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# Investor News

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## Xarelto™ from Bayer Submitted in Japan for the Treatment of Deep Vein Thrombosis and Pulmonary Embolism as well as for the Prevention of Recurrent Venous Thromboembolism

- Submission supported by successful global and Japanese EINSTEIN studies
- Oral single-drug approach with rivaroxaban proven effective for the treatment of deep vein thrombosis and pulmonary embolism

**Leverkusen, Germany, May 28, 2014** – Bayer HealthCare's oral anticoagulant Xarelto™ (rivaroxaban) has been submitted to the Japanese Ministry of Health, Labor and Welfare (MHLW) for marketing authorization to treat patients with deep vein thrombosis (DVT) and pulmonary embolism (PE) as well as to prevent recurrent venous thromboembolism (VTE).

"Venous blood clots are associated with a high risk of serious complications and the current standard of care for treating these patients involves multiple medications," said Dr. Joerg Moeller, Member of the Bayer HealthCare Executive Committee and Head of Global Development. "With this submission, Xarelto is one step closer to being available to provide patients and physicians in Japan with a single-drug treatment option from the moment of diagnosis through to the completion of therapy."

The submission to the MHLW is based on the results of three global clinical trials within the pivotal 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 DVT and EINSTEIN PE studies evaluated rivaroxaban alone versus the dual-drug regimen of low molecular weight heparin (LMWH) and a vitamin K antagonist (VKA) in the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) respectively, and in the prevention of recurrent DVT and PE. The EINSTEIN Extension study compared rivaroxaban with placebo for the long term prevention of recurrent

symptomatic DVT and PE in patients who previously completed 6 or 12 months of anticoagulation treatment with either VKA or rivaroxaban.

Pooled data of over 8,000 patients reaffirmed that the single-drug approach with Xarelto is effective in both the treatment and subsequent prevention of recurrent DVT and PE, with an overall safety profile comparable to the traditional dual-drug regimen. In addition, compared to the traditional dual-drug approach of injectable LMWH followed by a VKA, Xarelto significantly reduced the rate of major bleeding events by 46 per cent, including the risk of fatal bleeding, whilst offering an improved benefit-risk profile regardless of patient age, frailty, gender, weight or renal function.

Results from the three global studies have been published in the *New England Journal of Medicine* (10.156/NEJMoa1113572 and 10.1056/NEJMoa1007903). Results of the J-EINSTEIN studies are planned to be presented at an upcoming scientific meeting.

Xarelto has been approved as the only oral single-drug approach for the treatment of DVT and PE as well as for the prevention of recurrent DVT and PE in more than 100 countries worldwide, including Europe and the U.S.

**About Venous Arterial Thromboembolism (VAT)**
Thrombosis is the formation of a blood clot inside a blood vessel, blocking a vein (venous thrombosis) or artery (arterial thrombosis). Venous Arterial Thromboembolism (VAT) is caused when some or all of a clot detaches and is moved within the blood stream until it obstructs a smaller vessel. This can result in damage to vital organs, because the tissue beyond the blockage no longer receives nutrients and oxygen.

VAT is responsible for a number of serious and life threatening conditions:

- Venous Thromboembolism (VTE) occurs when part of a clot formed in a deep vein, for example in the leg (known as deep vein thrombosis, or DVT), is carried to the lung, via the heart, preventing the uptake of oxygen. This is known as a pulmonary embolism (PE), an event which can be rapidly fatal. Blood clots that obstruct blood flow in deep veins or in the lungs kill one person every 37 seconds in the Western World

- Arterial Thromboembolism occurs when oxygenated blood flow from the heart to another part of the body (via an artery) is interrupted by a blood clot. If this occurs

in a vessel supplying blood to the brain, it can lead to a stroke, an event that can be severely debilitating or fatal. If it occurs in a coronary artery, it can lead to acute coronary syndrome (ACS), a complication of coronary heart disease which includes conditions such as myocardial infarction and unstable angina

VAT is responsible for significant morbidity and mortality, and requires active or preventative treatment to avoid potentially serious or fatal patient outcomes.

To learn more about VAT, please visit http://www.VATspace.com

**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 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 EUR 18.9 billion (2013), 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 56,000 employees (Dec 31, 2013) and is represented in more than 100 countries. More information at www.healthcare.bayer.com.

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