Bayer AG
Investor Relations
51368 Leverkusen
Germany
www.investor.bayer.com

Investor News

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Complete Response Submitted to U.S. FDA on Bayer's Rivaroxaban for the Reduction of Secondary Cardiovascular Events in Patients with Acute Coronary Syndrome

Supplemental New Drug Application for Rivaroxaban to reduce the risk of stent thrombosis in patients with Acute Coronary Syndrome also resubmitted

Leverkusen, Germany, September 7, 2012 – Bayer's cooperation partner, Janssen Research & Development, LLC has submitted its reply to the Complete Response Letter from the U.S. Food and Drug Administration (FDA) for the use of Xarelto® (rivaroxaban) 2.5 mg twice daily in combination with standard antiplatelet therapy to reduce the risk of secondary cardiovascular events in patients with Acute Coronary Syndrome (ACS). The submission includes the information requested by the FDA in its letter to Janssen Research & Development on June 21, 2012.

In addition, the supplemental New Drug Application (sNDA) for the use of rivaroxaban, in combination with standard antiplatelet therapy, to reduce the risk of stent thrombosis in patients with ACS has been resubmitted. Data from the ATLAS ACS 2-TIMI 51 trial support both filings.

"We are pleased we could quickly provide the information the U.S. FDA requested regarding rivaroxaban and we will continue to work with our cooperation partner, Janssen, to help bring this important treatment to patients who are at risk of another life-threatening blood clot following their heart attack, unstable angina event or stent procedure," said Dr. Kemal Malik, Member of the Bayer HealthCare Executive Committee and Head of Global Development.

ACS is a complication of coronary heart disease, which is the leading cause of death in the developed world and one of the most prevalent non-communicable diseases. ACS occurs when a blood clot blocks a coronary artery, reducing blood supply to the heart.

This disruption of blood flow can cause a heart attack (myocardial infarction), or unstable angina, a condition indicating that a myocardial infarction may soon occur.

Coronary stents are implanted in more than 1.5 million patients each year. Stent thrombosis is a rare, but catastrophic complication that can occur after a stent has been inserted into a patient's coronary artery to keep the vessel open. If blood flow through the stent is restricted or blocked completely, the individual's risk of forming a clot will increase and can lead to a heart attack or even death.

In Europe, an application for marketing authorization of Xarelto for secondary prevention after an ACS was submitted in December 2011 and is currently under review.

About ATLAS ACS 2-TIMI 51

The ATLAS ACS 2-TIMI 51 (**A**nti-Xa **T**herapy to **L**ower cardiovascular events in **A**ddition to aspirin with/without thienopyridine therapy in **S**ubjects with **A**cute **C**oronary **S**yndrome) study was designed to test the efficacy of rivaroxaban compared to placebo in preventing cardiovascular death, myocardial infarction or stroke in patients after an ACS. Patients were given standard antiplatelet therapy plus rivaroxaban dosed at 2.5 mg or 5 mg BID, or a placebo. Of the 15,526 patients randomized into the study, 93% received aspirin plus thienopyridine in addition to rivaroxaban or placebo, and the balance were treated with aspirin plus rivaroxaban or placebo.

The double blind, randomized, placebo-controlled study was coordinated by the TIMI Study Group and Brigham and Women's Hospital and Harvard Medical School, Boston, US, and was funded and led by Bayer HealthCare and Janssen Research & Development, LLC.

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 60 countries worldwide

- The treatment of deep vein thrombosis (DVT) and prevention of recurrent DVT and pulmonary embolism (PE) following an acute DVT in adults in more than 50 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 million patients worldwide have received Xarelto in daily clinical practice in this indication alone.

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.

Bayer AG, Investor Relations contacts:

Dr. Alexander Rosar (+49-214-30-81013)
Dr. Juergen Beunink (+49-214-30-65742)
Peter Dahlhoff (+49-214-30-33022)
Judith Nestmann (+49-214-30-66836)
Dr. Olaf Weber (+49-214-30-33567)
Fabian Klingen (+49-214-30-35426)

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