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News Release

Not intended for U.S. and UK Media

American College of Cardiology's 69th Annual Scientific Session together with World Congress of Cardiology (ACC.20/WCC Virtual):

Bayer announces five late-breaking presentations which include data from VICTORIA (vericiguat) and VOYAGER PAD (Xarelto™) Phase III studies

- The VICTORIA study provides insight into the efficacy of vericiguat, the first soluble guanylate cyclase (sGC) stimulator investigated in patients with chronic heart failure following a worsening event
 - The VOYAGER PAD study investigated the use of Xarelto 2.5 mg twice daily plus aspirin 100 mg once daily in patients with symptomatic peripheral artery disease (PAD) post peripheral revascularization
 - Five late-breaking abstracts have been accepted for presentation and demonstrate Bayer's ongoing commitment to the treatment of cardiovascular disease
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Berlin, March 20, 2020 – New clinical data regarding the investigational compound vericiguat and the Factor Xa inhibitor Xarelto (rivaroxaban) will be presented in late-breaking clinical trial sessions at [The American College of Cardiology's](#) 69th Annual Scientific Session Together With World Congress of Cardiology (ACC.20/WCC Virtual). The ACC.20/WCC Virtual Experience will take place from March 28-30, 2020.

Vericiguat study data:

The VICTORIA study evaluated the efficacy and safety of the investigational compound vericiguat versus placebo, in combination with available heart failure therapies in symptomatic heart failure patients (ejection fraction <45%) following a worsening event. This patient population were suffering from higher event rates than in other contemporary heart failure studies.

Full data from the VICTORIA study will be presented in the following virtual late-breaking clinical trial session:

- [The VICTORIA \(Vericiguat Global Study In Subjects With Heart Failure With Reduced Ejection Fraction\) Trial](#)
 - o Session 402 - Joint American College of Cardiology and Journal of American College of Cardiology Late-Breaking Clinical Trials
 - o Saturday 28 March, 09.00-09.12 CT

In November 2019, Bayer announced that the study met its primary endpoint, with the findings demonstrating the superiority of vericiguat in prolonging the time to first occurrence of the composite endpoint of cardiovascular death or heart failure hospitalization. Vericiguat is being jointly developed with MSD (known as Merck & Co., Inc. in the U.S. and Canada).

The findings of the VICTORIA trial provide the first Phase III data for vericiguat, the first sGC stimulator to be evaluated in a chronic heart failure patient population following a worsening event.

Xarelto study data:

Bayer and its development partner Janssen Research & Development, LLC announced that four abstracts for its oral Factor Xa inhibitor Xarelto (rivaroxaban), including data from the Phase III VOYAGER PAD study, will be presented.

The results from the VOYAGER PAD study will be featured in two virtual late-breaking clinical trial sessions:

- [Rivaroxaban for Prevention of Cardiovascular and Limb Events After Lower Extremity Revascularization: Primary Results of the Voyager PAD Randomized Trial](#)
 - o Session 402 - Joint American College of Cardiology and Journal of American College of Cardiology Late-Breaking Clinical Trials
 - o Saturday 28 March, 09.20-09.32 CT

- [The Benefit and Risk of Rivaroxaban Plus Aspirin In Patients with Peripheral Artery Disease After Lower Extremity Revascularization \(ler\) with and Without Concomitant Clopidogrel: A Key Subgroup Analysis from Voyager-PAD](#)
 - o Session 406 - Late-Breaking Clinical Trials III
 - o Sunday 29 March, 11.15-11.25 CT

Currently, there is no proven combination of an antithrombotic and an antiplatelet that has demonstrated efficacy against the combined risk of major limb and cardiovascular events following peripheral revascularization.

The VOYAGER PAD study investigated Xarelto vascular dose, 2.5 mg twice daily, plus aspirin 100 mg once daily in comparison to aspirin alone for the reduction of risk of the composite outcome of the composite outcome of acute limb ischemia (ALI), major amputation due to a vascular etiology, heart attack, ischemic stroke or cardiovascular death in patients with symptomatic peripheral artery disease (PAD) following lower extremity revascularization procedures.

Virtual Presentation Sessions:

Additional abstracts on Xarelto accepted for presentation feature results from clinical trials in the areas of vascular protection and venous protection:

- [Rivaroxaban Versus Enoxaparin in Nonmajor Orthopedic Surgery](#)
 - o Session 406 - Late-Breaking Clinical Trials III
 - o Sunday 29 March, 11.00-11.10 CT
- [The Role of Combination Antiplatelet and Anticoagulation Therapy in Diabetes and Cardiovascular Disease: Insights from the COMPASS Trial](#)
 - o Session 403 - Featured Clinical Research I
 - o Saturday 28 March, 10.45-10.55 CT

Note: Per ACC Embargo Policy, all mentioned abstracts are under embargo to the start of the session.

About Vericiguat

Vericiguat (BAY 1021189 / MK-1242) is an investigational, oral, once-daily, direct

stimulator of the soluble guanylate cyclase (sGC) enzyme. While sGC is important for the function of both the blood vessels and the heart, it is insufficiently stimulated in heart failure patients due to impaired nitric oxide (NO) availability resulting in myocardial and vascular dysfunction. Vericiguat is the first-in-class sGC-stimulator in late-stage clinical development in this indication.

About Rivaroxaban (Xarelto™)

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

Xarelto is approved in more than 130 countries, although the approved labeling, including the number of indications may differ from country to country.

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 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

To learn more about Xarelto, please visit www.xarelto.com

About Cardiology at Bayer

Bayer is an innovation leader in the area of cardiovascular diseases, with a long-standing commitment to delivering science for a better life by advancing a portfolio of innovative treatments. The heart and the kidneys are closely linked in health and disease, and Bayer is working in a wide range of therapeutic areas on new treatment approaches to address cardiovascular and kidney diseases with high unmet medical needs. The cardiology franchise at Bayer already includes a number of products and several other compounds are in various stages of preclinical and clinical development. Together, these products reflect the company's approach to research, which prioritizes targets and pathways with the potential to impact the way that cardiovascular diseases are prevented and treated.

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 2019, the Group employed around 104,000 people and had sales of 43.5 billion euros. Capital expenditures amounted to 2.9 billion euros, R&D expenses to 5.3 billion euros. For more information, go to www.bayer.com.

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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.