



Pierre Fabre

Pharmaceuticals Inc.

New ways to care

Pierre Fabre Pharmaceuticals Announces FDA Acceptance of BLA Resubmission for Tabelecleucel for the Treatment of Epstein-Barr Virus-Positive Post-Transplant Lymphoproliferative Disease

The BLA has a Prescription Drug User Fee Act target action date of March 31, 2027

Accepted resubmission includes an updated dataset with additional patients and longer follow-up from the Phase 3 single-arm ALLELE study, as well as expansive supplemental data

If approved, tabelecleucel will be the first FDA-authorized treatment for relapsed/refractory EBV+ PTLD patients whose survival is measured in only a few weeks to months following failure of initial therapy

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

SECAUCUS, N.J., October 14, 2026 - Pierre Fabre Pharmaceuticals Inc. (PFP) announces the acceptance by U.S. Food and Drug Administration (FDA) of the Biologics License Application (BLA) resubmission for tabelecleucel, with a proposed indication as monotherapy for treatment of adult and pediatric patients two years of age and older with Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLD) who have received at least one prior therapy.

“People diagnosed with relapsed or refractory EBV+ PTLD urgently need new treatment options as they have no approved FDA therapies, and after failure of initial treatment their survival is limited, measured in only weeks to months,” said Adriana Herrera, Chief Executive Officer of PFP, the Laboratoires Pierre Fabre Pharmaceutical subsidiary in the U.S. “We look forward to a collaborative review process focused on the growing body of evidence supporting tabelecleucel approval including more patients and increased follow-up within our pivotal study and extensive supplemental data primarily from our ongoing early access programs and commercial experience in Europe.”

PFP resubmitted the BLA based on April 2026 Type A meeting alignment with the FDA. The submission includes an updated dataset with additional patients and longer follow-up from the ongoing, pivotal Phase 3 single-arm ALLELE study of tabelecleucel in adults and children two years of age and older with relapsed/refractory EBV+ PTLD following SOT or HCT. The resubmission also includes additional supplemental data from expanded access programs, a separate clinical study, and commercial experience in Europe.

“When your child receives a transplant, you celebrate. You breathe again. You start to imagine a future, but then sometimes, the phone rings with news that no parent should ever have to hear: your child has cancer,” said Melissa McQueen, President of Transplant Families, a pediatric non-profit connecting heart, liver, kidney, and bone marrow transplant patients and families. “We are hopeful that following the extensive dialogue with FDA, this resubmission will result in a path to patient access for U.S. families.”



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Tabelecleucel is an allogeneic, off-the-shelf, EBV-specific T-cell immunotherapy which is designed to target and attack EBV-infected cells. It was granted marketing authorization under the brand name EBVALLO™ in December 2022 by the European Commission. Marketing authorization was also granted by the Medicines and Healthcare Products Regulatory Agency in the United Kingdom in May 2023 and by Swissmedic in Switzerland in May 2024. In the U.S., tabelecleucel is investigational and has not yet been approved by the FDA. For eligible patients, it is available through clinical trials and expanded access programs.

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 SOT or allogeneic HCT. SOT patients have a life-long risk of contracting the disease. Poor median survival of 3 weeks and 4.1 months for HCT and SOT, respectively, is reported in EBV+ PTLD patients for whom initial treatment failed, underscoring the significant need for new therapeutic options.

About Pierre Fabre Pharmaceuticals and Laboratoires Pierre Fabre

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 US pharmaceutical subsidiary of Laboratoires Pierre Fabre, a foundation-owned company with seven decades of impact. Laboratoires Pierre Fabre 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 Laboratoires Pierre Fabre 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 Laboratoires Pierre Fabre, 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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