Pierre Fabre
Pharmaceuticals Inc.

Updated Results of Phase 3 ALLELE Study Presented at 66th American Society of Hematology Annual Meeting Confirm Efficacy, Safety and Durability of Novel Allogeneic Cell Therapy Tabelecleucel in Relapsed or Refractory Epstein-Barr Virus Positive Post-Transplant Lymphoproliferative Disease (EBV+ PTLD)

Tabelecleucel treated relapsed or refractory EBV+ PTLD patients achieved a 50.7% Objective Response Rate (ORR), 23.0-month Median Duration of Response (DOR), and Median Overall Survival (OS) of 18.4 months

Safety findings consistent with prior studies with no reports of cytokine release syndrome, tumor flare reactions, immune effector cell-associated neurotoxicity syndrome, and organ rejection,

Biologics license application (BLA) under priority review by U.S. Food and Drug Administration (FDA) with a Prescription Drug User Fee Act (PDUFA) target action date of January 15, 2025

If approved, tabelecleucel would be the first approved allogeneic, off-the-shelf, T-cell therapy in U.S. and only FDA approved treatment for R/R EBV+ PTLD an ultra-rare, acute, and potentially deadly hematologic malignancy that occurs after life-saving transplantation

PARSIPPANY, N.J., Dec. 7, 2024- Pierre Fabre Pharmaceuticals Inc., today announced updated results presented at the 66th American Society of Hematology (ASH) Annual Meeting of the pivotal Phase 3 ALLELE study of tabelecleucel in adults and children two years of age and older with relapsed or refractory (R/R) EBV+ PTLD following solid organ transplant (SOT) or hematopoietic cell transplant (HCT). The oral presentation titled "Updated Clinical Results: A Multicenter, Open-Label, Phase 3 Study of Tabelecleucel for Solid Organ or Allogeneic Hematopoietic Cell Transplant Recipients with Epstein–Barr Virus-Driven Post Transplant Lymphoproliferative Disease after Failure of Rituximab or Rituximab Plus Chemotherapy," confirmed the efficacy, safety and durability of responses observed in prior studies.

"These clinically meaningful results highlight the potential of tabelecleucel in improving survival for R/R EBV+ PTLD patients, who after undergoing a potentially life-saving solid organ or hematopoietic cell transplant suddenly face yet another life-threatening illness. Currently, these patients have no FDA-approved treatment options and experience poor overall survival of only weeks to a few months following the failure of first-line treatment," said presenter and clinical investigator, Armin Ghobadi, MD, Professor of Medicine and Clinical Director of the Center for Gene and Cellular Immunotherapy at Washington University in St. Louis. "The updated data confirm the potential of tabelecleucel as a practice changing advance in addressing the significant unmet need in EBV+ PTLD."

The presentation of ALLELE data encompassed a larger cohort of 75 patients (49 SOT, 26 HCT) compared to the 43 patients included in the previously published data in *The Lancet Oncology*. The updated findings showed patients receiving tabelecleucel achieved a 50.7% objective response rate (ORR) with SOT ORR at 51.0% and HCT ORR at 50.0%. The median duration of response was 23 months, and median overall survival was 18.4 months.

In the study, patients received a median of two cycles of therapy. Each cycle of tabelecleucel included three infusions given on days 1, 8 and 15 with an imaging assessment of efficacy around day 28. Infusions were

given on an outpatient basis 67% of the time.

Safety findings presented were consistent with previously published data. Serious treatment emergent AEs (TEAEs) and fatal TEAEs were reported in 65.4% and 19.2% of HCT and 61.2% and 18.4% of SOT patients, respectively. No fatal TEAEs were reported by investigators to be treatment related and there were no reports of cytokine release syndrome, tumor flare or infusion reactions, immune effector cell-associated neurotoxicity syndrome, or transmission of infectious diseases. No events of graft vs host disease or organ rejection were reported as tabelecleucel related.

“The consistency of these data enhances our confidence in the potential tabelecleucel may bring to people living with R/R EBV+ PTLD. These patients and their families face a difficult journey to undergo a potentially life-saving transplant only to be diagnosed with this very rare form of cancer,” said Adriana Herrera, Chief Executive Officer of Pierre Fabre Pharmaceuticals Inc., the new Pierre Fabre Laboratories pharmaceutical subsidiary in the United States. “We look forward to the FDA target action date in January 2025 and if approved, the subsequent transfer of the BLA license from Atara Biotherapeutics, so we can bring this novel allogeneic cell therapy to people living with R/R EBV+ PTLD who urgently need new treatment options.”

In August 2024, the FDA accepted the BLA submitted by Atara Biotherapeutics and granted priority review for tabelecleucel indicated as monotherapy for treatment of adult and pediatric patients two years of age and older with EBV+ PTLD who have received at least one prior therapy. For solid organ transplant patients, prior therapy includes chemotherapy unless chemotherapy is inappropriate. The BLA is supported by pivotal and supportive data covering more than 430 patients treated with tabelecleucel across multiple life-threatening diseases.

Tabelecleucel is an allogeneic, off-the-shelf, EBV-specific T-cell immunotherapy designed to selectively target and eliminate EBV-infected cells. Unlike autologous CAR-T therapies, allogeneic T-cells are derived from third-party donors and are not genetically modified. Immune cells are collected from the blood of healthy donors and exposed to Epstein-Barr virus antigens to help enrich for T cells that recognize EBV. These EBV T cells are expanded, characterized, kept alive and stored for future use to treat patients.

Tabelecleucel was granted marketing authorization under the brand name EBVALLO® in December 2022 by the European Commission (EC) as a monotherapy for the treatment of adult and pediatric patients two years of age and older with r/r EBV+ PTLD who have received at least one prior therapy.

In December 2023, Atara announced an expanded global partnership with Pierre Fabre Laboratories for the U.S. and remaining global commercial markets for tabelecleucel, building on an initial partnership covering Europe, Middle East, Africa, and other select emerging markets.

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 solid organ transplant (SOT) or allogeneic HCT. Poor median survival of 3 weeks and 4.1 months for HCT and SOT, respectively, is reported in EBV+ PTLD patients for whom standard of care failed, underscoring the significant need for new therapeutic options.

Pierre Fabre
Pharmaceuticals Inc.

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 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 Parsippany, NJ.

# # #

Pierre Fabre Pharmaceuticals Inc. US Media Contact:
Dana Cooper
dana@dcoopercommunications.com
+1-732-239-6664
www.pierrefabrepharmaceuticals.com