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Investor News

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Bayer's Xarelto® Approved in Japan for the Treatment and Secondary Prevention of Pulmonary Thromboembolism and Deep Vein Thrombosis

Leverkusen, Germany, September 24, 2015 – Bayer HealthCare announced today the approval in Japan of its oral Factor Xa inhibitor Xarelto® (rivaroxaban) for the treatment and secondary prevention of pulmonary thromboembolism and deep vein thrombosis by the Japanese Ministry of Health, Labor and Welfare (MHLW).

Deep vein thrombosis (DVT) is a condition in which blood clots form in one of the large, deep veins, usually in the legs. Pulmonary embolism (PE) is a condition that most commonly occurs when part or all of a DVT dislodges and travels to the lung, via the heart, where it can partially or completely block a branch of a pulmonary artery. When PE occurs with large clots, multiple clots, or when the patient has pre-existing heart or lung disease, the event may be fatal. On average, every 37 seconds someone in the Western World dies from a venous blood clot, making PE and DVT (known collectively as Venous Thromboembolism, VTE) the third most common cardiovascular condition.

"Xarelto provides fast and effective treatment for patients suffering from PE and DVT. While the overall rates of major bleeding and clinically relevant non-major bleeding as the primary endpoint were comparable, Xarelto nearly halved the risk of major bleeding compared with the conventional dual-drug treatment approach", said Dr Joerg Moeller, Member of the Bayer HealthCare Executive Committee and Head of Global Development. "With the approval of Xarelto for the treatment and secondary prevention of pulmonary thromboembolism and deep vein thrombosis, we can now provide physicians and patients in Japan with the first oral treatment without the need for injections."

Today's MHLW approval of Xarelto is based on data from the global EINSTEIN Clinical Trial Programme, and is supported by the J-EINSTEIN studies (J-EINSTEIN DVT and J-EINSTEIN PE), which were run entirely in Japan. The EINSTEIN Clinical Trial

Programme demonstrated the efficacy and safety profile of rivaroxaban in the treatment of patients with acute symptomatic PE or DVT and the prevention of recurrent PE and DVT in these patients.

About Xarelto® (Rivaroxaban)
Rivaroxaban is the most broadly indicated non-vitamin K antagonist oral anticoagulant (NOAC) 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 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 130 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. (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 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 and agriculture. 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.

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