European Commission Approves New Intravenous Formulation Of Pfizer’s Revatio® (Sildenafil) For The Treatment Of Pulmonary Arterial Hypertension

Monday, January 04, 2010 - 01:40am

Revatio is Only PAH Treatment in Its Class with Approved I.V. Formulation, Allowing Patients to Continue Treatment While Unable to Use Oral Therapy

(BUSINESS WIRE)--Pfizer Inc. announced today that the European Commission has approved Revatio® (sildenafil) solution for injection for patients who are currently prescribed oral Revatio and who are temporarily unable to take oral medicine, but are otherwise clinically and haemodynamically stable.

Revatio is the only phosphodiesterase 5 (PDE5) inhibitor with both oral and I.V. formulations approved in the European Union for the treatment of PAH.

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, 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.

“Pulmonary arterial hypertension is a life-threatening disease, and medical treatment can help delay damage caused by the disease,” said Jean-Luc Vachiery, M.D., professor of Cardiology and director of the Pulmonary Vascular Diseases Unit at Clinique Universitaire

De Bruxelles Hopital Erasme (Erasme Hospital) in Belgium and former chairman of the Working Group on Pulmonary Circulation and Right Ventricular Function of the European Society of Cardiology. “Now with the approval of Revatio solution for injection, we have an option to bridge interruptions in treatment of adult patients who may be temporarily unable to take this important therapy in tablet form.”

For some patients, continued 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 or tolerate an oral formulation is important to preserving health in patients with PAH. Revatio solution for injection is for adult patients with PAH who are stable on Revatio tablets but who are temporarily unable to take oral medication and for whom the physician considers continuity of treatment to be in the patients’ best interest.

“The approval of Revatio solution for injection is a clear demonstration of Pfizer’s commitment to developing treatments addressing the unmet needs of patients with pulmonary arterial hypertension,” said Cara Cassino, M.D., vice president of Pulmonary Vascular Disease, Clinical Development and Medical Affairs, Pfizer. “This important milestone highlights the Specialty Care Business Units dedication to advance treatments for serious and life-threatening conditions such as pulmonary vascular disease.”

About Revatio

Revatio was first approved by the European Commission in October 2005. Oral Revatio tablets are available as a 20mg tablet taken three times a day. The recommended dose of Revatio Injection is 10 mg (corresponding to 12.5 mL) three times a day administered as an intravenous bolus injection.

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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

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