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Investor News

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The American Thoracic Society International Conference 2013:

Bayer to Present Data on Pulmonary Hypertension Research at the ATS International Conference 2013 in Philadelphia

- Interim Analysis from Long-Term Extension Study PATENT-2 Phase III
- Hemodynamic data and clinical correlation from CHEST-1 Phase III
- New Data Sets from Pivotal PATENT-1 Phase III

Leverkusen, Germany, May 8, 2013 – Bayer HealthCare announced today that new data on treatments for patients with pulmonary hypertension will be presented at the American Thoracic Society (ATS) International Conference 2013, May 17-22 in Philadelphia, USA. Within the official program of the ATS, these data will be shared in oral presentations at a mini symposium dedicated to pulmonary hypertension at the Pennsylvania Convention Center on May 20th. The annual ATS International Conference brings together the latest information on clinical, basic and translational science in pulmonary, critical care and sleep medicine.

The studies to be presented include the latest data on Bayer's oral investigational drug riociguat from the Pulmonary Arterial Hypertension sGC-Stimulator Trial (PATENT) and Chronic Thromboembolic Pulmonary Hypertension sGC-Stimulator Trial (CHEST) trial programs.

"We are dedicated to promoting the scientific understanding of pulmonary hypertension and are committed to developing new treatment options for patients with this life-threatening condition", said Kemal Malik, MD, Head of Global Development and Member of the Bayer HealthCare Executive Committee. "We look forward to sharing new data

from studies of our oral investigational drug riociguat demonstrating robust safety and efficacy in two pulmonary hypertension indications."

The studies presented include:

Hemodynamic Assessment Phase III CHEST-1 Clinical Trial Data:
Hemodynamic Assessment of Patients with Inoperable Chronic Thromboembolic Pulmonary Hypertension (CTEPH) in the Phase III CHEST-1 Study
May 20, 2013, 2:30 p.m. – 2:45 p.m., Abstract A3529

Interaction Study PATENT PLUS Phase II Clinical Trial Data:
A Placebo-Controlled, Double-Blind Phase II Interaction Study to Evaluate Blood Pressure Following Addition of Riociguat to Patients With Symptomatic Pulmonary Aterial Hypertension (PAH) Receiving Sildenafil (PATENT PLUS)
May 20th, 2013, 2:45 p.m. - 3:00 p.m., Abstract A3530

Interim Analysis PATENT-2 Phase III Clinical Trial Data:
Riociguat for the Treatment of Pulmonary Arterial Hypertension (PAH): A Phase III Long-Term Extension Study (PATENT-2)
May 20th, 2013, 3 p.m. - 3.15 p.m., Abstract A3531

Response to Treatment in PATENT-1 Phase III Clinical Trial Data:
Baseline Characteristics and Response to Treatment in Pretreated Versus Treatment-Naïve Patients with Pulmonary Arterial Hypertension (PAH) in the Phase III PATENT-1 Study
May 20th, 2013, 3:15 p.m. - 3:30 p.m., Abstract A3532

Efficacy in the Subgroups of PATENT-1 Phase III Clinical Trial Data:
Efficacy of Riociguat in Pretreated Versus Treatment-Naïve Patients with Pulmonary Arterial Hypertension (PAH) in the Phase III PATENT-1 Study
May 20th, 2013, 3:45 p.m. - 4:00 p.m., Abstract A3534

All presentations will be held in Room 118 A-B-C (100 Level), Pennsylvania Convention Center.

At the beginning of February, Bayer HealthCare submitted riociguat, the first drug to demonstrate efficacy in two distinct forms of pulmonary hypertension (inoperable chronic

thromboembolic pulmonary hypertension (CTEPH) and pulmonary arterial hypertension (PAH)) for regulatory approval in the United States and in the European Union. In April, the U.S. Food and Drug Administration (FDA) granted priority review to the New Drug Application (NDA) in both indications.

Riociguat was discovered by Bayer and represents the first member of a novel class of compounds, the stimulators of soluble guanylate cyclase (sGC).

About Pulmonary Hypertension

Pulmonary hypertension (PH) is a severe, progressive and life-threatening disorder in which the pressure in the pulmonary arteries is significantly increased and which can lead to heart failure and death. Patients with PH develop a markedly decreased exercise tolerance and 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 is 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.

According to the clinical classification of PH (Dana Point), there are five different types of PH based on underlying causes which are: pulmonary arterial hypertension (PAH), pulmonary hypertension owing to left heart disease (e.g. PH-LVD), pulmonary hypertension owing to lung disease and/or hypoxemia (e.g. PH-COPD or PH-ILD), chronic thromboembolic pulmonary hypertension (CTEPH) and pulmonary hypertension with unclear multifactorial mechanisms. Currently available pharmacological treatments are only approved to treat one of the five types of PH, pulmonary arterial hypertension. As a result, there is a strong need for more research to improve understanding of how all five types of PH can be treated effectively.

About Pulmonary Arterial Hypertension (PAH)

PAH is a rare but life-threatening disease in which the pressure in the pulmonary arteries is above normal. PAH is characterized by morphological changes to the endothelium of the arteries 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 affects an estimated 52 people per million globally. It is more prevalent in younger women than men. In most cases, PAH has no known cause and, in some cases, it can be inherited.

Despite the availability of several approved therapies, the prognosis for patients with PAH remains poor.

About Chronic Thromboembolic Pulmonary Hypertension (CTEPH)
CTEPH is a rare but life-threatening disease in which it is believed that thromboembolic occlusion (blood clots) of pulmonary vessels gradually lead to an increased 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 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 are not operable and in some patients the disease persists or reoccurs after PEA. Currently, there are no approved pharmacological treatments available for CTEPH.

About Riociguat
Riociguat (BAY 63-2521) is a soluble guanylate cyclase (sGC) stimulator, the first member of a novel class of compounds 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 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 NO dependence, and is the first drug which has shown clinical benefits in CTEPH, where no pharmacological treatment is approved.

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 55,300 employees (Dec 31, 2012) and is represented in more than 100 countries. More information at www.healthcare.bayer.com.

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