Saudi Public Assessment Report

(Summary Report)

Kerendia®

Type of Application: New Drug Application

Type of Product: New Chemical Entity

Active Pharmaceutical Ingredient(s): Finerenone

ATC code: C03DA05

Dosage Form: Film-coated tablet

Dosage Strength: 10 mg - 20 mg

Pack Size: 28 Tablets

Shelf life: 36 Months

Storage Conditions: Do not store above 30°C

Marketing Authorization Holder: Bayer AG

Manufacturer: Bayer AG Wuppertal, Germany

Registration No.: 1003221837 - 0805222001

Decision and Decision Date: Approved on 19/4/2022

Proposed Indications: Indicated to reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, nonfatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D).

Product Background

This product is considered a new chemical entity for Saudi regulatory purposes. Furthermore, this product is qualified to follow the SFDA's normal submission regulatory pathway.

The SFDA approval for Kerendia® (Finerenone) is based on a review of the quality, safety and efficacy as summarized hereinafter:

Quality Aspects

Drug Substance

- Finerenone is non-hygroscopic white to yellow crystalline powder. Finerenone is soluble in methanol, sparingly soluble in ethanol, acetonitrile & acetone and slightly soluble in 2-Propanol. Finerenone does have chirality. Polymorphism has been observed.
- The drug substance is manufactured by a multiple-step chemical synthesis.
- The structure of Finerenone has been fully elucidated using several spectroscopic techniques.
- The drug substance specification includes relevant tests for proper quality control. The control methods are validated according to international guidelines.
- Appropriate stability data have been presented and justify the established re-test period.

Drug Product

- Kerendia drug product is available in two strengths:
    1. 10 mg tablet: Pink, oval-oblong, film-coated tablet with a length of 10 mm and a width of 5 mm, marked '10' on one side and 'FI' on the other side.
    2. 20 mg tablet: Yellow, oval-oblong, film-coated tablet with a length of 10 mm and a width of 5 mm, marked '20' on one side and 'FI' on the other side.
- Each tablet contains 10 mg of Finerenone and 20 mg of Finerenone. The composition of the drug product is adequately described, qualitatively and quantitatively. Suitable pharmaceutical development data have been provided for the finished product composition and manufacturing process.
- The manufacturing process is described narratively and in sufficient detail, taking into account pharmaceutical development data. Batch manufacturing formulas and in-process controls are included.
- The drug product specification covers appropriate parameters for this dosage form, which allow for proper control of the finished drug product. The control methods are validated according to international guidelines. Batch data show consistent quality of the drug product.

- The drug product is packaged in a carton box, containing 2 PVC/PVDC colorless transparent foil blisters sealed with aluminum foil, each blister contain 14 tablets.

- Appropriate stability data have been generated in the packaging material intended for commercial use and following relevant international guidelines. The data show good stability of the finished product and support the shelf life.

Clinical Aspects

Finerenone, a nonsteroidal, selective mineralocorticoid receptor antagonist, reduced albuminuria in short-term trials involving patients with chronic kidney disease (CKD) and type 2 diabetes. The clinical development programme for Kerendia consisted of one pivotal clinical study: Study16244 (FIDELIO): Randomized, double-blind, placebo-controlled, parallel-group, multicenter, event-driven phase III study to assess the efficacy and safety of finerenone, in addition to standard care in delaying the progression of kidney disease, in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D).

Summary of the clinical studies presented hereafter:

- Study16244 (FIDELIO): Randomized, double-blind, placebo-controlled, parallel-group, multicenter study conducted to demonstrate whether, in addition to standard of care, finerenone is superior to placebo in delaying the progression of kidney disease in 5734 Subjects with type 2 diabetes and chronic kidney disease treated with the individual maximum tolerated labeled dose of either angiotensin-converting enzyme inhibitors (ACEI) or an angiotensin receptor blockers (ARB). The primary endpoint was a composite of time to the first occurrence of kidney failure (defined as chronic dialysis or kidney transpl antation, or a sustained decrease in eGFR to < 15 mL/min/1.73 m2 over at least 4 weeks), a sustained decline in eGFR of 40% or more compared to baseline over at least 4 weeks, or renal death.

The clinical pharmacology, efficacy and safety results from the above study were assessed by the SFDA efficacy and safety department. Based on the efficacy and safety review of the submitted evidence, the benefit/risk balance of Kerendia is considered positive. Therefore, we recommend the approval of the marketing authorization of Kerendia.

Product Information

The approved Summary of Product Characteristics (SPC) with the submission can be found in Saudi Drug Information System (SDI) at: https://sdi.sfda.gov.sa/

The date of revision of this text corresponds to that of the Saudi PAR. New information concerning the authorized medicinal product in question will not be incorporated into the Saudi PAR. New findings that could impair the medicinal product's quality, efficacy, or safety are recorded and published at (SDI or Summary Saudi-PAR report).

For inquiry and feedback regarding Saudi PAR, please contact us at Saudi.PAR@sdfa.gov.sa