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

News Release

Not intended for U.S. and UK Media

Bayer extends clinical development program for finerenone with Phase III study in patients with heart failure and preserved ejection fraction

FINEARTS-HF is the first large-scale, long-term study to investigate the non-steroidal, selective mineralocorticoid receptor antagonist finerenone on morbidity and mortality outcomes in a heart failure patient population

Berlin, June 15, 2020 – Bayer announced today the initiation of the FINEARTS-HF study, a multicenter, randomized, double-blind, placebo-controlled Phase III study to evaluate the efficacy and safety of finerenone on morbidity and mortality in patients suffering from symptomatic heart failure (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).

“No therapy is currently approved for patients with heart failure and preserved ejection fraction. These patients have a substantial risk for cardiovascular events, which represents an enormous unmet need in cardiovascular disease,” said Scott D. Solomon, MD, The Edward D. Frohlich Distinguished Chair, Professor of Medicine at Harvard Medical School, Director of Non-invasive Cardiology and Senior Physician at Brigham and Women’s Hospital and Chair of the study’s Executive Committee. “The FINEARTS-HF study will assess whether finerenone leads to a reduction in the risk of cardiovascular death and other heart failure events in these underserved patients.”

“Blockade of the mineralocorticoid receptor system has been shown to be of benefit in the treatment of heart failure. With the novel compound finerenone, Bayer is pursuing a new research approach in another heart failure patient population where a targeted therapy to reduce mortality and morbidity is still lacking,” said Dr. Joerg Moeller, Member of the

Executive Committee of Bayer AG's Pharmaceutical Division and Head of Research and Development. “We are excited about finerenone being the first non-steroidal mineralocorticoid receptor antagonist that is being developed in heart failure with preserved ejection fraction.”

The planned Phase III FINEARTS-HF study will investigate finerenone compared to placebo in more than 5,500 symptomatic heart failure patients with a left ventricular ejection fraction of ≥40%. Patients will be randomized to receive either finerenone once daily (titrated up to 40 mg) or placebo. The study will be conducted in more than 34 countries including sites in Europe, Japan, China and the U.S.

About Finerenone

Finerenone (BAY 94-8862) is an investigational novel, non-steroidal, selective mineralocorticoid receptor antagonist (MRA) that has been shown to block the harmful effects of the overactivated mineralocorticoid receptor (MR) system. MR overactivation is a major driver of heart and kidney damage. Current steroidal MRAs on the market have proven to be effective in reducing cardiovascular mortality in patients suffering from heart failure with reduced ejection fraction (HFrEF). However, they are often underutilized due to the incidence of hyperkalemia, renal dysfunction, and anti-androgenic / progestogenic side effects.

The initiation of the Phase III FINEARTS-HF study (**FIN**erenone trial to investigate **E**fficacy and s**A**fety superio**R** to placebo in pa**T**ient**S** with **H**eart **F**ailure) builds upon the robust Phase II studies ARTS-HF and ARTS-DN which investigated the efficacy and safety of finerenone in patients with heart failure and chronic kidney disease, respectively. Data from the Phase II study program ARTS were presented at ESC Congress 2015 in London.

Finerenone is already being investigated in large, longterm outcome trials in patients with chronic kidney disease (CKD) and type 2 diabetes (T2D). Having randomized more than 13,000 patients around the world, the Phase III program 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. FIGARO-DKD (**FI**nerenone in reducin**G** c**A**rdiovascular mo**R**tality and m**O**rbidity in **D**iabetic **K**idney **D**isease) is investigating 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. FIDELIO-DKD (**Fi**nerenone in reducing ki**D**n**E**y fai**L**ure and d**I**sease pr**O**gression in **D**iabetic **K**idney **D**isease) is investigating 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. Both studies are being conducted in 47 countries including in Europe, Japan, China and the U.S.

About Heart Failure

Heart failure is a highly prevalent chronic condition: Within the last 8 years, the approximate global prevalence of HF has doubled to over 60 million people. Heart failure is characterized by the progressive decline in the heart's ability to pump enough blood to meet the body's needs for blood and oxygen. Symptoms may include shortness of breath, fatigue, chest discomfort and swelling in the lower body. Risk factors are hypertension, diabetes mellitus, smoking, a past myocardial infarction, and coronary artery disease. When categorized by ejection fraction, HF is divided into two main forms, each accounting for approximately 50% of HF patients: 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. The other form of HF is heart failure with preserved ejection fraction (HFpEF), a condition characterized by stiffness of the heart leading to filling abnormalities and increased pressure in the heart. The prevalence increases with age and hospitalizations for HFpEF have increased over time. Morbidity and mortality in HFpEF are similar to values observed in patients with HFrEF. While advances in therapy have been achieved in HFrEF, there is so far no treatment currently approved for HFpEF. Recommendations have been limited to symptomatic treatment of congestive symptoms by diuretics, and to treating causes and comorbidities.

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 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 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 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.

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

Find more information at www.pharma.bayer.com
Our online press service is just a click away: media.bayer.com
Follow us on Facebook: http://www.facebook.com/pharma.bayer
Follow us on Twitter: @BayerPharma

de (2020-0147E)