EDA Assessment Report for Biological Medicinal Product

(Scientific Discussion)

TECAVYLI 10 mg/ml
TECAVYLI 90 mg/ml

Date: August 2024

Assessment report

TECAVYLI

Unit: Technical Assessment Unit

Administrative information:

Trade name of the medicinal product:	TECVAYLI
INN (or common name) of the active substance(s):	Teclistamab 10 mg/ml Teclistamab 90 mg/ml
Manufacturer of the finished product	Patheon manufacturing services LLC, 5900 MARTIN LUTHER KING JR. HIGHWAY, GREENVILLE, NC,27834 - USA.
Marketing Authorization holder	Janssen-Cilag International NV, Turnhoutseweg 30, B-2340 Beerse-Belgium
Applied Indication(s):	TECVAYLI is indicated as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy.
Pharmaceutical form(s) and strength(s):	- Solution for injection -The strength is: 30 mg/vial (10 mg/mL) and 153 mg/vial (90 mg/mL)
Route of administration	Solution for S.C injection
Approved pack	For TECVAYLI 10mg/ml: Carton containing one glass vial of 3 mL solution for injection: -Glass vial: 6R Type 1 borosilicate glass European Blow Back (EBB) vial. -Rubber Stopper: 20 mm grey bromo butyl rubber stopper with fluoropolymer film and cross-linkable polydimethyl siloxane coating. -Aluminum seal with flip-off cap: 20 mm Flip Off seal, silver colored aluminum seal with a royal blue plastic flip off.with insert leaflet. -For TECVAYLI 90mg/ml: Carton containing one glass vial of 1.7 mL solution for injection: -Glass vial: 2 mL Type 1 borosilicate glass European Blow Back (EBB) vial. -Rubber Stopper: 13 mm grey chlorobutyl rubber stopper with fluoropolymer

	film and cross-linkable polydimethylsiloxane coating. -Aluminum seal with flip-off cap: 13 mm Flip Off seal, silver colored aluminum seal with an orange plastic flip off. With insert leaflet.

List of abbreviations

AI	Active ingredient
BCMA	B cell maturation antigen
CTD	Common Technical Document
DS	Drug substance
EBB	European Blow Back
EMA	European medicines Agency
IgG4	Immunoglobulin G4
SC	Subcutaneous

Dossier initial submission and evaluation process.

- The product was submitted for registration via reliance level I.
- The dossier evaluation by the registration administration units was started on 10.10.2023 after providing all the required documents (EMA list of questions along with Full CTD for the product).

1. **'General introduction about the product including brief description of the AI, its mode of action and indications:**

- Teclistamab drug substance (DS) is a novel immunoglobulin G4 (IgG4) bispecific antibody that binds to both B cell maturation antigen (BCMA) on malignant B-cells and cluster of differentiation 3 (CD3) receptors on T-lymphocytes. The BCMA targeting arm engages a BCMA presenting malignant B cell followed by the engagement of an activated T cell by the CD3 binding arm, resulting in malignant cell death due to cell lysis mediated by secreted perforin and various granzymes stored in the secretory vesicles of cytotoxic T cells.
- The finished product is presented as solution for injection containing 10 mg/mL or 90 mg/mL of teclistamab as active substance. Teclistamab should be administered by subcutaneous injection only. Other ingredients are: EDTA disodium salt dihydrate, Glacial acetic acid, Polysorbate 20, Sodium acetate trihydrate, Sucrose and Water for injection.
- The drug product is presented in Two concentrations:
  1-The 10 mg/mL teclistamab , each 10 mg/mL DP vial contains 30 mg of teclistamab in a 3.0 mL nominal fill volume and an excess volume of 0.5 mL per vial.

2-The 90 mg/mL teclistamab, each 90 mg/mL DP vial contains 153 mg of teclistamab in a 1.7 mL nominal fill volume and an excess volume of 0.3 mL per vial.

- Tecvayli is supplied as a sterile liquid in vial presentation for subcutaneous (SC) administration. The primary packaging consists of a Type 1 glass vial with an elastomeric closure and an aluminum seal with a flip off cap. The DP contains no preservative and is for single use only.
- TECVAYLI is indicated as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy.

2. **Quality aspects:**

Manufacturer(s)

- Drug substance:

Active substance is manufactured at:

- Biogen Inc. (BIIB), 5000 Davis Drive Research Triangle Park NC 27709 – USA
- Janssen Sciences Ireland UC,Barnahely,Ringaskiddy,Co.Cork – Ireland.
-Janssen Biologics B.V.Einsteinweg 101,-2333 CB Leiden- Netherlands.-Finished product:

- Drug product:

Finished product is manufactured at Patheon manufacturing services LLC, 5900 MARTIN LUTHER KING JR. HIGHWAY, GREENVILLE, NC,27834 - united states of America

Stability

- Drug substance:

- **Approved Storage Conditions:** -70 (±10) °C to -40 (±10) °C
- **Approved shelf life:**18 months

- Drug product:

- **Approved Storage Conditions:**

-Store in a refrigerator (2 °C - 8 °C). Do not freeze.
-Store in the original carton in order to protect from light.

- **Approved shelf life:** 18 months

3. Non-clinical and clinical aspects:

- Overall, teclistamab has been adequately characterized and acceptable from the non-clinical point of view.
- In conclusion the overall benefit/risk of Tecvayli is favorable in the treatment of: adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy.

- **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/assessment-report/tecvayli-epar-public-assessment-report_en.pdf