Saudi Public Assessment Report

(Summary Report)

Sogroya®

Type of Application: New Drug Application.

Type of Product: New Biologic Drug.

Active Pharmaceutical Ingredient(s): Somapacitan.

ATC code: H01AC07.

Dosage Form: Solution for injection in pre-filled pen.

Dosage Strength: 6.7 mg/ ml.

Pack Size: Multipack of 5 pre-filled pen each 1.5 ml.

Shelf life: 24 Months.

Storage Conditions: Store in a refrigerator (2°C- 8°C), Do not freeze, keep the container in the outer carton, in order to protect from light.

Reference Product in SA (if applicable): NA.

Marketing Authorization Holder: Novo Nordisk A/S, Hovedstaden, Denmark.

Manufacturer: Novo Nordisk A/S, Hovedstaden, Denmark.

Registration No.: 0903221831.

Decision and Decision Date: Approved on 28/02/2022.

Proposed Indications: Sogroya is indicated for the replacement of endogenous growth hormone (GH) in adults with growth hormone deficiency (AGHD).

Product Background

This product is considered as new biologic drug for Saudi regulatory purposes. Furthermore, this product is qualified to follow the SFDA's abridged submission regulatory pathway.

The SFDA approval for Sogroya® (Somapacitan 10 mg/1.5 mL) is based on a review of the quality, safety and efficacy data as summarized hereinafter:

Quality Aspects

The quality assessment for this medicine was undertaken to meet the last version of *GCC Data Requirements for Human Drugs Submission.* The submission included the required information about the somapacitan which is a long-acting recombinant analogue of GH derivative with a single substitution in the peptide backbone expressed intracellularly in an E. coli cell line. The manufacturing process occurs in three main stages described in sufficient detail, the manufacturing process parameters and in-process tests are listed associated with acceptance criteria and action limits showing the control of critical steps including microbial contamination. The process validation presented the process consistency and reproducibility. The primary structure of somapacitan had been confirmed to comply with the theoretical structure by using the qualified analytical methods which were validated to show suitability for the intended use. The applicant provided acceptable control for drug substance and drug product at both times of release and shelf life along with the acceptable strategy for controlling product-related and manufacturing process-related impurities. The standard material used for the control of drug substance and drug product generated from production batch manufactured in a drug substance campaign supplying material for clinical phase 3 trials and representative of the commercial process.

The manufacturing process for the drug product consists of mixing of solutions including formulation steps followed by sterile filtration, aseptic filling into sterilized and depyrogenated cartridges which are visually inspected then stored, protected from light at 2°C-8°C until the labeling, secondary packed and release. The proposed storage and shelf life for the finished product is 24 months at 2-8 °C. Including an in-use period of 6 weeks at 2-8 ºC and a total of 72 hours (3 days) at room temperature (at or below 30 ºC) and photostability data from a sufficient number of batches shows that the pen-injector provides suitable protection of somapacitan drug product.

There are no issues pertaining to drug substance and drug product specifications in general specifications are acceptable since it includes general parameters required by the *ICH Q6B* guideline: physical tests (pH, appearance), chemical tests (identity, specific bioactivity), and purity. All analytical procedures are sufficiently validated. There are no issues pertaining to drug substance and drug product stability. Stability studies for both drug substance and drug product cover all parameters from the specifications that are susceptible to change during storage, which potentially could influence the quality, safety and/or efficacy of somapacitan drug substance and drug product.

Clinical Aspects

The clinical development program for Sogroya consisted of one pivotal clinical study: Study NN8640-4054 assessing the efficacy and safety of the product.

Summary of the clinical studies presented hereafter:

- Study NN8640-4054: a phase III, randomized, multicenter, multinational, parallel-group, placebo-(double-blinded), and active-controlled (open; Norditropin®) trial. Which aims to compare the efficacy and safety of once-weekly somapacitan with a once-weekly placebo and daily Norditropin® in 300 growth hormone deficient (AGHD) patients who were growth hormone (GH) treatment-naïve, or with no exposure to GH, or GH secretagogues for at least 180 days prior to randomization. The trial consisted of the following periods; 34 weeks (main period) and 52 weeks (Extension period). The primary endpoint was the change from baseline to the end of main trial period (week 34) in truncal fat percentage. Body composition was measured by DXA (Dual-energy X-ray Absorptiometry) and truncal fat percentage was defined as 100 times truncal fat mass (kg) divided by the sum of truncal fat mass (kg) and truncal lean body mass (kg).

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

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