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Investor News

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U.S. FDA Issues Complete Response Letter for Bayer's Xarelto® to Reduce the Risk of Stent Thrombosis in Patients with Acute Coronary Syndrome

Leverkusen, Germany, June 28, 2013 – Bayer HealthCare announced today that the U.S. Food and Drug Administration (FDA) has issued a complete response letter regarding the supplemental New Drug Application (sNDA) for the oral anticoagulant Xarelto® (rivaroxaban) to reduce the risk of stent thrombosis in patients with acute coronary syndrome (ACS).

"We are confident in the positive benefit-risk profile of rivaroxaban, and will continue to work with our cooperation partner Janssen Research & Development, LLC, to address the questions received from the U.S. FDA," said Dr. Kemal Malik, Member of the Bayer HealthCare Executive Committee and Head of Global Development.

On March 4, 2013, the FDA issued a second complete response letter regarding the sNDA for Xarelto to reduce the risk of cardiovascular events in patients with ACS. Data from the ATLAS ACS 2 TIMI 51 trial support both sNDAs.

In May 2013, the European Commission approved Xarelto for the prevention of atherothrombotic events (cardiovascular death, myocardial infarction or stroke) after an Acute Coronary Syndrome (ACS) in adult patients with elevated cardiac biomarkers at a dose of 2.5 mg twice-daily (BID) in combination with antiplatelet therapy.

Xarelto is currently approved for six other clinical uses both in the U.S. as well as Europe:

- The prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (AF) with one or more risk factors
- The treatment of deep vein thrombosis (DVT) in adults

- The treatment of pulmonary embolism (PE) in adults
- The prevention of recurrent DVT and PE in adults
- The prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip replacement surgery
- The prevention of venous thromboembolism (VTE) in adult patients undergoing elective knee replacement surgery

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 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®. Whilst licences may differ from country to country, across all

indications Xarelto is approved in more than 120 countries.

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 18.6 billion (2012), 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 55,300 employees (Dec 31, 2012) and is represented in more than 100 countries. More information at www.healthcare.bayer.com.

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