



Venous Blood Clot Prevention after Hip or Knee Replacement Surgery:

Bayer's Novel Anticoagulant Rivaroxaban Submitted for Approval in the U.S.

- Rivaroxaban is first oral anticoagulant to achieve superior efficacy over the twice-daily injection of enoxaparin while maintaining low rates of major bleeding
- No evidence of safety issues attributable to rivaroxaban after long-term exposure

Leverkusen, July 30, 2008 – Bayer's cooperation partner Johnson & Johnson Pharmaceutical Research and Development (J&JPRD) has submitted the new drug application (NDA) to the U.S. Food and Drug Administration (FDA) for rivaroxaban (Xarelto[®]), a novel anticoagulant taken as one tablet, once-daily. It seeks approval for the use of rivaroxaban in the prevention of deep vein thrombosis and pulmonary embolism in patients undergoing hip or knee replacement surgery.

Rivaroxaban was invented in Bayer's Wuppertal laboratories and is being jointly developed by Bayer HealthCare and Johnson & Johnson Pharmaceutical Research & Development, L.L.C. Once marketing authorization has been granted in the U.S., rivaroxaban will be commercialized by Ortho-McNeil, a Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.

Rivaroxaban is the first oral anticoagulant to demonstrate superior efficacy over the U.S. approved twice-daily injectable regimen of enoxaparin, with a similar safety profile and no significant increase in major bleeding. Upon FDA approval, rivaroxaban will be the first novel oral anticoagulant introduced in the U.S. market for more than 50 years.

In addition to the FDA submission, filings are under review with regulatory agencies around the world. On July 24, rivaroxaban was recommended for approval in Europe for the prevention of venous thromboembolism (VTE) following elective hip and knee replacement surgery.

“We are pleased to see rivaroxaban take an important step toward regulatory approval so swiftly after demonstrating unparalleled success in the robust clinical trial program,” said Dr. Kemal Malik, member of the Bayer HealthCare Executive Committee, responsible for product development. “Current standards of anticoagulation therapy have limitations and new preventative therapies are needed. We are now on the cusp of revolutionizing the care of patients undergoing hip and knee replacement surgery.”

The NDA in the U.S. is supported by data from the RECORD clinical program, in which more than 12,500 orthopedic patients have been investigated – the largest ever conducted in the prevention of VTE in patients undergoing knee or hip replacement surgery. It comprised four pivotal Phase III clinical trials that compared rivaroxaban with enoxaparin. Rivaroxaban demonstrated superior efficacy over enoxaparin in head-to-head comparisons (RECORD1, 3 and 4), and a comparison of extended-duration (5 weeks) rivaroxaban with short-duration (2 weeks) enoxaparin (RECORD2). In all four trials, rivaroxaban and enoxaparin demonstrated similar safety profiles including low rates of major bleeding.

Almost 50,000 patients are planned to be evaluated in the total clinical development program which includes trials in prevention and treatment of a broad range of acute and chronic blood-clotting disorders. Based on the clinical evidence reported to date from over 32,000 patients (of which more than 18,000 patients have been exposed to rivaroxaban), no safety issues attributable to rivaroxaban have been observed. This includes long-term exposure of approximately 7,000 patients treated with rivaroxaban for at least 3 months of which approximately 4,500 patients were treated with rivaroxaban for 6 to 12 months or longer. A more definitive statement will be made once the data from long-term exposure to rivaroxaban in the VTE treatment, the acute coronary syndrome and stroke prevention in atrial fibrillation (SPAF) programs are available.

In the U.S., more than 900,000 people suffer from VTE events annually, and 300,000 Americans die from VTE every year. Each year, approximately 700,000 Americans elect to have hip and knee replacement surgeries, and a blood clot is the most common cause of re-hospitalization for this patient group.

Bayer estimates the global peak sales potential of rivaroxaban for all indications to exceed EUR 2 billion.

Please visit www.thrombosisadviser.com to learn more about VTE.

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