Bayer AG
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Investor News

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Treatment and Prevention of Venous Thromboembolism:

Bayer Initiates Two New Phase III Trials to Evaluate Rivaroxaban in Medically-ill Patients and Children at High Risk of Blood Clots

- MARINER trial to evaluate rivaroxaban for venous thromboembolism prevention in high-risk medically-ill patients following hospital discharge
- EINSTEIN JUNIOR study will investigate rivaroxaban for the treatment and secondary prevention of venous thromboembolism in children

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Leverkusen, Germany, March 31, 2014 – Bayer HealthCare and its U.S. development partner Janssen Research & Development, LLC announced today the initiation of two new Phase III trials to evaluate rivaroxaban in medically-ill patients and children at high risk for blood clots. The MARINER trial will evaluate the safety and efficacy of rivaroxaban to reduce the risk of post-hospital discharge symptomatic venous thromboembolism (VTE) in patients hospitalized for acute medical illness. The EINSTEIN JUNIOR trial will assess the efficacy and safety of rivaroxaban for the treatment and secondary prevention of venous thromboembolism (VTE) in children.

“We have already completed an extensive clinical study program with more than 10,000 patients to demonstrate the clinical benefits of rivaroxaban in the treatment and secondary prevention of deep vein thrombosis and pulmonary embolism, but we still see significant unmet needs in the area of venous thrombosis which we want to address through these additional studies,” said Dr. Joerg Moeller, Member of the Bayer HealthCare Executive Committee and Head of Global Development.

Patients who have been hospitalized for the treatment of acute medical illnesses are at high risk for the development of VTE during their hospital stay and immediately after hospital discharge. Thromboprophylaxis is a therapeutic approach to reduce the risk of VTE events in these patients. The MARINER study will evaluate rivaroxaban 10mg once

daily compared to placebo in approximately 8,000 patients in more than 15 countries for up to 45 days following hospital discharge. The EINSTEIN JUNIOR study will evaluate rivaroxaban according to an age- and body weight-adjusted dosing schedule in 150 patients in 20 countries.

About Xarelto® (Rivaroxaban)

Rivaroxaban is the most broadly indicated novel oral anticoagulant and is marketed under the brand name Xarelto®. Xarelto is approved for five indications across seven distinct areas of use, protecting patients across more venous and arterial thromboembolic (VAT) conditions than any other novel oral anticoagulant:

- The prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (AF) with one or more risk factors
- The treatment of deep vein thrombosis (DVT) in adults
- The treatment of pulmonary embolism (PE) in adults
- The prevention of recurrent DVT and PE in adults
- The prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip replacement surgery
- The prevention of VTE in adult patients undergoing elective knee replacement surgery
- The prevention of atherothrombotic events (cardiovascular death, myocardial infarction or stroke) after an Acute Coronary Syndrome in adult patients with elevated cardiac biomarkers when co-administered with acetylsalicylic acid (ASA) alone or with ASA plus clopidogrel or ticlopidine

Whilst licences may differ from country to country, across all indications Xarelto is approved in more than 125 countries.

Rivaroxaban was discovered by Bayer HealthCare, and is being jointly developed with Janssen Research & Development, LLC. Xarelto is marketed outside the U.S. by Bayer

HealthCare and in the U.S. by Janssen Pharmaceuticals, Inc. (a Johnson & Johnson Company).

Anticoagulant medicines are potent therapies used to prevent or treat serious illnesses and potentially life-threatening conditions. Before initiating therapy with anticoagulant medicines, physicians should carefully assess the benefit and risk for the individual patient.

Responsible use of Xarelto is a very high priority for Bayer, and the company has developed a Prescribers Guide for physicians and a Xarelto Patient Card for patients to support best practice.

To learn more, please visit https://prescribe.xarelto.com
To learn more about thrombosis, please visit www.thrombosisadviser.com
To learn more about Xarelto, please visit www.xarelto.com

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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