CHAMPIX® (varenicline) European Union Label Updated to Include New Safety and Efficacy Data from the EAGLES Clinical Trial Following Endorsement from CHMP

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Black triangle indicating additional safety monitoring requirement for CHAMPIX in the EU has been removed

“Smoking remains a major public health challenge, causing more than 5 million deaths worldwide each year”

Pfizer Inc. (NYSE:PFE) today announced that the European Summary of Product Characteristics (SmPC) and Package Leaflet for CHAMPIX® (varenicline) have been updated to include safety and efficacy data from the EAGLES (Evaluating Adverse Events in a Global Smoking Cessation Study) trial.1 As part of the update, the black triangle symbol, which indicated that additional safety monitoring for CHAMPIX in the EU was required, has been removed. EAGLES is a post-authorization safety study/post-marketing requirement study, which was conducted in 16 countries and designed to evaluate the neuropsychiatric safety of CHANTIX/CHAMPIX and bupropion versus placebo and nicotine replacement therapy patch (NRT) in patients with and without a history of psychiatric disorder. The outcomes of the EAGLES trial were recently published in The Lancet.2 The CHAMPIX EU label update was implemented following the adoption of a positive opinion by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency.

“Smoking remains a major public health challenge, causing more than 5 million deaths worldwide each year,” said Rory O’Connor, MD, Chief Medical Officer, Internal Medicine, Pfizer Inc. “Since its introduction in the EU nearly 10 years ago, CHAMPIX has been prescribed to millions of adults to help them stop smoking. The new safety and efficacy information in the European label further supports the importance of CHAMPIX as a treatment option for healthcare providers and for those who are trying to quit smoking.”

The EAGLES trial is a large randomized, double-blind, active and placebo-controlled study that was conducted by Pfizer in collaboration with GlaxoSmithKline at the request of, and designed in consultation with, the U.S. Food and Drug Administration (FDA) and the European Medicines Agency. The primary safety endpoint was a composite of neuropsychiatric adverse events that have been reported in the post-marketing experience for CHANTIX/CHAMPIX. The study also included an efficacy objective to determine smoking abstinence rates in patients treated with CHAMPIX or bupropion, relative to placebo, during the last four weeks of treatment.

The European Medicines Agency approval to update the CHAMPIX label applies to all 28 EU member states, plus Iceland, Norway and Liechtenstein. The EAGLES data are currently under review by other regulatory authorities worldwide.

The CHANTIX/CHAMPIX labeling globally includes a boxed warning/warning regarding serious neuropsychiatric adverse events that have been reported in some patients attempting to quit smoking while taking CHANTIX/CHAMPIX in the post-marketing experience. Some people have had changes in behavior, hostility, agitation, depressed mood, and suicidal thoughts or actions while using CHANTIX/CHAMPIX to help them quit smoking. If the CHANTIX/CHAMPIX patient, their family or caregiver notices any of these symptoms or behaviors, they should stop taking CHANTIX/CHAMPIX 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/CHAMPIX.

About CHANTIX®

CHANTIX® (also known as CHAMPIX® in the EU and other countries) was approved by the FDA in May 2006 as a prescription medication that, along with support, helps 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 CHANTIX/CHAMPIX. If patients slip up, they can stay on CHANTIX/CHAMPIX 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.

Some people had seizures during treatment with CHANTIX. Most cases happened during the first month of treatment. Patients should tell their doctor if they have a history of seizures. If a patient has a seizure during treatment with CHANTIX, he/she should stop taking CHANTIX and contact his/her healthcare provider right away.

Patients should decrease the amount of alcohol they drink while taking CHANTIX until they know if CHANTIX affects their ability to tolerate alcohol. Some people experienced increased drunkenness, unusual or sometimes aggressive behavior, or memory loss of events while consuming alcohol during treatment with 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.

Click here for Full Prescribing Information, including BOXED WARNING and Medication Guide.

About Pfizer Inc.: Working together for a healthier world®

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. For more information, please visit us at www.pfizer.com. In addition, to learn more, follow us on Twitter at @Pfizer and @Pfizer_News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

DISCLOSURE NOTICE: The information contained in this release is as of May 23, 2016. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information regarding CHANTIX/CHAMPIX, including its potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the commercial impact of the results of the EAGLES study; uncertainties regarding the impact of the EAGLES study on the product labeling for CHANTIX/CHAMPIX in the United States or other jurisdictions outside the European Union; the risk that clinical trial data are subject to differing interpretations, including by regulatory authorities; the uncertainties inherent in research and development; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer’s Annual Report on Form 10-K for the fiscal year ended December 31, 2015 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned “Risk Factors” and “Forward-Looking Information and Factors That May Affect Future Results,” as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

References:

1 Champix® (varenicline): EU Summary of Product Characteristics. Pfizer; May 2016.

2 Anthenelli RM, Benowitz NL, West R, et al. Neuropsychiatric safety and efficacy of varenicline, bupropion, and nicotine patch in smokers with and without psychiatric disorders (EAGLES): a double-blind, randomized, placebo-controlled clinical trial. Lancet. 2016 Apr 19:e1-e14.[Epub ahead of print].

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