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PRISTIQ® (desvenlafaxine) Extended Release Tablets Shown To Significantly Reduce Number And Severity Of Moderate-To-Severe Hot Flashes Associated With Menopause

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Results from Phase 3 Efficacy Sub-study Presented at the 59th Annual Clinical Meeting of the American College of Obstetricians and Gynecologists

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(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) today announced results from a Phase 3 12-week efficacy sub-study, which found that PRISTIQ® (desvenlafaxine), a serotonin-norepinephrine reuptake inhibitor (SNRI), significantly reduced the number and severity of moderate-to-severe hot flashes in postmenopausal women. The data were presented at the 59th Annual Clinical Meeting of the American College of Obstetricians and Gynecologists in Washington, D.C.[1]

PRISTIQ, which is approved by the U.S. Food and Drug Administration (FDA) for the treatment of major depressive disorder (MDD) in adults, is a non-hormonal therapy currently under review by the FDA for the treatment of moderate-to-severe vasomotor symptoms (VMS) associated with menopause – commonly referred to as hot flashes and night sweats.[2]

“Desvenlafaxine significantly reduced the number and severity of moderate-to-severe hot flashes among postmenopausal women compared with placebo, which is meaningful because up to 75 percent of women experience hot flashes associated with menopause,"[1,3] said JoAnn V. Pinkerton, M.D., lead author for the efficacy sub-study and Medical Director of Midlife Health Center and Professor of Obstetrics and Gynecology, University of Virginia.[1]

Women can experience hot flashes associated with menopause for varying periods of time, typically ranging from six months to a few years.[3]

“Pfizer is committed to women’s health and understands the impact that hot flashes and night sweats related to menopause can have on a woman’s life and the importance of having options to treat menopausal symptoms,” said Steven Romano, M.D., senior vice president and head, Medicines Development Group, Primary Care Business Unit, Pfizer. “If approved by the FDA for this indication, PRISTIQ will expand the range of effective treatment options available to help manage VMS in the United States.”

More About the Efficacy Sub-study

The efficacy sub-study of 365 patients was part of a year-long, double-blind, placebo-controlled safety trial conducted in the United States and Canada. Patients enrolled in the efficacy sub-study were required to have at least 7 bothersome moderate-to-severe hot flashes per day or 50 bothersome moderate-to-severe hot flashes per week at baseline.[1] In the efficacy sub-study, desvenlafaxine met all four co-primary endpoints – the change from baseline in both the number and severity of moderate-to-severe hot flashes at week 4 and at week 12 (all $p<0.001$ versus placebo).[1]

At week 4 of this efficacy sub-study, women in the PRISTIQ-treated group experienced a 55 percent reduction in hot flash frequency (average decrease of 6.5 hot flashes/day from a baseline mean of approximately 12 hot flashes/day) contrasted with a 31 percent reduction in hot flash frequency (average decrease of 3.6 hot flashes/day from a baseline mean of approximately 12 hot flashes/day) in the placebo group. At week 12, women in the PRISTIQ-treated group experienced a 62 percent reduction in hot flash frequency (average decrease of 7.3 hot flashes/day from a baseline mean of approximately 12 hot flashes/day) contrasted with a 38 percent reduction in hot flash frequency (average decrease of 4.5 hot flashes/day from a baseline mean of approximately 12 hot flashes/day) in the placebo group.[1]

Women in the PRISTIQ-treated group also experienced a 20 percent reduction in the severity of their hot flashes contrasted with an 8 percent reduction in the placebo group at week 4 of this efficacy sub-study. At week 12, women in the PRISTIQ-treated group experienced a 25 percent reduction in the severity of their hot flashes contrasted with a 12 percent reduction in the placebo group.[1]

During the 12-week efficacy sub-study, the most commonly reported adverse events were nausea, dry mouth, fatigue, constipation, diarrhea and somnolence.[1] Ten percent of the PRISTIQ-treated patients and 3.7 percent of the placebo-treated patients discontinued the study early due to adverse events.[1] A total of 2.5 percent of the PRISTIQ-treated patients and 8.4 percent of the placebo-treated patients discontinued due to lack of efficacy.[1]

About PRISTIQ Extended Release Tablets

PRISTIQ is a prescription medicine approved by the FDA for the treatment of major depressive disorder (MDD). PRISTIQ belongs to a class of medicines known as serotonin-norepinephrine reuptake inhibitors (or SNRIs). PRISTIQ is not approved for use in children and adolescents less than 18 years of age.

Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, teens, and young adults. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior when initiating or changing their dose of antidepressant therapy.

Patients taking MAOIs should not take PRISTIQ. Patients being considered for PRISTIQ therapy should discuss all of the medicines that they are taking with their health care provider including medicines for migraines or psychiatric disorders to avoid a potentially life-threatening condition, as well as aspirin, non-steroidal anti-inflammatory drugs (NSAIDS), or blood thinners because co-administration of PRISTIQ with these drugs may increase the risk of bleeding.

PRISTIQ may cause or make some conditions worse including high blood pressure, which should be controlled before starting PRISTIQ and monitored regularly during PRISTIQ therapy, glaucoma or increased eye pressure, mania, bipolar disorder, high cholesterol or triglyceride levels, stroke, heart problems, kidney or liver problems, seizures or convulsions, and low sodium levels.

Discontinuation symptoms may occur when stopping or reducing PRISTIQ. Side effects when taking PRISTIQ 50 mg may include nausea, dizziness, sweating, constipation, and decreased appetite.

For Full Prescribing Information and Medication Guide for PRISTIQ, please go to www.PRISTIQ.com.

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DISCLOSURE NOTICE: The information contained in this release is as of May 3, 2011. 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 a potential additional indication for PRISTIQ, including its potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; the decision by the FDA regarding whether and when to approve any new or supplement drug application that may be filed for such additional indication as well as the FDA's decisions regarding labeling and other matters that could affect its availability or commercial potential in the U.S.; and competitive developments.-6-

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, 2010 and in its reports on Form 10-Q and Form 8-K.

[1] Pinkerton JV, Constantine G, Hwang E, Cheng RJ. Desvenlafaxine efficacy vs placebo for the treatment of menopausal vasomotor symptoms. Poster presented at: 59th Annual Clinical Meeting of the American College of Obstetricians and Gynecologists (ACOG); April 30 - May 3, 2011; Washington, D.C.

[2] North American Menopause Society. Menopause glossary. http://www.menopause.org/glossary.aspx. Accessed February 23, 2011.

[3] North American Menopause Society. Clinical issues. In: *Menopause Practice: A Clinician's Guide*. 4th ed. Mayfield Heights, OH: North American Menopause Society; 2010:4-9.

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