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's finerenone meets primary endpoint in Phase III FIDELIO-DKD renal outcomes study in patients with chronic kidney disease and type 2 diabetes

- Finerenone significantly reduced the combined primary endpoint of chronic kidney disease progression, kidney failure or kidney death versus placebo when added to standard of care
- Finerenone significantly reduced the combined key secondary endpoint of cardiovascular death or non-fatal cardiovascular events
- Chronic kidney disease impacts 4 in 10 patients with type 2 diabetes and is a deadly condition that is underrecognized
- Finerenone is the first investigational non-steroidal, selective mineralocorticoid receptor antagonist to demonstrate renal and cardiovascular benefits in patients with chronic kidney disease and type 2 diabetes
- Bayer will discuss the data with health authorities regarding the submission of marketing authorization application

Berlin, July 9, 2020 – Bayer's Phase III study FIDELIO-DKD evaluating the efficacy and safety of finerenone versus placebo when added to standard of care in patients with chronic kidney disease (CKD) and type 2 diabetes (T2D)[1] has met its primary endpoint. The results show that the investigational drug finerenone delayed the progression of CKD by significantly reducing the combined risk of time to first occurrence of kidney failure, a sustained decrease of estimated glomerular filtration rate (eGFR) greater than or equal to 40% from baseline over a period of at least four weeks, or renal death. Finerenone significantly reduced the risk of the key secondary outcome, a composite of time to first occurrence of cardiovascular (CV) death, non-fatal myocardial infarction, non-fatal stroke, or heart failure hospitalization.

[1] The terms "Diabetic Kidney Disease" and "Chronic Kidney Disease in Type 2 Diabetes" are being used synonymously.

The FIDELIO-DKD study is part of the largest Phase III clinical trial program to date in CKD and T2D, which enrolled 13,000 patients across a broad range of disease severity including those with early kidney damage and more advanced stages of kidney disease. FIDELIO-DKD is a randomized, double-blind, placebo-controlled, parallel-group, multicenter, event-driven Phase III study investigating finerenone versus placebo in patients with CKD and T2D. The study included approximately 5,700 patients from more than 1,000 sites across 48 countries worldwide. Patients were randomized to receive either finerenone 10 mg or 20 mg orally once daily or placebo when added to standard of care, including blood glucose lowering therapies and maximum tolerated dose of RAS-blocking therapy such as angiotensin-converting enzyme (ACE) inhibitors or angiotensin II receptor blockers (ARBs).

The clinical data from FIDELIO-DKD will be presented at an upcoming scientific meeting. Bayer will discuss the data with health authorities regarding the submission of marketing authorization application.

About Finerenone

Finerenone (BAY 94-8862) is an investigational novel, non-steroidal, selective mineralocorticoid receptor antagonist (MRA) that has been shown to block many of the harmful effects of mineralocorticoid receptor (MR) overactivation. MR overactivation is a major driver of kidney and heart damage.

Having randomized more than 13,000 patients with CKD and T2D around the world, 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 (**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) 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. The study has met its primary efficacy endpoint. 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 still ongoing and 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 across 47 countries including sites in Europe, Japan, China and the U.S.

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 chronic kidney disease in type 2 diabetes

Chronic kidney disease (CKD) is one of the most frequent complications arising from diabetes and is also an independent risk factor of cardiovascular disease. Approximately 40% of all patients with type 2 diabetes develop chronic kidney disease. Chronic kidney disease in type 2 diabetes is the main cause of end stage kidney disease[2] and kidney failure and at advanced stages, patients may need dialysis or a kidney transplant to stay alive.[3] MR over-activation is known to trigger detrimental processes (e.g. inflammation and fibrosis) in kidneys and heart in patients with CKD and type 2 diabetes (T2D). CKD in T2D is the most common cause of kidney failure worldwide.

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 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.

References:

2. Doshi S M et al. Diagnosis and management of type 2 diabetic kidney disease. Clinical Journal of the American Society of Nephrology, 12(8), 1366-1373. 2017.
3. Kidney Fund.org. Kidney Failure. Available at: https://www.kidneyfund.org/kidney-disease/kidney-failure/ Last accessed 22 April 2020.

Contacts:

Astrid Kranz, phone +49 30 468-12057

Email: astrid.kranz@bayer.com

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 (2020-0161E)