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Investor News

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Stroke Prevention in Patients with Atrial Fibrillation:

Bayer's Xarelto® Approved in Japan for Stroke Prevention in Patients with Non-Valvular Atrial Fibrillation

Leverkusen, Germany, January 18, 2012 – Bayer's once-daily oral anticoagulant Xarelto® (rivaroxaban) has been approved for the prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation by the Japanese Ministry of Health, Labor and Welfare (MHLW).

"This approval is the result of many years of research and a robust development program and, in addition to the global ROCKET AF study, we conducted a trial specifically in Japanese patients, J-ROCKET AF", said Dr Kemal Malik, Member of the Bayer HealthCare Executive Committee and Head of Global Development. "Now the benefits of rivaroxaban one tablet, once daily are also available in Japan to patients with atrial fibrillation who are at risk of stroke".

The approval by the MHLW is based on the results of the global ROCKET AF study and the J-ROCKET AF study, which was run entirely in Japan. Both studies investigated rivaroxaban versus dose-adjusted warfarin in patients with non-valvular atrial fibrillation at risk of stroke. The J-ROCKET AF trial was conducted with a 15 mg dose of rivaroxaban once daily (10 mg in patients with renal impairment). Results of the J-ROCKET AF study were presented last year in the late breaking clinical trials session at the 23rd Congress of the International Society on Thrombosis and Haemostasis in Kyoto, Japan.

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 a clot becomes loose and is moved by the blood stream to obstruct

another vessel, which can result in damage to vital organs. VAT encompasses two serious 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 another vessel which delivers blood to an organ. If this occurs in a vessel supplying blood to the lungs, it 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 an important cause of morbidity and mortality across a broad range of acute and chronic blood-clotting disorders and requires active or preventative treatment to avoid potentially serious or fatal patient outcomes.

About Atrial Fibrillation

Atrial fibrillation is the most common sustained cardiac rhythm disorder and affects more than 800,000 people in Japan. People with AF are at a five-fold increased risk for stroke compared with the general population, and about one-third of them will suffer a stroke. An irregular heartbeat makes AF patients vulnerable to the formation of a blood clot in the atria of the heart, and this can travel to the brain, potentially resulting in a stroke. Strokes damage the brain, and can lead to both physical and behavioural impairment or even death.

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 or regular renal 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, 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, 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, reported and ongoing, 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 the secondary prevention of 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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