Bayer AG
Investor Relations
51368 Leverkusen
Germany
www.investor.bayer.com

Investor News

Stroke Prevention in Patients with Atrial Fibrillation:

US FDA Approves Bayer's Xarelto® (Rivaroxaban) to Reduce the Risk of Stroke and Systemic Embolism in Patients with Non-Valvular Atrial Fibrillation

- Rivaroxaban is highly effective and well tolerated in protecting patients with Atrial Fibrillation from stroke
- Rivaroxaban is the only anticoagulant with once-daily fixed dosing for stroke prevention in patients with atrial fibrillation
- Rivaroxaban does not require routine coagulation monitoring, making it more convenient to both patients and physicians

---

Leverkusen, November 4, 2011 – Bayer HealthCare announced today that the US Food and Drug Administration (FDA) has approved once-daily Xarelto® (rivaroxaban) to protect patients with non-valvular atrial fibrillation from the risk of stroke and systemic embolism. Rivaroxaban is the only oral anticoagulant now approved in the US that provides the benefits of once-daily fixed dosing and no need for routine blood monitoring, two important considerations when treatment needs to be maintained over time.

"The approval of once-daily rivaroxaban will benefit people with atrial fibrillation, in helping to reduce their risk of stroke," said Dr Joerg Reinhardt, Chairman of the Bayer HealthCare Executive Committee. "Today's approval of rivaroxaban in the US will contribute towards reducing the devastating burden that strokes have on patients and their families."

Rivaroxaban is approved to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation at a dose of 20 mg once daily, or 15 mg once daily for patients with moderate to severe renal impairment. The approval for stroke prevention in patients with Atrial Fibrillation is based on the important clinical benefits demonstrated in the double-blind Phase III 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) global clinical trial, the results of which were published in The New England Journal of Medicine in August 2011.

“Today’s approval of rivaroxaban offers physicians a new option to reduce stroke risk in patients who are living with atrial fibrillation, and the continuous threat of serious strokes,” said Gerald V. Naccarelli M.D., Professor of Medicine, Chief of Division of Cardiology, Pennsylvania State University College of Medicine and Milton S. Hershey Medical Center. “The majority of my atrial fibrillation patients are on multiple medicines for conditions that further increase the risk of stroke. I welcome a therapy like rivaroxaban that has demonstrated effectiveness and safety in these patients, with the added convenience of a fixed, once-daily dose.”

“The prevalence of atrial fibrillation is increasing, and many patients who are at risk for stroke are not currently being managed effectively or optimally,” said Robert M. Califf, M.D., ROCKET AF study co-chairman and Vice Chancellor for Clinical Research from Duke University. “In clinical studies, XARELTO® was shown to be effective in patients who are at increased risk of stroke due to the presence of co-morbidities such as high blood pressure or diabetes, and other factors that increase the risk of stroke. These patients represent many of those with the most to gain from effective anticoagulation.”

Janssen Pharmaceuticals, Inc. holds US marketing rights for rivaroxaban and will be supported by the Bayer HealthCare US sales force in designated hospital accounts.

To help ensure the risks of XARELTO® are communicated accurately, Janssen Pharmaceuticals, Inc. has developed a Risk Evaluation and Mitigation Strategy (REMS) for the medication in collaboration with the FDA. This REMS educates prescribers about appropriate use and management of XARELTO® with their patients.

About Atrial Fibrillation

Atrial fibrillation is the most common cardiac rhythm disorder and affects more than 6 million people in Europe, more than 2.2 million people in the U.S. and more than 800,000 individuals in Japan. In patients with atrial fibrillation, the heart’s irregular heartbeat makes them vulnerable to the formation of a blood clot in the atria, which can travel to the brain, potentially causing a stroke. Common conditions such as high blood pressure, diabetes, and prior stroke, along with being over the age of 75, are factors that further increase the risk of stroke in people living with atrial fibrillation. People with atrial

fibrillation are at a five-fold increased risk for stroke compared with the general population – and almost one third will suffer a stroke in their lifetime.

About the double-blind ROCKET AF study

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. The primary objective of ROCKET AF was to demonstrate the efficacy of once-daily rivaroxaban in comparison to dose-adjusted warfarin in the prevention of stroke and non-CNS systemic embolism in patients with non-valvular atrial fibrillation. The principal safety measure of ROCKET AF was the composite of major plus non-major clinically relevant bleeding events. The study has been published in The New England Journal of Medicine.

About Rivaroxaban (Xarelto®)

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 routine coagulation monitoring, and a limited potential for food and drug interactions.

Rivaroxaban (Xarelto®) is also marketed for the prevention of venous thromboembilism (VTE) 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 in this indication. Rivaroxaban is approved in more than 110 countries worldwide and to date has been successfully launched in more than 85 countries by Bayer HealthCare in this indication.

In the US, Janssen Pharmaceuticals, Inc. (a Johnson & Johnson Company) holds marketing rights for rivaroxaban, and they will be supported by Bayer HealthCare 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 (VAT) disorders across a broad range of acute and chronic conditions, including VTE prevention, 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 16.9 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.

Bayer AG, Investor Relations contacts:

Dr. Alexander Rosar (+49-214-30-81013)
Dr. Juergen Beunink (+49-214-30-65742)
Peter Dahlhoff (+49-214-30-33022)
Judith Nestmann (+49-214-30-66836)
Dr. Olaf Weber (+49-214-30-33567)
Fabian Klingen (+49-214-30-35426)
Ute Menke (+49-214-30-33021)

Forward-Looking Statements

This release may contain forward-looking statements based on current assumptions and forecasts made by the Bayer Group or subgroup management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.