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CHMP Recommends Approval of Atara Biotherapeutics' Ebvallo™ (tabelecleucel) for the Treatment of Epstein-Barr Virus-Positive Post-Transplant Lymphoproliferative Disease

Ebvallo™ on Track to be the First Ever Allogeneic T-Cell Therapy Approved

Positive Opinion Based on Pivotal Phase 3 ALLELE Study Demonstrating a Favorable Risk-Benefit Profile

European Commission Approval Expected in Q4 2022

SOUTH SAN FRANCISCO, Calif. & CASTRES, France--(BUSINESS WIRE)-- [Atara Biotherapeutics, Inc.](#) (Nasdaq: ATRA) and Pierre Fabre today announced the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending the European Commission (EC) approval of Ebvallo™ (tabelecleucel) as a monotherapy for 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. For solid organ transplant patients, prior therapy includes chemotherapy unless chemotherapy is inappropriate.

"Today's positive CHMP opinion is a major step forward for Atara's first-in-class product that addresses an ultra-rare and aggressive cancer with no approved therapies while providing further validation for our unique allogeneic EBV T-cell platform," said Pascal Touchon, President and CEO of Atara. "If approved, Ebvallo™ will be the first ever allogeneic T-cell therapy and has the potential to change the treatment paradigm for patients with relapsed or refractory EBV+ PTLD who face a poor prognosis and dismal median survival of only weeks to a few months."

The CHMP positive opinion is based on results from the pivotal Phase 3 ALLELE study.¹ In this study, Ebvallo™ demonstrated a favorable risk-benefit profile.

"This positive opinion is a landmark moment for patients suffering from an extremely rare cancer," said Eric Ducournau, CEO of Pierre Fabre, Atara's commercialization partner in Europe. "Ebvallo™ is on track to be the first ever allogeneic T-cell therapy approved in the European Union. Our teams are excited and poised to bring this first-in-kind innovation to European patients, as a testimony to our corporate purpose: every time we care for a single person, we make the whole world better."

“All patients undergoing transplant are at risk of developing EBV+ PTLD during their life, and in that case, those that do not respond to initial treatment have few treatment options left,” said Dr. Sylvain Choquet, Head of the Clinical Hematology Department at Pitié-Salpêtrière, APHP, France. “There is an urgent unmet need for effective therapies for this rare B-cell lymphoproliferative disease, with data from the pivotal study demonstrating the potential for Ebvallo™ to change the treatment of relapsed or refractory EBV+ PTLD and provide a much-needed therapeutic solution to both patients and physicians.”

With the CHMP positive opinion, the EC’s approval of the Ebvallo™ Marketing Authorization Application (MAA) under exceptional circumstances is expected by the end of 2022. If granted by the EC, the centralized marketing authorizations would be valid in all EU Member States as well as Iceland, Liechtenstein, and Norway. In addition, the MAA will be filed to the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK under the EC Decision Reliance Procedure (EC DRP) with an expected approval by the end of 2022. Under an existing collaboration agreement, Pierre Fabre will lead all commercialization and distribution activities in Europe and select other markets in addition to medical and regulatory activities after the anticipated MAA approval in Europe.

About Ebvallo™ and EBV+ PTLD

Ebvallo™ is an allogeneic, EBV-specific T-cell immunotherapy which targets and eliminates EBV-infected cells in an HLA-restricted manner. Ebvallo™ (tabelecleucel) has been granted Breakthrough Therapy Designation for the treatment of rituximab-refractory EBV-associated lymphoproliferative disease (LPD) by the U.S. Food and Drug Administration (FDA) and has orphan drug designation in the U.S. Ebvallo™ (tabelecleucel) received PRIME designation by the European Medicines Agency (EMA) for the treatment of patients with EBV-associated PTLD in the allogeneic hematopoietic stem cell transplant (HCT) setting who have failed on rituximab and has orphan drug designation in the EU. EBV+ PTLD is a rare, acute, and potentially deadly hematologic malignancy that occurs after transplantation when a patient’s T-cell activity is compromised by immunosuppression. It can impact patients who have undergone solid organ transplant (SOT) or an 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 rituximab ± chemotherapy failed, underscoring the significant need for effective, safe, and fast-acting 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, A-Derma, 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 colorectal, breast, lung cancers, melanoma and pre-cancerous conditions like actinic keratosis. Pierre Fabre provides specific solutions to help patients manage adverse side effects affecting the skin and mouth due to cancer treatment. 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 9,600 people worldwide. Pierre Fabre is 86%-owned by the Pierre Fabre Foundation, a government-recognized public-interest foundation since 1999, and secondarily by its own employees through an international employee stock ownership plan. Further information about Pierre Fabre can be found at www.pierre-fabre.com, @PierreFabre.

About Atara Biotherapeutics, Inc.

[Atara Biotherapeutics, Inc. \(@Atarabio\)](http://Atarabio) 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 in Phase 3 clinical development, 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 in Phase 3 development for Epstein-Barr virus-driven 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 South San Francisco. 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).

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 tab-cel[®]: the timing of, and Atara's plans for, and potential decision by, the EMA regarding the MAA submission for EBV+ patients with PTLD, the development, timing and progress of tab-cel[®], the potential characteristics and benefits of tab-cel[®], and the progress and results of, and prospects for, any collaboration involving tab-cel[®], the commercial prospects and business opportunity for tab-cel[®] in the territories licensed to Pierre Fabre, and the potential financial benefits to Atara as a result of the collaboration 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 COVID-19 pandemic, which may significantly impact (i) our business, research, clinical development plans and operations, including our operations in South San Francisco and Southern California 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 (SEC), 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.

¹ <https://doi.org/10.1182/blood-2021-147274>

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Atara:

Investors

Eric Hyllengren

805-395-9669

ehyllengren@atarabio.com

Media

Alex Chapman

805-456-4772

achapman@atarabio.com

Pierre Fabre:

Laure Sgandurra

+33 6 32 54 92 01

laure.sgandurra@pierre-fabre.com

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