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# Atara Biotherapeutics and Pierre Fabre Laboratories Announce Publication of Phase 3 ALLELE Tab-cel® Data in The Lancet Oncology

*First Phase 3 Results Published for an Allogeneic T-Cell Therapy*

*Significant 51.2% Objective Response Rate and 23.0 Month Median Duration of Response in Relapsed or Refractory EBV+ PTLD Patients*

*U.S. BLA on Track for Submission in Q2 2024 Based on Strong Clinical File*

THOUSAND OAKS, Calif. & CASTRES, France--(BUSINESS WIRE)-- [Atara Biotherapeutics, Inc.](#) (Nasdaq: ATRA), a leader in T-cell immunotherapy, leveraging its novel allogeneic Epstein-Barr virus (EBV) T-cell platform to develop transformative therapies for patients with cancer and autoimmune diseases, and Pierre Fabre Laboratories, a global player in oncology and responsible for worldwide commercialization of tabellecleucel (tab-cel® or EBVALLO™), today announced that data from the pivotal Phase 3 ALLELE study of tab-cel, approved in the European Union in adults and children two years of age and older with relapsed or refractory (r/r) Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLD) following solid organ transplant (SOT) or hematopoietic cell transplant (HCT), were published for the first time online in *The Lancet Oncology*.

The data were published in an article titled, "Tabellecleucel for allogeneic haematopoietic stem-cell or solid organ transplant recipients with Epstein–Barr virus-positive post-transplant lymphoproliferative disease after failure of rituximab or rituximab and chemotherapy (ALLELE): a phase 3, multicentre, open-label trial," and can be accessed at the following link: [https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045\(23\)00649-6/fulltext](https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(23)00649-6/fulltext)

"The results of the ALLELE study highlight the clinical value of tab-cel, which is now EMA and MHRA approved, and is being made available to patients in Europe through our partner Pierre Fabre Laboratories as a first-of-its-kind treatment for those with a devastating disease that previously had limited treatment options," said Pascal Touchon, President and Chief Executive Officer of Atara. "As we prepare for our tab-cel BLA submission in the second quarter 2024, we look forward to interacting with the FDA to progress towards approval based on our robust clinical data."

As reported in The Lancet Oncology publication, the ALLELE study met its primary endpoint. 22 of 43 EBV+ PTLD patients achieved an objective response (51.2% objective response rate, or ORR). Those that responded to tab-cel had longer survival, with an estimated one-year overall survival of 84.4% (95% CI: 58.9, 94.7) for responders versus 34.8% (95% CI: 14.6, 56.1) for non-responders. The median duration of response was 23.0 months and the median overall survival was 18.4 months. Tab-cel was well tolerated with no reports of tumor

flare reaction, cytokine release syndrome or immune effector cell-associated neurotoxicity syndrome, and no events of graft-versus-host disease or SOT rejection as related to tab-cel. These interim data were [previously presented](#) at the 2022 American Society of Hematology (ASH) Annual Meeting.

These pivotal trial data are supported by a recent updated analysis from the October 2023 data cut of the ongoing ALLELE study that continued to demonstrate a statistically significant 49% ORR ( $p < 0.0001$ ), consistent durability of response, estimated OS, and favorable safety profile in the intended population for the proposed U.S. label. In addition, real-world results from the multicenter Expanded Access Program study in Europe demonstrated an ORR of 66.7% in 24 EBV+ PTLD patients and were [presented](#) at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting.

“Patients with relapsed or refractory EBV+ PTLD have limited treatment options and poor overall survival measured in only weeks to months,” said Susan Prockop, MD, lead investigator, Boston Children’s Hospital-Dana Farber Cancer Institute. “These clinically meaningful data reinforce the life-saving potential of tabelecleucel for these patients, for whom there are no approved therapies in the U.S. and helps address an urgent unmet medical need.”

Tab-cel 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. For solid organ transplant patients, prior therapy includes chemotherapy unless chemotherapy is inappropriate. In the United States, Atara plans to submit a biologics license application (BLA) to the U.S. Food and Drug Administration for tab-cel for the treatment of EBV+ PTLD in the second quarter of 2024. Additionally, in December 2023, Atara [reported the first results](#) from the ongoing Phase 2 EBVision trial, which has the potential to further extend the clinical experience and potential of tab-cel into broader indications.

In December 2023, Atara announced the closing of the 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.

"Current results from the first global, multicenter, open-label Phase 3 study of the new allogeneic T-cell therapy, tabelecleucel, show significant clinical benefit and a favorable safety profile in a severely affected population. These results bring a lot of hope for patients, and confirm the innovative nature of this treatment, also recognized through the Prix Galien prize that we received in France. With the recent EU marketing authorization, EBVALLO™ is the first EBV-specific allogeneic T-cell therapy available for patients with r/r EBV+ PTLD after HCT or SOT and their families. All this resonates perfectly with our purpose ‘every time we care for a single person, we make the whole world better,’” said Núria Perez-Cullell, Director of Medical Affairs, Patients & Consumers at Pierre Fabre Laboratories.

### **About Atara Biotherapeutics, Inc.**

Atara is harnessing the natural power of the immune system to develop off-the-shelf cell therapies for difficult-to-treat cancers and autoimmune conditions that can be rapidly

delivered to patients within days. With cutting-edge science and differentiated approach, Atara is the first company in the world to receive regulatory approval of an allogeneic T-cell immunotherapy. Our advanced and versatile Epstein-Barr virus (EBV) T-cell platform does not require T-cell receptor or HLA gene editing and forms the basis of a diverse portfolio of investigational therapies that target EBV, the root cause of certain diseases, in addition to next-generation AlloCAR-Ts designed for best-in-class opportunities across a broad range of hematological malignancies and B-cell driven autoimmune diseases. Atara is headquartered in Southern California. For more information, visit [atarabio.com](https://atarabio.com) and follow [@Atarabio](#) on [X](#) and [LinkedIn](#).

## **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 commercialization in oncology. The company dedicated about 80% of its R&D spendings to oncology in 2022 with a focus on targeted therapies. Its current commercial portfolio in oncology covers colorectal, breast and lung cancers, melanoma, hematology, 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 90% of its products in France and employs some 10 000 people worldwide. The company is 86%-owned by the Pierre Fabre Foundation, a government-recognized public-interest foundation, and by its own employees through an international employee stock ownership plan. Pierre Fabre Laboratories' 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](https://www.pierre-fabre.com), [@PierreFabre](#).

## **Forward-Looking Statements**

This press release contains or may imply "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. For example, forward-looking statements include statements regarding the development, data, timing and progress, as applicable, of: (1) the tab-cel program, including a potential BLA submission for tab-cel in the United States; (2) the potential characteristics and benefits of tab-cel, including data and analyses from the ALLELE study and timing of when such data will be received and communicated; and (3) the amended and restated commercialization agreement with Pierre Fabre. Because such statements deal with future events and are based on Atara's current expectations, they are subject to various risks and uncertainties and actual results, performance or achievements of Atara could differ materially from those described in or implied by the statements in this press release. These forward-looking statements are subject to risks and uncertainties, including, without limitation, risks and uncertainties associated with the costly and time-consuming pharmaceutical product development process and the uncertainty of clinical success; the ongoing COVID-19 pandemic and the wars in Ukraine and the Middle East, which may significantly impact (i) our business, research, clinical development plans and operations, including our operations in Southern California and Denver and at our clinical trial sites, as

well as the business or operations of our third-party manufacturer, contract research organizations or other third parties with whom we conduct business, (ii) our ability to access capital, and (iii) the value of our common stock; the sufficiency of Atara's cash resources and need for additional capital; and other risks and uncertainties affecting Atara's and its development programs, including those discussed in Atara's filings with the Securities and Exchange Commission, including in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of the Company's most recently filed periodic reports on Form 10-K and Form 10-Q and subsequent filings and in the documents incorporated by reference therein. Except as otherwise required by law, Atara disclaims any intention or obligation to update or revise any forward-looking statements, which speak only as of the date hereof, whether as a result of new information, future events or circumstances or otherwise.

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**Atara Investor and Media Relations:**

Alex Chapman

Vice President, Corporate Communications & Investor Relations

(805) 456-4772

[achapman@atarabio.com](mailto:achapman@atarabio.com)

Jason Awe, Ph.D.

Senior Director, Corporate Communications & Investor Relations

(805) 217-2287

[jawe@atarabio.com](mailto:jawe@atarabio.com)

**Pierre Fabre Laboratories Media Contact:**

Laurence Marchal

+33 7 88 88 54 47

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

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