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Investor News

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Bayer Terminates Phase II Study with Riociguat in Patients with Pulmonary Hypertension Associated with Idiopathic Interstitial Pneumonias

Leverkusen, Germany, May 12, 2016 – Following the recommendation of an independent Data Monitoring Committee (DMC), Bayer is terminating its Phase II study investigating riociguat in patients with pulmonary hypertension associated with idiopathic interstitial pneumonias (PH-IIP) with immediate effect. The DMC is an independent committee which monitors the safety of patients during the course of a study. In the ongoing review of the data, the DMC observed that patients receiving riociguat were at a possible increased risk for death and other serious adverse events as compared to patients in the placebo group. The DMC did not identify any specific cause or common feature among the patients who died except that many appeared to have more serious and advanced underlying lung disease than the study population as a whole. The patients in this trial will be continuously monitored for safety immediately after stopping treatment and for a period of at least four months.

PH-IIP is a serious and rare disease. According to the clinical classification system of pulmonary hypertension (PH), there are five types of PH based on the different underlying causes (Nice Classification 2013). While PH-IIP belongs to Group 3, the etiology and patient characteristics of this type of PH are distinct from other types of PH. Patients with PH-IIP are a high-risk patient population who suffer both from pulmonary hypertension and idiopathic interstitial pneumonias. Prognosis is poor as there are no approved treatments. The unmet medical need is high with an estimated mortality rate of over 20% within one year.

Riociguat is approved in the US, the EU and Japan, and many other countries for use in inoperable chronic thromboembolic pulmonary hypertension (CTEPH) or persistent or recurrent CTEPH after surgery, and in pulmonary arterial hypertension (PAH). PAH is classified as PH Group 1, and CTEPH is classified as PH Group 4. The positive benefit-

risk profile of riociguat in its approved indications based on a large, controlled clinical database and supported by the available postmarket pharmacovigilance information remains unchanged. Bayer is closely monitoring the safety and efficacy of riociguat on an ongoing basis. Medical monitoring of safety in other ongoing studies with riociguat in other patient populations supports the continuation of those studies.

“We understand that the need to terminate the study in PH-IIP is very disappointing for patients suffering from this disease, as well as for their doctors and healthcare providers. There is a significant unmet medical need for PH-IIP patients as there are no approved treatments, and finding an effective treatment remains a challenge,” said Dr. Joerg Moeller, Member of the Bayer Pharmaceuticals Executive Committee and Head of Global Development. “Bayer remains committed to identifying new therapeutic options and to improving the lives of patients in disease areas where there is a high unmet medical need such as pulmonary hypertension.”

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. 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 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 inoperable CTEPH or persistent or recurrent CTEPH after surgery and PAH in March 2014. In Japan, riociguat has been granted orphan drug designation in the CTEPH indication and was approved in inoperable CTEPH or persistent or recurrent CTEPH after surgery in January 2014 and in PAH in February 2015.

Since October 2014, the worldwide strategic collaboration with MSD (known as Merck in the U.S. and in 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 may hold 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.

Bayer: Science For A Better Life

Bayer is a global enterprise with core competencies in the Life Science fields of health care and agriculture. Its products and services are designed to benefit people and improve their quality of life. At the same time, the Group aims to create value through innovation, growth and high earning power. Bayer is committed to the principles of sustainable development and to its social and ethical responsibilities as a corporate citizen. In fiscal 2015, the Group employed around 117,000 people and had sales of EUR 46.3 billion. Capital expenditures amounted to EUR 2.6 billion, R&D expenses to EUR 4.3 billion. These figures include those for the high-tech polymers business, which was floated on the stock market as an independent company named Covestro on October 6, 2015. For more information, go to www.bayer.com.

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