Romano, M.D, senior vice president and Medicines Development Group Head, Global Innovative Pharmaceuticals, Pfizer Inc. “This study was designed with this quitting approach in mind.”

In the study of smokers (N=1,510) who were willing to gradually reduce smoking with a goal of quitting within 12 weeks, patients were randomized to either varenicline (CHANTIX/CHAMPIX) 1mg BID or placebo for 24 weeks of treatment, followed by a 28-week non-treatment phase. All patients received brief smoking-cessation counseling throughout the study. Preliminary results demonstrated that continuous abstinence rates (CAR) at weeks 15 through 24, the primary endpoint, were significantly higher in patients treated with CHANTIX/CHAMPIX than in patients treated with placebo (32.1 percent vs.

6.9 percent, Odds Ratio [OR]=8.74, p=<0.0001).

The safety and tolerability of varenicline in this study were generally consistent with findings seen in previous clinical studies. The most common treatment-emergent all-causality adverse events reported in over 10 percent of patients in either the varenicline or placebo treatment group were (varenicline versus placebo): nausea (27.8 percent vs. 9.0 percent), nasopharyngitis (13.0 percent vs. 12.0 percent), abnormal dreams (11.5 percent vs. 5.8 percent) and insomnia (10.7 percent vs. 6.9 percent).

Study Background

This study was a 52-week, randomized, double-blind, placebo-controlled, multinational, parallel group study evaluating the efficacy and safety of varenicline 1 mg BID for smoking cessation using the reduce-to-quit approach. Patients included in this study were adult smokers (N=1,510) who were unwilling or unable to quit within four weeks, but were willing to reduce their smoking with the ultimate goal of quitting within 12 weeks.

Participants were treated with varenicline (n=760) or placebo (n=750) for 24 weeks and targeted at least a 50 percent reduction in the number of cigarettes smoked by the end of the first four weeks of treatment, and a further 50 percent reduction after the following eight weeks of treatment, with the goal of complete abstinence by 12 weeks. Smokers who had not made a quit attempt in the 12-week reduction phase of the study were encouraged to do so in the next 12 weeks of treatment.

The study inclusion criteria allowed for enrollment of smokers with certain psychiatric diagnoses, with appropriate monitoring throughout the study.

These are preliminary data and are subject to additional analyses. Results from this study will be submitted for publication in a peer-reviewed journal.

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 smoking-cessation 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 operating machinery. Common side effects include nausea, trouble sleeping and unusual dreams. CHANTIX should not be taken with other smoking cessation 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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worked to make a difference for all who rely on us. To learn more, please visit us at www.pfizer.com.

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