



News Release

Not intended for U.S. Media

Stroke Prevention in Patients with Atrial Fibrillation:

Bayer's Rivaroxaban Submitted for Approval in Japan

Berlin, Germany, April 14, 2011 – Bayer's rivaroxaban (Xarelto[®]) has been submitted for marketing approval in the prevention of stroke in patients with atrial fibrillation to the Japanese Ministry of Health, Labor and Welfare (MHLW).

The submission to the MHLW is based on the results of the global ROCKET AF study and the Phase III J-ROCKET AF study, which was run entirely in Japan. Both studies investigated rivaroxaban versus dose-adjusted warfarin in patients with non-valvular atrial fibrillation at risk of stroke. The J-ROCKET AF trial was conducted with a 15 mg dose of rivaroxaban once daily, in recognition of the Japanese guideline environment. Results of the J-ROCKET AF study are planned to be presented at an upcoming major scientific meeting.

As communicated in January 2011, rivaroxaban 20 mg once daily has previously been submitted for marketing authorization in stroke prevention in patients with atrial fibrillation in the EU and the US. These submissions were supported by data from the pivotal, global Phase III ROCKET AF trial that was presented at the American Heart Association (AHA) Congress in November 2010.

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 the prevention of venous thromboembolism (VTE) in adult patients following elective hip or knee replacement surgery. Xarelto® is approved in more than 100 countries worldwide and has been successfully launched in more than 80 countries by Bayer HealthCare.

The extensive clinical trial program supporting rivaroxaban makes it the most studied oral, direct Factor Xa inhibitor in the world today. In total, more than 65,000 patients are expected to participate in the rivaroxaban clinical development program evaluating the product in the prevention and treatment of a broad range of venous and arterial thromboembolic diseases, including VTE treatment and secondary prevention of acute coronary syndrome (ACS).

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 16.913 billion (2010), 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 55,700 employees (Dec 31, 2010) and is represented in more than 100 countries. Find more information at www.bayerhealthcare.com.

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