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Investor News

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Bayer secures approval in the EU for Xarelto® (rivaroxaban) for patients with coronary or peripheral artery disease

- Xarelto is the only non-vitamin K antagonist oral anticoagulant (NOAC) indicated in combination with acetylsalicylic acid (ASA) for the prevention of atherothrombotic events in patients with coronary artery disease or symptomatic peripheral artery disease at high risk for ischemic events
- Launch first expected in Germany

Leverkusen, Germany, August 24, 2018 – The European Commission (EC) has approved a regimen of Xarelto® (rivaroxaban) 2.5 mg twice daily plus acetylsalicylic acid (ASA) 75-100 mg once daily for the prevention of atherothrombotic events in adult patients with coronary artery disease (CAD) or symptomatic peripheral artery disease (PAD) at high risk for ischemic events. The first country where Xarelto is planned to become available for these patients is Germany.

The EU approval is based on data from the Phase III COMPASS study, which showed that rivaroxaban vascular dose, 2.5 mg twice daily, plus ASA 100 mg once daily reduced the risk of the composite of stroke, cardiovascular death and heart attack by 24% (relative risk reduction) compared with ASA 100 mg once daily alone in patients with CAD or PAD[1].

“The approval of Xarelto into the area of vascular protection reflects Bayer’s ongoing commitment to innovation, and we are delighted that the product is now available to these patients,” said Dr Joerg Moeller, Member of the Executive Committee of Bayer AG´s Pharmaceutical Division and Head of Research and Development.

“Despite many advances in the area of cardiovascular care, CAD and PAD have remained an area of unmet need. Even with currently available treatments for secondary prevention, patients remain at an unacceptable high risk of thrombotic events which can

lead to disability, loss of limb and death," said Professor John Eikelboom, Associate Professor, Division of Hematology & Thromboembolism, Department of Medicine, McMaster University, Canada. "The approval of this combination approach of the vascular dose of an anticoagulant plus an antiplatelet provides physicians and patients with a much-needed improved treatment option."

Data from the COMPASS study are also currently under review by regulatory authorities globally, and notably by the U.S. Food and Drug Administration (FDA) where it is part of a supplemental New Drug Application (sNDA).

About Rivaroxaban (Xarelto®)

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 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 after an Acute Coronary Syndrome in adult patients with elevated cardiac biomarkers when co-administered with acetylsalicylic acid (ASA) alone or with ASA plus clopidogrel or ticlopidine

• The prevention of atherothrombotic events in adult patients with coronary artery disease (CAD) or symptomatic peripheral artery disease (PAD) at high risk for ischaemic events

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 and while continuing 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

About Bayer
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 2017, the Group employed around 99,800 people and had sales of EUR 35.0 billion. Capital expenditures amounted to EUR 2.4 billion, R&D expenses to EUR 4.5 billion. For more information, go to www.bayer.com.

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[1] Eikelboom, JW, Connolly SJ, Bosch J, et al. N Engl J Med 2017; 377:1319-1330.