Bayer

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Investor News

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Xarelto® Recommended for Approval in the Prevention of AF Related Stroke and Treatment of Deep Vein Thrombosis in EU

- CHMP recommends approval of rivaroxaban for two new chronic indications
- Upon approval, rivaroxaban would be the only new oral anticoagulant approved in three indications in all EU member states
- Decision of European Commisson on approval expected in fourth quarter 2011

Leverkusen, September 23, 2011 – Bayer HealthCare's oral anticoagulant Xarelto® (rivaroxaban) has been recommended for approval by the European Committee for Medicinal Products for Human Use (CHMP) for both the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (AF), as well as for the treatment of deep vein thrombosis (DVT) and prevention of recurrent DVT and pulmonary embolism (PE) following an acute DVT in adults.

"The recommendation by the CHMP to approve rivaroxaban in these two additional indications is a significant milestone for our company," said Dr Kemal Malik, Member of the Bayer HealthCare Executive Committee and Chief Medical Officer. "We expect that we will soon be able to provide patients and physicians in Europe with an effective alternative for the prevention of strokes in patients with atrial fibrillation as well as a new, convenient single drug approach to the treatment of DVT."

The decision of the European Commission is expected in the fourth quarter 2011 and an approval would make rivaroxaban the only new oral anticoagulant available for adult patients across three indications in all EU member states, including:

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

- Treatment of DVT and prevention of recurrent DVT and PE following an acute DVT

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

“The decision to recommend rivaroxaban for these new indications speaks to its validated efficacy and safety in the management of potentially deadly blood clots across a wide range of arterial and venous settings,” said Professor Ajay Kakkar, Professor of Surgery, University of London. “This is important for patients and their physicians because rivaroxaban offers a highly effective and well tolerated therapy option. Importantly, it is not restricted by the limitations of current therapies, including unpredictable anticoagulation, frequent monitoring, drug and food interactions, and the inconvenience associated with regular injections.”

“Patients have waited over 50 years for new treatments which offer improved outcomes to traditional therapies that can have limitations such as routine monitoring and regular injections, as well as dietary challenges and interactions with other treatments,” said Eve Knight, Co-Founder and CEO of AntiCoagulation Europe (ACE). “Today’s recommendation for rivaroxaban is another welcome signal that the era of advanced oral anticoagulants which offer protective benefits beyond traditional therapies has arrived in Europe.”

The CHMP recommendation to approve rivaroxaban for stroke prevention in atrial fibrillation 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 presented at the American Heart Association (AHA) Congress in November 2010 and published in the *New England Journal of Medicine* in August 2011.

The positive recommendation for rivaroxaban in 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 presented at the European Society of Cardiology (ESC) Congress in August 2010, as well as data from the Phase III EINSTEIN-Extension study, presented in December 2009 at the 51st Annual Meeting of the American Society of Hematology (ASH). Both EINSTEIN-DVT and EINSTEIN-Extension were published in the *New England Journal of Medicine* in December 2010.

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 – 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, which can travel to the brain, potentially resulting in a stroke. Strokes cause damage to the brain, and can lead to physical and behavioral 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 deaths due to VTE each year. VTE is estimated to be the third most common cardiovascular disease after heart disease and stroke, and 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. It is estimated that nearly 700,000 DVT events occur in the EU each year. The majority of patients suffering from a venous blood clot will experience a DVT alone. 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 compounds, low molecular weight heparin administered by subcutaneous injection, followed by a vitamin K antagonist, a complex and problematic regimen.

About Xarelto® (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 Johnson & Johnson Pharmaceutical Research & Development, L.L.C. It has a rapid onset of action with a predictable dose response and high bioavailability, no requirement for coagulation monitoring, as well as a limited potential for food and drug interactions.

Xarelto® is marketed 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 for this indication. To date, Xarelto® is approved in more than 110 countries worldwide and has been successfully launched in more than 85 countries by Bayer HealthCare in this indication. In the U.S., where Xarelto® has been successfully launched in its first indication in July 2011, Janssen Pharmaceuticals, Inc. (a Johnson & Johnson Company) holds marketing rights. The Bayer HealthCare sales force is supporting the Janssen Pharmaceuticals, Inc. in designated hospital accounts.

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 disorders across a broad range of acute and chronic conditions, including stroke prevention in patients with atrial fibrillation, VTE treatment, 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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