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Investor News

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Bayer Expands Finerenone Clinical Development Programme with Three Phase III Studies in Patients with Chronic Heart Failure and Patients with Diabetic Kidney Disease

Decision based on data of four dose-finding studies in patients with chronic heart failure and diabetic kidney disease

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Leverkusen, Germany, August 31, 2015 – Bayer HealthCare announced today the expansion of the clinical development programme for its novel, oral, non-steroidal mineralocorticoid receptor antagonist (MRA) finerenone (BAY 94-8862) with three Phase III studies. The studies will investigate the efficacy and safety of finerenone in patients with chronic heart failure (CHF) and patients with diabetic kidney disease (DKD) with the first patients expected to be enrolled by the year-end. Despite recent advances, chronic heart failure is still a deadly disease with 5-years survival rates similar to those of patients with advanced cancer. Diabetic kidney disease is a common complication of diabetes and the most frequent cause of end-stage renal disease (ESRD) in Western countries. Diabetes causes more than 40 per cent of new cases of ESRD.

“The data we have seen for finerenone to date across the clinical development programme make us very confident to move finerenone forward into Phase III across two important indications of high unmet medical need,” said Dr Joerg Moeller, Member of the Bayer HealthCare Executive Committee and Head of Global Development. “We are excited about finerenone being the first mineralocorticoid receptor antagonist that is being developed in parallel in chronic heart failure and diabetic kidney disease. The studies will investigate whether finerenone can reduce cardiovascular morbidity and mortality as well as the progression of renal disease in these patients with a well-tolerated safety profile.”

The initiation of the Phase III FINESSE-HF study in chronic heart failure is based on promising data from the exploratory Phase IIb ARTS-HF study, which was presented today in a Hot Line Session at ESC Congress 2015 in London. ARTS-HF investigated the

effects of different finerenone dosages compared to eplerenone in patients with worsening chronic heart failure with reduced ejection fraction (HFrEF) and type 2 diabetes mellitus and/or chronic kidney disease. Finerenone showed a reduction of surrogate marker NT-proBNP comparable to highly effective eplerenone when comparing Day 90 to baseline while demonstrating meaningful reductions in key exploratory endpoints of all-cause death and cardiovascular hospitalization versus eplerenone with the lowest incidence observed in the finerenone 10/20 mg dose group. All doses of finerenone were well-tolerated and incidences of treatment-emergent adverse events (TEAEs) were similar between eplerenone and all finerenone dose groups. ARTS-HF involved a total of 1,055 patients across 25 countries.

The planned Phase III study, FINESSE-HF, will investigate finerenone compared to eplerenone in more than 3,600 chronic heart failure patients with reduced ejection fraction and type 2 diabetes mellitus and/or chronic kidney disease across more than 35 countries including Europe, Japan, China and the US. Patients will receive finerenone or eplerenone on top of standard medical treatment currently represented by angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blocker (ARBs) and β-blockers.

The initiation of the Phase III studies FIGARO-DKD and FIDELIO-DKD in diabetic kidney disease is based on promising data from the Phase IIb ARTS-DN study, which was presented at the World Congress of Nephrology (WCN) in March this year. ARTS-DN included 823 patients with type 2 diabetes and the clinical diagnosis of diabetic kidney disease from 23 countries, who were treated for 90 days. The addition of once-daily oral finerenone to RAS-blocking therapy resulted in a significant reduction of albuminuria without adversely affecting serum potassium or kidney function compared with placebo on top of RAS-blocking therapy. All finerenone doses were well-tolerated and incidences of treatment-emergent adverse events (TEAEs) and serious adverse events (SAEs) were comparable between all finerenone treatment groups and standard therapy.

The Phase III programme in DKD comprises two studies. FIGARO-DKD will investigate finerenone versus placebo in 6,400 patients with the clinical diagnosis of diabetic kidney disease mainly comprising of patients with high albuminuria (previously known as ‘micro-albuminuria’, defined as Urine Albumin-to-Creatinine Ratio (UACR) ≥ 30mg/g and < 300mg/g) while FIDELIO-DKD will investigate finerenone in comparison to placebo in 4,800 patients with the clinical diagnosis of diabetic kidney disease mainly comprising of patients with very high albuminuria (previously known as ‘macro-albuminuria’, defined as

UACR ≥ 300mg/g). Both studies will be conducted in about 40 countries including Europe, Japan, China and the U.S. Patients will receive finerenone or placebo on top of current standard of care, which includes RAS-blocking therapy such as ACE inhibitors or ARBs.

About Finerenone

Finerenone (BAY 94-8862) is a novel potent and selective oral non-steroidal mineralocorticoid receptor antagonist (MRA) blocking deleterious effects of mineralocorticoid receptor (MR) over-activation by aldosterone. Increased activation of the MR leads to pathological changes in the heart and kidneys, which can be prevented by effective blockade of the MR. 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. Finerenone, a third-generation MRA, has demonstrated a promising efficacy and safety profile in preclinical studies as well as in Phase I and Phase II clinical trials.

About Heart Failure

The prevalence of heart failure has increased progressively over the past several decades owing primarily to a reduction in myocardial infarction mortality and a steady ageing of the population around the world. When categorized by ejection fraction, heart failure is divided into two different forms: heart failure with reduced ejection fraction (HFrEF), formerly known as systolic heart failure, is characterized by the compromised ability of the heart to eject oxygen rich blood sufficiently during its contraction phase. HFrEF is a final common pathway for many cardiovascular diseases, notably coronary artery disease. Once established, HFrEF progresses through activation of a variety of pathways that adversely affect cardiac structure and function. Currently, the most effective pharmacological therapies for HFrEF target the over-activation of the renin–angiotensin–aldosterone system and the β-adrenergic sympathetic nervous system that occurs in heart failure. However, even with the current treatment options, morbidity and mortality remain high and increase further after episodes of acute decompensation or hospitalization. The other form of heart failure is heart failure with preserved ejection fraction (HFpEF), previously known as diastolic heart failure, a condition characterized by stiffness of the heart leading to filling abnormalities and increased pressure in the heart. There is no treatment currently approved for HFpEF.

About Diabetic Kidney Disease

Continuously increased sugar levels in the blood of diabetic patients can damage the kidneys. Excessive increased aldosterone levels and MR over-activation are known to trigger detrimental processes (e.g. inflammation and fibrosis) in heart and kidneys in these patients. Kidney performance (the so-called glomerular filtration rate or GFR) is reduced, and in addition the damaged kidney loses increased amounts of protein in the urine (albuminuria). Over time, the kidneys may fail completely. Without either regular dialysis or a kidney transplant, kidney failure is always fatal. Diabetic kidney disease is the most common cause of kidney failure world-wide.

About Cardiology at Bayer

Bayer is committed to delivering *Science For A Better Life* by advancing a portfolio of innovative treatments. Cardiovascular diseases have become a severe problem in our society. Bayer is working in a wide range of therapeutic areas on new treatment approaches for cardiovascular, lung and kidney diseases. 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 HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care, agriculture and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of around EUR 20.0 billion (2014), is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Medical Care and Pharmaceuticals divisions. Bayer HealthCare's aim is to discover, develop, manufacture and market products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 60,700 employees (Dec 31, 2014) and is represented in more than 100 countries. More information is available at www.healthcare.bayer.com.

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