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Investor News

Not intended for U.S. and UK media

Bayer's Xarelto® (Rivaroxaban) Approved for the Treatment of Pulmonary Embolism (PE) and the Prevention of Recurrent Deep Vein Thrombosis (DVT) and PE in the EU

- Blood clots obstructing blood flow in deep veins or in the lungs kill more than 2,300 people every day worldwide and urgent action is essential to save lives
- Rivaroxaban works as fast as injectable enoxaparin, providing efficacy when needed for as long as needed
- Rivaroxaban offers the only oral single-drug solution for the treatment of PE and long-term prevention of DVT and PE, without the need for injections or monitoring
- Rivaroxaban is approved to protect patients from blood clots across more venous and arterial thromboembolic diseases than any other novel oral anticoagulant

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Leverkusen, Germany, November 20, 2012 – Bayer HealthCare's oral anticoagulant Xarelto® (rivaroxaban) has been approved by the European Commission (EC) for the treatment of pulmonary embolism (PE) and the prevention of recurrent deep vein thrombosis (DVT) and PE in adults. This approval makes rivaroxaban the only novel oral anticoagulant approved in this indication in the EU.

"Approximately 1 in 10 patients who suffer a pulmonary embolism dies, and concerningly, PE remains a leading cause of hospital death," said Dr. Kemal Malik, Member of the Bayer HealthCare Executive Committee and Head of Global Development. "This new approval will bring the benefits of Xarelto to more patients and physicians, where the need for a fast, effective and convenient therapy against blood clots is essential for both acute and long-term treatment."

Pulmonary embolism occurs when a blood clot in the deep veins of the leg or pelvis detaches and travels to the lung via the heart, where it can block one of the pulmonary arteries. Without fast treatment, the resulting loss of lung function can rapidly lead to death.

Until now, the standard therapy has been the dual drug combination of daily injections of a low molecular weight heparin, together with an oral vitamin K antagonist.

Professor Harry R. Büller, M.D., Academic Medical Center in Amsterdam, The Netherlands, who led the pivotal EINSTEIN clinical trial programme for rivaroxaban commented, “Today’s approval marks a turning point for both doctors and patients in the treatment and prevention of life-threatening blood clots in patients with pulmonary embolism. As a new treatment option, rivaroxaban offers a single-drug solution that works as fast as injectable enoxaparin and can provide protection for as long as needed.”

“A pulmonary embolism is a frightening experience for patients,” said Eve Knight, Co-Founder and CEO of the charity AntiCoagulation Europe (ACE). “The current standard of care can be complicated which adds to the stress and burden on the patient so today's news is great for patients. With the approval of rivaroxaban for the treatment and prevention of PE, patients at last have the choice of a simple, fast and effective treatment option."

The approval of rivaroxaban for the treatment of PE and the prevention of recurrent DVT and PE in adults is based on the important clinical findings from the pivotal, global Phase III EINSTEIN-PE study. With 4,833 patients enrolled, EINSTEIN-PE is the largest study ever conducted in the acute treatment of PE. The study compared the oral single-drug solution of rivaroxaban 15 mg twice daily for three weeks, followed by 20 mg once daily, with the current dual drug approach of subcutaneous enoxaparin followed by a VKA. Patients were treated for 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 DVT and non-fatal or fatal PE, without the need for laboratory monitoring. The overall bleeding rates were similar between the treatment groups, but importantly rivaroxaban was associated with significantly lower rates of major bleeding. The results from this study were published in the New England Journal of Medicine in April this year.

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 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 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.

To learn more about VAT, please visit www.VATspace.com

About Xarelto® (Rivaroxaban)
Rivaroxaban is the most broadly indicated new oral anticoagulant and is marketed under the brand name Xarelto®. To date, Xarelto is approved for use in the following venous arterial thromboembolic (VAT) indications:

- The prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (AF) with one or more risk factors in more than 80 countries worldwide

- The treatment of deep vein thrombosis (DVT) and prevention of recurrent DVT and pulmonary embolism (PE) in adults in more than 80 countries worldwide

- The treatment of PE and prevention of recurrent DVT and PE in adults in more than 20 countries worldwide

- The prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery in more than 120 countries worldwide

Since the first approval of Xarelto in 2008, more than two and a half million patients worldwide have now received Xarelto in daily clinical practice.

Rivaroxaban was discovered by Bayer HealthCare, and is being jointly developed with Janssen Research & Development, LLC. Xarelto is marketed outside the U.S. by Bayer HealthCare and in the U.S. by Janssen Pharmaceuticals, Inc. (a Johnson & Johnson Company).

Anticoagulant medicines are potent therapies used to prevent or treat serious illnesses and potentially life-threatening conditions. Before initiating therapy with anticoagulant medicines, physicians should carefully assess the benefit and risk for the individual patient.

Responsible use of Xarelto is a high priority for Bayer, and the company has developed a Prescribers Guide for physicians and a Xarelto Patient Card for patients to support best practices.

To learn more, please visit https://prescribe.xarelto.com
To learn more about thrombosis, please visit www.thrombosisadviser.com
To learn more about Xarelto, please visit www.xarelto.com

About Bayer HealthCare
The Bayer Group is a global enterprise with core competencies in the fields of health care, agriculture 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. More information at www.healthcare.bayer.com.

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