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News Release

For UK Media

Bayer announces new licensed indication for use of Xarelto® ▼ (rivaroxaban) in patients with coronary or peripheral artery disease

Xarelto, co-administered with aspirin, is indicated in the EU for the prevention of atherothrombotic events in adult patients with coronary artery disease (CAD) or symptomatic peripheral artery disease (PAD) at high risk of ischaemic events

- Xarelto is the only non-vitamin K antagonist oral anticoagulant (NOAC) indicated in combination with aspirin (acetylsalicylic acid / ASA) for the prevention of atherothrombotic events in adult patients with coronary artery disease (CAD) or symptomatic peripheral artery disease (PAD) at high risk of ischaemic events
- CAD remains one of the UK's leading causes of death – more than 66,000 patients die in the UK each year¹. PAD is estimated to affect 1 in 5 people over 60 in the UK²

Reading, August 24, 2018 – Today, the European Commission (EC) approved a combination of Xarelto® (rivaroxaban) 2.5 mg twice daily plus low dose aspirin (acetylsalicylic acid / ASA) once daily for the prevention of atherothrombotic events in adult patients with coronary artery disease (CAD) or symptomatic peripheral artery disease (PAD) at high risk of ischaemic events.

The EU approval is based on data from the COMPASS study, the largest Phase III study with rivaroxaban (27,395 patients), which showed that the rivaroxaban vascular dose, 2.5 mg twice daily, plus ASA 100 mg once daily reduced the risk of the composite of stroke, cardiovascular (CV) death and heart attack by 24% (relative risk reduction, ARR: 1.3%) compared with ASA 100 mg once daily alone in patients with CAD and/or PAD³.

Dr Derek Connolly, Consultant Interventional Cardiologist at Birmingham City Hospital and COMPASS trial investigator commented: "Cardiovascular diseases are one of the leading causes of death in the UK, and coronary artery disease and peripheral artery disease represent a major

public health burden – despite many advances in the area of cardiovascular care, CAD and PAD have remained an area of unmet need. Even with currently available treatments for secondary prevention, patients remain at an unacceptably high risk of thrombotic events which can lead to disability, loss of limb and death. This was the biggest study of rivaroxaban to date, and now that it is licensed for these conditions, it provides UK clinicians with a new option for treating CAD and PAD.”

Lars Bruening, CEO Bayer UK & Ireland, said: “The story and momentum behind the COMPASS data continues to grow – from the study being stopped one year early for overwhelming efficacy, the presentation of the results themselves at the European Society of Cardiology congress last year, and now to this exciting news from the European Commission. Ten years ago this October saw Bayer just starting out on the Xarelto journey with the first indication in orthopaedics – and this year we welcome our eighth indication for the management of patients with CAD and PAD in the UK. It is especially exciting to see the continuing impact that Xarelto will have on patients with PAD, most of whom have concurrent CAD, as it has been many years since a new medical therapy has been proven in this high risk patient population.”

Following the licence approval across Europe, the new indication will be submitted to the National Institute for Health and Care Excellence (NICE) and the Scottish Medicines Consortium (SMC) for review for routine reimbursement across the UK.

Reporting of side effects:

This medicine is subject to additional monitoring ▼. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See www.mhra.gov.uk/yellowcard for how to report side effects.

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Notes for Editors:

About CAD and PAD

It is estimated that cardiovascular disease, which includes CAD and PAD, is responsible for some 150,000 deaths in the UK each year, representing more than a quarter of all deaths in the UK¹. Additionally, patients with cardiovascular disease have a reduction in life expectancy of over 7 years⁴.

CAD is the most common type of cardiovascular disease and is estimated to affect approximately 2.3 million people in the UK¹. Up to half of all middle-aged men and a quarter of all middle-aged women are at risk of developing CAD during their lifetime⁵.

PAD, while often undiagnosed, is estimated to affect 1 in 5 people over 60 in the UK².

About Xarelto® (Rivaroxaban)

Xarelto has undergone an extensive clinical development programme and has been approved for use in more than 125 countries, across a range of indications. In the UK specifically it is previously approved for use in the following conditions⁶:

- The prevention of stroke and systemic embolism in adult patients with non-valvular AF with one or more risk factors
- The treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) and prevention of recurrent DVT and PE in adults
- The prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery
- The prevention of atherothrombotic events in adult patients after an acute coronary syndrome (ACS) with elevated cardiac biomarkers, co-administered with acetylsalicylic acid (ASA) alone or with ASA plus clopidogrel or ticlopidine

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. (a Johnson & Johnson Company). Anticoagulant medicines are potent therapies used to prevent and treat blood clots the consequences of which may be serious, or to 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 'Prescriber's Guide' for physicians and a 'Xarelto Patient Alert Card' for patients to support best practice.

About Bayer

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 2017, the Group employed around 99,800 people and had sales of EUR35.0 billion. Capital expenditures amounted to EUR 2.4 billion, R&D expenses to EUR 4.5 billion. For more information, go to www.bayer.co.uk

Forward-Looking Statements

This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

¹ CVD statistics – BHF UK Factsheet. Available at: <https://www.bhf.org.uk/-/media/files/...statistics/bhf-cvd-statistics---uk-factsheet.pdf> [Last accessed August 2018]

² British Heart Foundation. Focus on: Peripheral arterial disease (PAD). Available at: <https://www.bhf.org.uk/information-support/heart-matters-magazine/medical/peripheral-arterial-disease> [Last accessed August 2018]

³ Eikelboom, JW., *et al.* N Engl J Med 2017; 377:1319–30.

⁴ Bakhai A., *Pharmacoeconomics* 2004;22:11–18.

⁵ Lloyd-Jones, D., *et al.* Lifetime risk of developing coronary artery heart disease. *Lancet*. 1999;353(9147):89–92.

⁶ eMC. 2018. Xarelto SPC. Available at: <https://www.medicines.org.uk/emc/product/3410/smpc> [Last accessed August 2018]