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Investor News

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Bayer to Evaluate sGC Stimulator Riociguat in Patients With Diffuse Cutaneous Systemic Sclerosis

Phase II study initiated to investigate riociguat in new indication beyond pulmonary hypertension

Leverkusen, Germany, November 13, 2014 – Bayer HealthCare announced today the initiation of a randomized, double-blind, placebo-controlled Phase II study to investigate the efficacy and safety of riociguat against placebo in patients with diffuse cutaneous systemic sclerosis (dcSSc), the most severe form of systemic sclerosis (SSc). The development of riociguat in dcSSc is part of the recently announced worldwide strategic collaboration with Merck & Co., Inc. (known as MSD outside of the U.S. and Canada) in the field of soluble guanylate cyclase (sGC) modulation.

SSc is a rare multisystem, autoimmune disease resulting in the overproduction and abnormal accumulation of collagen, which causes fibrosis of the skin and internal organs. Tissue fibrosis contributes significantly to the high morbidity and the increased mortality of SSc. dcSSc is one of the two major forms of SSc and the most fatal rheumatic disease, mostly affecting people in their 40s and 50s. Patients with dcSSc are at greater risk of clinically significant major organ dysfunction including the kidneys, heart, lungs and gastrointestinal tract. 15-20% of patients die within the first 5 years after diagnosis.

The RISE-SSc study (Riociguat Safety and Efficacy in patients with diffuse cutaneous Systemic Sclerosis [dcSSc]) will include 130 patients at more than 60 sites in 15 countries and will evaluate whether 52 weeks of treatment with riociguat in dcSSc is superior to placebo. The effect of riociguat on fibrosis of the skin and the lung, as well as on circulation problems such as digital ulcers will be evaluated.

Currently, there are no approved drugs available to potentially stop or delay the progression of the fibrotic damage in patients with SSc. In July 2014, both the European

Commission and the FDA granted orphan drug status for riociguat as an oral investigational drug in SSc.

About Systemic Sclerosis

Systemic sclerosis (SSc) is a rare autoimmune rheumatic disease that affects between 70 and 400 people per million. SSc affects the connective tissue that supports, connects, or separates different types of tissues including the skin and internal organs, as well as the blood vessels.

In SSc, the immune system is overactive, causing inflammation. At the same time, changes in the endothelial cells lead to a narrowing of the blood vessels and make it more difficult for the blood to move through the vessels, causing tissue damage, circulation problems and high blood pressure.

Inflammation and vascular damage trigger fibrosis, i.e. the overproduction of collagen and, thus, excessive formation of connective tissue. This overproduction causes skin thickening, with the skin becoming tight and hard. It may also lead to the damage of major internal organs, including the kidneys, heart, lungs and gastrointestinal tract.

Based on the extent of skin involvement, SSc can be divided in two major forms, diffuse cutaneous SSc (dcSSc) and limited cutaneous SSc (lcSSc). Both dcSSc and lcSSc are associated with an impact on internal organs; however, patients with dcSSc are at a greater risk for clinically significant major organ dysfunction.

Among patients with SSc, 35-40% have the diffuse cutaneous form, which represents the most fatal rheumatic disease. dcSSc is a progressive rare disease which mostly affects people in their 40s and 50s and is characterized by vasculopathy and progressive fibrosis of the skin and internal organs, which may ultimately lead to death. Drugs currently used in the treatment of dcSSc or drugs that are under investigation have immune-suppressive and/or anti-inflammatory effects. So far, no therapy has been proved to stop or delay the fibrotic damage in patients with dcSSc.

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 pulmonary hypertension (PH). Riociguat is approved for two forms of PH (inoperable chronic thromboembolic pulmonary

hypertension [CTEPH] or persistent or recurrent CTEPH after surgical treatment and pulmonary arterial hypertension [PAH]) and is also being investigated as a new and specific approach to treat other types of PH. A Phase IIb study has been initiated in June 2014 to investigate the efficacy and safety of riociguat in patients with symptomatic PH associated with idiopathic interstitial pneumonia (IIP). Riociguat is also being investigated beyond PH, and Bayer has initiated a Phase II clinical study in diffuse cutaneous systemic sclerosis in November 2014. Bayer is committed to identifying and investigating new therapeutic options in disease areas with a high unmet medical need, such as pulmonary hypertension or systemic sclerosis.

sGC is found in multiple cell types, tissues and organs throughout the whole body. Riociguat directly stimulates sGC, thereby leading to an increased generation of cyclic guanosine monophosphate (cGMP). cGMP plays an important role in regulating cellular processes, such as vascular tone, proliferation, fibrosis, and inflammation.

Riociguat was approved under the name Adempas® in the US for use in inoperable CTEPH or persistent or recurrent CTEPH after surgery and PAH in October 2013. In Japan, riociguat was approved in the CTEPH indication in January 2014. 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.

Since October 2014, the worldwide strategic collaboration with Merck & Co., Inc. (known as MSD outside 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 desire 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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