



Investor News

Prevention of Venous Thromboembolism after Major Orthopedic Surgery:

Bayer HealthCare Submits Rivaroxaban for European Approval

Data Package for Rivaroxaban Involves Nearly 10,000 Patients in Three Phase III Trials

Leverkusen, October 31, 2007 – Bayer HealthCare AG announced today the submission of a Marketing Authorization Application to the European Agency for the Evaluation of Medicinal Products (EMA) for approval to market rivaroxaban (Xarelto[®]) for the prevention of venous thromboembolism (VTE) after major orthopedic surgery of the lower limbs. Rivaroxaban is an investigational, oral, once-daily direct Factor Xa inhibitor. Data from one of the pivotal studies (RECORD3) was presented prior to the EMA submission and revealed that rivaroxaban significantly reduces the risk of VTE in patients undergoing total knee replacement surgery compared with enoxaparin, the current standard of care therapy. Rivaroxaban is being jointly developed by Bayer HealthCare and Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

“The submission of the data for VTE prevention to the EMA is an important milestone in the development of this new treatment for the prevention of life-threatening blood clots,” said Dr. Kemal Malik, Head of Global Development and member of the Bayer HealthCare Executive Committee. “As an effective and convenient, once-daily oral treatment with a reassuring safety profile, we feel confident that rivaroxaban has the potential to set a new standard of care in the preventative treatment of thrombosis in patients undergoing major orthopedic surgery.”

VTE is a type of thromboembolic disease that is caused by the obstruction of a blood vessel by a blood clot. In the EU it is estimated that there are 543,000 deaths due to VTE each year. People undergoing major surgery, in particular total knee or hip replacement, are prone to developing VTE due to a combination of factors such as prolonged bed rest, damage to blood vessels and an increased tendency of the blood to clot. It is estimated

that up to 50% of patients undergoing lower limb surgery develop VTE if they do not receive preventative care.

The Marketing Authorization Application is based on data from three Phase III studies of rivaroxaban involving nearly 10,000 patients in total, and an extensive Phase I and Phase II program. One of the Phase III studies was in patients undergoing total knee replacement surgery, the results of which were presented at the International Society on Thrombosis and Hemostasis (ISTH) in July 2007 (RECORD3). The results of the other two studies in patients undergoing hip replacement surgery (RECORD1 and RECORD2) will be presented at the upcoming 49th Annual Meeting of the American Society of Hematology (ASH) meeting, 8–11 December 2007.

About RECORD3

The results of this study in 2,531 patients undergoing knee replacement surgery revealed that once-daily oral rivaroxaban 10 mg was superior in preventing VTE to once-daily subcutaneous enoxaparin 40 mg, the current standard of care therapy. Specifically, patients in this RECORD3 study (*REgulation of Coagulation in major Orthopedic surgery reducing the Risk of DVT and PE*) who were treated with rivaroxaban demonstrated a 49% relative risk reduction ($p<0.001$) in the composite primary endpoint of deep vein thrombosis (DVT), non-fatal pulmonary embolism (PE) and all-cause mortality compared to those treated with enoxaparin. Patients treated with rivaroxaban also had a 62% reduced risk ($p=0.01$) of developing major VTE (the composite of proximal DVT, non-fatal PE and VTE-related death), the main secondary endpoint of the trial. Importantly, there was a similar low rate of major bleeding for patients being treated with rivaroxaban and enoxaparin (0.6% and 0.5%, respectively).

About Rivaroxaban (Xarelto[®])

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 and enrolled thus far in the Phase III programs. More than 40,000 patients are expected to be evaluated in total.

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 if approved, it will be will commercialized by Scios Inc. and Ortho-McNeil, Inc., both of which are Johnson & Johnson companies.

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 health care, nutrition and high-tech materials. Bayer HealthCare AG, 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. 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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Forward-Looking Statements

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