

Media Statement:
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Statement Regarding FDA Drug Safety Communication on Revatio®

New York, August 30, 2012 - The U.S. Food and Drug Administration issued a Drug Safety Communication on Revatio® (sildenafil), following the observation in a long-term extension of a clinical trial in pediatric patients with pulmonary arterial hypertension (PAH) of an increase in mortality with increasing Revatio dose. Dr. Yvonne Greenstreet, senior vice president and head of the Medicines Development Group for Pfizer Specialty Care, issued the following statement.

We believe the benefit/risk profile for use of Revatio in adults with pulmonary arterial hypertension remains favorable. The FDA recommends that patients do not change their Revatio® dose or stop taking Revatio® without talking to their health care professional.

In our ongoing commitment to patient safety, we are working with the FDA to determine the best research-based approach to understanding the observation in the pediatric study and its implications, if any, to adults with PAH.

Pulmonary arterial hypertension is a rare, devastating, incurable disease characterized by high blood pressure in the pulmonary arteries, leading to heart failure and premature death. Revatio has accumulated more than 100,000 patient-years of experience in the treatment of PAH. Pfizer remains committed to improving the lives of patients suffering from this disease.

Background Information:

In January 2012, the FDA accepted Pfizer's New Drug Application for Revatio powder for oral suspension, a new formulation. The NDA was submitted to include an indication for treatment of pulmonary arterial

hypertension in pediatric patients. On August 30, the FDA approved the NDA for the oral suspension but did not approve the pediatric indication for Revatio. The FDA also introduced a warning in the Revatio U.S. prescribing information noting that use of Revatio, particularly chronic use, is not recommended in children. This warning is based on the data from the long-term extension study in pediatric patients with pulmonary arterial hypertension.

In May 2011, the European Commission approved Revatio for the treatment of pediatric patients aged 1 to 17 years old with pulmonary arterial hypertension. Pfizer updated the Summary of Product Characteristics in Europe in September 2011 to include the data from the long-term extension study and to reinforce the current dosing recommendations for this population. The powder for oral suspension formulation was approved in Europe in March 2012.

Important Safety Information

If you 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 you have ever had blockage of veins in your lungs, which is called pulmonary veno-occlusive disease, REVATIO is not recommended for you. If you feel dizzy, have chest pain, or discomfort while taking REVATIO, tell a doctor right away. Also, discuss your general health with your doctor, including if you 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 you are taking REVATIO with bosentan or medicines like barbiturates, carbamazepine, phenytoin, efavirenz, nevirapine, rifampin or rifabutin, your doctor may adjust your dose. Also, tell your doctor if you 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. Tell your doctor if you take such medicines.

The safety of REVATIO is not known in patients with bleeding problems and those with stomach ulcers. If you have a condition like these, tell your 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 you take a PDE5 inhibitor, including REVATIO, and experience a sudden decrease or loss of hearing, contact a 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 you take a PDE5 inhibitor, including REVATIO, and have a sudden decrease or loss of vision, call your doctor right away.

Erections that last for more than four hours may occur with all drugs in this class. Call a doctor right away if this happens to you. 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.

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