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Investor News

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Bayer's Adempas® (riociguat) Approved for the Treatment of Two Life-Threatening Forms of Pulmonary Hypertension in the EU

- Adempas® is approved for patients with chronic-thromboembolic pulmonary hypertension (CTEPH) and pulmonary arterial hypertension (PAH)
- Adempas® is the first and only drug approved to treat patients with CTEPH

Leverkusen, Germany, March 31, 2014 – Bayer today announced that Adempas® (riociguat) has been approved by the European Commission for the treatment of chronic thromboembolic pulmonary hypertension (CTEPH) and pulmonary arterial hypertension (PAH). Adempas is indicated for the treatment of adult patients with inoperable chronic thromboembolic pulmonary hypertension (CTEPH) or persistent or recurrent CTEPH after surgical treatment, and for the treatment of adult patients with pulmonary arterial hypertension (PAH) as a monotherapy or in combination with endothelin receptor antagonists. Adempas is a soluble guanylate cyclase (sGC) stimulator, and the first member of a novel class of compounds. Adempas is the first and only drug treatment approved for patients with CTEPH.

"With the approval of Adempas by the European Commission, an important new treatment option becomes available for patients with pulmonary hypertension in Europe," said Dr. Jörg Möller, Member of the Bayer HealthCare Executive Committee and Head of Global Development. "Adempas is the first drug that has shown benefits across multiple clinically-relevant endpoints in two pulmonary hypertension indications, namely CTEPH and PAH. For the first time, there is a pharmacological treatment option for patients with CTEPH who are not eligible for surgery or whose disease persists or reoccurs."

"The availability of riociguat is a significant step forward: It means that patients with CTEPH for the first time have an option if pulmonary endarterectomy (PEA), a highly specialized surgical procedure, is not an option for them or when the disease persists after surgery. Rather than struggling to breathe each day, with riociguat they can be more

active again. The therapy enables patients to take part in everyday activities which many of us take for granted," said Pisana Ferrari from the European Pulmonary Hypertension Assocation. "We also welcome the availability of a new class of medicines to help patients suffering from PAH meet their treatment goals."

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. Riociguat is the first and only drug to demonstrate significant and sustained clinical efficacy in patients with inoperable CTEPH or persistent or recurrent CTEPH after surgical treatment. Riociguat is the first oral treatment to show early, significant and sustained clinical efficacy in Phase III clinical trials across multiple clinically relevant endpoints in patients with PAH, either as a monotherapy or in combination with certain other medicines used to treat PAH, such as endothelin receptor antagonists (ERAs) or non-intravenous prostacyclin analogue (PCA) therapies. So far no other oral drugs, including PDE5-inhibitors, have been able to show this. The consistency and robustness of the positive results in the Phase III trials demonstrated that riociguat relieved many of the symptoms experienced by people living with CTEPH or PAH. Riociguat significantly improved the patient's ability to walk farther, helping the heart and lungs work better and making breathing easier when performing everyday basic tasks. Consequently, both CTEPH and PAH patients who received riociguat observed reductions in disease severity and these improvements are sustained over the long-term.

"With riociguat we have for the first time an effective drug treatment for two forms of PH. Under treatment with riociguat, the patient's quality of life is rapidly improving, which is noticeable to them and clearly visible to us," commented Professor Ardeschir Ghofrani, University Hospital Giessen and Marburg, Germany, Principal Investigator in the pivotal Phase III trials CHEST and PATENT.

The approval of Adempas is based on results 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 assessed the efficacy and safety of oral riociguat in the treatment of CTEPH and PAH respectively. Results of both studies were published in the New England Journal of Medicine (NEJM) in July 2013.

With the approval in the EU, the global prospective Adempas exposure registry EXPERT is started, which will collect data on the safety and clinical effect of this first-in-class sGC-stimulator in real-life clinical practice.

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 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, as it affects an estimated 8-40 people per million globally. 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 novel 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 currently approved PAH therapies, including nitric oxide (NO) dependence, and is the first drug which has shown clinical benefits in CTEPH, where until the approval of riociguat no pharmacological treatment was available.

The riociguat development program across different forms of PH demonstrates Bayer's ongoing commitment to understanding this severe and life-threatening condition, with high unmet medical need, to improve the lives of people with PH.

Riociguat was approved under the name Adempas® in the US for use in CTEPH and PAH in October 2013. In Canada, the approvals for CTEPH and PAH followed in September 2013 and March 2014 respectively. In Switzerland and Japan, riociguat was approved in the CTEPH indication in November 2013, and in January 2014 respectively.
In the EU, riociguat has been granted orphan drug designation and is approved by the European Medicines Agency (EMA) under the name Adempas® for use in CTEPH and PAH.

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 18.9 billion (2013), 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 56,000 employees (Dec 31, 2013) and is represented in more than 100 countries. More information is available at www.healthcare.bayer.com.

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