



Pierre Fabre Pharmaceuticals Announces Regulatory Update Following Type A Meeting with U.S. Food and Drug Administration (FDA) on Tabelecleucel Biologic License Application (BLA)

SECAUCUS, N.J., May 7, 2026 /PRNewswire/ -- Pierre Fabre Pharmaceuticals, Inc. (PFP), announces it has aligned with FDA on a potential path forward for resubmission of the BLA for tabelecleucel, an allogeneic T-cell therapy with a proposed indication for patients with Relapsed/Refractory (R/R) Epstein-Barr Virus Positive Post-Transplant Lymphoproliferative Disease (EBV+ PTLD) who have received at least one prior therapy including an anti-CD20 containing regimen.

“We thank the FDA review team for a productive discussion on the tabelecleucel BLA and look forward to finalizing the resubmission plan with the agency in the coming weeks,” said Adriana Herrera, Chief Executive Officer of PFP, the Pierre Fabre Laboratories pharmaceutical subsidiary in the United States. “U.S. patients living with this ultra-rare form of lymphoma urgently need an FDA-approved treatment option as none currently exist, and the lifespan of individuals with R/R EBV+ PTLD is often measured in weeks to months following failure of standard treatment.”

During the meeting, the FDA agreed that a single arm study using an appropriate historical control applicable to the trial population, conducted in a pre-specified manner, could serve as an adequate and well controlled study and provide safety and efficacy data in support of a marketing application of tabelecleucel for the proposed indication. As a part of the resubmission plan being defined with the FDA, PFP will submit an updated dataset with additional patients and longer follow up from the pivotal Phase 3 single arm ALLELE study of tabelecleucel in adults and children two years of age and older with R/R EBV+ PTLD following solid organ transplant or hematopoietic cell transplant as well as supportive data.

About Pierre Fabre Pharmaceuticals and Pierre Fabre Laboratories

The mission of Pierre Fabre Pharmaceuticals (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 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 life blood 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 Inc.

New ways to care

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

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