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News Release

Not intended for U.S. and UK Media

Additional studies with finerenone across a wide range of heart failure patients initiated

- Three new investigator-sponsored collaborative studies are funded by Bayer and will evaluate the efficacy and safety of finerenone, a non-steroidal, selective mineralocorticoid receptor antagonist (MRA), in approximately 9,300 heart failure (HF) patients
- Studies will complement the results from the ongoing Phase III FINEARTS-HF study
- With overall more than 15,000 patients, the MOONRAKER program, including FINEARTS-HF, is one of the largest HF study programs to date, and aims to establish a comprehensive understanding of finerenone as a treatment for HF across a broad spectrum of patients and clinical settings

Berlin, August 24, 2023 – Bayer will support the initiation of three additional studies to extend its heart failure (HF) program with finerenone (MOONRAKER program). In addition to the ongoing Phase III study FINEARTS-HF, which is investigating finerenone versus placebo in more than 6,000 HF patients with mildly reduced or preserved ejection fraction, the new studies will evaluate the efficacy and safety of finerenone in approximately 9,300 additional HF patients with reduced (HfrEF), mildly reduced (HfmrEF), and/or preserved ejection fraction (HfpEF). With more than 15,000 patients in total, MOONRAKER is set to be one of the largest heart failure study programs to date. Together, the three new studies will investigate finerenone in addition to standard of care (SOC) versus placebo or in combination with a sodium-glucose co-transporter-2 (SGLT2) inhibitor versus SOC in reducing HF events and CV death across a wide range of HF patients. The three new studies are investigator-sponsored collaborative studies. Sponsor of the studies is CPC Clinical Research, a non-profit academic research organization affiliated with University of Colorado, USA. CPC is conducting the three new studies within the MOONRAKER program in collaboration with other academic research organizations and Bayer, which is funding the program.

“The MOONRAKER program is designed to address several key objectives: extend the findings of FINEARTS-HF to a higher-risk, more acute patient population among those with heart failure with mildly reduced or preserved ejection fraction; develop an evidence-base for early implementation of intensive combination therapy in patients hospitalized with heart failure across the range of ejection fraction and, finally to create valuable additional evidence for a large proportion of patients with heart failure and reduced ejection fraction that cannot tolerate or are not eligible for steroidal MRAs,” said Dr. Mikhail Kosiborod, academic lead for the MOONRAKER program from Saint Luke’s Mid America Heart Institute in Kansas City, USA.

“With the addition of the REDEFINE-HF, CONFIRMATION-HF and FINALITY-HF studies to the MOONRAKER heart failure clinical trial program, we aim to gain a comprehensive understanding of finerenone for the treatment of heart failure, examining its efficacy and safety across a broad spectrum of patients and clinical settings,” said Dr. Michael Devoy, Chief Medical Officer, Bayer. “The three new studies will complement our Phase III FINEARTS-HF study and we hope findings will provide additional guidance around the potential clinical implementation of finerenone in helping to reduce the tremendous disease burden of heart failure and improve patient outcomes.”

The Phase III REDEFINE-HF study will provide data for initiation of finerenone versus placebo in patients with HFmrEF or HFpEF who are hospitalized or have recently been discharged following an episode of decompensated HF. The Phase III CONFIRMATION-HF study will help determine whether early and simultaneous initiation of combination therapy with finerenone and an SGLT2-inhibitor provides superior clinical benefit compared with local standard of care (SoC) in patients hospitalized due to HF independent of the left ventricular ejection fraction (LVEF). The Phase III FINALITY-HF study will explore finerenone versus placebo in patients with HFrEF who are intolerant or not eligible for steroidal MRAs such as spironolactone or eplerenone.

Mineralocorticoid receptor (MR) overactivation contributes to cardiovascular and kidney damage, which can be driven by metabolic, hemodynamic, or inflammatory and fibrotic factors. Finerenone offers protection as it selectively binds to the MR receptor, blocking harmful effects of MR overactivation.

About MOONRAKER heart failure clinical trial program

The MOONRAKER program with finerenone in patients with heart failure encompasses four Phase III studies:

- FINEARTS-HF, the ongoing randomized, double-blind, placebo-controlled, multicenter, event-driven Phase III study is evaluating the efficacy (including CV death and total HF events) and safety of finerenone in addition to SoC compared to placebo in patients suffering from symptomatic HF with an ejection fraction of ≥40% (HFmrEF/HFpEF).
- REDEFINE-HF is a randomized, double-blind, placebo-controlled, parallel-group, multicenter, event-driven Phase III study which will investigate efficacy and safety of finerenone compared to placebo in addition to SoC in reducing total (first and subsequent) HF events and CV death in approximately 5,200 patients who are currently hospitalized or recently discharged with a diagnosis of decompensated HF with an ejection fraction of ≥40% (HFmrEF/HFpEF).
- The Phase III study CONFIRMATION-HF is a randomized, controlled, open-label study to investigate finerenone in addition to an SGLT2-inhibitor compared to SoC in approximately 1,500 patients who have been hospitalized with HF (or recently discharged following a hospitalization for HF), independent of the LVEF.
- FINALITY-HF is a Phase III randomized, double-blind, placebo-controlled, parallel-group, multicenter, event-driven study to investigate efficacy and safety of finerenone in addition to SOC compared to placebo in reducing CV death or HF events in approximately 2,600 patients with HF with an ejection fraction <40% (HFrEF) who are intolerant to or not eligible for treatment with a steroidal MRA such as spironolactone or eplerenone.

The three new studies (REDEFINE-HF, CONFIRMATION-HF and FINALITY-HF) are investigator-sponsored collaborative studies. CPC Clinical Research, a non-profit academic research organization affiliated with University of Colorado, USA, is the sponsor and is conducting the studies in collaboration with other academic research organizations and Bayer, which is funding the program.

The study program with finerenone, FINEOVATE, currently comprises ten Phase III studies with dedicated programs in heart failure and chronic kidney disease, respectively. The THUNDERBALL chronic kidney disease program consists of FIDELIO-DKD, FIGARO-DKD, FIND-CKD, FIONA, FIONA-OLE, FINE-ONE, as well as the Phase II study

CONFIDENCE. The MOONRAKER program includes FINEARTS-HF, REDEFINE-HF, CONFIRMATION-HF, and FINALITY-HF.

About Kerendia™ / Firialta™ (finerenone)
Kerendia™ and Firialta™ are globally protected trademarks for finerenone. Finerenone is a non-steroidal, selective mineralocorticoid receptor (MR) antagonist that has been shown to block harmful effects of MR overactivation.

Finerenone is marketed as Kerendia™ or, in some countries, as Firialta™, and approved for the treatment of chronic kidney disease associated with type 2 diabetes (T2D) in more than 70 countries worldwide, including in China, Europe, Japan, and the U.S.

About Heart Failure
Heart failure (HF) is characterized by a progressive decline in the heart's ability to pump enough blood to meet the body's needs for blood and oxygen. HF affects more than 60 million people worldwide. This number is projected to increase drastically over the next decade, partly as a consequence of the ageing population. One in five people will develop HF. Patients with HF face a poor prognosis with mortality rates similar or worse than the most common cancers. Symptoms of HF may include dizziness, shortness of breath, fatigue, sleep disturbance, chest discomfort, edema (swelling of feet and legs), and chronic coughing or wheezing.

Risk factors include hypertension, diabetes mellitus, smoking, a past myocardial infarction, and coronary artery disease. Despite advances in treatment, around 30% of people diagnosed with HF die within one year, increasing to around 40% after five years.

When categorized by ejection fraction, which is a measure of cardiac function, HF is divided into three different categories:

- Heart failure with reduced ejection fraction (HFrEF) is characterized by the compromised ability of the heart to eject oxygen-rich blood sufficiently during its contraction phase (Left Ventricular Ejection Fraction, LVEF <40%).
- Heart failure with preserved ejection fraction (HFpEF) is a condition characterized by stiffness of the heart, leading to filling abnormalities as the left ventricle is unable to relax sufficiently to fill with blood (LVEF ≥50%).
- Heart failure with mildly reduced ejection fraction (HFmrHF) is a category for patients who fall between the two other categories (LVEF 40-49%).

Treatment of congestive symptoms by diuretics and treating causes and comorbidities have long been central in the treatment of HFpEF, aiming at reducing symptom burden and preventing hospitalisation. While advances in therapy have been achieved in HFrEF, there are limited treatment options for HFpEF.

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 the planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to driving sustainable development and generating 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 2022, the Group employed around 101,000 people and had sales of 50.7 billion euros. R&D expenses before special items amounted to 6.2 billion euros. For more information, go to www.bayer.com.

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