Pfizer Logo

Pfizer Announces Results from Phase 3 Trial of Revatio® (Sildenafil Citrate) in Newborns with Persistent Pulmonary Hypertension

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Pfizer Inc. (NYSE: PFE) announced today that a Phase 3 study to assess the efficacy and safety of intravenous (IV) sildenafil when added to inhaled nitric oxide (iNO) for the treatment of newborns with Persistent Pulmonary Hypertension (PPHN) did not meet its primary efficacy endpoint. Treatment with IV sildenafil when added to iNO did not result in a statistically significant reduction in treatment failure rate or time on iNO compared to treatment with iNO alone. Sildenafil is not indicated for the treatment of PPHN. The study was part of an EU Pediatric Investigational Plan (PIP).

About the Study

This Phase 3 study had two consecutive parts: Part A is the randomized, placebo-controlled, double-blind interventional phase to assess efficacy and safety; and Part B is the non-interventional phase with follow-up at 12 and 24 months after the end of study treatment to evaluate developmental progress. These results solely pertain to the outcomes observed from Part A of the study; Part B is ongoing. The co-primary endpoints are treatment failure rate, defined as need for additional PPHN treatment, need for extracorporeal membrane oxygenation[1] (ECMO), or death during the study; and time on iNO treatment after initiation of IV study drug for subjects without treatment failure.

The safety and adverse event profile observed in this study was comparable to the known safety profile of Revatio in prior studies in pediatric and adult patients 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 benefit-risk profile of Revatio remains favorable for the approved indications when used in accordance with the approved label.

About Pulmonary Hypertension and PPHN

Pulmonary hypertension (PH) is an incurable and life-threatening disease that occurs when the pulmonary arteries, which are responsible for transporting the blood from the heart to the lungs, become narrowed and obstructed. Due to this defect in the pulmonary arteries, the right heart ventricle needs to work harder to properly pump the blood, making the organ enlarged and weakened. When babies are born with the disease, it is called persistent pulmonary hypertension of the newborn (PPHN), or neonatal pulmonary hypertension. The disease is characterized by a failure in the normal circulatory transition that is inborn in babies and can result in hypoxemia and right-to-left intracardiac shunting of blood. PPHN is not very common, but is a greatly hazardous disease that leads to a high mortality rate.

About Revatio

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 in the EU and Japan.

Since its initial regulatory approval in 2005, Revatio has been approved and launched in more than 50 countries and has amassed more than 650,000 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/human_med_001033.jsp&m
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For full U.S. Patient and Prescribing Information for Revatio, please see
http://media.pfizer.com/files/products/uspi_revatio.pdf.

Important Safety Information:

DO NOT take Revatio with any nitrate medicines or with riociguat (Adempas®), a soluble guanylate cyclase (sGC) stimulator medicine. If you take any medicines that contain nitrates, daily or just once in a while (like nitroglycerin for chest pain), or riociguat, a soluble guanylate cyclase (sGC) stimulator medicine, your blood pressure could drop quickly to an unsafe level.

Do not take Revatio if you are allergic to sildenafil or any other ingredient in Revatio. Revatio is not for use in children[2].

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.

Adding Revatio to another medication used to treat PAH, bosentan (Tracleer®), does not result in improvement in your ability to exercise.

If you have ever had blockage of veins in your lungs, which is called pulmonary veno-occlusive disease, Revatio is not recommended for you. Also, discuss your general health with your doctor, including if you ever had angina, a heart attack, heart failure, irregular heartbeats, and problems with low blood pressure or blood circulation. If you feel dizzy, have chest pain, or discomfort while taking Revatio, tell a doctor right away.

Tell your healthcare provider if you have any blood cell problems including sickle cell anemia. Tell your doctor if you have any problem with the shape of your penis or Peyronie’s disease.

Revatio is not recommended for patients taking ritonavir (to treat HIV infection) or antifungal medicines, such as ketoconazole and itraconazole. Tell your doctor about all of the medicines you take. Revatio and certain other medicines can cause side effects if you take them together. Tell your doctor if you are taking blood pressure–lowering drugs or alpha-blockers for prostate.

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.

Tell your doctor if you have an eye problem called retinitis pigmentosa or you had loss of sight in one or both eyes.

Men who took PDE5 inhibitors for erectile dysfunction had a sudden decrease or loss of sight in one or both eyes (NAION). If you take a PDE5 inhibitor, including Revatio, and have a sudden decrease or loss of eyesight, 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.

Tell your doctor if you are pregnant or planning to become pregnant. It is not known if Revatio could harm your unborn baby.

Tell your healthcare provider if you are breastfeeding. Revatio passes into your breast milk, it is not known if it could harm your baby.

The most common side effects of Revatio are nosebleeds, headache, upset stomach, flushing, and trouble sleeping, as well as fever, erection increased, respiratory infection, nausea, vomiting, bronchitis, pharyngitis, runny nose, and pneumonia in children.

Indication

Revatio is a prescription medicine used in adults to treat pulmonary arterial hypertension (PAH). With PAH, the blood pressure in your lungs is too high. Your heart has to work hard to pump blood into your lungs. Revatio improves the ability to exercise and slow down worsening changes in your physical condition.

Limitation of Use: Adding Revatio to another medication used to treat PAH, bosentan (Tracleer®), does not result in improvement in your ability to exercise. Adempas® is a registered trade mark of Bayer HealthCare Pharmaceuticals. Tracleer® is a registered trade mark of Actelion Pharmaceuticals Ltd.

Please see Full Prescribing Information and Patient Information.

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At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care 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 one of the world's premier innovative biopharmaceutical companies, we 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, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on

our website at www.pfizer.com. In addition, to learn more, please visit us on www.pfizer.com and follow us on Twitter at @Pfizer and @Pfizer_News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

***DISCLOSURE NOTICE**: The information contained in this release is as of June 28, 2019. 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 Revatio (sildenafil), including its potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical trial commencement and completion dates and regulatory submission dates, as well as the possibility of unfavorable study results, including unfavorable new clinical data and additional analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations, and, even when we view data as sufficient to support the safety and/or effectiveness of a product candidate, regulatory authorities may not share our views and may require additional data or may deny approval altogether; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of Revatio; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results," as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

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[1] Extracorporeal membrane oxygenation, or ECMO, is an advanced life support technique used for patients with life-threatening heart and/or lung problems.
[2] In the EU and Japan, Revatio is indicated for the treatment of pediatric patients aged 1 year to 17 years old with pulmonary arterial hypertension

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