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New Study With CHANTIX®/CHAMPIX® (varenicline) Tablets Suggests Favorable Benefit-Risk Profile In Adult Smokers With Major Depressive Disorder

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Quitting Rates Compared to Placebo in Adult Smokers with Major Depressive Disorder Were Similar to Those in Other Populations of Smokers Previously Studied

"The results from this study offer important information which contributes to a further understanding of the clinical profile of CHANTIX/CHAMPIX,"

(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) announced today the completion of a double-blind, placebo-controlled, randomized clinical trial designed to assess the efficacy and safety of CHANTIX®/CHAMPIX® (varenicline) 1 mg BID in comparison to placebo for smoking cessation in patients with a past or present diagnosis of Major Depressive Disorder (MDD). The study met its primary and secondary efficacy endpoints. Subjects in the varenicline group had a higher likelihood of quitting at week 12 (primary endpoint) and at week 52 (key secondary endpoint). In addition, psychiatric scales included for safety assessments did not show a difference between varenicline and placebo.

“The results from this study offer important information which contributes to a further understanding of the clinical profile of CHANTIX/CHAMPIX,” said Steven J. Romano, M.D., senior vice president, head, Medicines Development Group, Global Primary Care Business Unit, Pfizer Inc.

The currently approved CHANTIX®/CHAMPIX® (varenicline) labeling states that the safety and efficacy of varenicline in patients with serious psychiatric illness such as schizophrenia, bipolar disorder and major depressive disorder have not been established. Pfizer developed this study protocol at the request of, and in consultation with, the European Medicines Agency (EMA) to investigate use of varenicline in patients with MDD.

Efficacy results

The primary endpoint was the 4-week Continuous Quit Rate (CQR) for weeks 9 through 12. Subjects were treated for 12 weeks and followed for up to 52 weeks. The key secondary endpoint was Continuous Abstinence Rate (CAR) from weeks 9 through 52. Subjects in the varenicline-treated group had a higher likelihood of quitting smoking at the end of the treatment period. The CQR between weeks 9-12 was 35.9% for varenicline vs. 15.6% for placebo and between weeks 9-52 was 20.3% vs. 10.4%, respectively. The efficacy results from this study were consistent with varenicline pivotal trials.

Safety results

The most commonly reported AEs in greater than or equal to 10% of subjects were: nausea, headache, abnormal dreams, irritability and insomnia.

Additionally, the most commonly reported neuropsychiatric AEs in greater than or equal to 2% of subjects were: anxiety, agitation, depression, tension, depressed mood, sleep disorders, hostility and restlessness.

Regarding the secondary endpoints, there were no differences between subjects on varenicline and placebo in psychiatric scales, including the Clinical Global Impression of Improvement (CGI-I), Clinical Global Impression of Severity (CGI-S), Montgomery-Asberg Depression Rating Scale (MADRS), Hamilton Anxiety Scale (HAM-A), Barratt Impulsiveness Scale (BIS-11) and the Columbia Suicide-Severity Rating Scale (C-SSRS). Other safety endpoints were physical examination findings, vital signs and laboratory measures.

“Smoking is common in psychiatric patients, including depressed patients, and it is important to have treatment options to help them quit,” said Dr. Robert Anthenelli, Professor of Psychiatry at the University of California, San Diego, Health System, VA San Diego Healthcare System, and the Principal Investigator for the study. “It’s encouraging to see that CHANTIX/CHAMPIX may be a viable option to help people with a history of depression quit smoking.”

About the study

The randomized, double-blind, placebo-controlled study was conducted at 38 centers in Europe and the United States. A total of 525 male and female smokers, aged 19-73 years, motivated to quit with a current or past diagnosis of MDD without psychotic features and who were either on stable antidepressant treatment or had a successfully treated episode of MDD in the past 2 years were treated for 12 weeks and followed for additional 40 weeks.

Patients with a current or past diagnosis of dementia, schizophrenia, schizoaffective disorder, or other psychotic disorder, bipolar I disorder, or bipolar II disorder; currently using either bupropion or nortriptyline; who were at suicidal or homicidal risk or had evidence of substance abuse were not eligible to participate in the study.

About CHANTIX/CHAMPIX

CHANTIX was approved by the U.S. Food and Drug Administration (FDA) in May 2006 as an aid to smoking-cessation treatment in adults 18 and older, and CHAMPIX was approved by the European Medicines Agency (EMA) in September 2006.

The CHANTIX labeling can be obtained at http://labeling.pfizer.com/ShowLabeling.aspx?id=557.

The EU Summary of Product Characteristics (SmPC) may be found at:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000699/human_med_000696.jsp&mu
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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. To learn more about our commitments, please visit us at www.pfizer.com.

Pfizer Inc. Media: MacKay Jimeson, 212-733-2324 MacKay.Jimeson@pfizer.com or Investors: Suzanne Harnett, 212-733-8009 Suzanne.Harnett@Pfizer.com