

European Medicines Agency (EMA) Validates Atara Biotherapeutics' Marketing Authorization Application for Tabelecleucel for the Treatment of Epstein-Barr Virus-Positive Post- Transplant Lymphoproliferative Disease

First-Ever Off-The-Shelf Allogeneic T-Cell Therapy to be Reviewed by any Regulatory Agency in the World

EMA Priority Medicines (PRIME) and Orphan Designated Tabelecleucel One Step Closer for Patients with High Unmet Need

EU Approval Decision Anticipated for Second Half of 2022, based on CHMP Accelerated Assessment

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)-- [Atara Biotherapeutics, Inc.](https://www.atara.bio) (Nasdaq: ATRA), a leader in T-cell immunotherapy, leveraging its novel allogeneic EBV T-cell platform to develop transformative therapies for patients with cancer and autoimmune diseases, today announced that the Marketing Authorization Application (MAA) for tabelecleucel (tab-cel®) has been fully validated by the European Medicines Agency (EMA). Tab-cel is an investigational treatment for patients with Epstein-Barr virus-positive post-transplant lymphoproliferative disease (EBV+ PTLD) who have received at least one prior therapy following solid organ transplant (SOT) or hematopoietic cell transplant (HCT).

The application will be evaluated by the EMA's Committee for Medicinal Products for Human Use (CHMP) under the centralized licensing procedure for all EU Member States, as well as in the European Economic Area countries Iceland, Liechtenstein, and Norway.

"EBV+ PTLD is a rare and aggressive cancer where the patients we seek to treat only have weeks to a few months survival after treatment failure, with no approved options," said Jakob Dupont, MD, Executive Vice President and Global Head of Research and Development at Atara. "Tab-cel is the first-ever off-the-shelf allogeneic T-cell therapy to be reviewed by a regulatory agency and is a watershed moment for the field and for patients with significant unmet need. We look forward to working with the EMA as the agency evaluates the transformative potential of tab-cel."

Tab-cel is Atara's lead candidate in development for EBV-positive cancers, including EBV+ PTLD, where it is being investigated in adults and children in the ongoing Phase 3, registration-enabling ALLELE study. The MAA includes positive data from this study, which demonstrates a 50% (19/38, 95% CI: 33.4, 66.6) objective response rate (ORR) as

measured by independent oncologic response adjudication (IORA) assessment, with an ORR of 50% (12/24, 95% CI: 29.1, 70.9) in PTLD following SOT and 50% (7/14, CI: 23.0, 77.0) in PTLD following HCT, with a best overall response of Complete Response (CR; n=5, SOT; n=5, HCT) or Partial Response (PR; n=7, SOT; n=2, HCT). Overall, the median time to response (TTR) was 1.1 months (0.7-4.7). Of 19 responders, 11 had a duration of response (DOR) lasting more than six months and median DOR has not been reached yet. Those who responded had a longer survival compared to the non-responders, with a one-year survival rate of 89.2% for patients responding to tab-cel compared with 32.4% among non-responders. Safety findings were consistent with previously published data, with no new signals. There were no reports of tumor flare reaction, and no confirmed evidence of graft versus host disease (GvHD), organ rejection, infusion reactions, or cytokine release syndrome (CRS) related to tab-cel.

Atara will [present](#) findings from the ALLELE study and additional tab-cel data in eight abstracts at the 63rd American Society of Hematology (ASH) Annual Meeting taking place December 11-14, 2021, in Atlanta, Georgia.

In October 2021, Atara entered into an exclusive commercialization agreement with Pierre Fabre for tab-cel in Europe, Middle East, Africa and other select emerging markets for Epstein-Barr virus (EBV)-positive cancers. In addition to responsibility for the pivotal ALLELE study in PTLD and submitting the EU MAA, Atara also remains responsible for the Phase 2 multi-cohort study, which is evaluating tab-cel in six additional patient populations with the goal of label expansion in other EBV-driven cancers. Pierre Fabre will lead all commercialization and distribution activities in the territories, as well as medical and regulatory activities after the anticipated MAA approval in Europe.

About Tabelecleucel

Tabelecleucel (tab-cel) is an off-the-shelf, allogeneic T-cell immunotherapy in development for the treatment of Epstein-Barr virus-positive post-transplant lymphoproliferative disease (EBV+ PTLD). EBV+ PTLD is a type of lymphoma (cancer) that may occur after a solid organ transplant (SOT) or allogeneic hematopoietic cell transplant (HCT). There are currently no approved treatments indicated to treat PTLD and if left untreated, PTLD can have life-threatening consequences.

Tab-cel is currently being investigated in the Phase 3 registration-enabling [ALLELE](#) study to assess efficacy and safety for the treatment of EBV+ PTLD in SOT and HCT after failure of standard of care.

Tab-cel has been granted Breakthrough Therapy Designation for EBV+ PTLD following allogeneic HCT by the U.S. Food and Drug Administration (FDA) and PRIME designation by the European Medicines Agency (EMA) for the same indication. Tab-cel has orphan drug designation in the U.S. and EU.

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 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 and our leading-edge research, development and manufacturing facility is based in Thousand Oaks, California. 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[®], including data and analyses from ALLELE study, the investigator-initiated Phase 2 study, and the EAP, the potential characteristics, benefits, safety and efficacy 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. 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.

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