Tabelecleucel: Adis Evaluation

Key Points

- A highly selective, non-covalent, reversible BTK inhibitor being developed by Lilly for the treatment of B-cell leukemias and lymphomas
- Received its first approval on 27 January 2023 in the USA under the Accelerated Approval pathway
- Approved for use in adult patients with relapsed or refractory MCL after at least two lines of systemic therapy, including a BTK inhibitor

Summary

Tabelecleucel (EbvalloTM) is an allogeneic Epstein-Barr virus (EBV)-specific T-cell immunotherapy that targets and eliminates EBV positive (EBV+) cells in a human leukocyte antigen (HLA) restricted manner.

Tabelecleucel has been developed by Atara Biotherapeutics under a license from Memorial Sloan-Kettering Cancer Center (MSKCC) for the treatment of lymphoproliferative disorders (LPDs), including rituximab relapsed/refractory EBV+ post-transplant lymphoproliferative disease (PTLD).

Tabelecleucel was granted marketing authorization under 'exceptional circumstances' on 16 December 2022 as monotherapy for the treatment of adult and paediatric patients 2 years of age and older with relapsed or refractory EBV+ PTLD who have received at least one prior therapy. For solid organ transplant patients, prior therapy includes chemotherapy unless chemotherapy is inappropriate.

Keam S. J. Drugs. 2023. https://doi.org/10.1007/s40291-023-00648-z