الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Saudi Public Assessment Report

(Summary Report)

Bimzelx®

Type of Application: New drug application.

Type of Product: New biological drug/ monoclonal antibody.

Active Pharmaceutical Ingredient(s): Bimekizumab.

ATC code: L04AC.

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

Dosage Strength: 160 mg/ml.

Pack Size: 1 ml.

Shelf life: 36 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: Farouk, Maamoun Tamer & Co.

Manufacturer: UCB Pharma (Belgium).

Registration No.: 3107222375.

Date of Decision: Approved on 20/06/2022.

Proposed Indications: Bimzelx is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

Product Background

This product is considered as new biosimilar drug, for Saudi regulatory purposes. Furthermore, this product is qualified to follow the SFDA's regulatory pathway abridge approval.

The active drug substance for Bimzelx is bimekizumab. Bimekizumab is a humanized, full-length monoclonal antibody (mAb) of immunoglobulin G1 (IgG1) that potently and selectively bind and neutralize interleukin- 17A (IL-17A), IL-17F, and IL-17AF cytokines. Bimekizumab is intended to be indicated for the treatment of moderate to severe plaque psoriasis in adult patients. Bimekizumab is administered as a solution for injection (160mg/mL).

The SFDA approval for Bimzelx® (Bimekizumab 160 mg/ml) is based on a review of the quality, safety and efficacy as summarised hereinafter:

Quality Aspects

Bimekizumab quality assessment undertaken to meet the last version of SFDA Data Requirements for Human Drugs Submission. The submission included the quality information about the drug substance (DS) and drug product (DP) submitted in a satisfactory way and assessed according to most recent quality guidelines to guarantee the product quality.

The bimekizumab manufacturing process has a defined set of controls, derived from product and process understanding, which ensure a consistent process performance and product quality as a part of the overall control strategy. The critical process parameters and the in-process controls for cell culture and downstream were confirming to the Good Manufacturing Practices (GMP) adherence and the process robustness. All raw materials are purchased from approved suppliers, the raw materials used in the bimekizumab manufacturing process are routinely tested or accepted based on the Certificate of Analysis from suppliers.

The manufucturing process validation strategy is defined to demonstrate that the manufacturing process is controlled and reproducible. Bimekizumab is characterized using a range of biochemical, biophysical and biological techniques to provide a comprehensive understanding of its structural and functional properties and to support the assessment of the criticality of product quality attributes. The provided results show consistent control of both process-related and product-related impurities in the drug substance.

Critical quality attributes had been identified through the systematic assessment of product quality attributes. A comprehensive control strategy has been defined that incorporates a planned set of controls, derived from current product and process understanding, that understanding ensures process performance and product quality. Brief description of control strategy and quality attributes covered in the control process.

Bimekizumab drug product is supplied as a sterile, preservative-free solution, suitable for administration by subcutaneous injection. The components of the drug product are fully described.

The excipients used in the final formulation of bimekizumab drug product are of pharmacopoeial quality, the choice of formulation components and solution pH is scientifically discussed.
The applicant provided a detailed description of the manufacturing process. Details of the in-process controls (IPC) are provided. Process performance qualification (PPQ) of the drug product manufacturing process is demonstrated by the successful completion of four consecutive PPQ batches according to a pre-approved protocol. Bimekizumab is developed according to the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Q8, Q9, Q10, and Q11 principles using a risk based approach. The control strategy has integrated the knowledge gathered during the development of the molecule and the manufacturing process. The control strategy ensures the ongoing quality of bimekizumab. The applicant will review periodically as additional process or product understanding is achieved.
There are no issues pertaining to drug substance and drug product stability. There are no issues pertaining to drug substance and drug product specifications. All analytical procedures are validated.

Clinical Aspects

Efficacy and Safety

The clinical development program for Bimzelx consisted of three pivotal clinical studies: PS0008, PS0009 and PS0013, all three studies assessed the efficacy and safety of the product.

Summary of the clinical studies presented hereafter:

- PS0008 study: A Phase III, randomized, double-blind, parallel group, active comparator "Adalimumab" controlled multicenter study consisting of a 16-week initial treatment period followed by a 40-week maintenance treatment period to evaluate the efficacy and safety of bimekizumab in 478 adult subjects with moderateto severe chronic plaque psoriasis (PSO).

- PS0009 study: A Phase III, randomized, double-blind, placebo and active comparator "Ustekinumab" controlled multicenter study consisting of a 16-week initial treatment period followed by a 36-week maintenance treatment period to evaluate the efficacy and safety of bimekizumab in 567 adult subjects with moderateto severe chronic plaque psoriasis (PSO).

- PS0013 study: A Phase III, randomized, double-blind placebo-controlled multicenter study consisting of a 16-week initial treatment period followed by a 40-week randomized-withdrawal period to evaluate the efficacy and safety of bimekizumab administered subcutaneously in 435 adult participants with moderate to severe chronic plaque psoriasis.

The clinical pharmacology, efficacy and safety results from the evidence, the benefit/risk balance of Bimzelx is considered positive. Therefore, we recommend the approval of the marketing authorization of Bimzelx.

Product Information

The approved Summary of Product Characteristics (SPC) with the aforementioned studies were assessed by the SFDA efficacy and safety department. Based on the review of the submitted 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