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Investor News

Not intended for U.S. and UK Media

Secondary Prevention of Acute Coronary Syndrome (ACS):

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

Leverkusen, Germany, June 21, 2012 – Bayer HealthCare announced today that the U.S. Food and Drug Administration (FDA) issued a 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 secondary 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 are confident of 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 set forth by the FDA," said Dr. Kemal Malik, Member of the Bayer HealthCare Executive Committee and Head of Global Development.

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

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

Bayer's cooperation partner Janssen Research & Development, LLC filed this sNDA with the FDA on December 29, 2011 and received a priority review designation from the FDA

on February 27, 2012. On May 23, 2012, the FDA's Cardiovascular and Renal Drugs Advisory Committee narrowly voted against recommending approval of rivaroxaban in this indication.

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. In addition, rivaroxaban significantly reduced cardiovascular death in patients with ACS. 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 ACS

ACS is a complication of coronary heart disease, which is the leading cause of death in the U.S. 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 cause a heart attack (myocardial infarction), or cause unstable angina indicating that a myocardial infarction may soon occur.

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, in combination with standard antiplatelet therapy, compared to placebo in preventing cardiovascular death, myocardial infarction or stroke in patients with 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 and thienopyridine in addition to rivaroxaban or placebo, whilst 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,

U.S., 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 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 more than 120 countries worldwide and is marketed outside the U.S. by Bayer HealthCare in this indication. In December 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, Bayer's cooperation partner Janssen Pharmaceuticals, Inc. (a Johnson & Johnson Company) holds marketing rights. The Bayer HealthCare sales force is supporting Janssen Pharmaceuticals, Inc. in designated hospital accounts. In November 2011, Xarelto® received further marketing approval in the U.S. to reduce the risk of stroke and systemic embolism in patients with nonvalvular 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 nearly 100,000 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.

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