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Investor News

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Long-term prevention of venous blood clots (VTE):

Bayer Initiates Rivaroxaban Phase III Study to Support Dose Selection According to Individual Benefit-Risk Profile in Long-Term VTE Prevention

- The risk of recurrence of deep vein thrombosis (DVT) and pulmonary embolism (PE) persists following acute VTE treatment but may reduce over time for some patients
- The EINSTEIN CHOICE study will investigate rivaroxaban 10 mg and 20 mg once daily for the long-term, secondary prevention of venous blood clots following acute DVT or PE treatment

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Leverkusen, Germany, February 17, 2014 – Bayer HealthCare announced today the initiation of EINSTEIN CHOICE, a Phase III clinical trial that will evaluate two doses of its once-daily novel oral anticoagulant rivaroxaban (Xarelto®) against acetylsalicylic acid (ASA) for the long-term, secondary prevention of symptomatic venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE).

The study supplements the EINSTEIN Trial Programme, which established in the EINSTEIN Extension study that rivaroxaban 20 mg once daily delivers a significant reduction in the risk of long-term prevention of recurrent symptomatic DVT and PE in patients who previously completed 6 or 12 months of anticoagulation treatment. EINSTEIN CHOICE will include approximately 2,850 patients at 250 centres in 30 countries worldwide, and will evaluate whether once-daily rivaroxaban in doses of 10 mg or 20 mg is superior to ASA at 100 mg in the prevention of fatal or non-fatal symptomatic recurrent venous thromboembolism, in patients who have completed between 6 and 12 months of anticoagulant treatment for their index DVT or PE event.

“If anticoagulant therapy is stopped after 6 to 12 months in patients with unprovoked venous thromboembolism, the risk of recurrence is about 10% at one year. Nonetheless,

many physicians stop warfarin treatment after 6 months and may switch patients to aspirin because of the inconvenience of warfarin management and fears about the risk of bleeding," said Jeffrey Weitz, Professor and Deputy Chair Research, Department of Medicine, McMaster University, and Executive Director of the Thrombosis and Atherosclerosis Research Institute, Hamilton, Canada and Co-Chair of the EINSTEIN CHOICE Steering Committee. "The EINSTEIN CHOICE study is designed to inform us as to whether reducing the dose of rivaroxaban from 20 mg once daily to 10 mg once daily maintains efficacy and lowers the risk of bleeding, and whether both doses of rivaroxaban are better than aspirin at reducing the risk of recurrence. Therefore, the results of this study may enable alignment of anticoagulant treatment with the benefit-risk profile of the individual patient."

"Bayer remains committed to providing the best possible understanding of the clinical utility of Xarelto, as real-world experience of its use grows across a broad range of venous and arterial thromboembolic disorders," said Dr. Joerg Moeller, Member of the Bayer HealthCare Executive Committee and Head of Global Development. "This study is a key part of that commitment and our ever-growing clinical trial programme that continues to make Xarelto the most widely studied novel oral anticoagulant."

About the EINSTEIN Clinical Trial Programme

The pivotal EINSTEIN Clinical Trial Programme comprises four Phase III studies. EINSTEIN DVT and EINSTEIN PE evaluated rivaroxaban alone (15 mg twice daily for 21 days followed by 20 mg once daily) versus the dual-drug regimen of low molecular weight heparin (LMWH) and a vitamin K antagonist (VKA) in the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) respectively, and the prevention of recurrent DVT and PE. The EINSTEIN Extension study compared rivaroxaban 20 mg once daily with placebo for the long term prevention of recurrent symptomatic DVT and PE in patients who previously completed 6 or 12 months of anticoagulation treatment with either VKA or rivaroxaban. Now EINSTEIN CHOICE will evaluate the long-term benefit of once-daily rivaroxaban 10 mg and 20 mg to prevent recurrent VTE compared to ASA at 100 mg in patients who have completed between 6 and 12 months of anticoagulant treatment for their index DVT or PE event.

Xarelto is approved as a single-drug solution for the treatment of DVT and PE as well as for the prevention of recurrent DVT and PE.

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 Aspirin
Aspirin is proven and recognized globally as cornerstone therapy for reducing the risk of recurrent cardiovascular disease (CVD) events, such as recurrent heart attack and ischemic stroke. Aspirin has been an important medicine for 115+ years because of its remarkable analgesic and, later, cardiovascular event prevention properties. The cornerstone role of aspirin continues to be supported and reinforced by the global scientific community through multiple international and national medical guidelines recommending its use in appropriate at-risk patients for prevention of CVD events in both the primary and secondary settings. Primary and secondary prevention indications vary and are dependent upon each country's health authority. The determination of who is an appropriate candidate for aspirin therapy is a decision that must be made in consultation between doctor and patient. Patients should always talk with their physicians before starting or adjusting a low-dose aspirin regimen.

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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