

Investor News

VTE Prevention After Hip Replacement Surgery:

Pivotal Phase III Data Show Superior Efficacy of Rivaroxaban over Enoxaparin

Head-to-Head Study Demonstrates Similar and Low Rate of Bleeding for Both Drugs

Abstract # 6

Leverkusen, December 8, 2007 – The oral, once-daily, investigational anticoagulant rivaroxaban (Xarelto®) is significantly more effective than enoxaparin, the standard of care, in preventing venous thromboembolism (VTE) in patients undergoing total hip replacement surgery. Data from the RECORD1 study show a 70% relative risk reduction (RRR) for rivaroxaban in total VTE when compared with enoxaparin ($p < 0.001$) and an 88% RRR ($p < 0.001$) in major VTE. Rivaroxaban and enoxaparin had similar low bleeding rates. These data were released today at an official press conference during the 49th Annual Meeting of the American Society of Hematology (ASH) and will be presented at the major plenary session on Sunday, December 9, 2007.

“The results of this pivotal trial are very exciting for physicians who are eagerly awaiting an improved oral anticoagulant therapy that is not associated with an increased risk of bleeding,” said Dr. Bengt Eriksson, Orthopaedic Surgeon at the Sahlgrenska University Hospital/Östra, Gothenburg, Sweden, Principal Investigator of the RECORD1 clinical trial. “For years, the research on antithrombotic agents has been making advances, but these data suggest we may be close to a breakthrough in how we treat patients after major orthopaedic surgery.”

Rivaroxaban is a novel, oral, once-daily direct Factor Xa inhibitor in advanced clinical development for a wide range of indications to prevent and treat blood clots. Rivaroxaban

works at a pivotal stage in the coagulation process to directly inhibit the enzyme Factor Xa.

The RECORD1 (**RE**gulation of **Co**agulation in major **O**rthopaedic surgery reducing the **R**isk of **D**VT and PE) clinical trial compared the safety and efficacy of rivaroxaban with enoxaparin in patients undergoing total hip replacement surgery. The duration of thromboprophylaxis in both treatments was five weeks. The primary endpoint was total VTE (composite of deep vein thrombosis, non-fatal pulmonary embolism and all-cause mortality) and the main secondary endpoint was major VTE (composite of proximal deep vein thrombosis, non-fatal pulmonary embolism and VTE-related death).

Further Phase III data evaluating rivaroxaban in major orthopaedic surgery – including results from the RECORD2 and RECORD3 trials – will be presented during oral sessions on Monday, December 10, 2007 at the ASH meeting in Atlanta. The corresponding abstracts (#307 and #308) can be viewed online at the ASH website at www.hematology.org/meetings/abstracts.cfm.

About Rivaroxaban

To date, rivaroxaban is the most studied oral, direct Factor Xa inhibitor in development. More than 20,000 patients have been evaluated in the completed Phase II programs or enrolled thus far in the Phase III programs. Almost 50,000 patients are expected to be evaluated in the total clinical development program. Rivaroxaban is being jointly developed by Bayer HealthCare AG and Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

Bayer HealthCare submitted a regulatory filing to the European Agency for the Evaluation of Medicinal Products (EMA) at the end of October 2007 for approval to market rivaroxaban in the EU for the prevention of VTE in patients undergoing major orthopaedic surgery of the lower limbs. Upon regulatory approval, rivaroxaban will be commercialized in Europe by Bayer Schering Pharma. A filing for rivaroxaban for a similar indication in the United States is planned in 2008, where upon approval, it will be commercialized by Scios Inc. and Ortho-McNeil, Inc., both of which are wholly-owned subsidiaries of Johnson & Johnson.

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

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, 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.

Bayer Schering Pharma is a worldwide leading specialty pharmaceutical company. Its research and business activities are focused on the following areas: Diagnostic Imaging, Hematology/Cardiology, Oncology, Primary Care, Specialized Therapeutics 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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