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New ways to care

Pierre Fabre Pharmaceuticals Inc. Announces FDA Acceptance and Priority Review of the Biologics License Application (BLA) for Tabelecleucel for the Treatment of Epstein-Barr Virus Positive Post-Transplant Lymphoproliferative Disease (EBV+ PTLD)

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

Tabelecleucel has a Prescription Drug User Fee Act (PDUFA) target action date of January 10, 2026 and would be the first approved therapy in the U.S. for EBV+ PTLD

Secaucus, New Jersey – July 24, 2025 - Pierre Fabre Pharmaceuticals Inc. (PFP) announces the acceptance by U.S. Food and Drug Administration (FDA) of the Biologics License Application (BLA) and Priority Review of tabelecleucel, indicated 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.

Atara Biotherapeutics Inc. (Nasdaq: ATRA) resubmitted the tabelecleucel BLA on July 11, having in collaboration with PFP, swiftly addressed the third-party manufacturing facility observations outlined in the January 2025 Complete Response Letter.

"Patients diagnosed with relapsed or refractory EBV+ PTLD have no approved FDA treatment options, and following failure of initial therapy their survival is unfortunately measured in only weeks to months. Today's BLA acceptance gives hope to these patients and is a significant step towards making this innovative cell therapy available in the United States," said Adriana Herrera, Chief Executive Officer of PFP, the Pierre Fabre Laboratories Pharmaceutical subsidiary in the U.S. "We are now completely focused on preparing for potential FDA approval of this innovative new treatment option."

Tabelecleucel is an 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.

Tabelecleucel was granted marketing authorization under the brand name EBVALLO™ in December 2022 by the European Commission (EC). 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.

Since March 31, 2025, PFP has assumed global responsibility for tabelecleucel manufacturing of commercial product for European markets and for global clinical trial supply. On July 15, 2025, Atara Biotherapeutics transferred the tabelecleucel Investigational New Drug Application to Pierre Fabre Medicament, a subsidiary

of Pierre Fabre Laboratories. As per the terms of the restated exclusive worldwide licensing agreement between Atara and Pierre Fabre Laboratories announced in November 2023, Atara is responsible for regulatory procedures up until BLA transfer to Pierre Fabre Pharmaceuticals.

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 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 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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