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Chronic Thromboembolic Pulmonary Hypertension and Pulmonary Arterial Hypertension:

U.S. FDA Advisory Committee Unanimously Recommends Approval of Bayer's Riociguat in Two Forms of Pulmonary Hypertension

Leverkusen, August 6, 2013 – Bayer HealthCare today announced that the U.S. Food and Drug Administration's (FDA's) Cardiovascular and Renal Drugs Advisory Committee recommended approval of the oral soluble guanylate cyclase (sGC) stimulator, riociguat, in two forms of pulmonary hypertension. The Committee voted 11 to 0 that riociguat should be approved for the treatment of pulmonary arterial hypertension (PAH) of WHO Group 1. The Committee also voted 11 to 0 that riociguat should be approved for the treatment of chronic thromboembolic pulmonary hypertension (CTEPH) of WHO Group 4.

In February 2013, Bayer submitted a new drug application for riociguat in two indications: a) the treatment of PAH to improve exercise capacity, WHO functional class and to delay clinical worsening; and b) the treatment of inoperable CTEPH, or persistent or recurrent CTEPH after surgical treatment to improve exercise capacity and WHO functional class.

"We appreciate the Advisory Committee's recommendation", said Dr. Kemal Malik, Member of the Bayer HealthCare Executive Committee and Head of Global Development. "Riociguat addresses a high unmet medical need. It is the first drug to demonstrate efficacy in two forms of pulmonary hypertension – for which one of these, CTEPH, has no drug treatment approved to date. The committee's vote confirms the positive benefit-risk profile of this new first-in-class therapeutic option. We hope we will soon be in the position to make riociguat available for patients and doctors in the U.S. Bayer appreciates the scientific discussions by the Advisory Committee, and looks forward to working with the FDA as they finalize their review."

PAH and CTEPH are both life-threatening forms of pulmonary hypertension that cause significantly increased pressure in the pulmonary arteries. Data presented at today's Advisory Committee meeting included results from the two randomized, double-blind, placebo-controlled, global Phase III studies CHEST-1 and PATENT-1. These assessed the efficacy and safety of oral riociguat in the treatment of CTEPH and PAH respectively. Both Phase III studies with riociguat met their primary endpoint, a change in exercise capacity, after 16 and 12 weeks respectively. Riociguat also demonstrated consistent improvements across multiple, relevant secondary endpoints, and was generally well-tolerated, with a good safety profile. Results of both studies were published in the New England Journal of Medicine (NEJM) in July 2013.

The FDA granted a Priority Review designation to the New Drug Application (NDA) for riociguat filed by Bayer in February 2013. The Advisory Committee's recommendations will be considered by the FDA in its review of the riociguat NDA, but the FDA is not required to follow the expert panel's advice.

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 Arterial Hypertension (PAH)
PAH, one of the five types of pulmonary hypertension (PH), is a progressive and life-threatening disease in which the blood pressure in the pulmonary arteries is significantly increased due to vasoconstriction and which can lead to heart failure and death. PAH is characterized by morphological changes to the endothelium of the artery 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 is a rare disease and 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 and advantages of several approved PAH therapies, the prognosis for patients remains poor and new treatment options are needed. Mortality of PAH patients remains high and is still 15% at 1 year; 32% at 3 years after diagnosis.

About Chronic Thromboembolic Pulmonary Hypertension (CTEPH)

CTEPH is a progressive and life-threatening disease and a type of PH, in which it is believed that thromboembolic occlusion (organized blood clots) of pulmonary vessels gradually lead to an increased blood 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 and potentially curative 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 (20%-40%) are not operable and in up to 35% of patients, the disease persists or reoccurs after PEA. 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 or who have persistent or recurrent pulmonary hypertension (PH) after surgery.

About Riociguat

Riociguat (BAY 63-2521) is a soluble guanylate cyclase (sGC) stimulator, the first member of a novel class of compounds, discovered and developed by Bayer as an oral treatment to target a key molecular mechanism underlying PH. Riociguat is being investigated as a new and specific approach to treat different types of PH. sGC is an enzyme found in the cardiopulmonary system and the receptor for nitric oxide (NO). When NO binds to sGC, the enzyme enhances synthesis of the signaling molecule cyclic guanosine monophosphate (cGMP). cGMP plays an important role in regulating vascular tone, proliferation, fibrosis, and inflammation.

PH is associated with endothelial dysfunction, impaired synthesis of NO and insufficient stimulation of sGC. Riociguat has a unique mode of action - it sensitizes sGC to endogenous NO by stabilizing the NO-sGC binding. Riociguat also directly stimulates sGC via a different binding site, independently of NO. Riociguat, as a stimulator of sGC, addresses NO deficiency by restoring the NO-sGC-cGMP pathway, leading to increased generation of cGMP.

With its novel mode of action, Riociguat has the potential to overcome a number of limitations of currently approved PAH therapies, including NO dependence, and is the first drug which has shown clinical benefits in CTEPH, where no pharmacological treatment is approved.

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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