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News Release

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American College of Cardiology's 70th Annual Scientific Session (ACC.21):

Bayer announces two late-breaking presentations which include data from FIDELIO-DKD (finerenone) and VOYAGER PAD (Xarelto™) Phase III studies

- New prespecified exploratory analysis from the FIDELIO-DKD study data provides insight into the efficacy of finerenone on new onset atrial fibrillation or flutter (AFF) in patients with chronic kidney disease (CKD) and type 2 diabetes (T2D)
- New VOYAGER PAD study data evaluates the impact of Xarelto (rivaroxaban) plus aspirin in patients with symptomatic peripheral artery disease (PAD), post peripheral revascularization, on the reduction in risk of total (first and potentially subsequent) events
- New data providing further insights into the use of vericiguat in patients with symptomatic chronic heart failure including those with coronary artery disease, a patient population known to have a poor prognosis

Berlin, May 10, 2021 – New clinical data regarding the investigational non-steroidal, selective mineralocorticoid receptor (MR) antagonist finerenone and the Factor Xa inhibitor Xarelto (rivaroxaban) will be presented in late-breaking clinical trial sessions at The American College of Cardiology's 70th Annual Scientific Session (ACC.21). ACC.21 will take place from May 15-17, 2021.

Finerenone FIDELIO-DKD study data:

New prespecified exploratory analysis from the FIDELIO-DKD study, investigating the effects of finerenone on new onset atrial fibrillation and flutter in patients with CKD and T2D, will be presented within the following live-streamed, late-breaking clinical trial session:

- [Finerenone And New Onset Of Atrial Fibrillation Or Flutter In Patients With Chronic Kidney Disease And Type 2 Diabetes](#)
 - o Session 411 - Late-Breaking Clinical Trials V
 - o May 17, 2021, 11:45 – 11:55 (EDT)/ 17:45 – 17:55 (CEST)

Primary results from FIDELIO-DKD were presented at the American Society of Nephrology's (ASN) Kidney Week Reimagined 2020, and simultaneously published in the [New England Journal of Medicine](#) in October 2020.

Xarelto VOYAGER PAD study data:

Patients with peripheral artery disease (PAD) undergoing lower extremity revascularization (LER) are at high risk of major adverse limb and cardiovascular (CV) events.

New late-breaking VOYAGER PAD study data evaluates, in comparison to aspirin alone, the impact of Xarelto 2.5 mg twice daily with aspirin 100 mg once daily on the reduction in risk of first and subsequent events in patients with symptomatic peripheral artery disease (PAD) following lower extremity revascularization procedures. Events measured included acute limb ischemia (ALI), major amputation due to a vascular etiology, heart attack, ischemic stroke or cardiovascular death:

- [Reductions In Total Ischemic Events With Rivaroxaban In Patients With Symptomatic PAD After Revascularization: The VOYAGER PAD Trial](#)
 - o Session 406 - Joint American College of Cardiology and Journal of the American Medical Association Late-Breaking Clinical Trials II
 - o May 16, 2021, 8:15 – 8:25 (EDT)/ 14:15 - 14:25 (CEST)

Additional VOYAGER PAD abstract data published at the congress evaluates the impact of Xarelto on the reduction in risk of ischemic events in two subpopulations of symptomatic PAD patients who are undergoing revascularization: elderly patients and patients who smoke. As patients are at heightened risk of bleeding as they get older, this was also evaluated in the elderly patient population.

- [Efficacy And Safety Of Rivaroxaban In Elderly Patients With Symptomatic PAD Undergoing Revascularization: Insights From Voyager PAD](#)

- o Session 905 - Highlighted Original Research: Vascular Medicine and the Year in Review
- o May 16, 2021, 15:17 – 15:27 (EDT)/ 21:17 – 21:27 (CEST)
- [Efficacy and Safety of Low-Dose Rivaroxaban in Symptomatic PAD Patients Undergoing Revascularization Currently Smoking: Insights from VOYAGER PAD](#)
 - o Session 2105 - Vascular Medicine: Clinical Science 2
 - o May 15, 2021, 15:45 – 16:30 (EDT)/ 21:45 – 22:30 (CEST)

Additional Xarelto study data:

Patients with nonvalvular atrial fibrillation (NVAF) and T2D have an increased risk of stroke or systemic embolism (SSE) and vascular death. By analyzing Optum® de-identified electronic health record (EHR) data from 11/2010–12/2019, a new study has evaluated the effectiveness and safety of Xarelto versus warfarin in NVAF patients with T2D:

- [Stroke/Systemic Embolism, Vascular Death and Bleeding In Nonvalvular Atrial Fibrillation Patients With Type 2 Diabetes Receiving Rivaroxaban Or Warfarin](#)
 - o Session 2151 - Vascular Medicine: Venous and Thromboembolic Disease 2
 - o May 16, 2021, 10:45 – 11:30 (EDT)/ 16:45 – 17:30 (CEST)

In venous thromboembolism (VTE) treatment, an extended treatment dose of non-vitamin K antagonist oral anticoagulants (NOACs) should be considered after 6 months. However, not all patients receive the extended treatment dose after standard treatment. New study results reveal the characteristics and treatment patterns of Danish VTE patients receiving an extended NOAC treatment dose:

- [Characteristics Of Patients Receiving Extended Treatment After Incident Venous Thromboembolism](#)
 - o Session 2146 - Vascular Medicine: Venous and Thromboembolic Disease 1
 - o May 15, 2021, 10:45 – 11:30 (EDT)/ 16:45 – 17:30 (CEST)

Vericiguat study data:

Bayer also announced that new data from the Phase III VICTORIA study is to be presented during the congress. Two abstracts will provide further insights into the use of vericiguat in patients with symptomatic chronic heart failure including patients with coronary artery disease, a patient population known to have a poor prognosis:

- [Coronary Artery Disease And Cardiovascular Outcomes In Heart Failure: Insights From The Vericiguat Global Study In Subjects With Heart Failure With Reduced Ejection Fraction \(VICTORIA\) Trial](#)
 - o Session 2247 - Ischemic Heart Disease: Clinical Science 2
 - o May 16, 2021, 13:15 – 14:00 (EDT)/ 19:15 - 20:00 (CEST)
- [Baseline Cardiac Troponin T, Clinical Outcomes And Vericiguat Treatment Effect In Heart Failure With Reduced Ejection Fraction Study: Insights From The VICTORIA Trial](#)
 - o Session 1040 - Omics, AI, and Precision Medicine in Heart Failure
 - o May 16, 2021, 13:30 – 13:40 (EDT)/ 19:30 - 19:40 (CEST)

Vericiguat is being jointly developed with MSD (a tradename of Merck & Co., Inc., Kenilworth, NJ, USA).

About Bayer's Commitment in Cardiovascular and Kidney Diseases

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 for cardiovascular and kidney diseases with high unmet medical needs. The cardiology franchise at Bayer already includes a number of products and several other compounds 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 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 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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Forward-Looking Statements

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