



Bayer AG
Investor Relations
51368 Leverkusen
Germany
www.investor.bayer.com

Investor News

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Bayer's Xarelto[®] Approved in China for Stroke Prevention in Patients with Non-Valvular Atrial Fibrillation and for the Treatment of Deep Vein Thrombosis

Xarelto is now approved in China across three indications in the area of venous and arterial thromboembolism

Leverkusen, Germany, May 4, 2015 – Bayer's once-daily oral anticoagulant Xarelto[®] (rivaroxaban) has been approved by the China Food and Drug Administration (CFDA) for the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors. Additionally, the CFDA has approved Xarelto for the treatment of deep vein thrombosis (DVT) and for the reduction of the risk of recurrent DVT and pulmonary embolism (PE) following an acute DVT in adults. Since 2009, Xarelto has been available in China for the prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery.

"This approval is the result of many years of research and a robust development program," said Dr. Joerg Moeller, Member of the Bayer HealthCare Executive Committee and Head of Global Development. "We are delighted to bring the benefits of Xarelto to patients and physicians in China in need of an effective and convenient therapy against blood clots to prevent strokes and treat DVT."

The approval of rivaroxaban for the prevention of stroke in patients with atrial fibrillation by the China Food and Drug Administration is based on the clinical benefits demonstrated in ROCKET AF, a double-blind global Phase III study that compared once-daily rivaroxaban with warfarin in more than 14,000 patients. The approval of rivaroxaban for 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, as well as data from the Phase III EINSTEIN-Extension study.

The extensive evaluation of rivaroxaban to protect different patient populations at risk of venous and arterial thromboembolism (VAT) makes it the most studied novel oral anticoagulant in the world. The investigation of rivaroxaban is planned to include more than 275,000 patients in both clinical trials and real world settings.

About Xarelto[®] (Rivaroxaban)

Rivaroxaban is the most broadly indicated novel oral anticoagulant and is marketed under the brand name Xarelto[®]. Xarelto is approved for five indications across seven distinct areas of use, protecting patients across more venous and arterial thromboembolic (VAT) conditions than any other novel oral anticoagulant:

- 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 deep vein thrombosis (DVT) in adults
- The treatment of pulmonary embolism (PE) in adults
- The prevention of recurrent DVT and PE 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 125 countries

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

HealthCare and in the U.S. by Janssen Pharmaceuticals, Inc. (a Johnson & Johnson Company).

Anticoagulant medicines are potent therapies used to prevent or treat serious illnesses and potentially life-threatening conditions. Before initiating therapy 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, please visit <https://prescribe.xarelto.com>

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

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

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care, agriculture and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of around EUR 20.0 billion (2014), 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, develop, manufacture and market products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 60,700 employees (Dec 31, 2014) and is represented in more than 100 countries. More information is available at www.healthcare.bayer.com.

Bayer AG, Investor Relations contacts:

Dr. Alexander Rosar (+49-214-30-81013)

Dr. Jürgen Beunink (+49-214-30-65742)

Peter Dahlhoff (+49-214-30-33022)

Judith Nestmann (+49-214-30-66836)

Constance Spitzer (+49-214-30-33021)

Dr. Olaf Weber (+49-214-30-33567)

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