Report Tecvayli® - teclistamab

Product & Mechanism of action	Authorized indications Licensing status	Essential therapeutic features	NHS impact
Substance: teclistamab **Brand Name:** Tecvayli **Originator/licensee:** Janssen-Cilag International N.V. **Classification:** NCE **ATC code:** / **Orphan Status:** **Eu:** Yes **Us:** No **Mechanism of action:** Teclistamab is a bispecific antibody that targets the CD3 receptor expressed on the surface of T cells and BCMA, which is expressed on the surface of malignant multiple myeloma B-lineage cells [1].	**Authorized Indication:** **EMA:** teclistamab is indicated as monotherapy for the treatment of adults 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 [1]. **Route of administration:** SC **Licensing status** **EU CHMP P.O. date:** 21/07/2022 **FDA M.A. date:** / **EU Speed Approval Pathway:** No **FDA Speed Approval Pathway:** / --- **ABBREVIATIONS:** **AE**: Adverse Event **BCMA**: B cell maturation antigen **CHMP**: Committee for Medicinal products for Human Use **CRS**: Cytokine Release Syndrome **FIH**: First in human **ICANS**: immune effector cell–associated neurotoxicity syndrome **M.A.**: Marketing Authorization **MM**: Multiple Myeloma **MRD**: minimal residual disease **ORR**: overall response rate **P.O.**: Positive Opinion **Pts**: patients **Yrs**: years	**Summary of clinical EFFICACY:** MajesTEC-1 (NCT04557098) is a phase I/II, FIH, open-label, dose escalation study of teclistamab in pts aged ≥ 18 yrs, who had relapsed or refractory MM after at least three therapy lines. Including triple-class exposure to an immunomodulatory drug, a proteasome inhibitor and an anti-CD38 antibody. The primary end-point was the ORR (partial response or better). Pts (N=165) received teclistamab 1.5 mg/kg once weekly, after receiving step-up doses of 0.06 mg and 0.3 mg/kg. With a median follow-up of 14.1 months, the ORR was 63.0%, with 65 pts (39.4%) having a complete response or better. A total of 44 pts (26.7%) were found to have no MRD; the MRD-negativity rate among the pts with a complete response or better was 46% [2]. **Summary of clinical SAFETY:** Common AEs included CRS (in 72.1% of the pts; grade 3, 0.6%; no grade 4), neutropenia (in 70.9% of the pts; grade 3 or 4, 64.2%), anemia (in 52.1% of the pts; grade 3 or 4, 37.0%), and thrombocytopenia (in 40.0% of the pts; grade 3 or 4, 21.2%). Infections were frequent (in 76.4% of the pts; grade 3 or 4, 44.8%). Neurotoxic events occurred in 24 pts (14.5%), including ICANS in 5 pts (3.0%; all grade 1 or 2) [2]. **Ongoing studies:** ● ***For the same indication:*** Yes ● ***For other indications:*** Yes **Discontinued studies (for the same indication):** No **References:** [1].https://www.ema.europa.eu/en/medicines/human/summaries-opinion/tecvayli [2].https://www.nejm.org/doi/10.1056/NEJMoa2203478?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed [3].https://pubmed.ncbi.nlm.nih.gov/30470751/ [4].https://www.io.nihr.ac.uk/wp-content/uploads/2022/01/30599-Teclistamab-for-Multiple-Myeloma-V1.0-JAN2022-NON-CONF.pdf	**Cost of therapy:** Price is not available yet. **Epidemiology:** MM is a plasma cell neoplasm that accounts for 1%-1.8% of all cancers and is the second most common hematological malignancy with an estimated incidence in Europe of 4.5-6.0/100,000/year. Despite the significant improvement in patient's survival over the past 20 years, only 10%-15% of pts achieve or exceed expected survival compared with the matched general population [3]. --- **POSSIBLE PLACE IN THERAPY** NICE guidelines recommend Pomalidomide in combination with low-dose dexamethasone, for treating MM in adults at third or subsequent relapse; that is, after three previous treatments including both lenalidomide and bortezomib [4]. **OTHER INDICATIONS IN DEVELOPMENT**: No **SAME INDICATION IN EARLIER LINE(S) OF TREATMENT:** No **OTHER DRUGS IN DEVELOPMENT for the SAME INDICATION:** No *Service reorganization: No *Possible off label use: No

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