



FDA Approves Intravenous Formulation Of Pfizer's Revatio® (Sildenafil) For The Treatment Of Pulmonary Arterial Hypertension

Thursday, November 19, 2009 - 05:00pm

Revatio is the Only Treatment in Its Class with Both Oral and Intravenous Formulations

(BUSINESS WIRE)--Pfizer announced today that the U.S. Food and Drug Administration (FDA) has approved Revatio® (sildenafil) Injection, an intravenous formulation of Revatio. Revatio is the only FDA-approved phosphodiesterase-5 (PDE5) inhibitor available in both tablet and intravenous formulations.

Revatio is indicated for the treatment of adult patients with pulmonary arterial hypertension (WHO Group I) to improve exercise ability and delay clinical worsening. The delay in clinical worsening was demonstrated when Revatio was added to background epoprostenol therapy. The efficacy of Revatio has not been adequately evaluated in patients taking bosentan concurrently. Revatio Injection is for the continued treatment of patients with pulmonary arterial hypertension who are currently prescribed Revatio Tablets but who are temporarily unable to take oral medication.

Pulmonary arterial hypertension is a rare, progressive disease that affects an estimated 100,000 men and women worldwide. This incurable disease is characterized by continuous high blood pressure in the pulmonary arteries, often leading to heart failure and premature death. Pulmonary arterial hypertension can occur with no known underlying cause, or it can occur in association with other disorders.

Due to the chronic nature of pulmonary arterial hypertension, maintaining medical therapy can delay clinical worsening for patients. However, in some cases, oral

medication may not be an option for a period of time. While oral treatment can often be re-introduced at a later stage, the ability to maintain treatment during periods when the patient is unable to take an oral formulation is important to preserving health in patients with pulmonary arterial hypertension.

“The approval of Revatio Injection is a clear demonstration of Pfizer’s commitment to developing treatments addressing the unmet needs of patients with pulmonary arterial hypertension,” said Dr. Cara Cassino, vice president of pulmonary vascular disease, clinical development and medical affairs, Pfizer. “This important milestone highlights the Specialty Care business unit’s dedication to advancing treatments for serious and life-threatening conditions such as pulmonary vascular disease.”

About Revatio

Revatio Tablets were approved by the FDA in June 2005 and by the European Medicines Agency (EMA) in November 2005. The American College of Chest Physicians recommends Revatio for adult pulmonary arterial hypertension patients in functional class II and III in its clinical practice guidelines for the treatment of pulmonary arterial hypertension.

Revatio Injection will be supplied in a single-use vial. The recommended dose of Revatio Injection is 10 mg (corresponding to 12.5 mL) administered as an intravenous bolus injection three times a day. Revatio is also available as a 20 mg tablet taken three times a day.

Important Safety Information

If patients take any medicines that contain nitrates (like nitroglycerin for chest pain) — daily or just once in a while – DO NOT take Revatio.

Revatio contains the same medicine as Viagra® (sildenafil), which is used to treat erectile dysfunction (impotence). Do not take Revatio with Viagra or other PDE5 inhibitors.

If patients have ever had blockage of veins in their lungs, which is called pulmonary veno-occlusive disease, Revatio is not recommended. If patients feel dizzy, have chest pain, or discomfort while taking Revatio, they should tell their doctor right away. Also, they should discuss their general health with their doctor, including if they have ever had problems with low blood pressure or blood circulation. Revatio is not recommended for patients taking ritonavir or antifungal medicines, such as ketoconazole and itraconazole. If

patients are taking Revatio with bosentan or medicines like barbiturates, carbamazepine, phenytoin, efavirenz, nevirapine, rifampin or rifabutin, their doctor may adjust their dose. Also, patients should tell their doctor if they are taking alpha-blockers for prostate or blood pressure problems.

Taking vitamin K antagonists (like Coumadin or warfarin) with Revatio may increase risk of nosebleeds. Patients should tell their doctor if they take such medicines.

The safety of Revatio is not known in patients with bleeding problems and those with stomach ulcers. If patients have a condition like this, they should tell their doctor.

Sudden decrease or loss of hearing has been reported in people taking PDE5 inhibitors, including Revatio. It is not possible to determine whether these events are related directly to the PDE5 inhibitors or to other factors. If patients take a PDE5 inhibitor, including Revatio, and experience a sudden decrease or loss of hearing, they should contact their doctor right away.

Men who took PDE5 inhibitors for erectile dysfunction had a sudden decrease or loss of sight in one or both eyes. It is not possible to know if these cases are related directly to these medicines or something else. If patients take a PDE5 inhibitor, including Revatio, and have a sudden decrease or loss of vision, they should contact their doctor right away.

Erections that last for more than four hours may occur with all drugs in this class. Patients should call their doctor right away if this happens. Erections that last more than six hours may lead to long-term loss of potency.

Patients who did not take part in the clinical trial were those who have had a heart attack, stroke, or life-threatening irregular heartbeat within the last 6 months; chest pain; blood pressure greater than 170/110; eye discoloration; or patients on bosentan.

The most common side effects of Revatio are nosebleeds, headache, upset stomach, flushing, and trouble sleeping.

At doses more than the approved 20 milligrams 3 times a day, some side effects increased. These included flushing, loose stools, muscle pain, and visual disturbances.

Please see Full Prescribing and Patient Information for Revatio at www.pfizer.com.

Pfizer Inc: Working together for a healthier world™

At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world's best-known consumer products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as the world's leading biopharmaceutical company, we also collaborate with 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 IncMedia:Gwen Fisher, 484-865-5160orInvestors:Jennifer M. Davis, 212-733-0717