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Investor News

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Rivaroxaban 10 mg Once Daily from Bayer Submitted to U.S. FDA as Additional Dose Option to Reduce the Risk of Recurrent Venous Thromboembolism

- If approved, rivaroxaban 10 mg once daily will provide an additional treatment option alongside the already approved rivaroxaban 20 mg once-daily dose
- Risk of recurrent thrombosis is up to 10% in the first year if anticoagulation therapy is stopped
- Application to FDA supported by data from the EINSTEIN CHOICE study

Leverkusen, Germany, April 28, 2017 – Bayer AG and its development partner Janssen Research & Development, LLC today announced the submission of a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) to update the prescribing information for the oral Factor Xa inhibitor rivaroxaban (Xarelto®), to include a 10 mg once-daily dose for reducing the risk of recurrent venous thromboembolism (VTE) after at least six months of standard anticoagulation therapy as an additional treatment option alongside the already approved rivaroxaban 20 mg once-daily dose.

This application is supported by data from the Phase III EINSTEIN CHOICE study, which showed that both 10 mg and 20 mg once-daily dosages of rivaroxaban significantly reduced the risk of recurrent VTE compared with aspirin 100 mg once daily (acetylsalicylic acid, ASA) in patients who had previously completed 6 to 12 months of anticoagulation therapy for treatment of pulmonary embolism (PE) and / or symptomatic deep vein thrombosis (DVT). Patients with a definitive need for continued therapeutic anticoagulation beyond the first 6 to 12 months were not included in the study. Both rivaroxaban dosages demonstrated comparable and low rates of major bleeding (the principal safety outcome) on the same level as aspirin therapy. Data from EINSTEIN CHOICE were recently published in *The New England Journal of Medicine* and have been submitted to the European Medicines Agency (EMA), with submissions to other Health Authorities worldwide to follow during the first half of 2017.

VTE, which includes DVT, a blood clot in a deep vein (often in the legs), and PE, a clot that travels to the lung, has a significant global impact as it is the third most common cause of cardiovascular death worldwide, after heart attack and stroke. The current treatment recommendation is anticoagulation therapy for 3 months or longer, depending on the balance between the risk of recurrent VTE and the risk of bleeding.

“Blood clots are related to 1 in 4 deaths worldwide. Given the potential for serious and life-threatening events like stroke, pulmonary embolism, and deep vein thrombosis among people at risk for clots, non-vitamin K antagonist oral anticoagulants such as Xarelto are a critical treatment option. For patients who have previously suffered a VTE, the risk of experiencing another event is up to 10 percent during the first year if anticoagulant therapy is stopped, and this figure rises to 20 percent within three years,” said Dr Joerg Moeller, Member of the Executive Committee of Bayer AG's Pharmaceutical Division and Head of Development. “Once approved, the 10 mg once-daily dose of rivaroxaban will offer an alternative treatment option in addition to the already approved 20 mg once-daily dose of rivaroxaban, which together will provide physicians with the choice to select the extended treatment option that will best suit the benefit-risk-assessment of the individual patient.”

EINSTEIN CHOICE adds to the extensive investigation of rivaroxaban, which, by the time of its completion, is expected to include more than 275,000 patients in both clinical trials and real-world settings. With more than 28 million patients prescribed Xarelto worldwide according to estimates based on IMS data, real-world research continues to confirm that the benefit-risk profile remains favorable and consistent with clinical trials for patients who have a high risk of life-threatening blood clots that may cause strokes and other serious medical complications. Specifically, results from XALIA, an observational real-world study that enrolled 5,142 patients with DVT across 21 countries, confirmed the well-established safety profile and efficacy seen with the approved rivaroxaban dosing regimen of 20 mg once daily in EINSTEIN DVT, and the real-world XAMOS study reaffirmed the benefit of rivaroxaban to prevent VTE following hip or knee replacement, as first shown in the RECORD studies. Additionally, the recent real-world evidence study REVISIT-US, a claims analysis of nearly 23,000 patients with non-valvular atrial fibrillation, supports the use of rivaroxaban for stroke prevention in patients with atrial fibrillation. These data complement findings from the Phase III ROCKET AF study as well as the non-interventional XANTUS study.

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 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 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

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 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

Bayer: Science For A Better Life

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 2016, the Group employed around 115,200 people and had sales of EUR 46.8 billion. Capital expenditures amounted to EUR 2.6 billion, R&D expenses to EUR 4.7 billion. These figures include those for the high-tech polymers business, which was floated on the stock market as an independent company named Covestro on October 6, 2015. For more information, go to www.bayer.com.

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