May 20, 2024

Atara Biotherapeutics Submits Tabelecleucel (Tab-cel®) Biologics License Application for Treatment of Epstein-Barr Virus Positive Post-Transplant Lymphoproliferative Disease with U.S. FDA

First Allogeneic T-Cell Therapy BLA Submission to U.S. Food and Drug Administration

If Approved, Tab-cel Would be First Approved Therapy in U.S. for EBV+ PTLD

Acceptance of BLA Will Trigger $20 Million Milestone Payment from Pierre Fabre Laboratories, with Potential for Additional $60 Million Milestone Upon FDA Approval

THOUSAND OAKS, Calif.--(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, today announced that Atara has submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for tabelecleucel (tab-cel®) indicated as monotherapy for treatment of adult and pediatric patients two years of age and older with 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. There are no FDA approved therapies in this treatment setting.

“The BLA submission for tab-cel represents a significant moment for Atara, our partner Pierre Fabre, and the broader allogeneic T-cell therapy field, and is a critical step towards our goal of delivering this first-of-its-kind treatment to EBV+ PTLD patients in the U.S.,” said Pascal Touchon, President and Chief Executive Officer of Atara. “I would like to thank the patients and physicians who participated in the tab-cel clinical trials, our long-time collaborators at Memorial Sloan Kettering Cancer Center, as well as our internal teams for their remarkable dedication and hard work. We now look forward to continued collaboration with the FDA on its review and with Pierre Fabre as they actively prepare for the potential launch of this innovative therapy in the U.S.”

Tab-cel is an allogeneic, EBV-specific T-cell immunotherapy designed to target and eliminate EBV-infected cells. The BLA is supported by pivotal and supportive data covering more than 430 patients treated with tab-cel across multiple life-threatening diseases including the latest pivotal ALLELE study data that demonstrated a statistically significant 48.8% Objective Response Rate (ORR) ($p<0.0001$) and favorable safety profile consistent with previous analyses.

Tab-cel has been granted Breakthrough Therapy Designation for the treatment of rituximab-refractory EBV-associated lymphoproliferative disease by the U.S. FDA and has orphan drug designation.

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 tab-cel, building on an initial partnership covering Europe, Middle East, Africa, and other select emerging markets. With the completion of the tab-cel BLA submission, Atara continues to advance the Pierre Fabre expanded global partnership, which includes potential milestone payments of $20 million and $60 million from Pierre Fabre contingent upon the successful FDA acceptance and approval of the tab-cel BLA, respectively. In addition, Pierre Fabre is reimbursing Atara for expected tab-cel global development costs through the BLA transfer and purchasing tab-cel inventory through the manufacturing transfer date. Atara is also eligible to receive double-digit tiered royalties on net sales of tab-cel in the U.S. and remaining global commercial markets referenced above.

Tab-cel was granted marketing authorization under the brand name Ebvallo™ in December 2022 by the European Commission. Marketing authorization was also granted by the Medicines and Healthcare Products Regulatory Agency in the United Kingdom in May 2023 and by Swissmedic in Switzerland in May 2024. In all three territories, Ebvallo is indicated as monotherapy for the treatment of adult and pediatric patients two years of age and older with relapsed or refractory EBV+ PTLD who have received at least one prior therapy. For solid organ transplant patients, prior therapy includes chemotherapy unless chemotherapy is inappropriate.

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 from inventory. 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 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 and follow @Atarabio on X 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 the development, timing and progress of tab-cel®, including a potential BLA acceptance, the potential characteristics and benefits of tab-cel®, the indication(s) for which tab-cel could potentially obtain FDA approval for, and the progress and results of, and prospects for, the expanded global partnership with Pierre Fabre Laboratories involving tab-cel®, including Pierre Fabre activities relating to the potential commercialization of tab-cel, and the potential financial benefits to Atara as a result of the expanded global partnership with Pierre Fabre

Laboratories, including any payments thereunder. 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 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 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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