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Phase III Trial Results Show Superiority of Rivaroxaban over Enoxaparin for the Prevention of Venous Thromboembolism in Patients Undergoing Knee Replacement Surgery

Rivaroxaban, a New Oral, Once-Daily Direct Factor Xa Inhibitor, Shows a Significant Reduction in Deep Vein Thrombosis and Pulmonary Embolism Compared with Enoxaparin with Similarly Low Bleeding Rates

Leverkusen, July 8, 2007 – Late-breaking Phase III clinical trial data presented today at the XXI International Society on Thrombosis and Haemostasis (ISTH) Congress demonstrate that once-daily rivaroxaban (Xarelto®) achieved superior efficacy in the prevention of venous thromboembolism (VTE) in patients undergoing knee replacement surgery in a head-to-head comparison with enoxaparin, the current standard of care therapy. Patients in the RECORD3 (**RE**gulation of **C**oagulation in major **O**rthopaedic surgery reducing the **R**isk of **D**VT and PE) study who were treated with rivaroxaban demonstrated a 49% relative risk reduction (RRR) ($p<0.001$) of the composite primary endpoint of deep vein thrombosis (DVT), non-fatal pulmonary embolism (PE) and all-cause mortality compared to those treated with enoxaparin. An even greater (62%) reduction of risk ($p=0.01$) of developing major VTE (the composite of proximal DVT, non-fatal PE and VTE-related death), the secondary endpoint of the trial, was observed in the patients treated with rivaroxaban. Importantly, rivaroxaban also demonstrated a similarly low rate of major bleeding compared to enoxaparin (0.6% and 0.5%, respectively).

Rivaroxaban is an investigational, oral, once-daily direct Factor Xa inhibitor. It is an anticoagulant (a drug designed to prevent and treat blood clots) in advanced clinical development for the prevention and treatment of thrombosis in acute and chronic settings, enabling convenient administration in both the hospital and at home.

Rivaroxaban is being jointly developed by Bayer HealthCare AG and Johnson & Johnson Pharmaceutical Research & Development (J&JPRD), L.L.C.

Lead RECORD3 investigator, Michael R. Lassen, MD, of Hoersholm Hospital, University of Copenhagen, Denmark, commented: “The RECORD3 results are exciting, as they indicate that rivaroxaban may better meet the needs of many patients undergoing orthopaedic surgery. It’s an important step for this category that a once-daily, oral medication has demonstrated better efficacy in preventing VTE than the current standard of care, while also displaying a promising safety profile. In addition, it is important to note that symptomatic VTE, a secondary endpoint of the study, showed results in favour of rivaroxaban.”

Detailed Study Results

RECORD3 is a 2,531-patient, Phase III, double-blind trial that assessed the safety and efficacy of 10 mg oral, once-daily rivaroxaban started 6-8 hours after surgery versus 40 mg subcutaneous, once-daily enoxaparin started the evening before surgery in elective total knee replacement (TKR) surgery. Both regimens were continued for 10-14 days. The primary efficacy endpoint of the study was the composite of DVT, as diagnosed by mandatory venography, non-fatal PE and all-cause mortality. The primary safety endpoint was major bleeding. Results showed that DVT, non-fatal PE and death occurred in 9.6% (79/824) of patients receiving rivaroxaban versus 18.9% (166/878) of patients receiving enoxaparin (RRR 49%; $p < 0.001$).

Major VTE (the composite of proximal DVT, non-fatal PE and VTE-related death) – the main secondary efficacy endpoint of the study – occurred in 1.0% of the rivaroxaban-treated group and in 2.6% of the enoxaparin-treated group. The difference was statistically significant ($p=0.01$) in favour of rivaroxaban, with an RRR of 62%.

A reduction was also demonstrated in symptomatic VTE, a pre-specified additional secondary endpoint in the study. Symptomatic VTE occurred in 1.0% of patients who received rivaroxaban, compared to 2.7% of those in the enoxaparin comparator group, resulting in an RRR of 64%.

In the rivaroxaban and enoxaparin groups, major bleeding rates were 0.6% and 0.5%, and any bleeding rates were 4.9% and 4.8%, respectively. The RECORD3 trial demonstrated superior efficacy of rivaroxaban versus enoxaparin, with similarly low bleeding rates, in patients undergoing TKR.

Head of Global Development Dr. Kemal Malik, a member of Bayer HealthCare Executive Committee and management board member of Bayer Schering Pharma, commented:

“Based on the data we have generated, rivaroxaban shows great promise that it could set a new standard of care in thromboembolic disease as a new benchmark for balancing safety and efficacy in anticoagulation. We hope that the clinical trials will continue to demonstrate the compelling efficacy and safety profile for rivaroxaban, while also demonstrating its utility in both the hospital and home settings without the need for routine monitoring.”

The trade name of rivaroxaban is expected to be Xarelto®, pending health authority approval.

Additional Phase III results of the ongoing RECORD program are expected to be available during H2 2007.

Unmet Needs in Venous Thromboembolism (VTE)
VTE is a type of thromboembolic disease that affects approximately 6.5 million people worldwide annually. Thromboembolic disease, which is caused by the obstruction of a blood vessel by a blood clot, is a leading cause of global mortality and a concern for many patient populations, including those with atrial fibrillation at risk for stroke; those at risk for acute myocardial infarction (heart attack); those undergoing orthopaedic surgery at risk for developing DVT and PE; and hospitalized, medically ill patients immobilized by cancer, congestive heart failure, acute respiratory disease, or other illnesses.

About Rivaroxaban (Xarelto®)
Phase IIb data – presented at ISTH in 2005, and published in the Journal of Thrombosis and Haemostasis in 2005 and 2006, and the additional once-daily ODIXa HIP study published in Circulation in 2006 – indicate that rivaroxaban offers predictable anticoagulation, which strongly suggests that routine coagulation monitoring will not be required. In addition, data show that rivaroxaban does not interact with a wide variety of drugs that are commonly given concomitantly with an anticoagulant.

To date, rivaroxaban is the most studied oral direct Factor Xa inhibitor in development. More than 15,000 patients have been evaluated in the completed Phase II programs and enrolled thus far in the Phase III programs. More than 40,000 patients are expected to be evaluated in total.

The RECORD3 trial is part of the joint clinical development program between Bayer HealthCare and J&JPRD. Upon regulatory approval, rivaroxaban will be commercialized

in the United States by Scios Inc. and Ortho-McNeil, Inc. Bayer Schering Pharma will market rivaroxaban throughout the rest of the world.

The companies plan to submit regulatory filing for the prevention of VTE in orthopaedic surgery in late 2007 in Europe and in 2008 in the United States.

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, Consumer Care, Diabetes Care and Pharmaceuticals divisions. The pharmaceuticals business operates under the name Bayer Schering Pharma AG. 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.

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