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Investor News

Not intended for UK and US Media

Secondary Prevention of Acute Coronary Syndrome (ACS):

Bayer's Xarelto® (Rivaroxaban) Granted Priority Review by US FDA to Prevent Secondary Cardiovascular Events in Patients with ACS

Leverkusen, Germany, February 28, 2012 – Bayer, together with its cooperation partner, Janssen Research & Development, L.L.C., announced today that the US Food and Drug Administration (FDA) has granted Priority Review designation to the supplemental New Drug Application (sNDA) filed on December 29, 2011 for the oral anticoagulant Xarelto® (rivaroxaban) in combination with standard antiplatelet therapy to reduce the risk of (thrombotic) cardiovascular events in patients with Acute Coronary Syndrome (ACS).

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

"The FDA's Priority Review designation for rivaroxaban is an important step towards making this treatment available in the US for patients with Acute Coronary Syndrome," said Dr Kemal Malik, Member of the Bayer HealthCare Executive Committee and Head of Global Development.

The submission was based upon data from the pivotal, global Phase III ATLAS ACS 2-TIMI 51 study. Results from the study, presented at the 2011 American Heart Association Scientific Sessions and simultaneously published by the *New England Journal of Medicine* (10.1056/NEJMoa1112277), showed that the combination of oral rivaroxaban 2.5 mg twice-daily (BID) with standard antiplatelet therapy 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 2.5 mg BID in combination with standard therapy

significantly reduced both the rate of cardiovascular death and the incidence of all-cause mortality by more than 30% over standard therapy alone.

The study also showed that 2.5 mg BID of rivaroxaban in combination with standard antiplatelet therapy exhibited a higher rate of TIMI major bleeding events not associated with coronary artery bypass graft (CABG) surgery, but did not increase the risk of fatal bleeding over standard therapy alone.

About Acute Coronary Syndrome (ACS)
ACS is a complication of coronary heart disease, which is one of the most prevalent non-communicable diseases in the world and the leading cause of death in the US. ACS occurs when a blood clot blocks a coronary artery, reducing blood supply to the heart. This disruption of blood flow can be the direct cause of a heart attack, or cause severe pain in the chest (unstable angina) 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.

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, L.L.C. 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 110 countries worldwide and is marketed outside the U.S. by Bayer HealthCare in this indication. On December 19, 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 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 involved 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 16.9 billion (2010), 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 and manufacture products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 55,700 employees (Dec 31, 2010) and is represented in more than 100 countries. Find more information at www.bayerhealthcare.com.

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