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Investor News

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Bayer's Xarelto® Approved in the EU for the Prevention of Stroke in Patients with AF and in the Treatment of DVT

- In stroke prevention in AF, Xarelto is the only oral anticoagulant offering patients a once-daily, highly effective therapy without need for routine coagulation monitoring
- For the treatment of DVT and the prevention of recurrent DVT and PE, Xarelto is the first oral anticoagulant to offer patients both efficacy and the convenience of a single-drug solution, without the need for injections or monitoring
- Xarelto is now approved in the EU across three indications in the area of venous and arterial thromboembolism (VAT)

Leverkusen, December 19, 2011 – Bayer HealthCare's oral anticoagulant Xarelto® (rivaroxaban) has been approved by the European Commission (EC) for use in two new indications, making it the only new oral anticoagulant approved in three indications across all 27 EU member states:

- Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (AF) with one or more risk factors

- Treatment of deep vein thrombosis (DVT) and prevention of recurrent DVT and pulmonary embolism (PE) following an acute DVT in adults

- The prevention of VTE in adult patients undergoing elective hip or knee replacement surgery

"Today's approval in these new indications by the European Commission marks the culmination of years of intensive research, and underscores Bayer's innovative strength," said Dr. Jörg Reinhardt, Chairman of the Bayer HealthCare Executive Committee. "We are delighted to bring the benefits of rivaroxaban to patients and physicians in the EU in

need of a highly effective and convenient therapy against blood clots to prevent strokes and treat DVT."

"These approvals have the potential to change clinical practice in Europe," said Professor Alexander G.G. Turpie, Professor of Medicine, McMaster University, Canada. "Rivaroxaban offers patients suffering from AF an effective and well-tolerated therapy option, while avoiding the drawbacks of traditional therapies. In the treatment of DVT and prevention of recurrent DVT and PE, physicians are now able to utilise a new single drug solution, making the therapy more convenient for both patients and physicians."

The approval of rivaroxaban for the prevention of AF-related stroke is based on the important clinical benefits demonstrated in ROCKET AF, a rigorous, double-blind global Phase III study that compared once-daily rivaroxaban with warfarin in more than 14,000 patients. The results from the ROCKET AF trial were published in the *New England Journal of Medicine* (NEJM) in August 2011.

The approval of rivaroxaban for the treatment of DVT and the prevention of recurrent DVT and PE following an acute DVT, follows submission of data from the Phase III EINSTEIN-DVT study, as well as data from the Phase III EINSTEIN-Extension study. Both EINSTEIN-DVT and EINSTEIN-Extension were published in the *NEJM* in December 2010.

"The decision of the European Commission to approve this therapy is welcome news for people at risk of the devastating consequences of blood clots," said Eve Knight, Co-Founder and CEO of the charity AntiCoagulation Europe (ACE). "Thrombosis remains a massive burden on patients and healthcare systems across the EU, and the approval of effective alternatives without the limitations of traditional therapies such as routine monitoring, regular injections and dietary challenges represents a much needed evolution in thrombosis management."

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 cause 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), 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 the brain, this can lead to a stroke, which 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 6 million people in Europe. 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 Deep Vein Thrombosis (DVT)

Venous Thromboembolism (VTE) is caused by the obstruction of a blood vessel by a blood clot. In the EU there are approximately 550,000 VTE related deaths each year and it is estimated to be the third most common cardiovascular disease after heart disease and stroke. Indeed, venous blood clots kill more people in Europe each year than breast cancer, prostate cancer, HIV / AIDS and road traffic accidents combined.

DVT is the formation of a blood clot in a deep vein that partially or totally blocks the flow of blood. However, DVT can progress to become a potentially fatal PE if the blood clot breaks apart and travels to the lungs, ultimately blocking a blood vessel there. Even in the absence of a PE, DVT alone can have devastating and costly consequences such as post-thrombotic syndrome and an increased risk of recurring blood clots, and thus the

achievement of treatment goals is critically important. The current treatment standard for DVT includes two drugs, low molecular weight heparin administered by subcutaneous injection, followed by a vitamin K antagonist, a complex and often problematic regimen.

About Rivaroxaban

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. (a Johnson & Johnson Company). 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, as well as 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 marketed outside the U.S. by Bayer HealthCare in this indication.

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. holds marketing rights. The Bayer HealthCare sales force is supporting Janssen Pharmaceuticals, Inc. in designated hospital accounts. On November 4, rivaroxaban received further marketing approval in the U.S. to reduce the risk of stroke in patients with 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 stroke prevention in patients with Atrial Fibrillation, DVT 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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