



Pierre Fabre

Pharmaceuticals Inc.

New ways to care

Pierre Fabre Pharmaceuticals Announces Type A Meeting Agreed with U.S. Food and Drug Administration (FDA) for Tabelecleucel Biologic License Application (BLA)

SECAUCUS, N.J., March 12, 2026 /PRNewswire/ -- Pierre Fabre Pharmaceuticals, Inc., announces the U.S. Food and Drug Administration (FDA) has agreed to Type A meeting for the biologic license application for tabelecleucel, an allogeneic T-cell therapy with a proposed indication for relapsed/refractory (R/R) Epstein-Barr Virus Positive Post-Transplant Lymphoproliferative Disease (EBV+ PTLD).

“We look forward to a collaborative and productive discussion with the FDA on a timely path forward to achieving accelerated approval of tabelecleucel in R/R EBV+ PTLD, an acute disease with no FDA-approved treatment options,” said Adriana Herrera, Chief Executive Officer of Pierre Fabre Pharmaceuticals Inc., the Pierre Fabre Laboratories pharmaceutical subsidiary in the United States. “It is essential to agree upon a timely approach to resubmission as the lifespan of patients with R/R EBV+ PTLD in the U.S. is often measured in weeks to months following failure of standard treatment.”

The meeting will address the Complete Response Letter received by PFP from the agency on January 9, 2026. The company anticipates providing a regulatory update on the outcome of the meeting in the second quarter.

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 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.

Pierre Fabre Pharmaceuticals, Inc.

500 Plaza Drive, Suite 701B, Secaucus, NJ, 07094

www.pierrefabrepharmaceuticals.com



Pierre Fabre

Pharmaceuticals Inc.

New ways to care

For more information, visit www.pierrefabrepharmaceuticals.com, www.pierrefabre.com, @Pierre Fabre Oncology

###

Pierre Fabre Pharmaceuticals Inc. US Media Contacts:

Dana Cooper

dana@dcoopercommunications.com

+1-732-239-6664

Eliza Schleifstein

eliza@schleifsteinpr.com

+1-917-763-8106

Pierre Fabre Pharmaceuticals, Inc.

500 Plaza Drive, Suite 701B, Secaucus, NJ, 07094

www.pierrefabrepharmaceuticals.com