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**Pierre Fabre**

## **Pierre Fabre Laboratories receives the Galien International Prize for EBVALLO<sup>®</sup>, the first allogeneic immunotherapy for patients with a rare cancer**

Castres, France, June 21, 2024 - Pierre Fabre Laboratories has been awarded the “Prix Galien International” Prize in the “Best Product for a Rare/Orphan Disease” category for EBVALLO<sup>®</sup> (tabelecleucel), indicated as monotherapy for the treatment of patients with post-transplant lymphoproliferative disorder positive for Epstein-Barr virus (EBV+ PTLD) who have received at least one prior treatment.

During the same ceremony, EBVALLO<sup>®</sup> received the “Prix Galien” Italy Award in the Advanced Therapy Medicinal Product category. These two exceptional recognitions follow the awarding of EBVALLO<sup>®</sup> for the “Prix Galien France” on December 2023

EBV+ PTLD is a rare and potentially lethal hematological malignancy. This type of lymphoma might arise in transplant patients with compromised immune response due to immunosuppression, allowing the EBV virus to proliferate and develop a lymphoproliferative disease. EBVALLO<sup>®</sup> is a cytotoxic treatment composed of T lymphocytes directed against the Epstein-Barr virus epitope present on the surface of the cancer cells. The treatment is prepared from cells from healthy donors immunized against the EBV virus. Cells from different donors are stored in a ready-to-be-selected bank and sent to a patient when needed.

As a symbol of scientific rigor, excellence, and innovation, the “Prix Galien International” awards remarkable recent health innovations available to the public, following an evaluation done by an independent committee of experts. Today this prize exists in fifteen countries, its reputation and influence have made it the most prestigious distinction in the medical field. Through this prize, the jury honors EBVALLO<sup>®</sup>, thanks to its innovative manufacturing process and mechanism of action. It offers rapid and lasting clinical results in over 50% of cases, in a rare disease with a particularly unfavorable prognosis, leading to significant morbidity and mortality.

This award highlights the innovation capacity of Pierre Fabre Laboratories in oncology, one of its priority areas of development, and its ability to establish successful collaborations, such as the one with Atara Biotherapeutics (ATARA), an American biotech company. A global agreement was signed in December 2023, providing Pierre Fabre Laboratories with the EBVALLO<sup>®</sup> development, manufacturing, and commercialization rights all over the world. EBVALLO<sup>®</sup> was approved by the European Medicines Agency (EMA) in December 2022, and to date, this promising new treatment is marketed in Germany and Austria. In Europe, EBVALLO<sup>®</sup> is available to patients as part of an Early Access Program since July 2023.

*“We are very proud to receive this award, which we dedicate to the patients. It is a recognition of the major therapeutic advancement that EBVALLO<sup>®</sup> represents for patients with a rare cancer and a very unfavorable prognosis, who until now had significant unmet needs. This cancer, which affects a few hundred people worldwide each year, resonates perfectly with our purpose: every time we take care for a single person, we make the whole world better.”* said Éric Ducournau, CEO of the Pierre Fabre Laboratories.

*“This distinction of EBVALLO<sup>®</sup>, the first allogeneic T-cell immunotherapy from a healthy donor, is a tremendous encouragement to continue our efforts against rare diseases in order to provide support and care to each patient who endures not only the difficulties associated with their condition, but who*



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*is also faced, all too often, with the absence of therapeutic solutions. Therefore, we would like to dedicate this award to the patients who are at the heart of our mission, as well as to the dedicated teams who have invested their expertise in our ongoing quest for research and innovation in the treatment of rare diseases."* said Núria Perez-Cullell, Director of Medical, Patient, and Consumer Affairs at Pierre Fabre Laboratories.

### **About the Galien Foundation and the Prix International**

The Galien Foundation is the world's leading institution dedicated to recognizing innovative actors in the life sciences field. The "Prix Galien International" is the highest distinction awarded every two years for pharmaceutical research. It distinguishes remarkable recent health innovations that are available to the public, as well as emblematic research work. It honors exceptional innovations in all areas of health: drugs, medical devices, e-health, and patient support. Eligible candidates have received a national "Prix Galien" in the past two years. Nominations for the 2024 Galien International Awards include winners who received a national Galien Prize in 2022 and 2023. The jury members include distinguished experts and specialists in each category. The reputation of the jury members, their scientific rigor, and independence have established the institutional nature of the Prix Galien with the healthcare sector and public authorities.

For more information: <https://www.galienfoundation.org/>

### **About EBVALLO® and EBV+ PTLD**

EBVALLO® (tabelecleucel) is an allogeneic immunotherapy composed of T lymphocytes specific for the Epstein-Barr virus (EBV) that targets and eliminates EBV-infected B cells in a human leukocyte antigen (HLA) restricted manner. PTLD EBV+ is a rare and potentially fatal hematological malignancy that occurs after transplantation when the patient's T-cell activity is compromised by immunosuppression. It can affect patients who have undergone organ transplantation (SOT) or hematopoietic stem cell transplantation (HSCT). Patients with EBV+ PTLD who have failed rituximab ± chemotherapy have an unfavorable prognosis with a poor median survival of 0.7 months for HSCT and 4.1 months for SOT, highlighting the need for new effective, safe, and fast-acting therapeutic solutions.

EBVALLO® has received orphan drug designation in Europe. Orphan drug designation is reserved for drugs intended for the treatment of rare diseases (affecting no more than five people per 10,000 in the EU) that pose a threat to life or chronic disability.

### **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 Môme 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

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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](http://www.pierre-fabre.com), [@PierreFabreGroup](https://twitter.com/PierreFabreGroup).

## **Pierre Fabre Laboratories Media Contact:**

Laurence Marchal

+33 7 88 88 54 47

[Laurence.marchal@pierre-fabre.com](mailto:Laurence.marchal@pierre-fabre.com)

