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Investor News

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Bayer Receives Approval for Riociguat in Japan for the Treatment of Chronic-Thromboembolic Pulmonary Hypertension

Leverkusen, Germany, January 17, 2014 – Bayer HealthCare has received approval for riociguat under the name Adempas® for the treatment of adults with inoperable chronic-thromboembolic pulmonary hypertension (CTEPH) or persistent or recurrent CTEPH after surgical treatment by the Ministry of Health, Labour and Welfare (MHLW) in Japan. The MHLW granted an orphan drug designation for riociguat in the CTEPH indication in September 2011.

“The approval of riociguat as the first approved drug treatment for this severe, life-threatening disease is great news for patients in Japan,” said Kemal Malik (MB, BS), Member of the Bayer HealthCare Executive Committee and Head of Global Development. “Riociguat achieves meaningful clinical improvements, which is a much needed step forward for patients whose CTEPH is inoperable or whose disease is persistent or recurrent.”

“CTEPH is a progressive disease, and the symptoms of breathlessness, dizziness and fainting severely impact daily activities of patients,” said Dr. Nobuhiro Tanabe, Associate Professor, Department of Respirology, Chiba University, Japan. “Pulmonary endarterectomy (PEA), a complex surgical procedure, is the potentially curative treatment for CTEPH. However, 20%-40% of CTEPH patients are not operable, and in 35% of patients who have had a PEA, the disease persists or reoccurs after surgery. For these patients, Riociguat may offer a valuable treatment option.”

Riociguat is the first drug therapy that has shown clinical efficacy in the treatment of inoperable CTEPH patients, or patients with persistent or recurrent CTEPH after surgery. The approval of riociguat by the MHLW is based on data from the randomized, double-blind, placebo-controlled, global Phase III study CHEST-1, as well as on interim results of the long-term extension study CHEST-2. Results of CHEST-1 were published in the New

England Journal of Medicine (NEJM) in July 2013. Within CHEST-1 the primary endpoint, a change in exercise capacity, was reached after 16 weeks: Compared to placebo, patients treated with riociguat showed a statistically significant improvement ($p<0.0001$) from baseline in the six-minute walk test (6MWT) after this time frame. Riociguat also demonstrated consistent improvements across multiple, relevant secondary endpoints, like cardiopulmonary hemodynamics, WHO Functional Class and disease-related biomarkers and was generally well-tolerated, with a good safety profile. The Phase III trial program CHEST is ongoing with the long-term extension study, CHEST-2. Interim results of CHEST-2 support the benefits of riociguat that were seen in the pivotal CHEST-1 trial, as sustained effects in exercise capacity and WHO FC have been observed in a cohort of patients that had reached one year of study treatment. Survival rate after one year of treatment with riociguat was 97%, and 87% of patients in this cohort were free from clinical worsening.

Riociguat was discovered and developed by Bayer and is the first of a novel class of drugs, the soluble guanylate cyclase (sGC) stimulators. Its new mode of action has been developed to target a key molecular mechanism underlying this serious disorder of the heart and lungs.

Riociguat was approved under the name Adempas® in the US for use in CTEPH and pulmonary arterial hypertension (PAH) in October 2013, and in Canada and Switzerland in the CTEPH indication in September and November 2013. In February 2013, Bayer HealthCare submitted riociguat for regulatory approval in the European Union in both indications.

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 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. These patients need an effective pharmacological treatment.

About Riociguat
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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