Bayer

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Investor News

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Stroke Prevention in Patients with Atrial Fibrillation:

Bayer Confident in Results of ROCKET AF Study to be Reviewed by the FDA Cardiovascular and Renal Drugs Advisory Committee

Leverkusen, September 6, 2011 – A Cardiovascular and Renal Drugs Advisory Committee meeting has been scheduled for September 8, 2011, to review the New Drug Application in the USA for rivaroxaban in the prevention of stroke and non-CNS systemic embolism in patients with atrial fibrillation. In preparation for the meeting, the U.S. Food and Drug Administration (FDA) reviewers have suggested that data from the ROCKET AF trial comparing rivaroxaban to warfarin do not show whether rivaroxaban is as effective for its proposed indication in comparison to warfarin when the latter is used skillfully. In addition, the FDA reviewers have stated that the proposed instructions for the transition from rivaroxaban to warfarin have not been evaluated in a clinical study.

As outlined in the submission package that Bayer's development partner, Johnson & Johnson Pharmaceutical Research & Development, L.L.C (J&JPRD), provided to the FDA in advance of the Advisory Committee hearing, the companies are confident that the results of the ROCKET AF study properly demonstrate a favorable benefit risk balance for rivaroxaban compared to warfarin, reducing stroke and non-CNS systemic embolism, with low and comparable bleeding rates.

According to the FDA reviewers' assessment, excess bleeding did not occur with rivaroxaban in ROCKET, and there are no other safety concerns that preclude approval. In ROCKET AF, rivaroxaban was associated with significantly fewer of the most concerning bleeds, including intracranial hemorrhages, critical organ bleeds, and bleeding related deaths compared to warfarin.

Importantly, all-cause mortality trended in favor of rivaroxaban and the results were achieved in a unique patient population with a higher risk for recurrent thromboembolic events with a rigorous double-blind methodology. The increase in events observed following discontinuation of study drug in the rivaroxaban arm was considered likely due to the double blind design of the ROCKET AF study, and not to the drug itself.

"We are looking forward to an open and productive discussion during the FDA Advisory Committee Meeting and are confident in the results of ROCKET AF," said Dr Kemal Malik, Member of the Bayer HealthCare Executive Committee and Chief Medical Officer.

The Advisory Committee will consider the Sponsors' presentation, the FDA presentation, and the questions posed by the FDA, and their subsequent recommendation will be assessed by the FDA in its review of the New Drug Application for rivaroxaban. A decision by the FDA is expected in early November 2011.

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. 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 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.

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