



Bayer AG
Communications
51368 Leverkusen
Germany
Phone +49 214 30-1
media.bayer.com

News Release

Not intended for U.S. and UK Media

U.S. FDA approves expansion of the peripheral artery disease (PAD) indication for Xarelto™ plus aspirin

- Patients after recent lower-extremity revascularization due to symptomatic PAD now included in the label in the US
 - Xarelto plus aspirin is the first treatment approach indicated in the US for both coronary artery disease (CAD) and PAD, now including patients post recent lower-extremity revascularization (LER) due to symptomatic PAD
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Berlin, August 24, 2021 – The U.S. Food and Drug Administration (FDA) has approved an expansion of the peripheral artery disease (PAD) indication for the Xarelto™ (rivaroxaban) vascular dose (2.5 mg twice daily plus aspirin 100 mg once daily) to include patients following recent lower-extremity revascularization (LER) due to symptomatic PAD.

“This FDA approval is an important advance for patients with PAD,” said Dr. Michael Devoy, Head of Medical Affairs & Pharmacovigilance of Bayer AG’s Pharmaceuticals Division and Chief Medical Officer at Bayer. “Xarelto is the only anticoagulant in more than 20 years to show a significant benefit in patients with PAD who remain at high risk for major thrombotic events post lower extremity revascularization. They are suffering from a disease which often goes undiagnosed and undertreated.”

“These data provide a new mechanism of treatment using an evidenced-based strategy for this vulnerable population,” said Marc P. Bonaca, M.D., MPH, Department of Medicine, Division of Cardiovascular Medicine, University of Colorado Anschutz Medical Campus, Aurora, Colorado. “The approval sets the stage to evolve the current standard of care for patients with PAD.”

The approval by the FDA is based on data from the Phase 3 VOYAGER PAD trial. In the EU, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion to include the data from the Phase 3 study in the label of Xarelto in July 2021. The treatment of patients with symptomatic PAD at high risk for ischemic events with Xarelto plus aspirin has already been approved in the EU based on the COMPASS study. The VOYAGER PAD study demonstrates a positive benefit-risk profile of starting Xarelto in patients with symptomatic PAD after recent lower-extremity revascularization and supports continued treatment.

PAD is caused by atherosclerosis, a chronic progressive disease, which is characterized by a build-up of plaque in the arteries limiting blood flow to the limbs. It is a serious underlying health crisis that impacts an estimated 20 million Americans with only 8.5 million diagnosed. PAD increases the risk for major CV events and is the leading cause of amputation in the US which can double a patient's risk of death.

Xarelto plus aspirin is the first therapy in the US indicated to help reduce both the risks of major cardiovascular (CV) events (CV death, myocardial infarction, and stroke) in patients with coronary artery disease (CAD), and of major thrombotic vascular events (myocardial infarction, ischemic stroke, acute limb ischemia, and major amputation of a vascular etiology) in patients with PAD, who have recently undergone LER due to symptomatic PAD.

About the VOYAGER PAD study

The Phase 3 VOYAGER PAD study included 6,564 patients from 542 sites across 34 countries worldwide. In the study, patients were randomized to receive either Xarelto 2.5 mg twice daily plus aspirin 100 mg once daily or aspirin 100 mg once daily alone. The primary efficacy endpoint was a composite of acute limb ischemia, major amputation of a vascular etiology, heart attack (myocardial infarction, MI), ischemic stroke or cardiovascular death. The primary safety outcome was major bleeding according to the Thrombolysis in Myocardial Infarction (TIMI) classification.

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. Worldwide 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) with 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/or 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 when co-administered with acetylsalicylic acid (ASA)
- Treatment of venous thromboembolism (VTE) and prevention of VTE recurrence in children and adolescents aged less than 18 years after at least 5 days of initial parenteral anticoagulation treatment

Xarelto is approved in more than 130 countries, although the approved labelling, including the number of indications may differ from country to country. Since launch in 2008, more than 86 million patients have been treated.

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 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 and www.vascularadviser.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 nutrition. Its products and services are designed to help people and planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to drive sustainable development and generate a positive impact with its businesses. At the same time, the Group aims to increase its earning power and create value through innovation and growth. The Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2020, the Group employed around 100,000 people and had sales of 41.4 billion euros. R&D expenses before special items amounted to 4.9 billion euros. For more information, go to www.bayer.com.

Contact for media inquiries:

Richard Breum, phone +49 30 468-17112

Email: richard.breum@bayer.com

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