

Pierre Fabre to commercialize and distribute the first approved allogeneic T-cell immunotherapy in Europe following transfer of the European Commission Marketing Authorization of EBVALLO® (tabelecleucel)

Pierre Fabre to Lead Launch and Commercialization Activities for EBVALLO® In Europe Following Transfer of European Commission Marketing Authorization from Atara Biotherapeutics

EBVALLO® is the Only Approved Therapy for the Treatment of Relapsed or Refractory Epstein-Barr Virus Positive Post-Transplant Lymphoproliferative Disease (EBV+ PTLD) in the EU

CASTRES, France & THOUSAND OAKS, Calif. USA - February 8, 2023 - [Pierre Fabre](#) and [Atara Biotherapeutics, Inc.](#) (Nasdaq: ATRA) today announced the transfer of the European Commission (EC) marketing authorization (MA) for EBVALLO® (tabelecleucel) for patients with relapsed or refractory Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLD) from Atara to Pierre Fabre. From today, Pierre Fabre will lead all commercialization, distribution, medical and regulatory activities in Europe, Middle East, Africa and other selected markets. Pierre Fabre is planning to launch EBVALLO® in the first European countries during quarter one of 2023.

“We are delighted that, at Pierre Fabre, we will now be able to make EBVALLO® available to patients with Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLD) as quickly as possible,” said Eric Ducournau, CEO of Pierre Fabre. *“As a Company, we are passionate in accelerating the development and delivery of ground-breaking treatments for solid tumors, hematologic malignancies and rare diseases. With EBVALLO® being the only approved therapy for EU patients affected by EBV+ PTLD, this is a significant milestone for people diagnosed with this rare and potentially deadly cancer and an important step forward in our commitment to addressing clinical challenges with solutions once considered unimaginable.”*

On December 16, 2022, the EC granted marketing authorization for EBVALLO® as a 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. The EC marketing authorization is based on results from the pivotal Phase 3 ALLELE study and additional supportive studies. Based on these results, EBVALLO® demonstrated a favorable risk-benefit profile.¹

“Following the EU approval of EBVALLO®, Atara is the first company to obtain regulatory approval for an allogeneic T-cell immunotherapy, reinforcing the significant advantages of our EBV platform and approach” said Pascal Touchon, President and Chief Executive Officer of Atara. *“We are excited for Pierre Fabre to now bring this innovative new treatment to EBV+ PTLD patients in Europe who, until now, have had no approved therapeutic options and faced just a few weeks to a few months median survival.”*

EBVALLO® has orphan designation in Europe. Orphan designation is reserved for medicines treating life-threatening or chronically debilitating diseases that are rare (affecting not more than five in 10,000 people in the EU).

Atara will continue to be responsible for the pivotal ALLELE study in PTLD and the Phase 2 multi-cohort study, which is evaluating EBVALLO® in additional patient populations. Atara retains full rights to EBVALLO® in other major markets, including North America, Asia Pacific, and Latin America.

About EBVALLO® and EBV+ PTLD

EBVALLO® (tabelecleucel) is an allogeneic, EBV-specific T-cell immunotherapy which targets and eliminates EBV-infected cells in an HLA-restricted manner. EBV+ PTLD is a 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 0.7 months 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.

About Pierre Fabre

Pierre Fabre is a French healthcare company with over 35-years of experience in innovation, development, manufacturing and commercialization in oncology. Its portfolio includes several medical franchises and international brands, namely Pierre Fabre Oncology, Pierre Fabre Dermatology, Pierre Fabre Health Care, Eau Thermale Avène, Klorane, René Furterer, ADerma, Darrow, Glytone, Naturactive and Pierre Fabre Oral Care. The company has declared oncology its top priority in medical care R&D and commercialization, focusing on targeted therapies, biotherapies and immuno-oncology. Its portfolio covers oncology (colorectal, breast, lung cancers, melanoma and pre-cancerous conditions like actinic keratosis), hematology and rare diseases. In 2021, Pierre Fabre posted 2.5 billion euros in revenues, 66% of which came from international sales in over 100 countries.

Established in the South-West of France since its creation, the group manufactures over 95% of its products in France and employs some 9,500 people worldwide. Pierre Fabre is 86%-owned by the Pierre Fabre Foundation, a government-recognized public-interest foundation, and secondarily by its own employees through an international employee stock ownership plan. Pierre Fabre's social responsibility approach has been assessed by the independent organisation AFNOR Certification at the "Exemplary" level of the CSR label (ISO 26 000 standard for sustainable development).

Further information about Pierre Fabre can be found at www.pierre-fabre.com, @PierreFabre.

About Atara Biotherapeutics, Inc.

[Atara Biotherapeutics, Inc. \(@Atarabio\)](http://www.atarabio.com) is a pioneer in T-cell immunotherapy leveraging its novel allogeneic EBV T-cell platform to develop transformative therapies for patients with serious diseases including solid tumors, hematologic cancers and autoimmune disease. With our lead program receiving marketing authorization in Europe, Atara is the most advanced allogeneic T-cell immunotherapy company and intends to rapidly deliver off-the-shelf treatments to patients with high unmet medical need. Our platform leverages the unique biology of EBV T cells and has the capability to treat a wide range of EBV-associated diseases, or other serious diseases through incorporation of engineered CARs (chimeric antigen receptors) or TCRs (T-cell receptors). Atara is applying this one platform, which does not require TCR or HLA gene editing, to create a robust pipeline including: tab-cel for Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLD) and other EBV-driven diseases; ATA188, a T-cell immunotherapy targeting EBV antigens as a potential treatment for multiple sclerosis; and multiple next-generation chimeric antigen receptor T-cell (CAR-T) immunotherapies for both solid tumors and hematologic malignancies. Improving patients' lives is our mission and we will never stop working to bring transformative therapies to those in need. Atara is headquartered in Southern California.

For additional information about the company, please visit atarabio.com and follow us on [Twitter](https://twitter.com/Atarabio) and [LinkedIn](https://www.linkedin.com/company/atarabio).

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¹ Mahadeo KM, *et al.* New and Updated Results from a Multicenter, Open-Label, Global Phase 3 Study of Tabelecleucel (Tab-cel) for Epstein-Barr Virus-Positive Post-Transplant Lymphoproliferative Disease (EBV+ PTLD) Following Allogeneic Hematopoietic Cell (HCT) or Solid Organ Transplant (SOT) after Failure of Rituximab or Rituximab and Chemotherapy (ALLELE). *Blood*. 2022;140(1): 10374–10376.