



## News Release

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Venous Blood Clot Prevention after Hip or Knee Replacement Surgery:

### **U.S. FDA Issues Complete Response Letter for Rivaroxaban**

No new clinical or non-clinical studies to be conducted as a pre-requisite for approval

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**Leverkusen, May 28, 2009** – The U.S. Food and Drug Administration (FDA) has issued a complete response letter for the new drug application (NDA) for Bayer’s rivaroxaban, a novel, oral anticoagulant taken as one tablet, once-daily. The NDA, filed in July 2008 by Bayer’s development partner Johnson & Johnson Pharmaceutical Research and Development, L.L.C. (J&JPRD), seeks approval to market rivaroxaban, a first-in-class direct Factor Xa inhibitor, in the United States for the prevention of deep vein thrombosis (DVT) and pulmonary embolism (PE) in patients undergoing hip or knee replacement surgery.

“Together with our development partner, we are evaluating the letter and we will promptly address the FDA’s questions,” said Kemal Malik, M.D., member of the Bayer HealthCare Executive Committee and Chief Medical Officer.

The FDA has not requested that any new clinical or non-clinical studies be conducted evaluating the efficacy or safety of rivaroxaban for this indication as a pre-requisite for approval. Bayer is confident in the positive benefit-risk profile of rivaroxaban and that the questions raised by the FDA can be promptly addressed.

On March 19, 2009, the U.S. FDA’s Cardiovascular and Renal Drugs Advisory Committee voted by 15-2 that the available clinical data for rivaroxaban demonstrated a favorable benefit-risk profile.

If approved by the U.S. FDA, Ortho-McNeil, a division of Ortho-McNeil-Janssen Pharmaceuticals, Inc., a Johnson & Johnson company, will commercialize rivaroxaban in the U.S. The U.S. Bayer HealthCare sales force will support the Ortho-McNeil sales force

by detailing rivaroxaban in designated hospital accounts. Bayer HealthCare is exclusively responsible for the marketing of rivaroxaban in countries outside the U.S.

### **About Venous Thromboembolism (VTE)**

Blood clots can break apart and travel through the bloodstream, blocking blood flow to vital organs. VTE includes DVT, a blood clot in a deep vein (usually in the leg), and PE, a blood clot in the lung, both of which are serious, life-threatening – but often preventable – conditions. Patients undergoing major orthopedic surgery are at high risk for VTE because during hip or knee replacement procedures, the large veins of the leg that carry blood back to the heart can be damaged, significantly increasing the risk of developing a clot. In fact, venous blood clots occur in 40 to 60 percent of patients undergoing major orthopedic surgery who do not receive preventive care. More than 800,000 patients undergo hip and knee replacement surgeries in the U.S. annually, and VTE is the most common cause of re-hospitalization for this patient group.

### **About Rivaroxaban**

Rivaroxaban was invented in Bayer's laboratories in Wuppertal, Germany, and is being jointly developed by Bayer HealthCare and J&JPRD. Rivaroxaban is approved in the European Union for the prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery, where it is marketed under the brand name Xarelto®. Additional approvals have been granted in other countries, including Australia, Canada, Mexico and Singapore. To date, Xarelto has been launched in more than 30 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.

To learn more about thrombosis, please visit [www.thrombosisadviser.com](http://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](http://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, General Medicine, Specialty Medicine 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](http://www.bayerscheringpharma.de).

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