FINESSE-HF

PHASE III

FINESSE-HF will provide insights into how best to manage chronic heart failure with reduced ejection fraction

Mineralocorticoid receptor antagonists (MRAs) have proven to be effective in reducing mortality in patients with chronic heart failure. However, they are often underutilised due to their side effect profile, which includes hyperkalemia (high blood potassium levels), renal dysfunction and anti-androgenic/progestogenic effects.[1]

Based on its physiochemical properties as a nonsteroidal molecule, Bayer anticipates that finerenone may result in a different organ distribution and accordingly, have a different balance of influences on renal electrolyte effects versus functional and structural end organ protection in comparison to steroidal MRAs.[1]

The Phase IIb ARTS-HF dose-finding study, which included 1,055 patients across 25 countries, investigated the effects of different finerenone doses, compared with eplerenone, in patients with worsening chronic heart failure with reduced ejection fraction and type 2 diabetes and/or chronic kidney disease. Topline findings included:[2]

- A reduction of surrogate marker NT-proBNP, used to screen for cardiac stress, with finerenone (comparable to eplerenone) at Day 90, compared to baseline
- Meaningful reductions in all-cause death and cardiovascular hospitalisation with finerenone versus eplerenone, with the lowest incidence in the 10/20 mg finerenone dose group
- All doses of finerenone were well tolerated

FINESSE-HF will investigate finerenone compared with eplerenone in people with reduced ejection fraction chronic heart failure and type 2 diabetes and/or chronic kidney disease.

FINESSE-HF study design

Randomised, double-blind, active comparator-controlled trial > 3,600 patients

Finerenone 10–20 mg OD on top of SoC

Eplerenone 25–50 mg OD on top of SoC

Event-driven study with expected duration of 3 years

Primary efficacy endpoint:

Time to the first occurrence of the primary cardiovascular (CV) event: CV death or hospitalisation for heart failure (HF)

The secondary objectives of this study are to determine the superiority of finerenone to eplerenone with regard to each of the following:

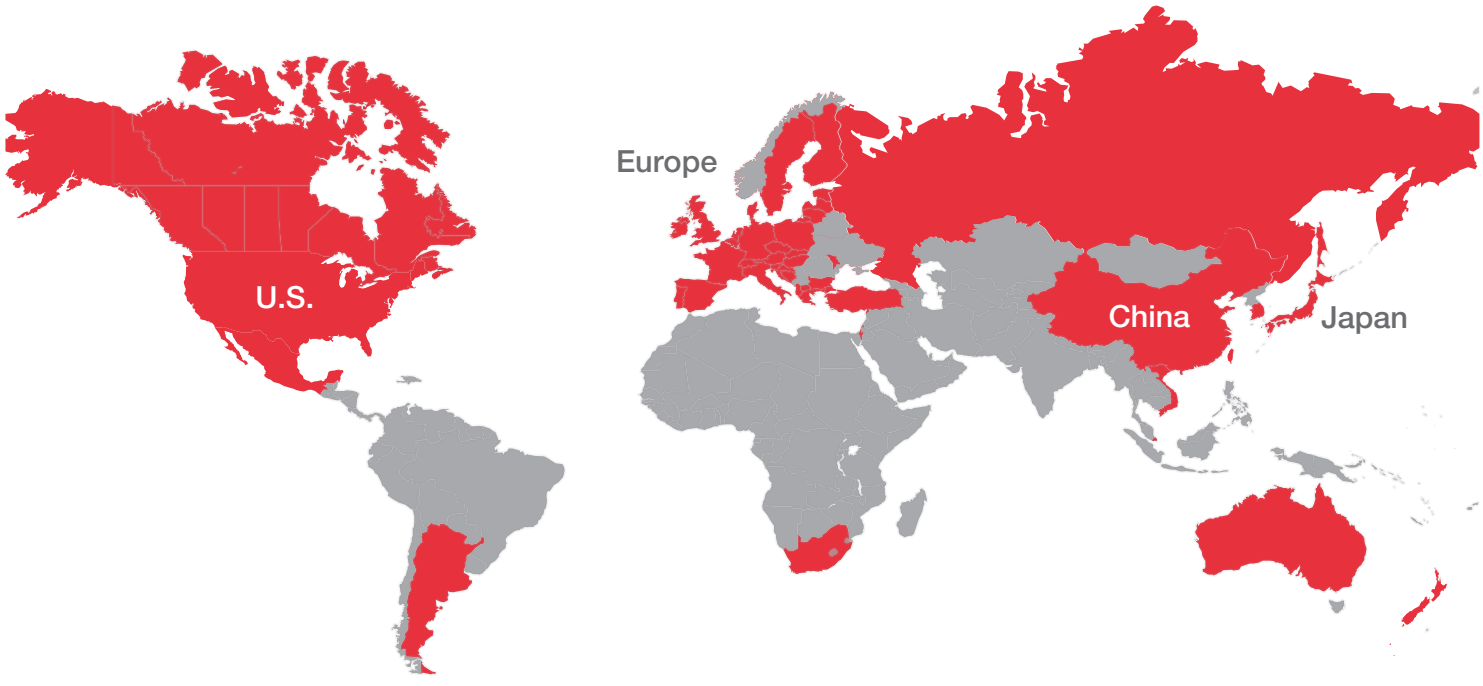
- **Total number of hospitalisations (or equivalent) for HF**
- **Time to first hospitalisation (or equivalent) for HF**
- **Time to all-cause mortality**
- **Time to first occurrence of the composite renal endpoint: onset of kidney failure, or sustained decrease in estimated glomerular filtration rate (eGFR) ≥40% from baseline over at least 4 weeks, or renal death**

Patients will receive the trial treatment in addition to current standard medical treatment of an ACE inhibitor, or an angiotensin receptor blocker (ARB), and a beta blocker.

FINESSE-HF

PHASE III

This study will involve multiple centres from across the globe, including sites in Europe, Japan, China and the U.S.



ABOUT CHF

1 in 5 people develop chronic heart failure,[3] when abnormal structure or function of the heart results in it being unable to pump enough blood around the body.[4] In reduced ejection fraction heart failure, the heart muscle becomes unable to contract properly and is the final stage for many people with cardiovascular disease.[5]

The incidence of chronic heart failure and kidney disease are increasing worldwide driven primarily by the ageing population and increase in the number of people living with diabetes.[3,6]

REFERENCES

1. Liu LC, Schutte E, Gansevoort RT, *et al.* Finerenone: third-generation mineralocorticoid receptor antagonist for the treatment of heart failure and diabetic kidney disease. *Expert Opin Investig Drugs*. 2015; 24:1123-1135. **2.** Filippatos G. Finerenone versus eplerenone in patients with worsening chronic heart failure with type 2 diabetes mellitus and/or chronic kidney disease: main results of the ARTS-HF trial. European Society of Cardiology Congress 2015. Abstract number 3150. **3.** Bui AL, Horwich TB, Fonarow GC. Epidemiology and risk profile of heart failure. *Nat Rev Cardiol*. 2011; 8:30-41. **4.** McMurray JJ, Adamopoulos S, Anker SD, *et al.* ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012: The Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2012 of the European Society of Cardiology. Developed in collaboration with the Heart Failure Association (HFA) of the ESC. *Eur Heart J*. 2012; 33:1787-1847. **5.** AHA. Types of heart failure. Available at: http://www.heart.org/HEARTORG/Conditions/HeartFailure/AboutHeartFailure/Types-of-Heart-Failure_UCM_306323_Article.jsp Last accessed 07.08.15. **6.** IDF Diabetes Atlas, 6th edn. 2014. Available at: http://www.idf.org/sites/default/files/EN_6E_Atlas_Full_0.pdf Last accessed 07.08.2015.

Finerenone is an investigational agent and is not an approved medicinal product in any country.
Media Infographic. For Ex-US and Ex-UK Use Only.
Date of Preparation August 2015