Pierre Fabre Pharmaceuticals, Inc. Announces Transfer of Investigational New Drug Application for Tabelecleucel from Atara Biotherapeutics, Inc.

Pierre Fabre Laboratories is now responsible for all global clinical trial activities for the tabelecleucel clinical program

Enrollment is ongoing for pivotal, Phase 3 ALLELE Study (NCT03394365) investigating tabelecleucel in patients with EBV+PTLD in Solid Organ Transplant and Allogeneic Hematopoietic Cell Transplant after failure of standard therapy

NCT04554914 also open for enrollment to patients with EBV-associated diseases

Atara Biotherapeutics resubmitted the tabelecleucel Biologics License Application (BLA) to the U.S. Food and Drug Administration on July 11

Secaucus, NEW JERSEY – July 15, 2025 – Pierre Fabre Pharmaceuticals, Inc. today announced the transfer of the Investigational New Drug Application for tabelecleucel from its partner, Atara Biotherapeutics, Inc. (Nasdaq: ATRA). *"This announcement marks an important milestone as Pierre Fabre Laboratories assumes global responsibility for clinical development of tabelecleucel following transfer of manufacturing responsibilities earlier in the year,"* said Adriana Herrera, Chief Executive Officer of Pierre Fabre Pharmaceuticals., the Pierre Fabre Laboratories pharmaceutical subsidiary in the United States. *"Ongoing recruitment into the ALLELE study demonstrates our commitment to clinical research and development as we await regulatory action on the BLA resubmitted by our partner Atara."*

Atara Biotherapeutics resubmitted the tabelecleucel BLA on July 11, having rapidly addressed the third-party manufacturing facility observations outlined in the January 2025 Complete Response Letter in collaboration with Pierre Fabre Pharmaceuticals (PFP). On March 31, PFP assumed global responsibility for tabelecleucel manufacturing, including commercial product supply for European markets where the innovative cell therapy is already approved, as well as for global clinical trial supply. On July 14, 2025, Atara Biotherapeutics transferred the tabelecleucel IND to Pierre Fabre Medicament, a subsidiary of Pierre Fabre Laboratories.

The two studies currently open for tabelecleucel access in the US are:

NCT03394365: Tabelecleucel for Solid Organ or Allogeneic Hematopoietic Cell Transplant Participants with Epstein-Barr Virus-Associated Post-Transplant Lymphoproliferative Disease (EBV+ PTLD) After Failure of Rituximab or Rituximab and Chemotherapy (ALLELE)

The ALLELE study is investigating the effects of tabelecleucel, an off-the-shelf allogeneic Epstein-Barr virus (EBV)-specific cytotoxic T cell therapy, to treat relapsed/refractory EBV-associated post-transplant lymphoproliferative disease arising after SOT or HCT.

NCT04554914: A Study to Evaluate Tabelecleucel in Participants with Epstein-Barr Virus-associated Diseases

This study is a multicenter, multicohort, open-label, single-arm, Phase 2 study investigating the efficacy and safety of tabelecleucel for the treatment of EBV-associated 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 patent 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 patents for whom standard of care failed, underscoring the significant need for new therapeutic options.

About Pierre Fabre Pharmaceuticals (PFP) 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.

PFP 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). PFP is headquartered in Secaucus, NJ.

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

# # #

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