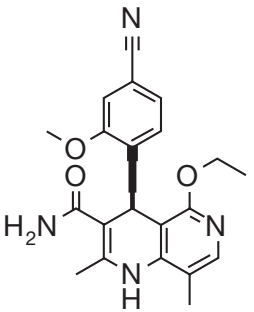
About Finerenone



What is finerenone?

Finerenone is the first oral, non-steroidal mineralocorticoid receptor antagonist (MRA) entering late stage clinical development. It has shown a promising safety and efficacy profile in preclinical, Phase I and Phase II clinical trials as a treatment for chronic heart failure and diabetic kidney disease. Phase III trials are scheduled to enroll the first patients later in 2015.

How does finerenone work?

Finerenone is a potent and selective inhibitor of the mineralocorticoid receptor (MR). It inhibits the deleterious effects of MR over-activation by aldosterone and cortisol, hormones which bind to this receptor.[1,2]

Aldosterone is important in the regulation of water and salt balance and accordingly for blood pressure, but high levels of aldosterone can also cause damage to the heart and kidneys.[1] Elevated levels of aldosterone are present in people with diabetic kidney disease and chronic heart failure.[3]

Blocking the deleterious effects of aldosterone could:[1]

- slow down long-term kidney damage
- reduce the adverse impact on the structure and function of the heart and vessels

Finerenone aims to address unmet medical needs

The incidence of chronic heart failure and diabetic kidney disease are increasing worldwide driven primarily by the ageing population and an increase in the number of people living with diabetes.[4,5]

Finerenone is unique

Preclinical *in vivo* studies have demonstrated that non-steroidal finerenone is equally distributed to cardiac and renal tissue. This may cause a different balance of influences on renal electrolyte effects versus functional and structural end organ protection in comparison to available steroidal MRAs.[1,2] *In vitro* studies have also demonstrated that finerenone is both selective and a potent inhibitor of the MR.[1]

Chronic heart failure

Older 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 and incidence of hyperkalemia (high blood potassium levels), renal dysfunction and anti-androgenic/progestogenic effects. Finerenone has demonstrated a promising safety and efficacy profile and could serve as a new therapeutic option if successful in further clinical development.[1]

Finerenone is being investigated as a new MRA, to be used alongside other classes of treatment for chronic heart failure including ACE inhibitors, ARBs and beta blockers.

Diabetic kidney disease

Continuously elevated glucose levels in the blood of people with diabetes can damage the kidneys.[4] Excessive increased aldosterone levels and MR over-activation are known to trigger detrimental processes (e.g. inflammation and fibrosis) in the kidneys and heart.[1]

Based on the clinical data seen to date, finerenone is being investigated in addition to standard of care, which consists of a RAS-blocking therapy like ACE inhibitors or ARBs, as a potential new treatment option for people with diabetic kidney disease.

The Bayer cardiology portfolio

Bayer is committed to delivering *Science For A Better Life* by advancing a portfolio of innovative treatments.

Bayer is working in a wide range of therapeutic areas on new treatment approaches for cardiovascular, lung and kidney diseases.

Together, these products reflect the company's approach to research, which prioritises targets and pathways with the potential to impact the way that cardiovascular diseases are treated.

REFERENCES

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