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Pfizer Announces New Long-Term Relapse Prevention Data For PRISTIQ® (desvenlafaxine) 50 mg/day For The Treatment Of Major Depressive Disorder In Adults

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These and Other PRISTIQ Data Presented for the First Time at the 165th Annual Meeting of the American Psychiatric Association (APA)

"Patients benefit when their healthcare providers have a variety of medicines from which to choose for complex medical conditions, such as major depressive disorder,"

(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) announced new data presented at the 165th Annual Meeting of the American Psychiatric Association (APA) in Philadelphia on PRISTIQ® (desvenlafaxine) Extended Release Tablets 50 mg/day for the treatment of major depressive disorder (MDD) in adults,[1] including a long-term relapse prevention study. These new data, and data from a study in peri- and post-menopausal women with MDD, add to the existing efficacy and safety profile of PRISTIQ for the treatment of MDD. Lastly, new data also provide information regarding the discontinuation of PRISTIQ 50 mg/day for the treatment of adults with MDD.[2,3,4]

Pfizer has continued to research and evaluate PRISTIQ, a selective serotonin and norepinephrine reuptake inhibitor (SNRI), since it was approved by the U.S. Food and Drug Administration (FDA) in 2008 for the treatment of MDD in adults.[1] These new PRISTIQ 50 mg/day data focus on key factors – efficacy, safety, long-term use and discontinuation – that clinicians often consider when assessing antidepressants for the treatment of MDD.

“Patients benefit when their healthcare providers have a variety of medicines from which to choose for complex medical conditions, such as major depressive disorder,” said Christine Guico-Pabia, M.D., MBA, M.P.H., senior director, Global Medical Affairs at Pfizer. “Millions of patients continue to seek relief from their depression and may look to different treatment options. With an established efficacy and safety profile, and new data that provide clinicians with valuable treatment insights, there is a robust body of evidence that supports the use of PRISTIQ for adult patients with major depressive disorder.”

Efficacy and Safety of Desvenlafaxine 50 mg/day for Prevention of Relapse in Adult Outpatients Treated for Major Depressive Disorder, Joshua Rosenthal, M.D., et al. [Abstract #35301]

According to a long-term relapse prevention study, adult MDD patients receiving PRISTIQ 50 mg/day experienced statistically significant longer time to relapse over six months compared with patients receiving placebo. In the trial, 548 adult patients — who had responded to eight weeks of open-label treatment with PRISTIQ 50 mg/day and subsequently remained stable for 12 weeks on treatment — were assigned randomly in a double-blind manner to either remain on active treatment or switch to placebo for up to six months of

observation for relapse. The primary efficacy endpoint of the study was the time to relapse following randomization to the double-blind phase compared between the two groups.[3]

“These data are important because, as a psychiatrist, my goal is to help patients find a treatment that not only improves their depressive symptoms acutely but also maintains that effect over the longer term. Research like this can help patients to understand why they need to stay on their medications for a longer period of time and not just stop their antidepressant as soon as they feel better,” said Joshua Rosenthal, M.D., board certified adult psychiatrist in Columbia, Md., and lead investigator of the *Efficacy and Safety of Desvenlafaxine 50 mg/day for Prevention of Relapse in Adult Outpatients Treated for Major Depressive Disorder* study. “There is a solid foundation of clinical information about PRISTIQ, and I am pleased that it is an option for appropriate patients."

The data show that the probability of relapse with PRISTIQ 50 mg/day was 14.3 percent versus 30.2 percent with placebo at month six. These long-term results add to existing PRISTIQ relapse prevention data in the dose range of 200 – 400 mg/day, which were presented at the 160th APA Annual Meeting in 2007.[3]

PRISTIQ 50 mg/day demonstrated no significant mean weight change as compared to placebo at month six. In the initial open-label phase (eight weeks), the rate of treatment-emergent adverse events (TEAEs) was similar to those observed in prior short-term studies for PRISTIQ 50 mg/day. There were few TEAEs reported during the stability phase (12 weeks) of the study, with headache being the only TEAE reported in ?5 percent of patients. During the double-blind period (six months), the proportion of subjects who experienced at least one TEAE was comparable between groups (54.8 percent PRISTIQ-treated; 57.2 percent placebo). The most common TEAEs in both groups were headache, dizziness and depression, with dizziness and depression occurring in approximately twice as many in the placebo group. A larger percentage of patients on placebo in the double-blind phase (8.3 percent) discontinued treatment due to adverse events compared with patients who continued on PRISTIQ 50 mg/day (3.3 percent). PRISTIQ 50 mg/day was generally well tolerated over six months of treatment. Interpretation of these findings should take into consideration that only those patients who responded to and demonstrated a level of tolerability for PRISTIQ 50 mg/day in the open-label phase entered the double-blind phase of the study.[3]

Efficacy and Safety of Desvenlafaxine 50 mg/day in a Randomized, Placebo-Controlled Study of Peri- and Post-Menopausal Women with Major Depressive Disorder, Anita Clayton, M.D., et al. [Abstract #35318]

According to an eight-week, multicenter, double-blind, placebo-controlled study, peri- and post-menopausal women with MDD taking PRISTIQ 50 mg/day achieved statistically significant reductions in the 17-item Hamilton Rating Scale for Depression (HAM-D17) total scores compared to those taking placebo (–9.9, –8.1; P=0.004). The primary efficacy endpoint was the change from baseline in HAM-D17 total score at week eight.[4] The HAM-D17 is a validated assessment tool that clinicians often use to rate the severity of a patient's major depressive symptoms.[5] The risk of MDD in a woman’s lifetime is significantly greater than that of a man’s[6,7] and also is particularly prevalent for women going through the menopausal transition.[8]

The trial evaluated the efficacy and safety of PRISTIQ 50 mg/day in peri- and post-menopausal women with a primary diagnosis of MDD, aged 40 – 70 years old (n=434). Treatment-emergent adverse events (TEAEs) were reported by 71 percent of PRISTIQ-treated patients and 68 percent of patients in the placebo group. The most common TEAEs reported by both groups (?5 percent in either treatment group) were: headache, nausea, upper respiratory tract infection, constipation, nasopharyngitis (sore throat), dry mouth, dizziness and diarrhea. In all, 5.5 percent of PRISTIQ-treated patients discontinued the study due to adverse events (AEs) compared with 2.3 percent of those receiving placebo.[4]

Abrupt Discontinuation Compared with a One-Week Taper Regimen in Depressed Outpatients Treated for 24 Weeks with Desvenlafaxine 50 mg/day, Arif Khan, M.D., et al. [Abstract #35328]

This study demonstrated that abrupt discontinuation of treatment with PRISTIQ 50 mg/day resulted in no statistically significant difference in Discontinuation-Emergent Signs and Symptoms Scale (DESS) total scores compared to a one-week taper using 25 mg/day, the primary endpoint of this study. Abrupt discontinuation of PRISTIQ 50 mg/day was associated with a numerically greater number of new-onset adverse events (AEs) in the double-blind phase compared with the one-week taper using 25 mg/day.[2] PRISTIQ is available in 50 mg and 100 mg extended release tablets.

Adult patients (n=361) with MDD who completed 24-week, open-label treatment with PRISTIQ 50 mg/day were randomly assigned to one of the following three groups (1:2:2 ratio) for the double-blind taper phase:

- No-discontinuation group: PRISTIQ 50 mg/day for four weeks;
- Taper group: PRISTIQ 25 mg/day for one week followed by placebo for three weeks; and
- Abrupt discontinuation group: placebo for four weeks.

The DESS is a validated, clinician-rated instrument that evaluates changes in 43 signs and symptoms associated with discontinuation or interruption of antidepressant treatment during the past seven days.[9] There was no statistically significant difference in adjusted mean DESS scores for these three groups, which were 4.1, 4.8 and 5.3, respectively.[2]

The incidence of taper-emergent adverse events (TPEAEs) in the double-blind phase was greatest in the abrupt discontinuation group (51.4 percent), as compared to the taper group (38.8 percent) and the no-discontinuation group (36.1 percent). The most commonly reported AEs with onset or worsening during the double-blind period (?5 percent of patients in any group) included headache, nausea and dizziness.[2]

According to PRISTIQ Prescribing Information, a gradual reduction in the dose rather than abrupt cessation is recommended whenever possible.[1] Healthcare professionals should use clinical judgment when discontinuing treatment with PRISTIQ.[2]

About Major Depression

An estimated 33 to 35 million U.S. adults are likely to experience major depression at some point during their lifetime.[6] The criteria for clinical depression include having five or more of the symptoms of depression listed below during the same two-week period and representing a change from previous functioning. Depressed mood or diminished interest or pleasure must be among the depression symptoms reported from the following list: depressed mood; diminished interest or pleasure; significant weight loss or change in appetite; insomnia/hypersomnia; psychomotor agitation, fatigue or loss of energy; feelings of worthlessness or excessive/inappropriate guilt; difficulty concentrating; and recurrent thoughts of death.[7]

Important Safety Information About PRISTIQ

Suicidality and Antidepressant Drugs

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 who are started on antidepressant therapy or when the dose is changed should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior such as becoming agitated, irritable, hostile, aggressive, impulsive or restless. Should these occur, report them to a doctor. PRISTIQ is not approved for use in children under 18.

People taking MAOIs should not take PRISTIQ. Tell your healthcare professional about all prescription and over-the-counter medications you are taking or plan to take, including: medicines to treat migraines or psychiatric disorders, to avoid a potentially life-threatening condition; and aspirin, NSAID pain relievers, or blood thinners because they may increase the risk of bleeding.

PRISTIQ may cause or make some conditions worse, so tell your healthcare professional about all your medical conditions, including:

- High blood pressure which should be controlled before you start taking PRISTIQ and monitored regularly
- Heart problems, high cholesterol or triglyceride levels, or a history of stroke, glaucoma or increased eye pressure, kidney or liver problems, low sodium levels in your blood
- Have or had bleeding problems
- Have or had depression, suicidal thoughts or behavior
- Mania, bipolar disorder, or seizures or convulsions
- If nursing, pregnant, or plan to become pregnant

Discontinuation symptoms may occur when stopping or reducing PRISTIQ, so talk to your healthcare professional before stopping or changing your dose of PRISTIQ. Until you see how PRISTIQ affects you, be careful driving a car or operating machinery. Avoid drinking alcohol while taking PRISTIQ. Side effects when taking PRISTIQ 50 mg may include nausea, dizziness, sweating, constipation, and decreased appetite.

For full prescribing information for PRISTIQ, please go to www.PRISTIQ.com.

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DISCLOSURE NOTICE:

The information contained in this release is as of May 7, 2012. 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 for the maintenance treatment of major depressive disorder in adults, including its potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, decisions by regulatory authorities regarding whether and when to approve any drug applications that have been or may be filed for that additional indication as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; 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, 2011 and in its reports on Form 10-Q and Form 8-K.

[1] PRISTIQ® (desvenlafaxine) Extended Release Tablets Prescribing Information, Pfizer Inc. Philadelphia.

[2] Khan A, Ninan PT, Ramey T, et al. Abrupt Discontinuation Compared With a 1-Week Taper Regimen in Depressed Outpatients Treated for 24 Weeks With Desvenlafaxine 50 mg/d. Paper to be presented at: American Psychiatric Association Annual Meeting (APA); May 5-9, 2012; Philadelphia.

[3] Rosenthal J, Boyer P, Vialet C, et al. Efficacy and Safety of Desvenlafaxine 50 mg/d for Prevention of Relapse in Adult Outpatients Treated for Major Depressive Disorder. Paper to be presented at: American Psychiatric Association Annual Meeting (APA); May 5-9, 2012; Philadelphia.

[4] Clayton A, Kornstein SG, Dunlop BW, et al. Efficacy and Safety of Desvenlafaxine 50 mg/d in a Randomized, Placebo-Controlled Study of Peri/Postmenopausal Women With Major Depressive Disorder. Paper to be presented at: American Psychiatric Association Annual Meeting (APA); May 5-9, 2012; Philadelphia.

[5] American Psychiatric Association. *Practice Guideline for the Treatment of Patients with Major Depressive Disorder.* Third Edition. Arlington, Va., American Psychiatric Association, 2010.

[6] Kessler RC, Berglund P, Demler O, et al. The epidemiology of major depressive disorder: results from the National Comorbidity Survey Replication (NCS-R). *JAMA.* 2003; 289 (23):3095-3105.

[7] American Psychiatric Association: *Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition, Text Revision. Washington, DC, American Psychiatric Association, 2000.

[8] Kornstein S, Jiang Q, Reddy S, et al. Short-Term Efficacy and Safety of Desvenlafaxine in a Randomized, Placebo-Controlled Study of Perimenopausal and Postmenopausal Women With Major Depressive Disorder. *J Clin Psych*. 2010; 71 (8): 1088-1096.

[9] Pfizer Inc. Data on file.

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