December 19, 2022

Atara Biotherapeutics' Ebvallo™ (tabelecleucel) Receives European Commission Approval as First Ever Therapy for Adults and Children with EBV+ PTLD

Only Approved Therapy for EU Patients with Rare and Potentially Deadly Cancer Facing Median Survival of Only a Few Months

Represents First Approval of an Allogeneic T-Cell Immunotherapy Globally

Pierre Fabre to Lead Commercialization and Distribution Activities in Europe

THOUSAND OAKS, Calif. & CASTRES, France--(BUSINESS WIRE)-- Atara Biotherapeutics, Inc. (Nasdaq: ATRA) and Pierre Fabre today announced that the European Commission (EC) has granted marketing authorization for Ebvallo™ (tabelecleucel) as a monotherapy 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. For solid organ transplant patients, prior therapy includes chemotherapy unless chemotherapy is inappropriate.

The approval follows a positive opinion in October by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) and is applicable to all 27 European Union member states plus Iceland, Norway, and Liechtenstein. 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.

"The approval of Ebvallo™ in Europe is a medical breakthrough for patients with significant unmet need," said Pascal Touchon, President and Chief Executive Officer of Atara. "As the first allogeneic, or donor-derived, T-cell immunotherapy to receive approval from any regulatory agency in the world, this marks a historic moment for Atara, our European partner, Pierre Fabre, and for the broader cell therapy field."

EBV+ PTLD is a rare, acute, and potentially deadly hematologic malignancy that occurs after transplantation when a patient's T-cell immune response is compromised by immunosuppression. It can impact patients who have undergone solid organ transplant (SOT) or allogeneic hematopoietic cell transplant (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.

Under a previously announced License Agreement with Atara, Pierre Fabre will lead all commercialization and distribution activities in Europe and select other markets, in addition

to medical and regulatory activities following the transfer of the Ebvallo™ Marketing Authorization Application (MAA) from Atara to Pierre Fabre.

“Ebvallo™ represents a significant moment in the cell therapy space and a breakthrough for European patients with EBV+ PTLD,” said Eric Ducournau, CEO of Pierre Fabre, Atara's commercialization partner in Europe. “We are proud and excited to bring this innovative therapy to the marketplace, which will reinforce Pierre Fabre’s portfolio in oncology, hematology, and rare diseases.”

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). Authorized orphan medicines benefit from ten years of market exclusivity, protecting them from competition with similar medicines with the same therapeutic indication, which cannot be marketed during the exclusivity period.

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 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) 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 and LinkedIn.

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 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, Pierre Fabre's ability to successfully launch and commercialize tab-cel® 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 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 (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

View source version on businesswire.com:
https://www.businesswire.com/news/home/20221218005055/en/

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

Source: Atara Biotherapeutics, Inc.