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

Investor News

Not intended for UK and US Media

Treatment of Pulmonary Embolism (PE):

Bayer's Xarelto® (Rivaroxaban) Proven Effective in Treating Patients with Pulmonary Embolism and in Preventing Recurrent Venous Blood Clots in Phase III EINSTEIN-PE Study

- Rivaroxaban as effective as current standard of care in treatment of pulmonary embolism and secondary prevention of venous blood clots
- Patients receiving rivaroxaban showed significantly reduced major bleedings compared to current standard of care
- Rivaroxaban offers the first oral single-drug solution for the initial treatment and long-term prevention of pulmonary embolism
- Study results presented as a Late-Breaker at the American College of Cardiology Annual Scientific Sessions and published in the *New England Journal of Medicine*

Leverkusen, Germany, March 26, 2012 – Bayer HealthCare announced today that the oral anticoagulant Xarelto® (rivaroxaban), used as a single drug intervention, was as effective and safe as the current dual drug approach of subcutaneous enoxaparin followed by Vitamin K antagonist (VKA), in treating patients with acute symptomatic pulmonary embolism (PE) and preventing them from developing a secondary venous blood clot (known as venous thromboembolism or VTE). Rivaroxaban demonstrated similar overall bleeding rates, but was associated with significantly lower rates of major bleeding versus the current standard regimen. These data were presented today as a late-breaker at the American College of Cardiology Annual Scientific Sessions, and published in the *New England Journal of Medicine*.

The EINSTEIN-PE study compared the oral single-drug approach with rivaroxaban 15 mg twice daily for three weeks followed by 20 mg once daily with the current standard of care of subcutaneous enoxaparin followed by a VKA in the treatment of 4,833 patients with acute symptomatic PE for the prevention of recurrent VTE. Patients received treatment

for three, six or 12 months. In the study, rivaroxaban demonstrated efficacy comparable to that of the current standard therapy in reducing the primary endpoint of recurrent symptomatic VTE, a composite of symptomatic deep vein thrombosis (DVT) and non-fatal or fatal PE [2.1% vs. 1.8%, respectively (p=0.003 for non-inferiority)]. Rivaroxaban also demonstrated similar safety results compared to current standard of care for the principal safety outcome measuring a composite of major and non-major clinically relevant bleeding events [10.3% vs. 11.4% (p=0.23), respectively]. Importantly, rivaroxaban treatment resulted in a significant reduction in major bleeding events [1.1% vs. 2.2% (p=0.003), respectively] compared to the current standard therapy.

“The results of the EINSTEIN-PE study convincingly demonstrate that rivaroxaban offers clinicians a simple, single-drug solution to the initial treatment of PE and the long-term prevention of recurrent VTE, which is as effective as the current dual-drug approach and equally well tolerated,” said Dr. A.G.G. Turpie, Professor of Medicine at McMaster University, Hamilton, Canada. “These new findings are of particular importance given the appalling level of morbidity and mortality associated with venous thromboembolism in Europe and the U.S. and the frequency of recurrence”.

VTE is the collective term for both DVT and PE. DVT occurs when blood clots form in one of the large, deep veins in the legs. PE is a serious, clinical condition that most commonly occurs when part or all of a DVT dislodges and travels to the lung via the heart, where it can partially or completely block a branch of the pulmonary artery. When PE occurs with large clots, multiple clots, or when the patient already has pre-existing heart or lung disease, the event may be fatal.

“Following the recent EU approval of rivaroxaban in DVT treatment, these results reinforce the clinical importance of rivaroxaban in treating the even more dangerous pulmonary blood clots, and preventing their recurrence,” said Dr. Kemal Malik, Member of the Bayer HealthCare Executive Committee and Head of Global Development. ”We are planning to file rivaroxaban for marketing authorization in this indication during the second quarter of this year.”

About the EINSTEIN Program

EINSTEIN-PE is one of three Phase III studies in the global EINSTEIN program that evaluated the safety and efficacy of rivaroxaban in the treatment of venous thromboembolism in almost 10,000 patients. This multinational, randomized, event-driven

study with blinded outcome assessment was sponsored by Bayer HealthCare and Janssen Research & Development, LLC.

The other two trials – EINSTEIN-DVT and EINSTEIN-EXT – have already been presented at the European Society of Cardiology (ESC) Congress in August 2010 and at the 51st Annual Meeting of the American Society of Hematology (ASH) in December 2009 respectively. Data from EINSTEIN-DVT and EINSTEIN-EXT were published together in the *New England Journal of Medicine* in December 2010 (n engl j med 363;26). On December 9, 2011, 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.

About Venous and 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) is 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 nonvalvular 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)