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FDA Advisory Committees Recommend to Remove Boxed Warning in Labeling for Pfizer's Smoking Cessation Therapy, CHANTIX® (varenicline)

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"We are pleased with the Committees' recommendation to remove the boxed warning and believe this is an important step toward updating the CHANTIX labeling to more accurately reflect its neuropsychiatric safety profile and help patients and prescribers make informed decisions about treatment options."

Today, a joint meeting of the U.S. Food and Drug Administration's (FDA) Psychopharmacologic Drugs Advisory Committee and Drug Safety Risk Management Advisory Committee reviewed data from EAGLES (**E**valuating **A**dverse Events in a **Gl**obal Smoking C**e**ssation **S**tudy) evaluating the neuropsychiatric safety of CHANTIX® (varenicline). The Committees recommended by a majority vote to remove the boxed warning regarding serious neuropsychiatric adverse events from the CHANTIX labeling. The role of the Advisory Committees is to provide recommendations to the FDA; however, the FDA makes the final labeling decisions.[1]

Earlier this year, Pfizer (NYSE:PFE) submitted to the FDA a supplemental New Drug Application (sNDA) requesting updates to the CHANTIX labeling based on the safety and efficacy outcomes of EAGLES. In addition to requesting removal of the boxed warning, Pfizer proposed retaining the Warnings and Precautions section in the labeling regarding serious neuropsychiatric events occurring in patients attempting to quit smoking and updating it with EAGLES data. Pfizer believes that such a warning would sufficiently inform prescribers of the possibility that these types of events may occur.

EAGLES is a randomized, blinded, placebo-controlled clinical trial, which was conducted by Pfizer in collaboration with GlaxoSmithKline and at the request of and designed in consultation with the FDA and the European Medicines Agency. The study is the first and largest to compare the safety and efficacy of all three currently approved smoking cessation therapies, including CHANTIX, in more than 8,000 smokers with and without a history of psychiatric disorders. It included a novel composite primary endpoint developed by Pfizer with input from the FDA, comprised of 16 components reflecting the type of events reported in the CHANTIX postmarketing experience and included in the labeling. Results from EAGLES were published in *The Lancet* in April.[2]

"The totality of available scientific evidence, including the outcomes of EAGLES, supports the safety and efficacy of CHANTIX, and we look forward to the FDA's decision on the CHANTIX labeling," said Freda Lewis-Hall, M.D., DFAPA, Chief Medical Officer and EVP, Pfizer Inc. "We are pleased with the Committees' recommendation to remove the boxed warning and believe this is an important step toward updating the CHANTIX labeling to more accurately reflect its neuropsychiatric safety profile and help patients and prescribers make informed decisions about treatment options."

About Smoking in the U.S.

In the U.S., smoking causes more than 480,000 deaths each year and is a leading cause of preventable death and disease.[3] Stopping smoking can have significant health benefits, reducing the risk of tobacco-related diseases such as lung cancer, heart disease, stroke, chronic respiratory disease and other conditions.[4] While smoking rates have declined overall, some segments of society have not made the same progress.[5,6] Of note, individuals with mental illness comprise a large section of the smoking population as they have a higher smoking rate than adults without mental illness (33% and 20%, respectively as reported in the 2014 National Survey).[7] Nearly one in five adults in the U.S. have some type of mental illness, but they smoke almost one-third of all cigarettes.[8] Quitting is not easy and many people who want to quit struggle to do so without help.[9]

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. CHANTIX is approved in more than 100 countries and has been prescribed to over 20 million patients worldwide, including more than 11 million in the U.S. 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.

Sleepwalking can happen with CHANTIX, and can sometimes lead to behavior that is harmful to the patient, other people or to property. The patient should stop taking CHANTIX and tell their doctor if they start sleepwalking.

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 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.

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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 healthcare 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 September 14, 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 about CHANTIX/CHAMPIX (varenicline), 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 and the Advisory Committees' recommendation regarding the labeling for CHANTIX; whether and when the FDA may approve the sNDA regarding the CHANTIX labeling, which will depend on the assessment by the FDA of the available safety information; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of CHANTIX (including uncertainties regarding the impact of the EAGLES study on the product labeling for CHANTIX/CHAMPIX in the United States or other jurisdictions); 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:

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