



Positive Results from Chronic Study with Bayer's Rivaroxaban Will be Presented As a Late Breaker at ASH 2009

Endpoints met in EINSTEIN-Extension Trial in the Secondary Prevention of Recurrent Symptomatic VTE

Leverkusen, November 19, 2009 – Findings from the Phase III EINSTEIN-Extension study will be presented in the Late Breaking Abstract Session on December 8, 2009, (7:45 am CST, Hall F, Ernest N. Morial Convention Center) at the 51st Annual Meeting of the American Society of Hematology (ASH) in New Orleans, Louisiana.

The study investigated the long-term benefits of 20 mg rivaroxaban once-daily compared with placebo in the secondary prevention of recurrent symptomatic venous blood clots in approximately 1,200 patients with symptomatic deep vein thrombosis (DVT) or pulmonary embolism (PE). These patients had already completed 6 or 12 months of anticoagulant therapy, either as part of their routine care for an acute episode of venous thromboembolism (VTE) or as a participant in the EINSTEIN-DVT or EINSTEIN-PE clinical trials, where patients received either rivaroxaban or a vitamin K antagonist.

The abstract (Iba-2) is available online at the ASH website:
www.hematology.org/Meetings/Annual-meeting/.

About EINSTEIN

EINSTEIN is a global clinical development program of three trials in approximately 8,000 patients. Two of these studies enrolled patients with acute, symptomatic deep vein thrombosis (EINSTEIN-DVT, enrollment complete) or pulmonary embolism (EINSTEIN-PE). In these two programs, patients received oral rivaroxaban 15 mg twice-daily for 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, was designed to evaluate the long-term benefits of rivaroxaban treatment in the secondary prevention of recurrent symptomatic VTE versus placebo.

New Findings Reinforce Landmark Results from RECORD Program

Rivaroxaban, a novel oral, direct Factor Xa inhibitor, consistently demonstrated superior efficacy over enoxaparin, whilst maintaining a similar safety profile, in the Phase III RECORD clinical trial program. The aim of the RECORD program was to evaluate rivaroxaban in the prevention of VTE following elective total hip or knee replacement surgery. Results of the RECORD1, 2 and 3 trials were presented at ASH in 2007.

About rivaroxaban

Rivaroxaban was invented in Bayer's Wuppertal laboratories in Germany, and is being jointly developed by Bayer HealthCare and Johnson & Johnson Pharmaceutical Research & Development, L.L.C. Rivaroxaban is marketed under the brand name Xarelto®, and approvals have been granted for the prevention of VTE in adult patients undergoing elective hip or knee replacement surgery in over 80 countries, including the EU, Australia, Canada, China and Mexico. To date, Xarelto® has been launched in more than 50 countries around the world by Bayer HealthCare.

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 VTE treatment, 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 health care, 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 and manufacture products that will improve human and animal health worldwide. Find more information at www.bayerhealthcare.com.

About Bayer Schering Pharma

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