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Investor News

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U.S. FDA Approves Xarelto® (Rivaroxaban) to Treat Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE) as well as to Reduce the Risk of Recurrent Events

Rivaroxaban is the only oral single-drug solution proven effective for the treatment of DVT and PE

Leverkusen, Germany, November 2, 2012 – Bayer HealthCare announced today that the U.S. Food and Drug Administration (FDA) has approved the oral anticoagulant Xarelto® (rivaroxaban) for the treatment of deep vein thrombosis (DVT), pulmonary embolism (PE), and to reduce the risk of recurrent DVT and PE.

Rivaroxaban was approved by the FDA on a priority review timeline, making it the only novel oral anticoagulant approved and the first oral single-drug solution proven effective for the treatment of DVT and PE in the U.S.

“Xarelto provides a single-drug treatment option from the moment of diagnosis through the completion of therapy, and in the initial treatment phase, it can cut a patient’s risk of major bleeding by nearly half," said Jack E. Ansell, M.D., MACP, Professor of Medicine at New York University School of Medicine and Chairman of the Department of Medicine at Lenox Hill Hospital in New York. “Venous blood clots are associated with a high risk of serious complications, so the approval of Xarelto will immediately impact how we treat these patients and may set a new standard of care.”

DVT is a condition in which blood clots form in one of the large, deep veins, usually in the legs. PE is a serious 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 has pre-existing heart or lung disease, the event may be fatal.
“Before the approval of Xarelto, a patient who presented with a DVT or a PE would face a treatment that involved multiple medications,” said Dr. Kemal Malik, Member of the Bayer

HealthCare Executive Committee and Head of Global Development. “Today’s FDA approval of Xarelto offers physicians an effective, well-tolerated and convenient single-drug solution for treating patients with venous blood clots, and for reducing the risk of recurrent events.”

Rivaroxaban is approved to treat patients with DVT or PE at a dose of 15 mg twice daily for three weeks, followed by 20 mg once daily for the remaining treatment period. Rivaroxaban is also approved to reduce the risk of recurrent episodes of DVT and PE at a dose of 20 mg once daily following an initial six months of treatment for acute venous thromboembolism.

The approval of rivaroxaban for these new uses was based on data from the global EINSTEIN program, which included three Phase III studies that demonstrated the efficacy and safety profile of rivaroxaban in the treatment of patients with acute symptomatic DVT or PE and the long-term prevention of recurrent DVT and PE in these patients. In total, the program included almost 10,000 patients, making it the largest DVT- and PE-treatment-related clinical trial program ever conducted.

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 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, 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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