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Pfizer Statement on CHANTIX (varenicline) Labeling Update in the United States

Thursday, January 17, 2008 - 05:00pm

(BUSINESS WIRE)--Cigarette smoking is associated with significant morbidity and mortality. Smoking is the leading preventable cause of disease and premature death in the United States, with more than 438,000 U.S. deaths annually attributable to smoking. Patients who smoke cigarettes should be counseled to quit. CHANTIX® was approved in May of 2006 in the U.S. as an aid to smoking cessation.

Based upon post-marketing reports first reflected in a November 2007 labeling update, Pfizer today updated the CHANTIX label in the U.S. to include a warning that patients who are attempting to quit smoking with CHANTIX should be observed for serious neuropsychiatric symptoms, including changes in behavior, agitation, depressed mood, suicidal ideation and suicidal behavior.

The current update, based on Pfizer and FDA's ongoing safety review of post-marketing reports, is provided to better ensure that healthcare providers and patients will appropriately consider this information in their discussions about CHANTIX. A causal relationship between CHANTIX and these reported symptoms has not been established. In some reports, however, an association could not be excluded. More specifically, some reports may have been complicated by the symptoms of nicotine withdrawal in patients who stopped smoking, but not all patients with these symptoms had quit smoking. Some patients with pre-existing psychiatric illness experienced a worsening of their conditions. By heightening awareness of these post-marketing events and facilitating this discussion, patients and doctors can play an important role in mitigating potential risk and ensuring the full benefits of CHANTIX can be realized.

"There are few things that provide greater health benefits than quitting smoking. When considering the use of CHANTIX for their patients, healthcare providers should discuss the risks of smoking, the health benefits of quitting smoking, and the product's efficacy and safety profile," said Dr. Joe Feczko, chief medical officer, Pfizer. "CHANTIX is a real breakthrough medicine that has helped many smokers who want to quit. We hope that today's labeling change will further facilitate the important dialogue that should always occur between patients and their doctors when considering any prescription medication."

In the controlled clinical trial program of more than 5,000 patients treated with CHANTIX, changes in behavior, agitation, depressed mood, suicidal ideation, and suicidal behavior occurred at a rate comparable to placebo-treated patients. There were no suicides attributed to CHANTIX in clinical trials. Patients with serious psychiatric illness such as schizophrenia, bipolar disorder, and major depressive disorder did not participate in the controlled clinical trial program.

CHANTIX, a selective nicotinic acetylcholine receptor partial agonist, is the first non-nicotine prescription treatment for smoking cessation in almost a decade. It has been prescribed to more than 4 million patients in the United States since approval.

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