



Results from Phase III EINSTEIN-DVT Study with Bayer's Rivaroxaban to be Presented at Hot Line Session at ESC 2010

Leverkusen, June 17, 2010 – Bayer Schering Pharma, Germany, today announced that findings from the Phase III EINSTEIN-DVT study will be presented at the Hot Line Session on August 31, 2010, 11:00-12:30 CET, at the Annual Meeting of the European Society of Cardiology (ESC) in Stockholm, Sweden, by lead investigator Harry R. Buller, MD, Academic Medical Center, Amsterdam, the Netherlands.

The multinational Phase III EINSTEIN-DVT study investigated a new single-drug approach with rivaroxaban compared with standard therapy in a randomized, open-label, assessor-blind, non-inferiority study involving more than 3,400 patients with acute symptomatic deep vein thrombosis (DVT), but without any symptoms of pulmonary embolism (PE). Standard therapy for venous thromboembolism, including DVT, currently includes two compounds: low molecular weight heparin administered by subcutaneous injection, followed by a vitamin K antagonist, which requires regular monitoring of the prothrombin time, reported as the International Normalized Ratio (INR), for safety.

Patients received either oral rivaroxaban or body weight-adjusted enoxaparin followed by warfarin or acenocoumarol, dose adjusted to maintain a therapeutic INR (target 2.5, range 2.0-3.0), for 3, 6 or 12 months, based on the physician's assessment at baseline. The primary efficacy outcome of EINSTEIN-DVT is the cumulative incidence of symptomatic recurrent venous thromboembolism (VTE), non-fatal or fatal pulmonary embolism (PE). The principal safety outcome is the composite of major and clinically relevant non-major bleeding.

About the EINSTEIN Clinical Trial Program

EINSTEIN is a global clinical development program composed of three clinical studies in more than 8,000 patients. Two of these studies enrolled patients with acute, symptomatic deep vein thrombosis (EINSTEIN-DVT) or pulmonary embolism (EINSTEIN-PE). In these

two trials, patients received oral rivaroxaban 15 mg twice-daily for the first three weeks, followed by oral rivaroxaban 20 mg once-daily, compared with initial enoxaparin treatment followed by a vitamin K antagonist.

The third study, EINSTEIN-Extension, compared the efficacy and safety of rivaroxaban to placebo in the secondary prevention of recurrent symptomatic venous blood clots by extending preventative treatment by 6 or 12 months beyond a previously completed regimen of 6 or 12 months of therapy, and enrolled approximately 1,200 patients from 28 countries around the world with symptomatic DVT or PE. The results of the Phase III EINSTEIN-Extension study were presented in December 2009 at the 51st Annual Meeting of the American Society of Hematology (ASH) in New Orleans (USA). The data demonstrated that rivaroxaban 20 mg once-daily significantly reduced the risk of recurrent symptomatic venous thromboembolism (VTE) compared to placebo in patients who had been treated for a previous deep vein thrombosis (DVT) or pulmonary embolism (PE). The rate of major bleeding was low.

About Rivaroxaban

Rivaroxaban is a novel oral anticoagulant that was invented in Bayer Schering Pharma's Wuppertal laboratories in Germany, and is being jointly developed by Bayer HealthCare and Johnson & Johnson Pharmaceutical Research & Development, L.L.C. In clinical studies, rivaroxaban has been shown to be effective in preventing VTE in adult patients following elective hip or knee replacement surgery. It has a rapid onset of action with a predictable dose response and high bioavailability, no requirement for coagulation monitoring, as well as a limited potential for food and drug interactions. Rivaroxaban is marketed under the brand name Xarelto[®] for VTE prevention in adult patients following elective hip or knee replacement surgery, and it is the only new oral anticoagulant that has consistently demonstrated superior efficacy over enoxaparin for this indication. Xarelto[®] is approved in more than 100 countries worldwide and has been successfully launched in more than 75 countries by Bayer Schering Pharma achieving the market leader position among the new oral anticoagulants.

The extensive clinical trial program supporting rivaroxaban makes it the most studied oral, direct Factor Xa inhibitor in the world today. More than 65,000 patients are expected to be enrolled into the rivaroxaban clinical development program, which will evaluate the product in the prevention and treatment of a broad range of acute and chronic blood-clotting disorders, including stroke prevention in patients with atrial fibrillation, secondary

prevention of acute coronary syndrome, and VTE prevention in hospitalized, medically ill patients.

To learn more about thrombosis, please visit www.thrombosisadviser.com.

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of healthcare, nutrition and high-tech materials. Bayer HealthCare, a subsidiary of Bayer AG, 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, Bayer Schering Pharma, Consumer Care and Medical Care divisions. Bayer HealthCare's aim is to discover, manufacture and market products that will improve human and animal health worldwide. Find more information at www.bayerhealthcare.com.

About Bayer Schering Pharma

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Forward-Looking Statements

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