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Investor News

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U. S. FDA Grants Priority Review to Bayer's Riociguat for the Treatment of two Life-Threatening Pulmonary Hypertension Indications

Leverkusen, Germany, April 8, 2013 – Bayer HealthCare announced today that the U.S. Food and Drug Administration (FDA) has granted priority review to the New Drug Application (NDA) for the oral investigational drug riociguat. At the beginning of February, Bayer HealthCare submitted riociguat, the first drug to demonstrate efficacy in two distinct forms of pulmonary hypertension (inoperable chronic thromboembolic pulmonary hypertension (CTEPH) and pulmonary arterial hypertension (PAH)) for regulatory approval in the United States and in the European Union.

The FDA grants priority review to medicines that offer major advances in care or that provide a treatment where no adequate therapy exists. Under the Prescription Drug User Fee Act (PDUFA), the FDA aims to complete its review within eight months from the submission of the NDA, rather than the standard 12-month review cycle.

"In the pivotal Phase III studies, riociguat was shown to be the first drug therapy to demonstrate robust efficacy in two potentially fatal pulmonary hypertension indications," said Dr. Kemal Malik, member of the Bayer HealthCare Executive Committee and Head of Global Development. "To date, no approved pharmacological therapy exists for CTEPH and as a result there is an urgent unmet medical need for patients who are unable to undergo surgery. We hope that we will soon be in a position to provide patients and doctors with a new treatment option."

The submission is supported by data from the two randomized, double-blind, placebo-controlled pivotal, global Phase III studies, namely CHEST-1 and PATENT-1. Results of both studies were presented at the 2012 annual meeting of the American College of

Chest Physicians (ACCP) in Atlanta, USA. Both Phase III studies with riociguat met their primary endpoint, a change in exercise capacity, after 12- or 16 weeks respectively. Riociguat was generally well tolerated, with a good safety profile.
Bayer HealthCare announced positive data from the interim analysis of the on-going CHEST-2 trial with riociguat, the open-label long-term extension of the pivotal Phase III study CHEST-1, at the 5th World Symposium of Pulmonary Hypertension (WSPH) in Nice, France. The results of the CHEST-2 trial support the positive data of the pivotal CHEST-1 trial, showing long-term safety and sustained clinical benefits in patients with inoperable chronic thromboembolic pulmonary hypertension (CTEPH).

Riociguat was discovered by Bayer and is the first member of a novel class of compounds, the stimulators of soluble guanylate cyclase (sGC).

About Pulmonary Hypertension
Pulmonary hypertension (PH) is a severe, progressive and life-threatening disorder in which the pressure in the pulmonary arteries is significantly increased and which can lead to heart failure and death. Patients with PH develop a markedly decreased exercise tolerance and reduced quality of life. The most common symptoms of PH include shortness of breath, fatigue, dizziness and fainting, all of which are worsened by exertion. As the symptoms of PH are non-specific, diagnosis can be delayed by as much as two years. Early diagnosis is essential as a delay in treatment initiation can have a negative impact on survival. Continuous treatment monitoring is then vital to ensure that patients are receiving optimal care for their particular type and stage of disease.

According to the clinical classification of PH (Dana Point), there are five different types of PH based on underlying causes which are: pulmonary arterial hypertension (PAH), pulmonary hypertension owing to left heart disease (e.g. PH-LVD), pulmonary hypertension owing to lung disease and/or hypoxemia (e.g. PH-COPD or PH-ILD), chronic thromboembolic pulmonary hypertension (CTEPH) and pulmonary hypertension with unclear multifactorial mechanisms. Currently available pharmacological treatments are only approved to treat one of the five types of PH, pulmonary arterial hypertension. As a result, there is a strong need for more research to improve understanding of how all five types of PH can be treated effectively.

About Pulmonary Arterial Hypertension (PAH)
PAH is a rare but life-threatening disease in which the pressure in the pulmonary arteries is above normal. PAH is characterized by morphological changes to the endothelium of the arteries of the lungs causing remodeling of the tissue, vasoconstriction and thrombosis-in-situ. As a result of these changes, the blood vessels in the lungs are narrowed, making it difficult for the heart to pump blood through to the lungs. PAH affects an estimated 52 people per million globally. It is more prevalent in younger women than men. In most cases, PAH has no known cause and, in some cases, it can be inherited.

Despite the availability of several approved therapies, the prognosis for patients with PAH remains poor.

About Chronic Thromboembolic Pulmonary Hypertension (CTEPH)
CTEPH is a rare but life-threatening disease in which it is believed that thromboembolic occlusion (blood clots) of pulmonary vessels gradually lead to an increased pressure in the pulmonary arteries, resulting in an overload of the right heart. CTEPH may evolve after prior episodes of acute pulmonary embolism, but the pathogenesis is not yet completely understood. The standard treatment for CTEPH is pulmonary endarterectomy (PEA), a surgical procedure in which the blood vessels of the lungs are cleared of clot and scar material. However, a considerable number of patients with CTEPH are not operable and in some patients the disease persists or reoccurs after PEA. Currently, there are no approved pharmacological treatments available for CTEPH.

About Riociguat
Riociguat (BAY 63-2521) is an oral agent being investigated as a new approach to treating different types of pulmonary hypertension. Riociguat is the first member of a novel class of compounds, the stimulators of soluble guanylate cyclase (sGC). sGC is an enzyme found in the cardiopulmonary system. When nitric oxide (NO) binds to sGC, the enzyme catalyzes synthesis of the signaling molecule cyclic guanosine monophosphate (cGMP). cGMP plays an important role in regulating vascular tone, proliferation, fibrosis, and inflammation.

Pulmonary hypertension is associated with endothelial dysfunction, impaired synthesis of NO and thus insufficient stimulation of sGC. Riociguat is believed to have a unique mode of action: sensitizing sGC to endogenous NO and also directly stimulating sGC independent of NO.

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care, agriculture and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of EUR 18.6 billion (2012), is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Medical Care and Pharmaceuticals divisions. Bayer HealthCare's aim is to discover, develop, manufacture and market products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 55,300 employees (Dec 31, 2012) and is represented in more than 100 countries. More information at www.healthcare.bayer.com.

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