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Investor News

Not intended for U.S. and UK Media

Bayer's Xarelto® (Rivaroxaban) Granted Priority Review by U.S. FDA for the Treatment of Deep Vein Thrombosis or Pulmonary Embolism and the Long-Term Prevention of Recurrent Venous Thromboembolism

Bayer also provides update on the U.S. filing of rivaroxaban in stent thrombosis

Leverkusen, Germany, July 9, 2012 – Bayer, together with its cooperation partner, Janssen Research & Development, LLC, announced today that the U.S. Food and Drug Administration (FDA) has granted Priority Review to the supplemental New Drug Applications (sNDAs) filed on May 2, 2012 for the oral anticoagulant Xarelto® (rivaroxaban) to treat patients with deep vein thrombosis (DVT) or pulmonary embolism (PE) and to prevent recurrent DVT and PE.

The FDA grants Priority Review to medicines that offer major advances in care or provide a treatment where no adequate therapy exists. Under the Prescription Drug User Fee Act (PDUFA), FDA will aim to complete its review within six months from the receipt of the sNDA submission, rather than the standard 10 month review cycle.

"The EINSTEIN studies have demonstrated convincingly that rivaroxaban can offer physicians a simple, single-drug solution for both the initial treatment of DVT or PE as well as the long-term prevention of recurrent VTE," said Dr. Kemal Malik, Member of the Bayer HealthCare Executive Committee and Head of Global Development. "The FDA's Priority Review designation for rivaroxaban is an important step towards making this treatment available to even more patients in the U.S."

The submissions are supported by data from the global EINSTEIN clinical development program, which included almost 10,000 patients. The three Phase III studies evaluated the safety and efficacy of rivaroxaban in the treatment of DVT and PE and the prevention of recurrent VTE. Results from these three studies have been published in the *New*

England Journal of Medicine and demonstrated that rivaroxaban can offer the first oral single-drug solution for the initial treatment and long-term prevention of VTE.

Separately, Bayer and the cooperation partner Janssen Research & Development, LLC announced today that the supplemental New Drug Application (sNDA) filed with the FDA for the use of the oral anticoagulant Xarelto® (rivaroxaban) to reduce the risk of stent thrombosis in patients with Acute Coronary Syndrome (ACS) has been withdrawn. The decision is due to the complete response letter issued by the FDA regarding the separate sNDA for rivaroxaban to reduce the risk of secondary cardiovascular events in patients with ACS. Data from the ATLAS ACS 2-TIMI 51 study support both sNDAs.

"Together with our cooperation partner Janssen Research & Development, LLC, we are putting all our efforts behind the original submission for secondary prevention of ACS to address the questions raised by the FDA in their complete response letter as soon as possible," said Dr. Kemal Malik.

Bayer and Janssen plan to resubmit the sNDA for rivaroxaban in stent thrombosis at the same time as the reply to the complete response letter in ACS.

Coronary stents are implanted in more than 1.5 million patients each year. Although stent thrombosis is rare, it is a 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 an unwanted clot increases and can lead to a heart attack of even death.

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 and has since then been approved in more than 50 countries worldwide 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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