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Investor News

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Acute Coronary Syndrome (ACS):

U.S. FDA Issues Complete Response Letter for Bayer's Xarelto® (Rivaroxaban) for the Reduction of Cardiovascular Events in Patients with ACS

Leverkusen, Germany, March 5, 2013 – Bayer HealthCare announced today that the U.S. Food and Drug Administration (FDA) issued a second complete response letter regarding the supplemental New Drug Application (sNDA) for the oral anticoagulant Xarelto® (rivaroxaban) 2.5 mg BID in combination with standard antiplatelet therapy for the reduction of cardiovascular events (cardiovascular death, myocardial infarction or stroke) in patients with Acute Coronary Syndrome (ACS). Bayer is evaluating the complete response letter from the FDA together with its cooperation partner Janssen Research & Development, LLC, and will respond to the Agency's questions.

"We remain confident in the safety and efficacy of rivaroxaban in this indication and will work closely with our development partner Janssen Research & Development, LLC, to address the questions from the FDA," said Dr. Kemal Malik, Member of the Bayer HealthCare Executive Committee and Head of Global Development.

Xarelto® is approved for six clinical uses in the U.S.:

- to reduce the risk of blood clots in the legs and lungs of adults who have just had knee replacement surgery
- to reduce the risk of blood clots in the legs and lungs of adults who have just had hip replacement surgery
- to reduce the risk of both hemorrhagic and thrombotic strokes as well as other blood clots in adults with atrial fibrillation not caused by a heart valve problem
- to treat adults with pulmonary embolism (PE)

- to treat adults with deep vein thrombosis (DVT)
- to reduce the risk of recurrence of DVT or PE following an initial six months of treatment for acute venous thromboembolism

The sNDA includes results from the pivotal, global Phase III ATLAS ACS 2-TIMI 51 study, which showed that rivaroxaban 2.5 mg dosed twice daily in addition to standard antiplatelet therapy (low-dose aspirin with or without a thienopyridine such as clopidogrel or ticlopidine) significantly reduced the composite primary efficacy endpoint of cardiovascular death, myocardial infarction or stroke in patients after a recent ACS compared to those receiving standard antiplatelet therapy alone.

Rates of TIMI (**T**hrombolysis **I**n **M**yocardial **I**nfarction) major bleeding events not associated with coronary artery bypass graft (CABG) surgery were low overall, but rivaroxaban was associated with higher rates of these bleeds compared with standard therapy alone. Importantly, these differences were not associated with an increase in the risk of fatal bleeding or fatal intracranial haemorrhage (ICH).

About Acute Coronary Syndrome (ACS)
ACS is a complication of coronary heart disease which is the single most common cause of death worldwide and one of the most prevalent non-communicable diseases in the world. ACS occurs when a blood clot blocks a coronary artery, reducing blood supply to the heart. This disruption of blood flow can directly cause a heart attack, or severe pain in the chest (unstable angina), a condition indicating that a heart attack may soon occur.

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.

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 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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