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

Investor News

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Bayer's Xarelto® (Rivaroxaban) Submitted to U.S. FDA for the Treatment of Venous Thromboembolism (VTE) and Long-Term Prevention of Recurrent VTE

- Submissions for marketing authorization supported by the successful global EINSTEIN study program
- Rivaroxaban is the first oral single-drug solution proven effective for the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE)

Leverkusen, Germany, May 2, 2012 – Bayer's cooperation partner, Janssen Research & Development, LLC has submitted supplemental New Drug Applications (sNDAs) to the U.S. Food and Drug Administration (FDA) seeking approval for the use of the oral anticoagulant Xarelto® (rivaroxaban) to treat patients with deep vein thrombosis (DVT) or pulmonary embolism (PE) and to prevent recurrent venous thromboembolism (VTE).

The submissions are supported by data from the global EINSTEIN program, which included almost 10,000 patients. The three Phase III studies evaluated the safety and efficacy of rivaroxaban in the treatment of DVT and PE and the prevention of recurrent VTE. Results from these three studies have been published in the *New England Journal of Medicine* (10.156/NEJMoa1113572 and 10.1056/NEJMoa1007903).

In Europe, Xarelto® (rivaroxaban) received European Commission approval for the treatment of DVT and the prevention of recurrent DVT and PE following an acute DVT in adults in December 2011. In addition, Bayer has recently submitted an application for marketing authorization in Europe for the treatment of PE and the prevention of recurrent DVT and PE, based on the EINSTEIN-PE study. With 4,833 patients enrolled, EINSTEIN-PE is the largest study ever conducted in the acute treatment of PE.

About Venous Arterial Thromboembolism (VAT)

Thrombosis is the formation of a blood clot inside a blood vessel, blocking a vein (venous

thrombosis) or artery (arterial thrombosis). Venous and Arterial Thromboembolism (VAT) are caused when some or all of a clot detaches and is moved within the blood stream until it obstructs a smaller vessel. This can result in damage to vital organs, because the tissue beyond the blockage no longer receives nutrients and oxygen.

VAT is responsible for a number of serious and life threatening conditions:

- Venous Thromboembolism (VTE) occurs when part of a clot formed in a deep vein, for example in the leg (known as deep vein thrombosis, or DVT), is carried to the lung, via the heart, preventing the uptake of oxygen. This is known as a pulmonary embolism (PE), an event which can be rapidly fatal.

- Arterial Thromboembolism (ATE) occurs when oxygenated blood flow from the heart to another part of the body (via an artery) is interrupted by a blood clot. If this occurs in a vessel supplying blood to the brain, it can lead to a stroke, an event that can be severely debilitating or fatal. If it occurs in a coronary artery, it can lead to acute coronary syndrome (ACS), a complication of coronary heart disease which includes conditions such as myocardial infarction (heart attack), and unstable angina.

VAT is responsible for significant morbidity and mortality, and requires active or preventative treatment to avoid potentially serious or fatal patient outcomes.

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 Janssen Research & Development, LLC. 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 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 in this indication. Rivaroxaban is approved in more than 110 countries worldwide and is marketed outside the U.S. by Bayer HealthCare in this indication. On December 9, 2011, Xarelto® received further marketing approval in the EU for the prevention of stroke and systemic embolism in patients with atrial fibrillation, as well as for the treatment of deep

vein thrombosis (DVT) and the prevention of recurrent DVT and pulmonary embolism following an acute DVT in adult patients.

In the U.S., where rivaroxaban has been available since July 2011 for VTE prevention in adult patients following elective hip or knee replacement surgery, Janssen Pharmaceuticals, Inc. (a Johnson & Johnson Company) holds marketing rights. The Bayer HealthCare sales force is supporting Janssen Pharmaceuticals, Inc. in designated hospital accounts. On November 4, 2011, Xarelto® received further marketing approval in the U.S. to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation.

The extensive clinical trial program supporting rivaroxaban makes it the most studied and widely published oral, direct Factor Xa inhibitor. The studies 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 in adult patients following elective hip or knee replacement surgery, stroke prevention in patients with atrial fibrillation, VTE treatment and the prevention of recurrent DVT or PE, and for secondary prevention after an 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 17.2 billion (2011), 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, develop, manufacture and market products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 55,700 employees (Dec 31, 2011) 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)

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