Pierre Fabre
Pharmaceuticals Inc.
New ways to care

Pierre Fabre Pharmaceuticals Inc. announces the FDA Acceptance and Priority Review of the Biologics License Application for Tabelecleucel (Tab-cel®) for the Treatment of Epstein-Barr Virus Positive Post-Transplant Lymphoproliferative Disease

First Allogeneic T-Cell Therapy BLA Filing acceptance by U.S. Food and Drug Administration with a Prescription Drug User Fee Act (PDUFA) Target Action Date of January 15, 2025

If Approved, Tab-cel Would be the First Approved Therapy in U.S. for EBV+ PTLD and will be commercialized in the US by the newly established subsidiary Pierre Fabre Pharmaceuticals Inc.

The BLA is supported by data from the pivotal Phase 3 ALLELE study which was investigating Tab-cel in relapsed or refractory EBV+ PTLD following solid organ transplant (SOT) or hematopoietic cell transplant (HCT)

Parsippany, New Jersey – July 18, 2024 **-** Pierre Fabre Pharmaceuticals Inc. announces the acceptance by U.S Food and Drug Administration (FDA) of the Biologics License Application (BLA) and Priority Review of Tabelecleucel (Tab-cel®), 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. For solid organ transplant patients, prior therapy includes chemotherapy unless chemotherapy is inappropriate. There are no FDA approved therapies in this treatment setting.

The BLA has been granted Priority Review with a Prescription Drug User Fee Act (PDUFA) target action date of January 15, 2025.

"Patients facing relapsed or refractory EBV+ PTLD have no approved FDA treatment options, and with current therapeutic options their survival is unfortunately often measured in weeks or months. Today's BLA acceptance is a significant step towards making Tab-cel® available to patients in the United States. We congratulate our partner ATARA on this significant achievement and are now focused on preparing for potential FDA approval and launch of this innovative new treatment option for EBV+ PTLD." **said Adriana Herrera, Chief Executive Officer of Pierre Fabre Pharmaceuticals Inc., the new Pierre Fabre Medical Care subsidiary in the United States.** *"Following international recognition on June 24 for Tab-cel® with the Galien International Prize, we know we are on the right path to embody our purpose: every time we take care for a single person, we make the whole world better."*

Tab-cel® is an allogeneic, EBV-specific T-cell immunotherapy which targets and eliminates EBV-infected cells. The BLA is supported by data covering more than 430 patients treated with Tab-cel® including the latest pivotal ALLELE study data Tab-cel® in adults and children two years of age and older with relapsed or refractory EBV+ PTLD following solid organ transplant (SOT) or hematopoietic cell transplant (HCT).

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. Approval by the FDA and transfer of the BLA from ATARA to Pierre Fabre are anticipated in Q1 2025.

Tab-cel® 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. In all three territories, Ebvallo is indicated as monotherapy for the treatment of adult and pediatric patients two years of age and older with relapsed or refractory EBV+ PTLD who have received at least one prior therapy. For solid organ transplant patients, prior therapy includes chemotherapy unless chemotherapy is inappropriate.

About Pierre Fabre Pharmaceutical Inc.
Pierre Fabre Pharmaceuticals (PFP) is the new US pharmaceutical subsidiary of Pierre Fabre Laboratories, one of Europe's leading pharmaceutical companies. PFP is building on the company's 40-year history in oncology by delivering innovative breakthrough therapies for rare cancers and diseases with high unmet needs and limited treatment options. Headquartered in Parsippany, NJ, the company has therapies in development for NRAS-mutant melanoma, non-small cell lung cancer with mutation or amplification of MET, and X-Linked Hypohidrotic Ectodermal Dysplasia (XLHED).

About Pierre Fabre Laboratories
Pierre Fabre Laboratories is one of Europe's leading pharmaceutical companies. For over 40 years, it has established itself as an international player in oncology, mastering the entire value chain from R&D to marketing. Its portfolio of oncology specialties covers colorectal, breast, lung and skin cancers, as well as certain hematologic malignancies and precancerous dermatological conditions such as actinic keratosis. In 2023, its oncology revenue amounted to nearly 500 million euros, over 90% of which was generated outside France.

In 2023, Pierre Fabre Laboratories posted 2.83 billion euros in revenue, 70% of which came from international sales in 120 countries. Its portfolio includes several international brands and medical franchises such as Pierre Fabre Innovative Oncology, Pierre Fabre Medical Dermatology, Pierre Fabre Pharmaceutical Care, Eau Thermale Avène, Ducray, A-Derma, Klorane, René Furterer and Même Cosmetics.

Historically based in the southwest of France and manufacturing 95% of its products in France, Pierre Fabre Laboratories employs over 10,000 people worldwide. Its annual R&D budget amounts to nearly 200 million euros, of which about 50% is dedicated to targeted therapies in oncology and 40% to skin health and care solutions.

Pierre Fabre Laboratories' majority shareholder (86%) is the eponymous Foundation, which is recognized by the French government as being a public–interest foundation. This capital structure guarantees the company's independence and long-term vision. Dividends paid to the Pierre Fabre Foundation enable it to design and finance humanitarian healthcare-access programs in developing countries. Employees are the company's secondary shareholder, through an international employee shareholding plan.

Pierre Fabre Laboratories' sustainability policy has been assessed by the independent AFNOR Certification body and has been awarded the "Exemplary" level of its CSR label (ISO 26 000 standard for sustainable development).

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

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