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News Release

Not intended for U.S. and UK Media

U.S. FDA approves Xarelto™ to treat venous thromboembolism (VTE) and to prevent VTE in children

- Xarelto is the only Factor Xa anticoagulant FDA approved for pediatric patients and offers a flexible weight-based dosing
- Xarelto is available in both oral tablet and liquid suspension formulations for use in appropriate children less than 18 years of age
- Convenient liquid formulation advances standard of care for children; alleviates administration challenges found with injectable alternatives

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Berlin, December 21, 2021 – The U.S. Food and Drug Administration (FDA) has approved two pediatric indications for Xarelto™ (rivaroxaban): the treatment of venous thromboembolism (VTE) and reduction in the risk of recurrent VTE in patients from birth to less than 18 years after at least five days of initial parenteral (injected or intravenous) anticoagulant treatment; and thromboprophylaxis (prevention of VTE and VTE related events) in children aged two years and older with congenital heart disease who have undergone the Fontan procedure.

“The approval of two new indications for Xarelto in the US is an important step in helping to address the burden of venous thromboembolism in a vulnerable patient population. It will provide doctors with body weight-based dosing options in pediatric patients,” said Dr. Michael Devoy, Head of Medical Affairs & Pharmacovigilance of Bayer AG's Pharmaceuticals Division and Chief Medical Officer at Bayer. “The Xarelto suspension for oral use will obviate the need for adjustments of adult dosage forms and substantially reduce the number of injections needed for anticoagulation treatment and blood sampling.”

Xarelto is the only Factor Xa anticoagulant FDA approved for primary prevention of clots in pediatric patients following the Fontan procedure and the only anticoagulant to offer a liquid formulation for flexible, body weight adjusted dosing options for pediatric patients.

Current guideline options are limited and recommend treating pediatric patients with or at risk for reoccurrence of blood clots with standard anticoagulation therapy which requires injections or dietary restrictions, and regular laboratory monitoring.

Earlier this year, Xarelto was approved in Canada, the EU including UK, Japan, Switzerland and in various Latin American countries for the treatment of VTE and prevention of VTE recurrence in children and adolescents aged less than 18 years after at least 5 days of initial parenteral anticoagulation treatment.

The approval is based on evidence from three robust and well-controlled studies of Xarelto in adults (EINSTEIN DVT, PE and EXTENSION) with additional data from two Phase III clinical trials of Xarelto in pediatric patients: EINSTEIN-Jr., which examined pediatric patients with diagnosed VTE, and UNIVERSE, which evaluated pediatric patients who are at risk of VTE after recently undergoing the Fontan procedure.

EINSTEIN-Jr. is the largest study completed to date evaluating the treatment of pediatric patients with VTE, and UNIVERSE is the first clinical trial to examine a non-vitamin K antagonist oral anticoagulant (NOAC) for the prevention of thromboembolism in congenital heart disease post-Fontan pediatric patients.

About the EINSTEIN-Jr. Study

The randomized, open-label phase III EINSTEIN-Jr. study included 500 children aged from birth to below 18 years with documented acute VTE who had started heparin therapy for at least 5 days. Children were assigned, in a 2:1 ratio, to receive body weight-adjusted rivaroxaban (tablets or oral suspension) in a 20 mg-equivalent dose, or standard of care with (low molecular weight) heparin, fondaparinux or vitamin K antagonist therapy. The main treatment period was 3 months, but in children younger than 2 years with catheter related VTE it was 1 month. Repeat imaging was carried out at the end of the treatment period. Results were also interpreted in the context of previous studies evaluating rivaroxaban in adults with VTE.

About the UNIVERSE Study

UNIVERSE is a randomized, multicenter, open-label, active controlled, two-part, Phase III study that examined the use of an oral liquid suspension Xarelto formulation in children 2-8 years old with single ventricle physiology who had the Fontan procedure within four months before enrollment. From November 2016 to June 2019, a total of 112 participants were enrolled across 36 sites in 10 countries. UNIVERSE was conducted in two parts. Part A evaluated the single- and multiple-dose pharmacokinetic and pharmacodynamic properties of Xarelto while Part B evaluated the comparative safety and efficacy of Xarelto versus aspirin when used for thromboprophylaxis for 12 months.

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. Xarelto 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) 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/or 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 ischaemic events when co-administered with acetylsalicylic acid (ASA)
• Treatment of venous thromboembolism (VTE) and prevention of VTE recurrence in children and adolescents aged less than 18 years after at least 5 days of initial parenteral anticoagulation treatment
• Thromboprophylaxis (prevention of VTE and VTE related events) in children aged two years and older with congenital heart disease who have undergone the Fontan procedure

Xarelto is approved in more than 130 countries, although the approved labelling, including the number of indications may differ from country to country. Since launch in 2008, more than 96 million patients have been treated.

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 therapies used to prevent or treat serious illnesses and potentially life-threatening conditions. Before initiating treatment 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 and www.vascularadviser.com

To learn more about Xarelto, please visit www.xarelto.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 help people and planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to drive sustainable development and generate a positive impact with its businesses. At the same time, the Group aims to increase its earning power and create value through innovation and growth. The Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2020, the Group employed around 100,000 people and had sales of 41.4 billion euros. R&D expenses before special items amounted to 4.9 billion euros. For more information, go to www.bayer.com.

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