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Investor News

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Adempas® Approved in Japan for the Treatment of Pulmonary Arterial Hypertension

Adempas® is the first drug to be approved in Japan for the treatment of two forms of pulmonary hypertension, a progressive, life-threatening disorder of the lungs and heart

Leverkusen, Germany, February 20, 2015 – Adempas® (riociguat) has received approval for the treatment of patients with pulmonary arterial hypertension (PAH) by the Ministry of Health, Labour and Welfare (MHLW) in Japan. Following the approval of Adempas in January 2014 for the treatment of inoperable chronic thromboembolic pulmonary hypertension (CTEPH) or persistent or recurrent CTEPH after surgery, Adempas is now the first drug approved in Japan to treat two forms of pulmonary hypertension (PH). The development and commercialization of riociguat is part of the worldwide strategic collaboration with Merck (through a subsidiary) in the field of soluble guanylate cyclase (sGC) modulation. Merck is known as MSD outside of the U.S. and Canada.

“PAH is a rare disease that usually presents with symptoms such as breathlessness, dizziness and fainting. It severely impacts patients’ daily lives, and if untreated, PAH may be fatal,” said Norifumi Nakanishi, M.D., Ph.D., Director of Endowed Department of Pulmonary Hypertension and Pulmonary Vascular Medicine, National Cerebral and Cardiovascular Center Research Institute, Osaka, Japan. “Physicians have been awaiting the approval of Adempas in PAH as an additional indication. With its novel mode of action, we expect Adempas may improve the symptoms of many patients with PAH whose prognosis has remained poor despite the availability of several approved PAH therapies.”

“In the pivotal PATENT-1 Phase III trial, riociguat demonstrated significant clinical efficacy 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 prostanoids," said Dr. Joerg Moeller, Member of the Bayer HealthCare Executive Committee and Head of Global Development. "Riociguat is an important new treatment option for patients with PAH."

The approval of Adempas is based on results from the randomized, double-blind, placebo-controlled, global Phase III study PATENT-1 as well as long-term data from PATENT-2 available at the time. These assessed the efficacy and safety of oral riociguat in the treatment of PAH. Results of PATENT-1 were published in the New England Journal of Medicine (NEJM) in July 2013. One-year data from the open-label long-term extension study PATENT-2 published in the European Respiratory Journal demonstrate that the significant improvement in exercise capacity was further improved, whilst the safety profile was sustained and confirmed. An analysis of the PATENT-2 two-year data cut-off confirmed the sustained improvements in patients with PAH after two years of treatment with riociguat.

About Pulmonary Hypertension

Pulmonary hypertension (PH) is a severe, progressive, life-changing and life-threatening disorder of the lungs and heart in which the blood pressure in the pulmonary arteries is above normal, and which can lead to right heart failure and death. People 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 types are essential as a delay in treatment initiation of even a few months can have a negative impact on survival. Continuous treatment monitoring by a PH specialist is 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 of PH. For the best chance of success patients need to be treated at a PH specialist center.

About Pulmonary Arterial Hypertension

Pulmonary arterial hypertension (PAH), one of the five types of 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 right heart failure and death. PAH is characterized by morphological changes to the endothelium of the

arteries of the lungs causing remodeling of the tissue and vasoconstriction. As a result of these changes, the blood vessels in the lungs constrict, making it more 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, though it can sometimes 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, resulting in the need for effective alternative treatment options. Currently, mortality of PAH patients remains high and is still 15% at 1 year and 32% at 3 years after diagnosis.

About Riociguat

Riociguat is a soluble guanylate cyclase (sGC) stimulator, the first member of a distinct 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 endothelial cells 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 dual 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 distinct mode of action, riociguat has the potential to overcome a number of limitations of other approved therapies for PAH, including NO dependence, and is the first drug which has shown clinical benefits in patients with inoperable CTEPH or persistent or recurrent CTEPH after surgery, where until the approval of riociguat no approved pharmacologic treatment was available.

Riociguat was approved under the name Adempas® in the US for use in inoperable CTEPH or persistent or recurrent CTEPH after surgery and in PAH in October 2013. In the EU and US, riociguat has been granted orphan drug designation and was approved

by the European Medicines Agency (EMA) under the name Adempas® for use in CTEPH and PAH in March 2014. In Japan, riociguat has been granted orphan drug designation in the CTEPH indication and was approved in CTEPH in January 2014.

Since October 2014, the worldwide strategic collaboration with Merck & Co., Inc. (known as MSD outside of the U.S. and Canada) in the field of sGC modulators brings together the two leading companies in this field, who both have the stated intent to make full use of this promising novel class of compounds and the potential it holds for the benefit of patients. Riociguat, the first sGC stimulator approved and made available to patients, is the first product which is part of this collaboration.

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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