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Investor News

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Stroke Prevention in Patients with Atrial Fibrillation:

U.S. FDA Advisory Committee Recommends Approval of Bayer's Xarelto® (Rivaroxaban)

Leverkusen, September 9, 2011 – Bayer HealthCare announced today that the U.S. Food and Drug Administration's (FDA's) Cardiovascular and Renal Drugs Advisory Committee recommended approval of rivaroxaban (Xarelto®) for the prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation (AF) in the U.S. The committee voted 9-2 (with one abstention) in favor of approving rivaroxaban in this indication. A decision by the FDA is expected in early November 2011.

The Advisory Committee's recommendation is not binding, but the FDA will consider the panel's recommendation and deliberations, as well as the sponsors' presentation in its assessment of the new drug application (NDA) for rivaroxaban. The New Drug Application was submitted by Bayer's cooperation partner Johnson & Johnson Pharmaceutical Research & Development, L.L.C (J&JPRD) for rivaroxaban in the prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation on January 5, 2011.

Bayer holds the marketing rights for rivaroxaban in all markets outside the U.S., while Bayer's cooperation partner Janssen Pharmaceuticals, Inc. (a Johnson & Johnson Company) has the rights to market the product in the U.S.

As previously communicated, the application for marketing authorisation for rivaroxaban in the prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation as well as the treatment of DVT and the prevention of recurrent DVT and PE has been submitted to the EMA in Europe. In addition, rivaroxaban 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).

About Atrial Fibrillation (AF)

Atrial fibrillation is the most common sustained cardiac rhythm disorder and affects more than 6 million people in Europe, more than 2.3 million people in the U.S. and more than 800,000 individuals in Japan. In patients with atrial fibrillation, the irregular heartbeat makes them vulnerable to the formation of a blood clot in the atria, which can travel to the brain, potentially resulting in a stroke. Strokes cause damage to the brain, and can lead to physical and behavioral impairment, or even death. Significantly, people with atrial fibrillation are at a five-fold increased risk for stroke compared with the general population – about one-third of them will suffer a stroke.

About ROCKET AF

ROCKET AF (**R**ivaroxaban **O**nce daily oral direct Factor Xa inhibition **C**ompared with vitamin **K** antagonism for prevention of stroke and **E**mbolism **T**rial in **A**trial **F**ibrillation) was a prospective, randomized, double-blind, double-dummy parallel group outcomes study comparing once-daily rivaroxaban (20 mg, or 15 mg for patients with moderate renal impairment) with dose-adjusted warfarin in 14,264 patients with non-valvular atrial fibrillation who were at risk for stroke or non-CNS systemic embolism.
This was an event-driven trial, which ended when the pre-specified number of events was accumulated. The primary objective of ROCKET AF was to demonstrate the efficacy of once-daily rivaroxaban in comparison to well controlled warfarin in the prevention of stroke and non-CNS systemic embolism in patients with non-valvular AF. The principal safety measure of ROCKET AF was the composite of major plus non-major clinically relevant bleeding events.

About Rivaroxaban

Rivaroxaban is an oral anticoagulant that was discovered 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, and 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, and it is the only oral anticoagulant that has consistently demonstrated superior efficacy over enoxaparin for this indication. To date, rivaroxaban is approved in more than 110 countries worldwide and has been successfully launched in more than 85 countries by Bayer HealthCare in this indication. In the U.S., where rivaroxaban has been successfully launched in

July 2011, Janssen Pharmaceuticals, Inc. (a Johnson & Johnson Company) holds marketing rights for rivaroxaban. Bayer HealthCare sales force is supporting the Janssen Pharmaceuticals, Inc. sales force in designated hospital accounts.

The extensive clinical trial program supporting rivaroxaban makes it the most studied and widely published oral, direct Factor Xa inhibitor. The studies, reported and ongoing, involve over 75,000 patients for the prevention and treatment of venous and arterial thromboembolic disorders across a broad range of acute and chronic conditions, including stroke prevention in patients with Atrial Fibrillation, VTE treatment, and the 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 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.

Find more information at www.bayerpharma.com.

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