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Investor News

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Bayer receives FDA approval for Xarelto® 10 mg once daily for the extended treatment of venous thromboembolism

- Rivaroxaban (Xarelto®) 10 mg once daily significantly reduces the risk of recurrent venous thromboembolism compared with aspirin 100 mg once daily following at least six months of standard anticoagulation therapy
- FDA approval based on data from the EINSTEIN CHOICE study

Leverkusen, Germany, October 30, 2017 – Bayer AG and its development partner Janssen Research & Development, LLC advise that the U.S. Food and Drug Administration (FDA) has approved a label update for their oral Factor Xa inhibitor Xarelto® (rivaroxaban) to include a 10 mg once daily dose for the extended treatment of recurrent venous thromboembolism (VTE) in the USA. This label update applies to patients at a continued risk of deep vein thrombosis (DVT) and/or pulmonary embolism (PE) who have already received at least six months of standard anticoagulation therapy. It provides physicians with an opportunity to strengthen the treatment paradigm of these patients from no treatment or aspirin to rivaroxaban 10 mg.

“Patients who have previously suffered a VTE are often at increased risk of experiencing another event if anticoagulant treatment is stopped,” said Dr Joerg Moeller, Member of the Executive Committee of Bayer AG's Pharmaceutical Division and Head of Development. “The FDA approval of the 10 mg dose provides physicians with an additional therapeutic option enabling them to continue the extended treatment with the regimen that best suits the benefit-risk-assessment of the individual patient.”

The European Commission already approved an update to the label for Xarelto in the EU at October 19th.

VTE, which includes pulmonary embolism, a clot that travels to the lung, and deep vein thrombosis, a blood clot in a deep vein (often in the legs), has a significant global impact

and after heart attack and stroke, is the third most common cause of cardiovascular death worldwide. The current treatment recommendation for the prevention of recurrent venous thromboembolism is anticoagulation therapy for three months or longer, depending on the balance between the risk of recurrent VTE and the risk of bleeding.

About Xarelto® (Rivaroxaban)
Rivaroxaban is the most broadly indicated non-vitamin K antagonist oral anticoagulant (NOAC) worldwide and is marketed under the brand name Xarelto®. Xarelto is approved for seven indications, protecting patients across more venous and arterial thromboembolic (VAT) conditions than any other NOAC:

- The prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (AF) and one or more risk factors
- The treatment of pulmonary embolism (PE) in adults
- The treatment of deep vein thrombosis (DVT) in adults
- The prevention of recurrent PE and DVT in adults
- The prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip replacement surgery
- The prevention of VTE in adult patients undergoing elective knee replacement surgery
- The prevention of atherothrombotic events (cardiovascular death, myocardial infarction or stroke) after an Acute Coronary Syndrome in adult patients with elevated cardiac biomarkers and no prior stroke or transient ischaemic attack (TIA) when co-administered with acetylsalicylic acid (ASA) alone or with ASA plus clopidogrel or ticlopidine

Whilst licences may differ from country to country, across all indications Xarelto is approved in more than 130 countries.

Rivaroxaban was discovered by Bayer, and is being jointly developed with Janssen Research & Development, LLC. Xarelto is marketed outside the U.S. by Bayer and in the

U.S. by Janssen Pharmaceuticals, Inc. (Janssen Research & Development, LLC and Janssen Pharmaceuticals, Inc. are part of the Janssen Pharmaceutical Companies of Johnson & Johnson).

Anticoagulant medicines are potent therapies used to prevent or treat serious illnesses and potentially life-threatening conditions. Before initiating treatment with anticoagulant medicines, physicians should carefully assess the benefit and risk for the individual patient.

Responsible use of Xarelto is a very high priority for Bayer, and the company has developed a Prescribers Guide for physicians and a Xarelto Patient Card for patients to support best practice.

To learn more about thrombosis, please visit www.thrombosisadviser.com
To learn more about Xarelto, please visit www.xarelto.com

Bayer: Science For A Better Life
Bayer is a global enterprise with core competencies in the Life Science fields of health care and agriculture. Its products and services are designed to benefit people and improve their quality of life. At the same time, the Group aims to create value through innovation, growth and high earning power. Bayer is committed to the principles of sustainable development and to its social and ethical responsibilities as a corporate citizen. In fiscal 2016, the Group employed around 99,600 people and had sales of EUR 34.9 billion. Capital expenditures amounted to EUR 2.2 billion, R&D expenses to EUR 4.4 billion. For more information, go to www.bayer.com.

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