Pierre Fabre
Pharmaceuticals Inc.
New ways to care

Pierre Fabre Pharmaceuticals Announces, Inc., Transfer from Atara Biotherapeutics, Inc. of the Biologics License Application (BLA) for Tabelecleucel as Treatment of Epstein-Barr Virus Positive Post-Transplant Lymphoproliferative Disease (EBV+ PTLD)

Tabelecleucel BLA currently under U.S. Food and Drug Administration (FDA) Priority Review as potentially the first approved therapy in the U.S. for EBV+ PTLD with a Prescription Drug User Fee Act (PDUFA) target action date of January 10, 2026

First allogeneic T-Cell therapy BLA offers hope to EBV+ PTLD patients who have limited treatment options and lifespan measured in only a few weeks to months following failure of initial treatment

EBV+ PTLD is an ultra-rare, acute, and potentially deadly blood malignancy that occurs after hematopoietic cell transplant (HCT) or solid organ transplant (SOT) when T-cell activity is impaired by immunosuppression

Pierre Fabre Laboratories and its subsidiaries are now responsible for all clinical development, regulatory, commercial, and manufacturing activities for tabelecleucel worldwide

SECAUCUS, NJ – November 3, 2025 - Pierre Fabre Pharmaceuticals Inc. (PFP) announces the transfer of the Biologics License Application (BLA) for tabelecleucel from Atara Biotherapeutics Inc. (Nasdaq: ATRA) with PFP now accountable for all aspects of the submission. Atara will continue to observe the regulatory process and provide support to PFP as needed. The tabelecleucel BLA has an FDA PDUFA target action date of January 10, 2026. If approved, the tabelecleucel will be indicated as monotherapy for treatment of adult and pediatric patients two years of age and older with EBV+ PTLD who have received at least one prior therapy.

Atara resubmitted the tabelecleucel BLA on July 11, 2025, in collaboration with PFP, and the FDA accepted the BLA with Priority Review on July 23. With completion of the transfer of the BLA, Pierre Fabre Laboratories and its subsidiaries are now responsible for all clinical development regulatory, commercial and manufacturing activities for tabelecleucel worldwide. The innovative cell therapy is manufactured by PFP in the US for global clinical development and commercial access.

"Transfer of the BLA represents another critical milestone in our efforts to bring this innovative cell therapy to EBV+ PTLD patients in the US who have limited treatment options and lifespan measured in only a few weeks to months following failure of initial treatment," said Adriana Herrera, Chief Executive Officer of PFP, the Pierre Fabre Laboratories Pharmaceutical subsidiary in the U.S. "We look forward to our continued engagement with the FDA in completing the review of tabelecleucel BLA as we seek to transform outcomes for this ultra-rare, acute, and potentially deadly blood malignancy that occurs after transplantation."

Tabelecleucel is an investigational, allogeneic, off the shelf, EBV-specific T-cell immunotherapy which targets and eliminates EBV-infected cells. The BLA includes data covering more than 430 patients treated with tabelecleucel including the ongoing pivotal ALLELE study investigating the therapy in adults and children two years of age and older with relapsed or refractory EBV+ PTLD following SOT or HCT.

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About EBV+PTLD

EBV+ PTLD is an ultra-rare, acute, and potentially deadly hematologic malignancy that occurs after transplantation when patient T-cell immune responses are compromised by immunosuppression. It can impact patients who have undergone solid organ transplant (SOT) or allogeneic HCT. Poor median survival of 3 weeks and 4.1 months for HCT and SOT, respectively, is reported in EBV+ PTLD patients for whom standard of care failed, underscoring the significant need for new therapeutic options.

About Tabelecleucel

Tabelecleucel is an allogeneic, off-the-shelf, EBV-specific T-cell immunotherapy designed to selectively target and eliminate EBV-infected cells. Unlike autologous CAR-T therapies, allogeneic T-cells are derived from third-party donors and are not genetically modified. Immune cells are collected from the blood of healthy donors and exposed to Epstein-Barr virus antigens to enrich for T cells that recognize EBV. These EBV T cells are expanded, characterized, kept alive, and stored for future use in treating patients.

About Pierre Fabre Pharmaceuticals and Pierre Fabre Laboratories

The mission of PFP is to deliver breakthrough therapies in oncology and rare diseases to patient populations with high unmet needs and limited treatment options. Our belief is that every time we care for a single person, we make the whole world better.

PFP is the U.S. pharmaceutical subsidiary of Pierre Fabre Laboratories, a foundation-owned company with seven decades of impact. Pierre Fabre Laboratories is a global healthcare company, established in 43 countries, with over 10,000 employees, and with products distributed in 120 territories across the globe. The Pierre Fabre Laboratories foundation ownership enhances the ability of the company to create long-term value for patients. Partnerships and acquisitions drive its innovative precision treatment pipeline and are enabled by the unique corporate structure.

Building on the legacy of Pierre Fabre Laboratories, innovation is the lifeblood of PFP, and patient experience drives everything the company does. PFP aspires to design and develop therapeutic solutions inspired by patients and healthcare professionals; draw on science and nature as perpetual sources of inspiration; develop long-term partnerships with researchers and innovators worldwide; and place pharmaceutical ethics and climate transition at the heart of our action.

Pierre Fabre Pharmaceuticals has therapies in development for Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLD), NRAS-mutant melanoma, non-small cell lung cancer with mutation or amplification of MET, and X-Linked Hypohidrotic Ectodermal Dysplasia (XLHED). Pierre Fabre Pharmaceuticals is headquartered in Secaucus, NJ.

For more information, visit www.pierrefabrepharmaceuticals.com, www.pierre-fabre.com, @Pierre Fabre Oncology.

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