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Investor News

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U.S. FDA Approves Bayer's Adempas® (riociguat), the first soluble Guanylate Cyclase Stimulator, in Two Forms of Pulmonary Hypertension

- Adempas is now available in the U.S. as the first and only drug approved to treat chronic thromboembolic pulmonary hypertension (CTEPH)
- Adempas also received approval in Pulmonary Arterial Hypertension (PAH)
- Adempas has been developed to target a key molecular mechanism underlying this serious disorder of the heart and lungs

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Leverkusen, Germany, October 9, 2013 – Bayer HealthCare announced today that the United States Food and Drug Administration (FDA) has approved Adempas® (riociguat) tablets for use in two forms of pulmonary hypertension, a group of life-threatening and progressive diseases: The treatment of adults with persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4) after surgical treatment or inoperable CTEPH to improve exercise capacity and WHO functional class; and the treatment of adults with pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise capacity, improve WHO functional class and delay clinical worsening.

Adempas is the only treatment approved in the US for use in two types of pulmonary hypertension. It is the only FDA-approved drug therapy for CTEPH that is inoperable or persistent/recurrent after surgical treatment. Last month, Adempas was approved in Canada in the CTEPH indication.

"The FDA's approval is a key milestone in our efforts to provide patients and physicians with a much-needed new treatment option for this rare, serious and potentially fatal disorder: It is the first drug to be approved for inoperable CTEPH or for persistent or recurrent disease after surgery, and it is also an important new class of treatment for

patients with PAH," said Dr. Kemal Malik, Member of the Bayer HealthCare Executive Committee and Head of Global Development.

"The clinical studies CHEST-1 and PATENT-1 met their primary endpoint by demonstrating a statistically significant improvement in exercise capacity as measured by the six-minute walk test (6MWT), a marker of disease severity and a predictor of survival in patients suffering from pulmonary hypertension," said Principal Investigator Professor Ardeschir Ghofrani, University Hospital Giessen and Marburg, Germany. "Riociguat is the first drug to demonstrate efficacy in two distinct forms of pulmonary hypertension. The extent and consistency of improvements across both the primary and the multiple secondary endpoints as shown in the treatment with riociguat are impressive. CHEST-1 and PATENT-1 provide comprehensive information with regard to endpoints that form the basis for therapeutic decisions and are relevant in daily clinical practice for patients and their treating physicians, as e.g. six-minute walk test (6MWT), cardiopulmonary hemodynamics, WHO Functional Class and a disease-related biomarker."

PAH and CTEPH are two rare and life-threatening forms of pulmonary hypertension characterized by significantly increased pressure in the pulmonary arteries. The approval of Adempas is based on data from the two randomized, double-blind, placebo-controlled, global Phase III studies CHEST-1 and PATENT-1 as well as long-term data from CHEST-2 and PATENT-2 available at the time. These studies investigated the efficacy and safety of oral riociguat in the treatment of CTEPH and PAH respectively. Both Phase III studies, CHEST-1 and PATENT-1 met their primary endpoint, a change in exercise capacity, after 16 and 12 weeks respectively. Adempas also demonstrated consistent improvements across multiple, relevant secondary endpoints, and was generally well-tolerated, with a good safety profile.

The most commonly reported adverse reactions, occurring in greater than or equal to 10 percent of patients under Adempas treatment (up to 2.5 mg TID), were headache, dizziness, dyspepsia, peripheral edema, nausea, diarrhea, and vomiting.

Results of both studies were published in the New England Journal of Medicine (NEJM) in July 2013.

The Phase III trial programs CHEST and PATENT are ongoing with the long-term extension studies, CHEST-2 and PATENT-2.

In February 2013, Bayer HealthCare submitted riociguat for regulatory approval in the European Union and in May 2013 in Japan.

Riociguat was discovered and developed 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, life-changing and life-threatening disorder of the heart and lungs in which the blood pressure in the pulmonary arteries is above normal, and which can lead to heart failure and death. Patients with PH develop a markedly decreased exercise capacity and a 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 and accurate identification of the PH type are 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.

There are five different types of PH; each can affect the patient in a different way and every patient may have a different etiology and manifestation of PH. For the best chance of success patients need to be treated at a PH specialist center.

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 15-52 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.

In spite of several pharmacological treatment options for PAH having been available for over a decade, the prognosis for these patients has remained poor and so new treatment options are needed. Currently, mortality of PAH patients remains high and is still 15% at 1 year and 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 is a rare disease and is comparable in terms of population size to PAH, though there are fewer diagnoses made so far. 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. These patients need an effective pharmacological treatment.

About Adempas (riociguat)
Adempas (riociguat) 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 the issue of 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 other approved PAH therapies, including NO dependence, and is the first drug which has shown clinical benefits in CTEPH, where until the approval of riociguat no approved pharmacological treatment was available.

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 54,900 employees (Dec 31, 2012) and is represented in more than 100 countries. More information at www.healthcare.bayer.com.

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