



Pierre Fabre

Pierre Fabre Laboratories to accelerate their development in onco-hematology by acquiring the license for a breakthrough T-cell immunotherapy in North America

Pierre Fabre Laboratories to Acquire from Atara Biotherapeutics Commercialization Rights to EBVALLO® in the United States, Canada and All Remaining Markets

Pierre Fabre Laboratories to Take Over All Manufacturing, Clinical, and Regulatory Activities for EBVALLO® Following Transition Period

This strategic acquisition enables Pierre Fabre Laboratories to gain a foothold in the United States in the field of oncology

Castres, France, November 3, 2023 — Pierre Fabre Laboratories announced today an expanded global partnership with Atara Biotherapeutics, a leader in T-cell immunotherapy, leveraging its novel allogeneic Epstein-Barr virus (EBV) T-cell platform, for EBVALLO® (tabelecleucel) a monotherapy already registered in the EU for the treatment of adult and pediatric patients two years of age and older with relapsed or refractory Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLD) who have received at least one prior therapy. 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.

This geographical expansion of the licensing rights encompasses the USA, Canada and all remaining territories. Pierre Fabre Laboratories already acquired the rights for Europe in October 2021 and EBVALLO® was approved by EMA in December 2022. EBVALLO® is, as of today, commercialized in Germany and Austria.

“Since EBVALLO®’s marketing authorization in Europe less than a year ago, patients have already been treated in Germany, or have benefited from the treatment through the Early Access Program in place in other European countries” said Eric Ducournau, CEO of Pierre Fabre Laboratories. *“We are now eager to progress on the upcoming FDA milestones in the next months and ensure American patients diagnosed with EBV+ PTLD can access this novel therapy”.*

“We are proud to expand our global EBVALLO® partnership with Pierre Fabre Laboratories, who is committed to deliver this first-of-its kind treatment to patients in need across the globe” said Pascal Touchon, President and Chief Executive Officer of Atara.

According to the expanded Global EBVALLO® Partnership between Pierre Fabre Laboratories and Atara Biotherapeutics:

- Atara will receive up to \$640M and significant double-digit tiered royalties on net sales from Pierre Fabre Laboratories. In addition, Pierre Fabre Laboratories has agreed to reimburse Atara for expected EBVALLO® global development costs through transfer of the BLA (Biologics License Application) approval by the FDA in the US and purchase current and future EBVALLO® inventory through the BLA transfer date.
- Near-term payments to Atara include:
 - Approximately \$30M in cash up front and initial inventory purchase at closing
 - \$100M in potential regulatory milestones through BLA approval
- Substantially all EBVALLO® manufacturing, clinical, and regulatory activities are planned to transition from Atara to Pierre Fabre Laboratories at the time of BLA approval transfer
- Atara expects to submit the EBVALLO® PTLD BLA in Q2 2024

The closing of the transaction, subject to expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and other customary closing conditions, is expected to occur in December 2023.

“Pierre Fabre Laboratories have made oncology their top priority in Medical Care. Since 2019, we have almost tripled our revenues in this therapeutic field, and we expect to pass the 500M€ bar this year. This expansion of our partnership with Atara will allow us to make a first step in the US, by far the largest oncology market in the world, and to reach even more patients in need for innovative treatments” added Eric Ducournau, CEO of Pierre Fabre Laboratories.

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.

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).

About Pierre Fabre Laboratories

Pierre Fabre Laboratories is a leading French medical and beauty care company with 4 decades of experience in innovation, development, manufacturing, and commercialisation in oncology. The company dedicated about 80% of its R&D spendings to oncology in 2022 and has recently declared targeted therapies as its main R&D priority. Its current commercial portfolio in oncology covers colorectal, breast and lung cancers, melanoma, haematology, and pre-cancerous skin conditions like actinic keratosis.

In 2022, Pierre Fabre Laboratories posted 2.7 billion euros in revenues, 69% of which came from international sales in 120 countries. Established in the South-West of France since its creation in 1962, the Group manufactures over 90% of its products in France and employs some 9,600 people worldwide. The company is 86%-owned by the Pierre Fabre Foundation, a government-recognised public-interest foundation, and secondarily by its own employees through an international employee stock ownership plan. Pierre Fabre Laboratories 's sustainability policy has been assessed by the independent AFNOR Certification body at the "Exemplary" level of its CSR label (ISO 26 000 standard for sustainable development).

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

Media Contacts:

Laure Sgandurra
+33 6 32 54 92 01
laure.sgandurra@pierre-fabre.com