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News Release

Not intended for U.S. and UK Media

U.S. FDA approves rivaroxaban to help prevent blood clots in acutely ill medical patients

- A new oral option for patients in the U.S. with acute medical illnesses at risk for thromboembolic complications who are not at high risk of bleeding
- Rivaroxaban is the only non vitamin K antagonist oral anticoagulant (NOAC) approved in the U.S for the continuum of venous thromboembolism (VTE) care, from prevention and treatment of initial VTE through extended prevention of recurrent VTE

Berlin, October 14, 2019 – Bayer AG and its development partner Janssen Research & Development, LLC announced today that the U.S. Food and Drug Administration (FDA) has approved rivaroxaban (Xarelto™) for the prevention of venous thromboembolism (VTE), or blood clots, in acutely ill medical patients at risk for thromboembolic complications who are not at high risk of bleeding. The approval is based on data from the Phase III MAGELLAN trial, and supported by the data from the MARINER trial. These trials evaluated rivaroxaban for the prevention of VTE in acutely ill medical patients during hospitalization and immediately following discharge.

“With this new approval, rivaroxaban as an oral-only option now has the potential to change how acutely ill medical patients in the US are managed for the prevention of blood clots, both in the hospital and for an extended period after discharge,” said Alex C. Spyropoulos, M.D., Professor of Medicine, The Donald and Barbara Zucker School of Medicine at Hofstra/Northwell, Northwell Health at Lenox Hill Hospital, New York, NY. “The Phase 3 clinical studies in this high-risk patient group show us that rivaroxaban at the 10mg dose is an effective option with a well-established safety profile to help prevent blood clots, which can be fatal in this population.”

“Acutely ill” is a broad term used to describe people who are hospitalized for serious, yet common, medical conditions such as heart failure, infectious diseases or ischemic stroke. More than seven million Americans are hospitalized with acute medical illnesses each

year. These patients are at increased risk of VTE for some three months after hospital discharge, with 80 percent of events happening within the first six weeks.

Although VTE is largely preventable, guidelines currently recommend acutely ill medical patients receive anticoagulants, typically injectable agents, in the hospital to protect them from VTE, but advise against routine anticoagulant use after leaving the hospital. However, research has shown that many acutely ill medical patients refuse treatment with injectable anticoagulants out of fear, discomfort, anxiety or inconvenience.

About MAGELLAN and MARINER

Rivaroxaban has been studied in acutely ill medical patients in two Phase 3 studies: MAGELLAN and MARINER. Published in 2013, MAGELLAN evaluated the use of rivaroxaban in preventing VTE in patients with acute medical illnesses, starting with their hospital stay and continuing through post-hospital discharge. The study met its two co-primary endpoints, with rivaroxaban demonstrating non-inferiority to enoxaparin, a low-molecular-weight heparin (LMWH), in short-term use (10 ± 4 days) and superiority in long-term use (35 ± 4 days) compared to short-term use of enoxaparin followed by placebo. The combined rates of major and non-major clinically relevant bleeding were higher in the rivaroxaban group. Of note, an important analysis from MAGELLAN found that the vast majority of acutely ill medical patients could receive rivaroxaban. By applying additional exclusionary criteria to remove a small subgroup of patients at high risk for bleeding, researchers defined the appropriate benefit-risk profile for VTE prevention with rivaroxaban.

Building on the foundation provided by the results from MAGELLAN, the MARINER trial was conducted in a similar population of acutely ill medical patients, but excluding those same patients at high risk for bleeding. Published in 2018, MARINER evaluated rivaroxaban for the prevention of VTE and VTE-related death following hospital discharge compared to placebo. While rivaroxaban did not reduce the composite endpoint of VTE and VTE-related death, it did significantly reduce symptomatic VTE with consistent and favorable safety, reinforcing rivaroxaban’s positive benefit-risk profile.

About Rivaroxaban (Xarelto™)

Rivaroxaban is the most broadly indicated non-vitamin K antagonist oral anticoagulant (NOAC) worldwide and is marketed under the brand name Xarelto. Rivaroxaban is

approved for 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) and 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 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
- The prevention of atherothrombotic events in adult patients with coronary artery disease (CAD) or symptomatic peripheral artery disease (PAD) at high risk for ischemic events when co-administered with acetylsalicylic acid (ASA)
- The prevention of venous thromboembolism (VTE) in acutely ill medical patients at risk for thromboembolic complications who are not at high risk of bleeding

Whilst licences may differ from country to country, across all indications Rivaroxaban is approved in more than 130 countries.

Rivaroxaban was discovered by Bayer and is being jointly developed with Janssen Research & Development, LLC. Rivaroxaban 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 and while continuing treatment with anticoagulant medicines, physicians should carefully assess the benefit and risk for the individual patient.

Responsible use of Rivaroxaban is a very high priority for Bayer, and the company has developed a Prescribers Guide for physicians and a Rivaroxaban Patient Card for patients to support best practice.

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

About Bayer
Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. Its products and services are designed to benefit people by supporting efforts to overcome the major challenges presented by a growing and aging global population. At the same time, the Group aims to increase its earning power and create value through innovation and growth. Bayer is committed to the principles of sustainable development, and the Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2018, the Group employed around 117,000 people and had sales of 39.6 billion euros. Capital expenditures amounted to 2.6 billion euros, R&D expenses to 5.2 billion euros. For more information, go to www.bayer.com.

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Forward-Looking Statements
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