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# Investor News

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## Bayer's Xarelto® (Rivaroxaban) Submitted for EU Marketing Authorisation for the Treatment of Pulmonary Embolism (PE) and Prevention of Recurrent Deep Vein Thrombosis (DVT) and PE

- Submission based on the successful outcome of EINSTEIN-PE study
- Rivaroxaban offers the first oral single-drug solution for the initial treatment of PE and long-term prevention of DVT and PE

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**Leverkusen, Germany, April 12, 2012** – Bayer HealthCare has submitted an application for marketing authorization to the European Medicines Agency (EMA) for the oral anticoagulant Xarelto® (rivaroxaban) for the treatment of pulmonary embolism (PE) and the prevention of recurrent deep vein thrombosis (DVT) and PE in adults.

"In the EINSTEIN-PE study we demonstrated that rivaroxaban is the first oral single-drug solution for the initial treatment of PE and long-term prevention of recurrent venous thromboembolism," said Dr Kemal Malik, Member of the Bayer HealthCare Executive Committee and Head of Global Development. "Rivaroxaban is already approved in most of the major venous and arterial thromboembolic areas. This breadth of clinical utility is unique amongst the new oral anticoagulants, and the current filing for the treatment of PE and prevention of recurrent VTE has the potential to further extend the benefits of rivaroxaban to an even wider patient population."

The submission is supported by data from the pivotal, global Phase III EINSTEIN-PE study, the results of which were presented at the American College of Cardiology's 61st Annual Scientific Session (ACC) in March this year and were published simultaneously by the *New England Journal of Medicine* (10.156/NEJMoa1113572). The EINSTEIN-PE study compared the oral single-drug approach of rivaroxaban 15 mg twice daily for three weeks followed by 20 mg once daily with the current standard of care, subcutaneous enoxaparin followed by a VKA. The study recruited 4,833 patients with acute symptomatic PE and they were treated for either three, six or 12 months. 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. The overall bleeding rates were similar between the treatment groups, but importantly rivaroxaban was associated with significantly lower rates of major bleeding.

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. The other two trials – EINSTEIN-DVT and EINSTEIN-EXT – were published together in the *New England Journal of Medicine* in December 2010 (10.1056/NEJMoa1007903). 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.

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