Bayer AG
Communications
51368 Leverkusen
Germany
Phone +49 214 30-1
media.bayer.com

News Release

Not intended for U.S. and UK Media

ESC Congress 2021 – The Digital Experience:

Bayer to present data from cardiovascular portfolio, including late breaking data from Phase III FIGARO-DKD (finerenone) and various Xarelto™ studies

- Detailed results from the FIGARO-DKD study will be presented, which investigated the efficacy and safety of finerenone regarding cardiovascular and kidney outcomes versus placebo in addition to standard of care in patients with chronic kidney disease (CKD) and type 2 diabetes (T2D)
- Data for finerenone from FIDELITY, a prespecified integrated analysis of FIDELIO-DKD and FIGARO-DKD which together formed the largest Phase III study program to date in CKD and T2D, will be presented
- New rivaroxaban (Xarelto™) data from the VOYAGER PAD study in patients with peripheral artery disease and ANTENNA, EMIR and AFIRE studies in patients who have atrial fibrillation
- Further data from the Phase III VICTORIA trial provides new insights into use of vericiguat (Verquvo™), including those receiving an angiotensin receptor neprilysin inhibitor (ARNI)
- For the first time, worsening heart failure has been explicitly recognized in an update to the European Society of Cardiology (ESC) Guidelines for Acute and Chronic Heart Failure

---

Berlin, August 17, 2021 – Bayer will present new cardiovascular data across its approved and investigational treatments at the ESC Congress 2021 from 27-30 August. A total of three late breaking abstracts will be presented including detailed results for the investigational, non-steroidal, selective mineralocorticoid receptor (MR) antagonist finerenone and the Factor Xa inhibitor Xarelto (rivaroxaban). These data highlight Bayer's

ongoing commitment to improving the lives of patients with kidney and cardiovascular diseases.

Following a topline presentation at the ESC Heart Failure Congress in June, the updated European Society of Cardiology and Heart Failure Association Guidelines on Acute and Chronic Heart Failure will also be presented during the ESC Congress and made available for use. This update explicitly recognizes worsening heart failure for the first time. In the Guidelines, vericiguat is the only treatment recommended following a worsening heart failure event, on top of foundational, recommended heart failure therapies.

Finerenone FIGARO-DKD study and FIDELITY analysis data:

The topline results of Bayer's Phase III study FIGARO-DKD, evaluating the efficacy and safety of the investigational drug finerenone versus placebo when added to standard of care in patients with chronic kidney disease (CKD) and type 2 diabetes (T2D), were shared in May. The FIGARO-DKD study met its primary endpoint, showing that finerenone significantly reduced the composite risk of time to first occurrence of cardiovascular (CV) death, non-fatal myocardial infarction, non-fatal stroke, or hospitalization for heart failure. At the upcoming ESC Congress, Bayer will present the detailed results from the FIGARO-DKD study.

Together with FIGARO-DKD, Bayer will also present new findings from FIDELITY, the integrated analysis of both FIDELIO-DKD and FIGARO-DKD. The aim of FIDELITY was to evaluate the efficacy and safety of finerenone across the spectrum of patients with CKD in T2D.

The detailed results from the FIGARO-DKD study and data from the FIDELITY analysis will be presented within the following live-streamed, late-breaking clinical trial session:

- FIGARO-DKD: finerenone in patients with chronic kidney disease and type 2 diabetes
    - Hot Line - FIGARO-DKD / FIDELITY Analysis; August 28, 2021, 17:25 (CEST)

- FIDELITY Analysis: finerenone in mild-to-severe chronic kidney disease and type 2 diabetes

    - Hot Line - FIGARO-DKD / FIDELITY Analysis; August 28, 2021, 17:25 (CEST)

Xarelto VOYAGER PAD study data:

New VOYAGER PAD study data will evaluate sex-based outcomes in patients with symptomatic peripheral artery disease (PAD) post-revascularization:

- Sex-based Outcomes in VOYAGER PAD
    - Latest Science in Special Populations; on demand

Additional VOYAGER PAD data published at the congress will evaluate the impact of Xarelto on patients with symptomatic PAD with and without comorbid diabetes and fragile patients:

- VOYAGER PAD - rivaroxaban in symptomatic PAD with and without comorbid diabetes
    - Latest Science in Special Populations; on demand

- VOYAGER PAD - rivaroxaban in fragile patients with symptomatic PAD
    - Latest Science in Special Populations; on demand

Xarelto ANTENNA study data:

New ANTENNA study data that will be presented as a poster at the congress will shed light on kidney function outcomes over a 2.5 years time period of AF patients using Xarelto vs warfarin for stroke prevention:

- Renal decline in patients with atrial fibrillation treated with rivaroxaban or warfarin: a population-based cohort study in the United Kingdom
    - Congress committee e-posters choice in pharmacology and pharmacotherapy; on demand

Xarelto EMIR study data:

New EMIR study data published at the congress will evaluate the impact of Xarelto on patients with atrial fibrillation:

- 2MACE score predicts cardiovascular adverse events in real world atrial fibrillation patients under rivaroxaban therapy. Data from EMIR study
    - Risk Factors and Prevention ePosters; on demand

- Incidence of cardiovascular events in patients with atrial fibrillation anticoagulated with rivaroxaban after 2.5 years of follow-up: not all is stroke or bleeding
    - Atrial fibrillation e-posters; on demand

- Predictors of adverse clinical outcomes in atrial fibrillation patients with concomitant renal impairment under rivaroxaban therapy
    - Atrial fibrillation e-posters; on demand

Additional Xarelto study data:

- Aspirin vs. P2Y12 inhibitors with anticoagulation therapy for atrial fibrillation: insights from the AFIRE trial
    - Congress committee e-posters choice in pharmacology and pharmacotherapy; on demand

Vericiguat (Verquvo) VICTORIA study data:

New data from the Phase III VICTORIA trial will also be presented at the congress. Three abstracts will provide further insights into the use of Verquvo in patients with symptomatic chronic heart failure, including those receiving an angiotensin receptor neprilysin inhibitor (ARNI):

- Hemoglobin, anemia, and clinical outcomes in vericiguat global study in subjects with heart failure with reduced ejection fraction (VICTORIA)
    - Congress committee e-posters choice in heart failure; on demand

- Efficacy and safety of vericiguat in patients with HFrEF treated with sacubitril/valsartan: results from the VICTORIA trial

    - Congress committee e-posters choice in heart failure; on demand

- Vericiguat and health status outcomes in heart failure with reduced ejection fraction: Insights from the VICTORIA trial
    - Congress committee e-posters choice in heart failure; on demand

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

About Finerenone

Finerenone (BAY 94-8862) is an investigational, non-steroidal, selective antagonist of the mineralocorticoid receptor (MR) that in pre-clinical studies has been shown to block harmful effects of mineralocorticoid receptor (MR) overactivation. In T2D, MR overactivation is thought to contribute to CKD progression and cardiovascular damage which can be driven by metabolic, haemodynamic or inflammation and fibrosis factors.

Having randomized more than 13,000 patients from around the world who had early to late stage chronic kidney disease (CKD) and type 2 diabetes (T2D), the Phase III programme with finerenone in CKD and T2D comprises two studies evaluating the effect of finerenone versus placebo on top of standard of care on both renal and cardiovascular outcomes. FIDELIO-DKD (FInerenone in reducing kiDnEy faiLure and dIsease prOgression in Diabetic Kidney Disease) investigated the efficacy and safety of finerenone in comparison to placebo in addition to standard of care on the reduction of kidney failure and kidney disease progression in approximately 5,700 patients with CKD and T2D. Based on the positive data from FIDELIO-DKD, the U.S. FDA has approved finerenone for marketing authorization in the U.S. Finerenone has been submitted for marketing authorization in the EU and other countries worldwide based on the positive data from FIDELIO-DKD and these applications are currently under review.

FIGARO-DKD (FInerenone in reducinG cArdiovascular moRtality and mOrbidity in Diabetic Kidney Disease) investigated the efficacy and safety of finerenone versus placebo in addition to standard of care on the reduction of cardiovascular morbidity and mortality in approximately 7,400 patients with CKD and T2D across 48 countries including sites in Europe, Japan, China and the U.S. The study met its primary endpoint.

Bayer also recently announced the initiation of the FINEARTS-HF study, a multicenter, randomized, double-blind, placebo-controlled Phase III study which will investigate finerenone compared to placebo in more than 5,500 symptomatic heart failure patients (New York Heart Association class II-IV) with a left ventricular ejection fraction of ≥40%. The primary objective of the study is to demonstrate superiority of finerenone over placebo in reducing the rate of the composite endpoint of cardiovascular death and total (first and recurrent) heart failure (HF) events (defined as hospitalizations for HF or urgent HF visits).

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

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 86 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 Vericiguat
Verquvo 2.5 mg, 5 mg, and 10 mg is an oral once daily stimulator of soluble guanylate cyclase (sGC), an important enzyme in the nitric oxide (NO) signaling pathway. When NO binds to sGC, the enzyme catalyzes the synthesis of intracellular cyclic guanosine monophosphate (cGMP), a second messenger that plays a role in the regulation of vascular tone, cardiac contractility, and cardiac remodeling. Heart failure is associated with impaired synthesis of NO and decreased activity of sGC, which may contribute to myocardial and vascular dysfunction. By directly stimulating sGC, independently of and synergistically with NO, vericiguat augments levels of intracellular cGMP, leading to smooth muscle relaxation and vasodilation.

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.

Dr. Daniela Esser, phone +49 30 468-15805
Email: daniela.esser@bayer.com

Richard Breum, phone +49 30 468-17112
Email: richard.breum@bayer.com

Doreen Schroeder, phone +49 30 468-11399
Email: doreen.schroeder@bayer.com

Contact for investor inquiries:
Bayer Investor Relations Team, phone +49 214 30-72704
Email: ir@bayer.com
www.bayer.com/en/investors/ir-team

Find more information at https://pharma.bayer.com/
Follow us on Facebook: http://www.facebook.com/bayer

Follow us on Twitter: @BayerPharma

Rib (2021-0163E)

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.