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Investor News

Not intended for U.S. and UK Media

U.S. FDA approves Bayer's Xarelto® for patients with coronary or peripheral artery disease

- Xarelto, in combination with aspirin, is indicated to reduce the risk of major cardiovascular events in patients with chronic coronary artery disease or peripheral artery disease
- Xarelto, in combination with aspirin, is the only non-vitamin K antagonist oral anticoagulant (NOAC) indicated for this patient group
- Approval in the U.S. follows regulatory clearance in both Europe and Canada

Leverkusen, Germany, October 12, 2018 – The U.S. Food and Drug Administration (FDA) has approved rivaroxaban (Xarelto®), 2.5 mg twice daily, plus aspirin low dose once daily to reduce the risk of major cardiovascular events including cardiovascular (CV) death, heart attack or stroke in patients with chronic coronary artery disease (CAD) or peripheral artery disease (PAD).

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

"The decision by the FDA follows the recent European Commission approval and the approval in Canada for Xarelto, and provides patients in the U.S. with CAD and PAD with an important new treatment option," said Dr Joerg Moeller, Member of the Executive Committee of Bayer AG´s Pharmaceutical Division and Head of Research and Development. "CAD and PAD remain a major public health burden. Event rates remain substantial, and until this approval, PAD patients had no available treatment options which clearly reduced their event risk. We believe that Xarelto will make a meaningful difference to the lives of patients and we are working with other regulatory authorities

globally to ensure as many patients as possible have the opportunity to benefit from this new treatment option."

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 (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
- 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 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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Forward-Looking Statements
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[i] *Eikelboom, JW, Connolly SJ, Bosch J, et al. N Engl J Med 2017; 377:1319-1330.*