The European Commission Approves Pfizer’s Revatio® (sildenafil) for the Treatment of Pulmonary Arterial Hypertension in Children

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New Indication Specifically for use in Pediatric Patients Based on Largest Placebo-Controlled Study Conducted in this Population

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(BUSINESS WIRE)--Pfizer Inc. announced that Revatio® (sildenafil citrate) has been approved by the European Commission for the treatment of pediatric patients aged 1 to 17 years old with pulmonary arterial hypertension. Efficacy in terms of improvement of exercise capacity or pulmonary hemodynamics has been shown in primary pulmonary hypertension and pulmonary hypertension associated with congenital heart disease.

“Pulmonary arterial hypertension is a rare, devastating disease that can affect children," said Dr. Cara Cassino, vice president, Pfizer Medicines Development Group. “With the approval of Revatio, these young patients now have an important treatment option that may help manage their condition. This approval is another example of our ongoing commitment to rare diseases.”

The approval was based on results of a dose-ranging phase 3 study that evaluated the efficacy and safety of Revatio versus placebo in 234 pediatric patients with primary pulmonary hypertension or pulmonary hypertension associated with congenital heart disease. The primary endpoint was improvement from baseline in exercise capacity as

assessed by change in peak volume of oxygen consumption (peak VO2) following 16 weeks of treatment. In children who were deemed developmentally unable to perform the test due to young age or the presence of other conditions, efficacy was assessed using secondary endpoints, including hemodynamics and change in WHO functional class.

Estimated change in peak VO2 in evaluable patients receiving any dose of Revatio was 7.71 percent (95 percent confidence interval: -0.19 percent to 15.60 percent, P=0.056). Dose-related improvements in pulmonary vascular resistance index (PVRI) and mean pulmonary arterial pressure (mPAP) were observed in patients treated with Revatio, and improvements in cardiac index were observed with all three Revatio groups over placebo. Of 120 patients who were WHO functional class II, III or IV at baseline who received Revatio, 32 improved by one functional class, and one subject improved by two functional classes. Four of the 35 patients in the placebo group improved by one functional class.

The adverse reaction profile seen in this pediatric study was generally consistent with that in adults with pulmonary arterial hypertension taking Revatio. Most adverse events were of mild to moderate severity and were consistent with the known pharmacology of phosphodiesterase-5 inhibitors, the class of medications to which Revatio belongs. The most common adverse reactions observed in patients treated with Revatio were vomiting, cough, pyrexia, nausea, lower abdominal pain, upper abdominal pain and photophobia.

Pulmonary arterial hypertension is a rare, progressive disease characterized by high blood pressure in the pulmonary arteries, leading to heart failure and premature death. Pulmonary arterial hypertension can occur with no known underlying cause, or it can be found in association with other disorders such as connective tissue disease or congenital heart disease.

For pediatric patients, Revatio will be available as an extemporaneously prepared oral suspension compounded from Revatio 20 mg tablets and recommended diluents. Revatio is also available in oral and I.V. formulations for the treatment of adults with pulmonary arterial hypertension.

Revatio was first approved by the European Commission in October 2005 for the treatment of adult patients with pulmonary arterial hypertension classified as WHO functional class II and III, to improve exercise capacity. Efficacy has been shown in primary pulmonary hypertension and pulmonary hypertension associated with connective tissue disease. Revatio is approved for the treatment of pediatric pulmonary arterial hypertension only in the EU, with applications pending in other countries.

Since its initial regulatory approval in 2005, Revatio has been approved and launched in more than 50 countries and has amassed more than 100,000 patient-years of experience.

For full Revatio product information for the EU, please see http://www.emea.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000638/hu

For full U.S. Patient and Prescribing Information for Revatio, please see \files\pressrelease_assets\pdf\USPI_PPI_IFU- REVATIO - sildenafil citrate-Tablet-Injection--.pdf.

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DISCLOSURE NOTICE: The information contained in this release is as of May 5, 2011. 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 an additional indication for Revatio for the treatment of children with pulmonary arterial hypertension, including its potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by regulatory authorities regarding whether and when to approve any supplemental drug applications that have been or may be filed for this additional indication for Revatio, including the applications pending for this additional indication in countries outside of the EU, as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; and competitive developments.

A further list and description of risks and uncertainties can be found in Pfizer’s Annual Report on Form 10-K for the fiscal year ended December 31, 2010 and in its reports on Form 10-Q and Form 8-K.

Pfizer Inc. Media: Victoria Davis, 347-558-3455 Victoria.davis@pfizer.com or Investors: Jennifer Davis, 212-733-0717 Jennifer.M.Davis@pfizer.com