Factsheet

U.S. Tabelecleucel Timeline

Last updated: *February 12, 2026*

> ***Tabelecleucel is seeking approval in the U.S. to treat patients with Epstein-Barr virus–positive post-transplant lymphoproliferative disease or disorder (EBV⁺ PTLD)*** *after at least one prior line of therapy. The safety and efficacy profile of tabelecleucel therapy has not been approved by the U.S. Food and Drug Administration.*

pre 2024

March 2015: FDA grants tabelecleucel, an EBV-targeted cytotoxic T lymphocyte, breakthrough designation. [source]

April 2016: FDA grants tabelecleucel orphan drug designation. [source]

November 2023: Pierre Fabre Laboratories acquires commercialization rights from Atara Biotherapeutics for US, Canada, and all remaining markets. [source]

2024

May 2024: BLA for tabelecleucel is submitted to the FDA. [source]

July 2024: FDA **accepts BLA submission** and grants priority review, expected PDUFA date ~January 2025. [source]

2025

January 2025: FDA issues a **Complete Response Letter (CRL)** and does not grant approval, solely citing **manufacturing issues**. [source 1] [source 2]

May 2025: Type A meeting with FDA results in agreement on a manufacturing remediation strategy and a BLA re-filing strategy. [source]

July 2025: BLA is re-submitted to the FDA, with the issues cited in the January 2025 CRL resolved. [source]

July 2025: FDA accepts BLA re-submission and grants priority review, expected PDUFA date ~January 2026. [source]

November 2025: Atara Biotherapeutics transfers BLA to partner Pierre Fabre Pharmaceuticals (PFP). [source]

December 2025: Expanded Access Program to support U.S. patients is launched.

2026

January 9, 2026: FDA issues a second **CRL** and does not grant approval. FDA confirms manufacturing issues resolved, but raises new concerns that were not communicated in the January 2025 CRL. [source 1] [source 2]

2022:
EBVALLO (tabelecleucel) is authorized and **commercially available to patients in the European Union.** [source 1] [source 2]

2023:
EBVALLO (tabelecleucel) is authorized and **commercially available to patients in the United Kingdom.** [source 1] [source 2]

2024:
EBVALLO (tabelecleucel) is authorized and **commercially available to patients in Switzerland.** [source 1] [source 2]

Key terms

FDA: U.S. Food and Drug Administration

BLA: Biologic license application

PDUFA date: approximate date for when FDA will make a decision about a drug approval

CRL: complete response letter

As of February 2026, ***over 120 patients*** *have been treated commercially outside of the U.S.*