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

Investor News

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Bayer's Xarelto® (Rivaroxaban) Submitted to U.S. FDA to Reduce the Risk of Stent Thrombosis in Patients with Acute Coronary Syndrome

Leverkusen, Germany, May 9, 2012 – Bayer's cooperation partner, Janssen Research & Development, LLC has submitted a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) seeking approval for the use of the oral anticoagulant Xarelto® (rivaroxaban) 2.5 mg BID in combination with standard antiplatelet therapy to reduce the risk of stent thrombosis in patients with Acute Coronary Syndrome (ACS). An application for marketing authorization to reduce the risk of secondary cardiovascular events in patients with ACS has been filed with the U.S. FDA in December and is currently under review.

The filing is supported by data from the pivotal, global Phase III ATLAS ACS 2-TIMI 51 study, which was presented in November 2011 at the American Heart Association Scientific Sessions and published in the New England Journal of Medicine (10.1056/NEJMoa1112277). In the trial, rivaroxaban 2.5 mg BID was associated with a 35% relative risk reduction in the rate of stent thrombosis compared to placebo [2.2% vs. 2.9% (HR 0.65; 0.45-0.94)]. Rates of TIMI major bleeding events not associated with coronary artery bypass graft surgery were low overall in the trial, but rivaroxaban was associated with higher rates of these bleeds in the 2.5 mg BID dose compared to placebo [1.8% vs. 0.6% (HR 3.46; 2.08-5.77)]. Importantly, these differences were not associated with an excess risk of fatal bleeding. Additional data on stent thrombosis, from the ATLAS ACS 2-TIMI 51 trial, will be presented later this year.

Coronary stents are implanted in more than 1.5 million patients each year. Although stent thrombosis is rare, it remains a dangerous complication that may occur after a stent has been inserted into a patient's coronary artery to keep the passageway open. If blood flow through the stent is restricted or blocked completely, the individual's risk of forming an unwanted clot will increase and can lead to ACS.

In Europe, Bayer submitted an application for marketing authorization for secondary prevention after an ACS in December 2011. Reducing the risk of stent thrombosis is part of that application, based on the ATLAS ACS 2-TIMI 51 study.

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, L.L.C.

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 and Arterial Thromboembolism (VAT) are 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.

About Rivaroxaban (Xarelto®)

Rivaroxaban is an oral anticoagulant that was discovered in Bayer HealthCare's Wuppertal laboratories in Germany, and is being jointly developed by Bayer HealthCare and Janssen Research & Development, LLC. It has a rapid onset of action with a predictable dose response and high bioavailability, no requirement for routine coagulation monitoring, and a limited potential for food and drug interactions.

Rivaroxaban is marketed under the brand name Xarelto® for VTE prevention in adult patients following elective hip or knee replacement surgery, and it is the only oral anticoagulant that has consistently demonstrated superior efficacy over enoxaparin in this indication. Rivaroxaban is approved in 120 countries worldwide and is marketed outside the U.S. by Bayer HealthCare in this indication. On December 9, 2011, Xarelto® received further marketing approval in the EU for the prevention of stroke and systemic embolism in patients with atrial fibrillation, as well as for the treatment of deep vein thrombosis (DVT) and the prevention of recurrent DVT and pulmonary embolism following an acute DVT in adult patients.

In the U.S., where rivaroxaban has been available since July 2011 for VTE prevention in adult patients following elective hip or knee replacement surgery, Janssen Pharmaceuticals, Inc. (a Johnson & Johnson Company) holds marketing rights. The Bayer HealthCare sales force is supporting Janssen Pharmaceuticals, Inc. in designated hospital accounts. On November 4, 2011, Xarelto® received further marketing approval in the U.S. to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation.

The extensive clinical trial program supporting rivaroxaban makes it the most studied and widely published oral, direct Factor Xa inhibitor. The studies involve over 75,000 patients for the prevention and treatment of venous and arterial thromboembolic (VAT) disorders across a broad range of acute and chronic conditions, including VTE prevention in adult

patients following elective hip or knee replacement surgery, stroke prevention in patients with atrial fibrillation, VTE treatment and the prevention of recurrent DVT or PE, and for secondary prevention after an Acute Coronary Syndrome.

To learn more about thrombosis, please visit www.thrombosisadviser.com

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care, nutrition 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. Find more information at www.bayerhealthcare.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)
Ute Menke (+49-214-30-33021)

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