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## News Release

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### **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

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**Whippany, 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 investigational 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  $\geq 40$  percent. 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).

“Currently, there are no approved therapies for patients suffering from preserved ejection fraction. Given their substantial risk for cardiovascular events, this represents a critical 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 has been shown to be beneficial in the treatment of certain forms of heart failure.<sup>1,2</sup> With the 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

that with finerenone, this trial is the first to investigate the use of a non-steroidal, selective mineralocorticoid receptor antagonist for 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  $\geq 40$  percent. 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 United States (U.S.). Patient enrollment is expected to begin in fall 2020.

### **About Finerenone**

Finerenone (BAY 94-8862) is an investigational, non-steroidal, selective mineralocorticoid receptor antagonist 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.<sup>3</sup>

The initiation of FINEARTS-HF builds upon the robust Phase II studies ARTS-HF and ARTS-DN which investigated the efficacy and safety of finerenone in patients with HF and chronic kidney disease (CKD), respectively.<sup>4</sup> Data from the Phase II study program ARTS were presented at ESC Congress 2015 in London.

Finerenone is already being investigated in large, long-term outcome trials in patients with 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 (**F**inerenone in reducing **C**ardiovascular mo**R**tality and m**O**rbitidity 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 (**F**inerenone 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, affecting about 6.5 million adults in the U.S.<sup>5</sup> 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.<sup>5</sup> 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.<sup>5,6</sup>

When categorized by ejection fraction, HF is divided into two main forms, each accounting for approximately 50 percent of HF patients<sup>7</sup>: 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 HFpEF, a condition characterized by stiffness of the heart leading to filling abnormalities and increased pressure in the heart.<sup>5</sup> The prevalence increases with age and hospitalizations for HFpEF have increased over time.<sup>8</sup> Morbidity and mortality in HFpEF are similar to values observed in patients with HFrEF.<sup>8</sup> Recommendations have been limited to symptomatic treatment of congestive symptoms by diuretics, and to treating causes and comorbidities.<sup>9</sup>

### **About Cardiology at Bayer**

Bayer is an innovation leader globally 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 includes several 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 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](http://www.bayer.com).

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**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](http://www.bayer.com). The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

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<sup>1</sup> Castaigne et al. The effect of spironolactone on morbidity and mortality in patients with severe heart failure. Randomized Aldactone Evaluation Study Investigators. *N Engl J Med*. 1999 Sep 2; 341(10): 709-17.

<sup>2</sup> Krum et al. Eplerenone in patients with systolic heart failure and mild symptoms. *N Engl J Med*. 2011 Jan 6; 364(1): 11-21.

<sup>3</sup> Belden et al. The role of the mineralocorticoid receptor in inflammation: focus on kidney and vasculature. *Am J Nephrol*. 2017; 46(4): 298-314.

<sup>4</sup> Anker S et al. A randomized controlled study of finerenone vs. eplerenone in patients with worsening chronic heart failure and diabetes mellitus and/or chronic kidney disease. *Eur Heart J*. 2016 Jul 14; 37(27): 2105-14.

<sup>5</sup> Shah S. Heart failure (HF). *MSD Manual Professional Version*. 2019 Nov; 1-8.

<sup>6</sup> Dunlay S et al. Risk factors for heart failure: A population-based case-control study. *Am J Med*. 2009 Nov; 122(11): 1023-1028.

<sup>7</sup> Butler J, Hamo C, Papadimitriou L. Heart failure guidelines on pharmacotherapy. *Heart Failure, Handbook of Experimental Pharmacology*.

<sup>8</sup> Oktay A, Rich J, Shah S. The emerging epidemic of heart failure with preserved ejection fraction. *Curr Heart Fail Rep*. 2013; 10(4): 401-410.

<sup>9</sup> Yancy CW, Jessup M, Bozkurt B, et al. ACC/AHA/HFSA focused update of 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation and American Heart Association Task Force on Practice Guidelines and the Heart Failure Society of America. C2017;136:e137-e161.