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Investor News

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

- Rivaroxaban offers the first oral single-drug solution for the treatment of PE and long-term prevention of DVT and PE
- Decision of European Commission on approval expected before year-end

Leverkusen, Germany, October 19, 2012 – Bayer HealthCare's oral anticoagulant Xarelto® (rivaroxaban) has been recommended for approval by the European Committee for Medicinal Products for Human Use (CHMP) for the treatment of pulmonary embolism (PE) and the prevention of recurrent deep vein thrombosis (DVT) and PE in adults. The decision of the European Commission on the approval is expected before the year-end.

"Rivaroxaban is the novel oral anticoagulant with the broadest range of indications. The recommendation by the CHMP to approve rivaroxaban for this additional use is an important milestone towards improved patient management in the treatment of pulmonary embolism," said Dr. Kemal Malik, Member of the Bayer HealthCare Executive Committee and Head of Global Development.

The CHMP recommendation to approve 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 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, 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.

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. In December 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 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 (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.

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 has been approved for use in the following indications across the venous arterial thromboembolic (VAT) space:

- 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 70 countries worldwide

- The treatment of deep vein thrombosis (DVT) and prevention of recurrent DVT and pulmonary embolism (PE) in adults in more than 70 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 in the orthopaedic setting, more than two and a half million patients worldwide have 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 very high priority for Bayer, and the company has developed a Prescribers Guide for physicians and a Xarelto Patient Card for patients to support best practice.

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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