



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

News Release

Not intended for U.S. and UK Media

ESC Congress 2024, a scientific congress of the European Society of Cardiology:

Bayer is advancing in studies on heart failure management showcasing late-breaking heart failure data from Phase III study FINEARTS-HF with finerenone

- In heart failure, a key focus area for Bayer in cardiology, detailed data from the Phase III FINEARTS-HF study evaluating the efficacy and safety of finerenone versus placebo when added to usual therapy in patients with heart failure (HF) and mildly reduced or preserved left ventricular ejection fraction (LVEF), i.e. a LVEF of $\geq 40\%$, will be presented in a Hot Line session at ESC Congress 2024
 - Data from FINEHEART, an integrated pooled analysis of finerenone which includes around 19,000 randomized patients from the pivotal Phase III studies FINEARTS-HF, FIDELIO-DKD, and FIGARO-DKD demonstrate the effects of finerenone on cardio-kidney outcomes in patients with HF with LVEF $\geq 40\%$, and/or chronic kidney disease (CKD) and type 2 diabetes (T2D), will also be presented in the same Hot Line session
-

Berlin, August 26, 2024 – Bayer will present late-breaking Phase III data on finerenone (Kerendia™) in patients with heart failure (HF) and a left ventricular ejection fraction (LVEF) of greater than or equal to 40%, as well as insights on the efficacy and safety of finerenone among patients included in the three completed pivotal trials (FINEARTS-HF, FIDELIO-DKD, and FIGARO-DKD) with overlapping cardio-kidney-metabolic conditions within a Hot Line session at ESC Congress 2024. Earlier this month, Bayer issued a press release on topline results, confirming that finerenone met its primary endpoint in the Phase III FINEARTS-HF study. At a separate Hot Line session, data will be presented from the OCEANIC-AF Phase III study investigating asundexian compared to apixaban (a direct oral anticoagulant) in patients with atrial fibrillation at risk of stroke.

Phase III finerenone data:

The FINEARTS-HF study evaluated the efficacy and safety of finerenone versus placebo when added to usual therapy in HF patients with a LVEF $\geq 40\%$. Around 6,000 patients were randomized to receive either finerenone or placebo once daily for up to 42 months:

- [FINEARTS-HF - Finerenone in heart failure with mildly reduced and preserved ejection fraction](#)
 - o Hot Line 7, Session 1120
 - o September 1, 2024, 11:00 am (BST) / 12:00 pm (CEST)

Prespecified pooled analysis of finerenone:

FINE-HEART, an integrated pooled analysis of the Phase III studies FINEARTS-HF, FIDELIO-DKD and FIGARO-DKD, explores the effects of finerenone on cardio-kidney outcomes in over 19,000 patients with heart failure with a LVEF $\geq 40\%$ and/or chronic kidney disease (CKD) and type 2 diabetes (T2D):

- [FINE-HEART - Participant-level pooled analysis of finerenone in heart failure and chronic kidney disease trials](#)
 - o Hot Line 7, Session 1120
 - o September 1, 2024, 11:44 am (BST) / 12:44 pm (CEST)

Asundexian* OCEANIC-AF Phase III study data:

The OCEANIC-AF Phase III study is designed to investigate asundexian compared to apixaban (a direct oral anticoagulant) in patients with atrial fibrillation at risk for stroke:

- [OCEANIC-AF – Asundexian versus Apixaban in Patients with Atrial Fibrillation](#)
 - o Hot Line 6, Session 11209
 - o September 1, 2024, 08:40 am (BST) / 9:40 am (CEST)

**Asundexian is an investigational agent and has not been approved by any health authority for use in any country for any indication.*

About Kerendia™ (finerenone) / Firalta™ (finerenone)

Kerendia™ and Firalta™ 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. MR overactivation contributes to chronic kidney disease (CKD) progression and cardiovascular damage which can be driven by metabolic, hemodynamic, or inflammatory and fibrotic factors.

Finerenone is marketed as Kerendia™ or, in some countries, as Firialta™, and approved for the treatment of adult patients with CKD associated with type 2 diabetes (T2D) in more than 90 countries worldwide, including in China, Europe, Japan, and the U.S.

The study program with finerenone, FINEOVATE, currently comprises ten Phase III studies with dedicated programs in HF and CKD, respectively. The MOONRAKER program includes FINEARTS-HF, as well as the ongoing collaborative, investigator-sponsored studies REDEFINE-HF, CONFIRMATION-HF, and FINALITY-HF. The THUNDERBALL CKD program consists of the completed studies FIDELIO-DKD and FIGARO-DKD, as well as the ongoing studies FIND-CKD, FIONA, FIONA-OLE, FINE-ONE, and the Phase II study CONFIDENCE.

About FXIa inhibitors and Asundexian

Factor XI is a protein in the blood which is converted into its active enzyme form - Factor XIa (FXIa) - as part of the blood coagulation cascade. Factor XIa plays an important role in pathological thrombus formation but leaves hemostasis intact. Therefore, FXIa inhibitors are a promising and distinct potential new antithrombotic class of drugs for stroke prevention.

Asundexian, as an oral direct, once-daily, potent inhibitor of activated coagulation factor XI (FXIa), is hypothesized to uncouple hemostasis from thrombosis, thereby offering the potential to prevent events like stroke without a corresponding increase in bleeding risk associated with the current standard of care (SoC). The OCEANIC-STROKE study, a Phase III study designed to evaluate asundexian as a potential treatment option in secondary stroke prevention, is currently ongoing.

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. In line with its mission, "Health for all, Hunger for none," the company's 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 2023, the Group employed around 100,000 people and had sales of 47.6 billion euros. R&D expenses before special items amounted to 5.8 billion euros. For more information, go to www.bayer.com.

Contact for media inquiries:

Dr. Daniela Esser, phone +49 30 2215-41588

Email: daniela.esser@bayer.com

Anne Jorgal, phone +49 30 2215-41592

Email: anne.jorgal@bayer.com

Find more information at <https://pharma.bayer.com>

Follow us on Facebook: <http://www.facebook.com/bayer>

Follow us on Twitter: [@BayerPharma](https://twitter.com/BayerPharma)

de (2024-0122E)

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.