# EDA Assessment Report for Biological Medicinal Product

**(Scientific Discussion)**

## Skyrizi 150mg

## Date: March 2024

**Unit: Technical Assessment Unit**

**Assessment report**

**Skyrizi**

## Administrative information:

| | |
|---|---|
| Trade name of the medicinal product: | Skyrizi |
| INN (or common name) of the active substance(s): | Risankizumab 150 mg |
| Manufacturer of the finished product | Abbvie Biotechnology Ltd, Road No.2, Km 59.2, Barceloneta, Puerto Rico 00617-USA |
| Product License holder | AbbVie Deutschland GmbH & Co. KG, Knollstrasse, 67061 Ludwigshafen, Germany. |
| Applied Indication(s): | Indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. |
| Pharmaceutical form(s) and strength(s): | Solution for injection, 150mg |
| Route of administration | Subcutaneous(S.C) |
| Approved Pack | Carton box that contains a prefilled pen that consists of 1ml (type I) borosilicate glass PFS glass. Each syringe includes a staked in place (integrated) 0.5 inch long, 27 gauge, special thin wall stainless steel needle, a fluoropolymer coated bromobutyl rubber plunger stopper and a rigid needle shield (RNS) composed of thermoplastic elastomer and polypropylene + insert leaflet |

## List of abbreviations

| | |
|---|---|
| CTD | common technical document |
| DS | Drug substance |
| EMA | European Medicines Agency |
| Ig G1 | immunoglobulin G1 |
| SC | Subcutaneous |

## Dossier initial submission and evaluation process.

- The product was submitted for registration via Reliance model level 1.
- The dossier was initially received from the registration administration units on 26.1.2022 when the applicant provided all the reliance required documents.
- EMA detailed assessment report was provided along with List of Questions day 120 and day 180.

- Full CTD was submitted as well.

1. **General introduction about the product including brief description of the AI, its mode of action and indications.**
   - The finished product is presented as solution for injection in Pre-filled Pen containing 150 mg of risankizumab as active substance.
     Other ingredients are: disodium succinate hexahydrate, succinic acid, sorbitol, polysorbate 20 and water for injection.
   - The product is available in pre-filled glass syringe with a fixed needle and needle cover, assembled in an automatic needle guard.
   - Risankizumab is a humanized immunoglobulin G1 (IgG1) monoclonal antibody that is directed against IL-23 p19. The framework of the risankizumab antibody has been engineered with 2 mutations in the Fc
     region to reduce Fcγ receptor and complement binding. Binding of risankizumab to IL-23 p19 inhibits the action of IL-23 to induce and sustain T helper (Th) 17 type cells, innate lymphoid cells, γδT cells, and natural killer (NK) cells responsible for tissue inflammation, destruction and aberrant tissue repair.

2. **Quality aspects:**

- **Manufacturer(s)**

  -Risankizumab drug substance (DS) is manufactured, tested and released under current good manufacturing practice (cGMP) at Boehringer Ingelheim Pharma GmbH & Co KG Birkendorfer Str. 65 88397 Biberach an der Riss - Germany.

  -The finished product is manufactured at: Abbvie Biotechnology Ltd, Road No.2, Km 59.2, Barceloneta, Puerto Rico 00617-USA

- **Stability:**
  **Drug Substance:**
  -Stability performed by: Boehringer Ingelheim Pharma GmbH & Co. KG Birkendorfer Strasse 65, 88397 Biberach an der Riss, Germany
  -Suggested Storage Conditions of the active substance: -70℃ or below
  -required shelf life for the active substance is 24 months.

  **Drug product:**
  -Stability performed by: AbbVie Deutschland GmbH & Co. KG, Knollstrasse, 67061 Ludwigshafen, Germany.
  -Suggested Storage Conditions: Store in a refrigerator 2-8 °C.
  -Do not freeze.

-Keep the Pre-filled pen in the outer carton in order to protect from light.
-Approved shelf life for the finished product is 2 years.

3. **Non-clinical and clinical aspects:**

-The risankizumab 150 mg/mL formulation did not show any test article-related signs of local intolerance following single intravenous, paravenous, or subcutaneous administration in animals.
-New drug delivery systems for risankizumab have been developed so that the recommended 150 mg dose can be administered as a single SC injection by a PFS or an AI device using PFS as a base.
-A single 150 mg SC injection of risankizumab (150 mg/mL formulation) PFS is bioequivalent to two 75 mg SC injections of the 90 mg/mL formulation PFS and the 150 mg/mL AI (1 × 150 mg injection) is bioequivalent to the 150 mg/mL PFS.
-In conclusion the overall benefit/risk of product name is favorable in the treatment of moderate to severe plaque psoriasis.

**General Conclusion and Recommendations if any:**
Based on the review of CTD modules and other supplementary documents, the product is approved.

**For more information, please visit EMA published assessment report link:**

**https://www.ema.europa.eu/en/documents/variation-report/skyrizi-h-c-004759-x-0020-g-epar-assessment-report-extension_en.pdf**