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Treatment of Deep Vein Thrombosis:

Bayer´s Rivaroxaban Successfully Meets Primary Efficacy Outcome and Demonstrates Similar Safety to Standard Therapy in Phase III EINSTEIN-DVT Non-Inferiority Study

Results from EINSTEIN-DVT Study Presented at European Society of Cardiology Congress 2010

Leverkusen, Germany, August 31, 2010 – The Phase III EINSTEIN-DVT clinical trial of the oral anticoagulant rivaroxaban demonstrated non-inferiority compared to the standard of care for the prevention of recurrent venous thromboembolism (VTE) in patients with acute symptomatic deep vein thrombosis (DVT), with a comparable safety profile. The data were presented today during a Hot Line session at the European Society of Cardiology (ESC) Congress.

“Results from EINSTEIN-DVT could transform the way physicians treat deep vein thrombosis,” said lead investigator Harry R. Büller, M.D., Academic Medical Center in Amsterdam, Netherlands, who presented the results. "While the current standard of care is effective when well-controlled, it is often associated with significant drawbacks for patients and physicians. A novel single-drug approach such as oral rivaroxaban could potentially provide an effective and well-tolerated, simple, fixed-dose regimen for the treatment of deep vein thrombosis as a replacement for current standard therapy.”

In the study, oral rivaroxaban demonstrated non-inferiority for the primary efficacy outcome, defined as the cumulative incidence of symptomatic recurrent DVT and non-fatal or fatal PE, in patients with acute symptomatic DVT compared with the current standard of care of enoxaparin followed by a vitamin K antagonist (VKA) [2.1% vs. 3.0%, respectively ($p < 0.0001$ for non-inferiority)]. Rivaroxaban also demonstrated similar results compared to the standard of care for the principal safety outcome measuring a

composite of major and non-major clinically relevant bleeding events [8.1% in both treatment groups, (p=0.77)]. Monthly liver function tests did not reveal a signal for impaired liver safety. Rivaroxaban was well tolerated in the study, and discontinuation rates related to adverse events were low and similar in both treatment groups.

Net clinical benefit, a pre-specified secondary outcome defined as the composite of the primary efficacy outcome plus major bleeding, demonstrated an improvement for rivaroxaban compared to standard therapy (2.9% vs. 4.2%, respectively; HR of 0.67, CI: 0.47 – 0.95). Other presented secondary outcomes, including all-cause mortality (2.2% vs. 2.9%, respectively; HR of 0.67, CI: 0.44 – 1.02) and cardiovascular events (0.7% vs. 0.8%, respectively; HR of 0.79, CI: 0.36 – 1.71) were not statistically significantly different.

EINSTEIN-DVT is the sixth Phase III trial in the ongoing rivaroxaban global development program that demonstrated either non-inferiority (EINSTEIN-DVT) or superiority (RECORD1-4 and EINSTEIN-EXTENSION).

Bayer's first regulatory filings in the VTE treatment setting are planned for the second half of 2010.

About the EINSTEIN Clinical Trial Program

EINSTEIN is a global clinical development program composed of three clinical studies in nearly 9,000 patients: EINSTEIN-DVT, EINSTEIN-PE and EINSTEIN-Extension. 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 multinational Phase III EINSTEIN-DVT study investigated a new single-drug approach with rivaroxaban compared with standard therapy in a randomized, open-label non-inferiority study involving more than 3,400 patients with acute symptomatic DVT, but without any symptoms of PE. Standard therapy for 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), to optimize efficacy and 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 DVT and non-fatal or fatal PE. The principal safety outcome is the composite of major and clinically relevant non-major bleeding.

The third study, EINSTEIN-Extension, evaluated the efficacy and safety of rivaroxaban compared 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 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 in patients who had been treated for a previous acute deep vein thrombosis (DVT) or pulmonary embolism (PE), oral rivaroxaban 20 mg once-daily significantly reduced the risk of recurrent symptomatic venous thromboembolism (VTE) by 82 % compared to placebo. The rate of major bleeding was low.

About Deep Vein Thrombosis (DVT)

DVT is the formation of a blood clot in a deep vein that partially or totally blocks the flow of blood. It is estimated that more than 680,000 DVT events occur in the EU each year. The majority of patients suffering from a venous blood clot will experience a DVT alone. However, DVT can progress to become a potentially fatal PE if the blood clot breaks apart and travels to the lungs, ultimately blocking a blood vessel there. Even in the absence of a PE, DVT alone can have burdensome and costly consequences such as post-thrombotic syndrome and an increased risk of recurring blood clots, therefore achieving treatment goals is essential.

Standard therapy for DVT currently includes two compounds: low molecular weight heparin administered by subcutaneous injection, followed by a vitamin K antagonist. The multinational EINSTEIN-DVT study compared the efficacy and safety of a novel single-drug approach with rivaroxaban to current dual standard therapy in a study involving

more than 3,400 patients with acute symptomatic DVT in the deep veins of the knee or thigh, but without any symptoms of PE.

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. 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 participating in 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.

If approved by the FDA, Ortho-McNeil, a division of Ortho-McNeil-Janssen Pharmaceuticals, Inc. (a Johnson & Johnson Company), will commercialize rivaroxaban in the U.S. The U.S. Bayer HealthCare sales force will support the Ortho-McNeil sales force by detailing rivaroxaban in designated hospital accounts. Bayer HealthCare is exclusively responsible for the marketing of rivaroxaban in countries outside the U.S.

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

Bayer Schering Pharma is a worldwide leading specialty pharmaceutical company. Its research and business activities are focused on the following areas: Diagnostic Imaging, General Medicine, Specialty Medicine and Women's Healthcare. With innovative products, Bayer Schering Pharma aims for leading positions in specialized markets worldwide. Using new ideas, Bayer Schering Pharma aims to make a contribution to medical progress and strives to improve the quality of life. Find more information at www.bayerscheringpharma.de.

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