Pfizer Affirms CHANTIX/CHAMPIX as Important Treatment Option for Smokers Wanting to Quit

Monday, July 04, 2011 - 04:14am

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(BUSINESS WIRE)--Pfizer said today that the reliable science on varenicline (CHANTIX/CHAMPIX), involving more than 14 clinical trials with more than 7,000 smokers, and the medicine’s approval by regulatory authorities around the world, demonstrate the importance of the medicine as an effective and appropriate treatment option for adult smokers wanting to quit. Pfizer stands behind the benefit/risk profile of Chantix.

The company expressed concerns about the reliability of the meta-analysis by Singh et al published today in the Canadian Medical Association Journal (CMAJ). These concerns, among others, are related to the appropriateness of the authors' measure of cardiovascular risk, or composite endpoint, which combines events that do not share a common biological cause; the manner in which cardiovascular events were counted and classified; and a small number of events, which forms the authors' conclusions.

The authors themselves acknowledge that the cardiovascular risk “estimates are imprecise owing to the low event rates.”

Notwithstanding these reliability concerns, the difference of 72 percent reported in the Singh analysis also needs to be put into appropriate context. The actual difference in cardiovascular event rates reported in this analysis was less than one quarter of one percent (i.e., 1.06 percent with varenicline versus 0.82 percent with placebo).

“Pfizer scientists and doctors continuously evaluate the benefits and risks of its medicines, including Chantix,” said Dr. Gail Cawkwell, Vice President of Medical Affairs. “The currently available safety data on Chantix, including a pooled analysis of clinical data in 7,375 people trying to quit smoking, do not support an increased cardiovascular

risk associated with Chantix.”

Pfizer is discussing with the U.S. Food and Drug Administration (FDA) a protocol to conduct a meta-analysis of Pfizer’s clinical trial data to help further evaluate the cardiovascular safety of Chantix. This meta-analysis will address a number of limitations in the Singh analysis; Pfizer expects that it will be based on a more reliable composite endpoint to measure cardiovascular risk, as well as a validated process to classify, or adjudicate, cardiovascular events that are part of the composite endpoint.

A video addressing the meta-analysis published in the CMAJ was posted to www.pfizer.com.

Each year, an estimated 5.4 million people worldwide die from smoking related causes, including cardiovascular disease.1 Chantix is a proven aid to smoking cessation treatment and an important treatment option that has been prescribed to over 13 million patients worldwide.

Chantix is currently approved for use in 99 countries around the world. Pfizer works with regulators worldwide on a continual basis to review and monitor data for Chantix.

Patients should consult with their health care providers to determine what medications are right for them. Patients should contact their healthcare professional if they experience new or worsening symptoms of cardiovascular disease.

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. Nearly 13 million people have been prescribed Chantix worldwide. The prescribing information for Chantix can be obtained at http://labeling.pfizer.com/ShowLabeling.aspx?id=557.

IMPORTANT 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 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 Chantix and call your doctor right away. Also tell your doctor about any history of depression or other mental health problems before taking Chantix , as these symptoms may worsen while taking Chantix .

Some people can have serious skin reactions while taking Chantix , 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 Chantix, 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 Chantix and get medical attention right away.

The most common side effects include nausea (30%), sleep problems, constipation, gas and/or vomiting. If you have side effects that bother you or don’t go away, tell your doctor. You may have trouble sleeping, vivid, unusual or strange dreams while taking Chantix . Use caution driving or operating machinery until you know how Chantix may affect you.

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

Before starting Chantix , 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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difference for all who rely on us. To learn more about our commitments, please visit us at www.pfizer.com.

1 Tobacco Free Initiative (TFI), World Health Organization (WHO). Facts and Figures About Tobacco, June 2007

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