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Investor News

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Stroke Prevention in Patients with Atrial Fibrillation:

New England Journal of Medicine Publishes Results of Landmark ROCKET AF Study of Bayer's Xarelto® (Rivaroxaban)

- Once-daily rivaroxaban successfully met primary efficacy outcome of non-inferiority in protecting patients with atrial fibrillation from stroke
- In the on treatment analysis rivaroxaban was superior to warfarin, while no difference was seen between the two treatment groups in the ITT population
- Overall bleeding rates were comparable to warfarin but rivaroxaban was associated with significantly fewer of the most concerning bleeds, such as fatal bleeds and intra-cranial haemorrhages
- Rivaroxaban showed a trend to fewer myocardial infarctions

Leverkusen, August 10, 2011 – Data published today in the *New England Journal of Medicine* demonstrate that Bayer's once-daily, oral, direct Factor Xa inhibitor rivaroxaban (Xarelto®) successfully met the primary efficacy outcome while maintaining comparable overall bleeding rates versus warfarin in the ROCKET AF study. ROCKET AF was a double-blind global Phase III study of rivaroxaban compared with warfarin for stroke prevention in patients with atrial fibrillation (AF) for whom guidelines recommended oral anticoagulation.

In ROCKET AF, once-daily rivaroxaban met the primary efficacy outcome – the prevention of stroke and non-CNS systemic embolism in patients with non-valvular AF – and was shown to be non-inferior compared with warfarin. This result allowed for testing of superiority in the pre-specified on treatment population, which showed that in patients receiving rivaroxaban outcomes were significantly improved over those receiving warfarin, with a 21% relative risk reduction in stroke and non-CNS systemic embolism. A subsequent sensitivity analysis in the intent to treat (ITT) population, which followed all

patients in the trial until completion, showed non-inferiority of rivaroxaban compared with warfarin with a consistent nonsignificant treatment effect in favour of rivaroxaban.

The principal safety outcome – the composite of major and non-major clinically relevant bleeding events – was similar in both treatment arms. Patients on rivaroxaban experienced significantly fewer bleeding events of most concern to clinicians, including bleeding into a critical organ or fatal bleeding. Importantly, patients on rivaroxaban also showed significantly fewer intra-cranial haemorrhages (ICH) compared with warfarin. There were significantly more falls of ≥2 g/dL in haemoglobin concentration and transfusions of ≥2 units of whole blood or packed red blood cells in the rivaroxaban arm compared with the warfarin arm.

In ROCKET AF, rivaroxaban was associated with favourable cardiovascular outcomes while patients were on treatment, with a statistically significant 15% relative risk reduction in the composite of stroke, non-CNS systemic embolism, myocardial infarction (MI) and vascular death – a pre-specified composite secondary endpoint. In addition, rivaroxaban showed a trend to lower rates of MI, vascular death, and all-cause mortality compared with warfarin.

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 as non-inferior 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, 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, 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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