



FDA Approves Pristiq for the Treatment of Adult Patients with Major Depressive Disorder

The FDA has approved PRISTIQ (desvenlafaxine), an SNRI, to treat adult patients with major depressive disorder (MDD). Wyeth expects to begin shipping PRISTIQ to wholesalers beginning in the second quarter of 2008.

Madison, NJ, March 01, 2008 --(PR.com)-- Wyeth Pharmaceuticals, a division of Wyeth (NYSE:WYE), announced today that the U.S. Food and Drug Administration (FDA) has approved PRISTIQ™ (desvenlafaxine), a structurally novel, once-daily serotonin-norepinephrine reuptake inhibitor (SNRI), to treat adult patients with major depressive disorder (MDD). Wyeth expects to begin shipping PRISTIQ to wholesalers beginning in the second quarter of 2008.

“We are pleased to be able to bring PRISTIQ to patients,” says Bernard Poussot, President and Chief Executive Officer of Wyeth. “PRISTIQ is Wyeth's fourth new drug to receive approval in the last twelve months, demonstrating our ability to achieve success through the rigorous scientific process of discovery and development. We look forward to working with FDA and other regulatory authorities around the world to continue to bring important new medicines to patients who need them.”

“PRISTIQ is an important new therapeutic option for patients and clinicians because no single therapy works for all people with major depression,” says Philip Ninan, M.D., Vice President of Wyeth Medical Affairs, Neuroscience. “PRISTIQ is approved at a once-daily 50-mg dose that does not require titration, allowing physicians to start their patients at the recommended therapeutic dose. We are encouraged by the tolerability profile seen in clinical studies.”

FDA approval was subject to several post-marketing commitments, including conducting and submitting data from a new long-term maintenance (relapse prevention) study, a sexual dysfunction study, pediatric studies and a study exploring lower doses. The agency also requested an additional non-clinical toxicity study.

The efficacy of PRISTIQ as a treatment for depression was established in four 8-week, randomized, double-blind, placebo-controlled, fixed-dose studies in adult outpatients who met the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) criteria for MDD. At the recommended dose of 50 mg, the discontinuation rate due to an adverse experience for PRISTIQ (4.1 percent) was similar to the rate for placebo (3.8 percent).

Side effects of many antidepressant therapies can cause some patients to stop taking their medication. The most commonly observed adverse reactions in patients taking PRISTIQ for MDD in short-term, fixed-dose studies (incidence >5 percent and at least twice the rate of placebo in the 50 or 100 mg dose groups) were nausea, dizziness, insomnia, hyperhidrosis, constipation, somnolence (sleepiness), decreased appetite, anxiety, and specific male sexual function disorders.

About PRISTIQ



PRISTIQ delivers the major active metabolite of EFFEXOR XR® (venlafaxine HCl) in its active state without going through the CYP2D6 metabolic pathway. This could be beneficial when PRISTIQ is coadministered with other commonly prescribed medications metabolized through that pathway. EFFEXOR XR, discovered and developed by Wyeth, was the first SNRI approved by the FDA for MDD and is currently the most widely prescribed antidepressant in the world.

PRISTIQ, also discovered and developed by Wyeth, demonstrates the Company's significant and continued commitment to developing new therapies in the field of neuroscience.

About Major Depressive Disorder

Major depressive disorder (MDD) is a common mental disorder, affecting about 121 million people worldwide. In the United States, MDD affects approximately 15 million adults, or 6.7 percent of the U.S. population age 18 and older in a given year. In fact, depression is among the leading causes of disability and the fourth leading contributor to the global burden of disease. Further, a research study estimated that the total economic burden of depression was \$83.1 billion in 2000, including direct treatment costs and suicide- and work-related costs.

MDD is a serious medical condition that is different from “feeling blue” and is not something that people just “get over.” Criteria for MDD include five or more of the following symptoms that have been present for at least two weeks, and at least one of the symptoms must be either depressed mood or loss of interest or pleasure: depressed mood; loss of interest or pleasure; changes in appetite or weight; changes in sleeping patterns; psychomotor agitation or retardation; fatigue or low energy; feeling worthless or guilty for no reason; difficulty thinking or concentrating; or thoughts of death or suicide. Further, people with MDD must experience clinically significant distress or impairment in social, occupational or other important areas of functioning.

Important Treatment Considerations for Antidepressants

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.
- 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, especially when starting therapy or at times of dose changes.
- PRISTIQ is not approved for use in pediatric patients.

Important Treatment Considerations for PRISTIQ



PRISTIQ is indicated for the treatment of major depressive disorder in adults.

Contraindications

- PRISTIQ is contraindicated in patients with a known hypersensitivity to PRISTIQ or venlafaxine.
- PRISTIQ must not be used concomitantly with an MAOI or within 14 days of stopping an MAOI. Allow 7 days after stopping PRISTIQ before starting an MAOI.

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.
- Development of a potentially life-threatening serotonin syndrome may occur with SNRIs and SSRIs, including PRISTIQ, particularly with concomitant use of serotonergic drugs, including triptans. If concomitant use is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases. Concomitant use of PRISTIQ with serotonin precursors is not recommended.
- Patients receiving PRISTIQ should have regular monitoring of blood pressure since sustained 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.
- SSRIs and SNRIs, including PRISTIQ, may increase the risk of bleeding events. Concomitant use of aspirin, 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.
- As with all antidepressants, PRISTIQ should be used cautiously in patients with a history or family history of mania or hypomania.
- 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.
- Dose-related elevations in fasting serum total cholesterol, LDL (low density lipoprotein) cholesterol, and triglycerides were observed in clinical studies. Measurement of serum lipids should be considered during PRISTIQ treatment.
- Symptoms associated with discontinuation of PRISTIQ have been reported. Patients should be monitored for symptoms when discontinuing treatment. A gradual reduction in dose rather than abrupt cessation is recommended whenever possible.



- Dosage adjustment (50 mg every other day) is necessary in patients with severe renal impairment or end-stage renal disease (ESRD). 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.

Adverse Reactions

- The most commonly observed adverse reactions in patients taking PRISTIQ for MDD in short-term fixed-dose premarketing studies (incidence >5% and twice the rate of placebo in the 50- or 100-mg dose groups) were nausea, dizziness, insomnia, hyperhidrosis, constipation, somnolence, decreased appetite, anxiety, and specific male sexual function disorders.

Full prescribing information for PRISTIQ will be available at Pristiq.com.

Important Treatment Considerations for EFFEXOR XR

- EFFEXOR XR is contraindicated in patients taking monoamine oxidase inhibitors (MAOIs).
- Adult and pediatric patients taking antidepressants can experience worsening of their depression and/or the emergence of suicidality. All patients should be monitored appropriately and observed closely for clinical worsening and suicidality, especially at the beginning of drug therapy, or at the time of increases or decreases in dose. Anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia, hypomania, and mania have been reported and may represent precursors to emerging suicidality. Stopping or modifying therapy should be considered especially when symptoms are severe, abrupt in onset, or not part of presenting symptoms.
- The development of potentially life-threatening serotonin syndrome may occur when EFFEXOR XR is coadministered with other drugs that may affect the serotonergic neurotransmitter systems. Concomitant use of EFFEXOR XR with MAOIs is contraindicated. If concomitant use of EFFEXOR XR with an SSRI, SNRI, or a triptan is clinically warranted, careful observation of the patient is advised. Concomitant use of EFFEXOR XR with tryptophan supplements is not recommended.
- Treatment with venlafaxine is associated with sustained increases in blood pressure (BP) in some patients. Postmarketing cases of elevated BP requiring immediate treatment have been reported. Pre-existing hypertension should be controlled. Regular BP monitoring is recommended.
- SSRIs and SNRIs, including EFFEXOR XR, may increase the risk of bleeding events. Concomitant use of aspirin, NSAIDs, warfarin, and other anticoagulants may add to this risk.
- Mydriasis has been reported in association with venlafaxine; therefore, patients with raised intraocular pressure or those at risk of acute narrow-angle glaucoma (angle-closure glaucoma) should be monitored.
- Abrupt discontinuation or dose reduction has been associated with discontinuation symptoms. Patients should be counseled on possible discontinuation symptoms and monitored while discontinuing the drug; the dose should be tapered gradually.
- The most common adverse events reported in EFFEXOR XR short-term placebo-controlled MDD, generalized anxiety disorder (GAD), social anxiety disorder (SAD), and/or panic disorder (PD) trials



(incidence >10% and >2x that of placebo) were anorexia, asthenia, constipation, dizziness, dry mouth, ejaculation problems, impotence, insomnia, nausea, nervousness, somnolence, and sweating.

For full prescribing information for EFFEXOR XR, please go to www.EffexorXR.com.

About Wyeth Pharmaceuticals

Wyeth Pharmaceuticals, a division of Wyeth, has leading products in the areas of women's health care, infectious disease, gastrointestinal health, central nervous system, inflammation, transplantation, hemophilia, oncology, vaccines and nutritional products.

Wyeth is one of the world's largest research-driven pharmaceutical and health care products companies. It is a leader in the discovery, development, manufacturing and marketing of pharmaceuticals, vaccines, biotechnology products and non-prescription medicines that improve the quality of life for people worldwide. The Company's major divisions include Wyeth Pharmaceuticals, Wyeth Consumer Healthcare and Fort Dodge Animal Health.

The statements in this press release that are not historical facts are forward-looking statements based on current expectations of future events and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. In particular, there can be no assurance that PRISTIQ will be commercially successful in the highly competitive market for antidepressants in the United States, or that PRISTIQ will be approved in the future for other indications (including treatment of vasomotor symptoms associated with menopause) and/or in other countries. Other risks and uncertainties include the inherent uncertainty of the timing and success of, and expense associated with, research, development, regulatory approval and commercialization of our products and our pipeline products (including future regulatory action regarding our other pending applications for desvenlafaxine for the treatment of major depressive disorder and the treatment of vasomotor symptoms, as to which no assurance can be given); government cost-containment initiatives; restrictions on third-party payments for our products; substantial competition in our industry, including from branded and generic products; data generated on our products; the importance of strong performance from our principal products and our anticipated new product introductions; the highly regulated nature of our business; product liability, intellectual property and other litigation risks and environmental liabilities; uncertainty regarding our intellectual property rights and those of others; difficulties associated with, and regulatory compliance with respect to, manufacturing of our products; risks associated with our strategic relationships; economic conditions including interest and currency exchange rate fluctuations; changes in generally accepted accounting principles; trade buying patterns; the impact of legislation and regulatory compliance; risks and uncertainties associated with global operations and sales; and other risks and uncertainties, including those detailed from time to time in our periodic reports filed with the Securities and Exchange Commission, including our current reports on Form 8-K, quarterly reports on Form 10-Q and annual report on Form 10-K, particularly the discussion under the caption "Item 1A, RISK FACTORS." The forward-looking statements in this press release are qualified by these risk factors. We assume no obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.



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