

Pfizer Announces Top-Line Efficacy Results From A Phase 4 Study Of PRISTIQ® (desvenlafaxine) For The Treatment Of Major Depressive Disorder (MDD) In Adults

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New Data Add to Evidence Supporting PRISTIQ as a Treatment Option for MDD

"These positive top-line results add to the growing body of evidence that supports PRISTIQ as a treatment option for adults with major depressive disorder,"

[\(BUSINESS WIRE\)](#)--Pfizer Inc. (NYSE: PFE) announced today that a Phase 4 study evaluating the efficacy of PRISTIQ® (desvenlafaxine) Extended Release Tablets met its primary endpoint. The study supports the efficacy of 50 mg/day and 100 mg/day doses of PRISTIQ compared with placebo over eight weeks of treatment in adult patients with major depressive disorder (MDD) as measured by the 17-item Hamilton Rating Scale for Depression (HAM-D17) total score.¹

In this study, the most common treatment-emergent adverse events observed were consistent with the known safety and tolerability profile of PRISTIQ.¹

"These positive top-line results add to the growing body of evidence that supports PRISTIQ as a treatment option for adults with major depressive disorder," said Steven J. Romano, M.D., senior vice president, head of Medicines Development Group, Global Primary Care Business Unit, Pfizer Inc. "We know how challenging it can be to treat and manage major depressive disorder. We continue to study PRISTIQ in order to provide clinicians with more information that can better guide their treatment decisions for MDD patients."

The Phase 4 study was designed as a multi-center, randomized, double-blind, placebo-controlled, eight-week, parallel group study in adult patients with MDD.¹ The primary efficacy endpoint was the change from baseline in HAM-D17 total score at week eight.¹ The HAM-D17 is a validated assessment tool used to rate the severity of a patient's major depressive symptoms.² The study enrolled 924 patients who were randomized in a 1:1:1 ratio to one of the following treatment arms: PRISTIQ 50 mg/day, PRISTIQ 100 mg/day or placebo.¹

Results from this PRISTIQ Phase 4 study will be submitted for presentation at upcoming scientific congresses and for publication in a peer-reviewed medical journal.

About Major Depressive Disorder (MDD)

An estimated 33 to 35 million U.S. adults are likely to experience major depression at some point during their lifetime.³ The criteria for MDD 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.⁴

About PRISTIQ® (desvenlafaxine)

PRISTIQ, a selective serotonin and norepinephrine reuptake inhibitor (SNRI), is a prescription medication that was approved by the U.S. Food and Drug Administration (FDA) in 2008 for the treatment of MDD in adults.⁵ The recommended dose for PRISTIQ is 50 mg once daily, with or without food. In clinical studies, doses of 50-400 mg/day were shown to be effective, although no additional benefit was demonstrated at doses greater than 50 mg/day and adverse events and discontinuations were more frequent at higher doses.⁵

Important Safety Information About PRISTIQ

WARNING: SUICIDALITY AND ANTIDEPRESSANT DRUGS

Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents and young adults in short-term studies of Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of PRISTIQ or any other antidepressant in a child, adolescent or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. 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 should be monitored appropriately and observed closely for clinical worsening, suicidality or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. PRISTIQ is not approved for use in pediatric patients.

Contraindications

PRISTIQ is contraindicated in patients with a known hypersensitivity to PRISTIQ or venlafaxine.

Serotonin syndrome and MAOIs: Do not use monoamine oxidase inhibitors (MAOIs) intended to treat psychiatric disorders with PRISTIQ or within seven days of stopping treatment with PRISTIQ. Do not use PRISTIQ within 14 days of stopping an MAOI intended to treat psychiatric disorders. In addition, do not start PRISTIQ in a patient who is being treated with an MAOI such as linezolid or intravenous methylene blue.

Selected Warnings and Precautions

All patients treated with antidepressants should be monitored appropriately and observed closely for clinical worsening, suicidality and unusual changes in behavior, especially during the first few months of treatment and when changing the dose. Consider changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently worse or includes symptoms of anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia, hypomania, mania or suicidality that are severe, abrupt in onset or were not part of the patient's presenting symptoms. **Families and caregivers of patients being treated with antidepressants should be alerted about the need to monitor patients.**

The development of a potentially life-threatening serotonin syndrome has been reported with selective serotonin reuptake inhibitors (SSRIs) and serotonin and norepinephrine reuptake inhibitors (SNRIs), including with PRISTIQ, both when taken alone, but especially when co-administered with other serotonergic agents (including triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone and St. John's Wort) and with drugs that impair metabolism of serotonin (in particular, MAOIs, both those intended to treat psychiatric disorders and also others, such as linezolid and intravenous methylene blue). If such events occur, immediately discontinue PRISTIQ and any concomitant serotonergic agents, and initiate supportive treatment. If concomitant use of PRISTIQ with other serotonergic drugs is clinically warranted, patients should be made aware of a potential increased risk for serotonin syndrome, particularly during treatment initiation and dose increase.

Patients receiving PRISTIQ should have regular monitoring of blood pressure since increases in blood pressure were observed in clinical studies. Pre-existing hypertension should be controlled before starting PRISTIQ. Caution should be exercised in treating patients with pre-existing hypertension or other underlying conditions that might be compromised by increases in blood pressure. Cases of elevated blood pressure requiring immediate treatment have been reported. For patients who experience a sustained increase in blood pressure, either dose reduction or discontinuation should be considered.

SSRIs and SNRIs, including PRISTIQ, may increase the risk of bleeding events. Concomitant use of aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), warfarin and other anticoagulants may add to this risk.

Mydriasis has been reported in association with PRISTIQ; therefore, patients with raised intraocular pressure or those at risk of acute narrow-angle glaucoma (angle-closure glaucoma) should be monitored.

PRISTIQ is not approved for use in bipolar depression. Prior to initiating treatment with an antidepressant, patients should be adequately screened to determine the risk of bipolar disorder.

PRISTIQ should be used cautiously in patients with a history or family history of mania or hypomania or with a history of seizure disorder.

Caution is advised in administering PRISTIQ to patients with cardiovascular, cerebrovascular or lipid metabolism disorders. Increases in blood pressure and small increases in heart rate were observed in clinical studies with PRISTIQ. PRISTIQ has not been evaluated systematically in patients with a recent history of myocardial infarction, unstable heart disease, uncontrolled hypertension or cerebrovascular disease.

Dose-related elevations in fasting serum total cholesterol, low-density lipoprotein (LDL) cholesterol and triglycerides were observed in clinical studies. Measurement of serum lipids should be considered during PRISTIQ treatment.

On discontinuation, adverse events, some of which may be serious, have been reported with PRISTIQ and other SSRIs and SNRIs. Abrupt discontinuation of PRISTIQ has been associated with the appearance of new symptoms. Patients should be monitored for symptoms when discontinuing treatment. A gradual reduction in dose rather than abrupt cessation is recommended whenever possible.

The recommended dose in patients with severe renal impairment or end-stage renal disease (ESRD) is 50-mg every other day. The dose should not be escalated in patients with moderate or severe renal impairment or ESRD.

Products containing desvenlafaxine and products containing venlafaxine should not be used concomitantly with PRISTIQ.

Hyponatremia may occur as a result of treatment with SSRIs and SNRIs, including PRISTIQ. Discontinuation of PRISTIQ should be considered in patients with symptomatic hyponatremia.

Interstitial lung disease and eosinophilic pneumonia associated with venlafaxine (the parent drug of PRISTIQ) therapy have been rarely reported.

Adverse Reactions

Adverse reactions in patients in short-term, fixed-dose studies (incidence 75% and twice the rate of placebo in the 50 mg or 100 mg dose groups) were: nausea, dizziness, insomnia, hyperhidrosis, constipation, somnolence, decreased appetite, anxiety and specific male sexual function disorders.

Full prescribing information and Medication Guide are available at www.PRISTIQ.com.

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¹ Pfizer, Inc. Data on file.

² American Psychiatric Association. *Practice Guideline for the Treatment of Patients with Major Depressive Disorder*. Third Edition. Arlington, VA, American Psychiatric Association, 2010.

³ 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.

⁴ American Psychiatric Association: *Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition, Text Revision. Washington, DC, American Psychiatric Association, 2000.

⁵ PRISTIQ® (desvenlafaxine) Extended Release Tablets Prescribing Information, Pfizer, Inc. Philadelphia, PA.

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