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Investor News

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Bayer receives positive CHMP opinion for rivaroxaban 10 mg once daily for the extended prevention of venous thromboembolism

- Rivaroxaban 10 mg once daily significantly reduces the risk of recurrent venous thromboembolism compared with aspirin 100 mg once daily after at least six months of standard anticoagulation therapy
- Positive CHMP Opinion is based on data from the Phase III EINSTEIN CHOICE study
- Final European Commission decision expected by November 2017

Leverkusen, Germany, September 15, 2017 – Bayer AG announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has granted a positive opinion to update the label for its oral Factor Xa inhibitor Xarelto® (rivaroxaban) to include a 10 mg once daily dose for the extended prevention of recurrent venous thromboembolism (VTE). This label update will apply to patients who have already received at least six months of standard anticoagulation therapy. Once approved, this will provide physicians with an additional treatment option alongside the 20 mg once daily dose already licensed in this indication. The final European Commission decision is expected by November 2017.

“Patients who have previously suffered a VTE are often at increased risk of experiencing another event if anticoagulant treatment is stopped,” said Dr. Joerg Moeller, Member of the Executive Committee of Bayer AG's Pharmaceutical Division and Head of Development. “Today’s positive CHMP opinion takes us one step closer to providing physicians with an additional therapeutic option enabling them to select the extended treatment that best suits the benefit-risk-assessment of the individual patient.”

VTE, which includes pulmonary embolism (PE), a clot that travels to the lung, and deep vein thrombosis (DVT), a blood clot in a deep vein (often in the legs), has a significant global impact and is the third most common cause of cardiovascular death worldwide, after heart attack and stroke. The current treatment recommendation for the prevention of

recurrent venous thromboembolism is anticoagulation therapy for three months or longer, depending on the balance between the risk of recurrent VTE and the risk of bleeding.

The positive CHMP opinion is based on 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) 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).

All three treatment groups showed comparable and low rates of major bleeding (the principle safety outcome). Data from EINSTEIN CHOICE were published in *The New England Journal of Medicine* in March 2017[1].

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 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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[1] J.I.Weitz, A.W.A. et al. N Engl J Med 2017; 376:1211-22