Bayer

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Investor News

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Bayer's Rivaroxaban Submitted for Marketing Authorisation in Stroke Prevention in Patients with Atrial Fibrillation in the US

Leverkusen, January 5, 2011 – Bayer's cooperation partner Johnson & Johnson Pharmaceutical Research & Development, L.L.C. (J&JPRD) has submitted a New Drug Application to the U.S. Food and Drug Administration (FDA) for the oral anticoagulant rivaroxaban for the prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation (AF).

The submission is based on positive results from the pivotal, global Phase III ROCKET AF (Rivaroxaban Once daily oral direct Factor Xa inhibition Compared with vitamin K antagonism for prevention of stroke and Embolism Trial in Atrial Fibrillation) trial in more than 14,000 patients that was presented at the American Heart Association (AHA) Congress in November 2010.

If approved by the FDA, Ortho-McNeil, a division of Ortho-McNeil-Janssen Pharmaceuticals, Inc. (a Johnson & Johnson Company), will commercialize rivaroxaban in the U.S. Bayer HealthCare is exclusively responsible for the marketing of rivaroxaban in countries outside the U.S.

About Rivaroxaban

Rivaroxaban is an oral anticoagulant that was invented in Bayer HealthCare's Wuppertal laboratories in Germany, and is being jointly developed by Bayer HealthCare and Johnson & Johnson Pharmaceutical Research & Development, L.L.C. It has a rapid onset of action with a predictable dose response and high bioavailability, no requirement for coagulation monitoring, as well as a limited potential for food and drug interactions.

Rivaroxaban is marketed under the brand name Xarelto® for VTE prevention in adult patients following elective hip or knee replacement surgery in more than 75 countries

outside the U.S. by Bayer Healthcare. It is the only oral anticoagulant that has consistently demonstrated superior efficacy over enoxaparin for this indication.

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 participating in the rivaroxaban clinical development program evaluating the product in the prevention and treatment of a broad range of acute and chronic blood-clotting disorders, including VTE prevention in medically ill patients, VTE treatment, and secondary prevention of acute coronary syndrome.

To learn more about thrombosis, please visit 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 subgroup of Bayer AG with annual sales of EUR 15,988 million (2009), 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, Medical Care and Pharmaceuticals divisions. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 53,400 employees and is represented in more than 100 countries. Find more information at www.bayerhealthcare.com.

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