Factsheet

Tabelecleucel Manufacturing

Overview of cell therapy production process

Tabelecleucel is an investigational cell therapy that does not require harvesting of cells directly from the patient being treated. It uses virus-specific T cells from healthy donors to create a therapy for multiple patients. Manufacturing of an allogeneic, donor-derived therapy requires substantial investment and creates a treatment that can be stored and provided rapidly when needed. This is important for an acute disease like relapsed refractory Epstein-Barr Virus Positive Post-Transplant Lymphoproliferative Disease or Disorder (EBV⁺ PTLD), in which many patients may have only weeks to a few months to live following failure of standard therapy.

Key terms

BLCL: B lymphoblastoid cell lines

CTL: cytotoxic T lymphocyte

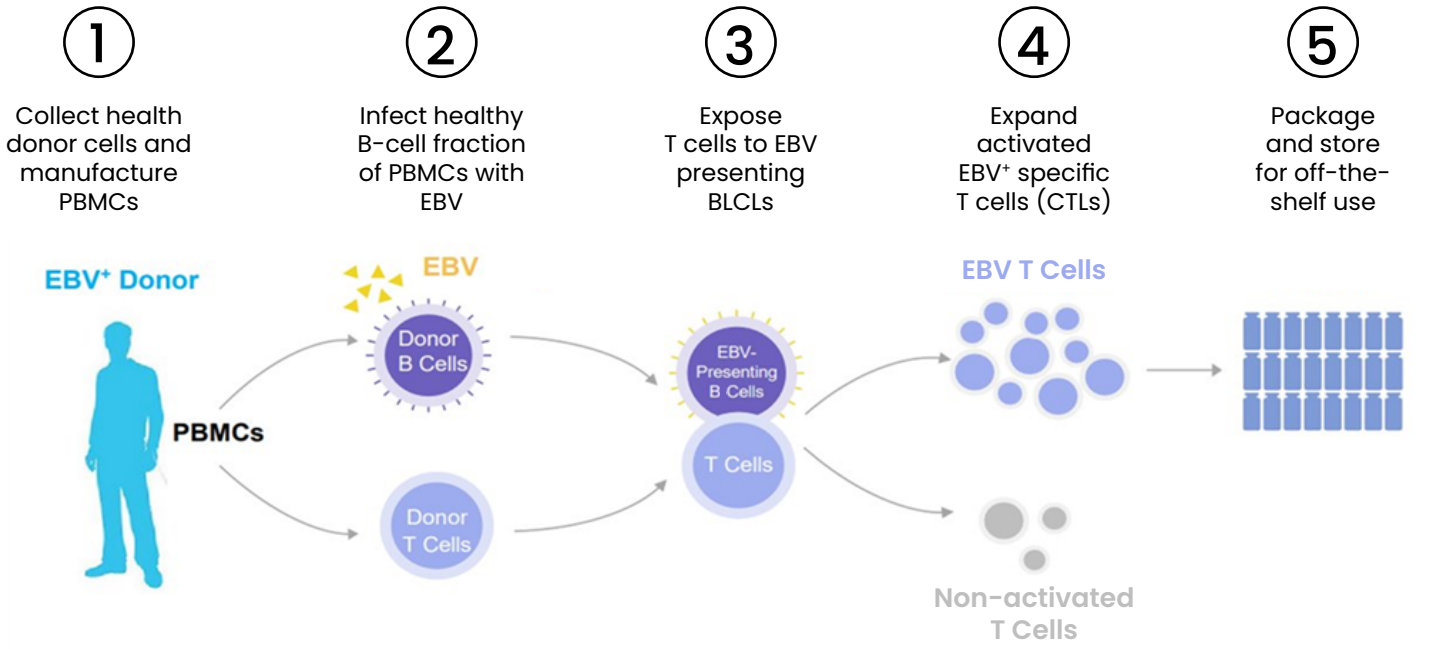
EBV: Epstein-Barr virus

EBV⁺: Epstein-Barr virus associated or positive

PMBC: peripheral blood mononuclear cells

PTLD: post-transplant lymphoproliferative disease or disorder

Overview of Tabelecleucel Manufacturing Process



Manufacturing steps

To achieve off-the-shelf availability, tabelecleucel is manufactured in the U.S. through a complex, multi-step process by an integrated network of partners across multiple states.

1 Collect health donor cells and manufacture PBMCs

Creation of the product starts with collection of cells from otherwise healthy EBV⁺ donors, a process that requires continuous screening of hundreds of candidates to find high-quality cells to begin manufacturing. Multiple candidates are needed as the immune status of each patient differs and different cell lots are needed to provide treatment that matches an appropriate lot for each patient. These cells are manufactured into Peripheral Blood Mononuclear Cells (PBMCs), the first intermediate in the manufacturing process.

2 Infect healthy B-cell fraction of PBMCs with EBV

Healthy B cells in the PBMCs are then infected with EBV.

3 Expose T cells to EBV presenting BLCLs

The T cells in the PBMCs are exposed to EBV infected B cells to augment their specificity for the virus. This produces the second intermediate of the manufacturing process B Lymphoblastoid Cell Lines (BLCLs). During this process, testing ensures the T cells are reactive to only EBV⁺ infected cells and are not harmful to normal healthy tissue.

4 Expand activated EBV specific T cells (CTLs)

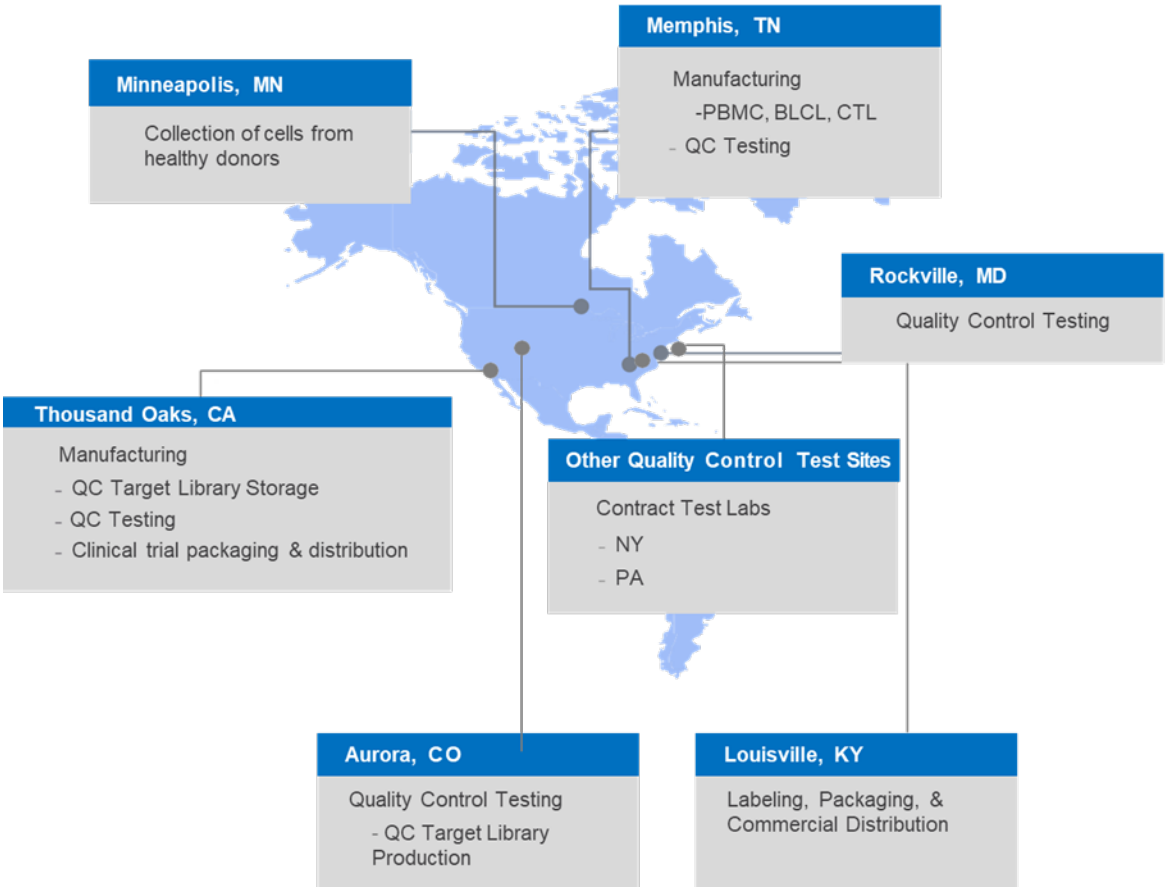
These highly EBV specific T cells are then expanded and characterized by immune status.

5 Package and store for off-the-shelf use

Tabelecleucel is packaged and cryopreserved (-17.22 °F or 150 °C) into treatment vials for long-term storage.

The failure rate at each step of the process is as high as 30%, as batches of cells that do not meet specific quality, purity, and safety standards are discarded. The manufacturing process is continuous, and inventory management is critical, as patients must be matched to a treatment based on immune system markers. New lots of tabelecleucel must be manufactured to replenish those used to help previously prescribed patients.

Overview of Tabelecleucel Manufacturing Network



What is tabelecleucel?

Tabelecleucel is investigational allogeneic, Epstein-Barr virus (EBV)-specific T cell immunotherapy, meaning it is made from EBV-specific T cells (immune cells that recognize the virus) collected from selected healthy donors. Tabelecleucel is being developed as a potential treatment for EBV^{+} PTLD in adults and pediatric patients 2 years of age and older who have received at least one prior therapy including an anti-CD20 containing regimen. The safety and efficacy profile of tabelecleucel has not been established and the investigational therapy has not been approved by the U.S. Food and Drug Administration (FDA).

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New ways to care

US--02-26-2600002 02/2026