

# **Atara Biotherapeutics Announces First Clinical Data from Ongoing Tab-cel® European Multicenter Expanded Access Program (EAP) at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting and Update on Tab-cel EMA Regulatory Progress**

*Overall Response Rate (ORR) of 60% Observed in Patients with Relapsed or Refractory (R/R) EBV+ PTLD Consistent with Previously Reported Studies*

*Completion of All Pre-Approval Inspections Required to Support EU Marketing Authorization Application; Anticipated European Commission Approval On-Track for Q4 2022*

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)-- [Atara Biotherapeutics, Inc.](#) (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 EMA regulatory progress and tabelecleucel (tab-cel®) clinical outcomes. Data is reported from the multicenter Expanded Access Program (EAP) study in Europe for patients with relapsed or refractory (r/r) Epstein-Barr virus-driven post-transplant lymphoproliferative disease (EBV+ PTLD) following solid organ transplant (SOT) or hematopoietic cell transplant (HCT) and will be featured in a poster presentation at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting taking place June 3-7, 2022, in Chicago, IL.

In the ongoing EAP, 22 patients from the first European centers consented to this observational study, of which 16 patients presented with EBV+ PTLD and six with EBV+ non-PTLD between July 2020 and November 2021. The primary objective of the study is to describe the demographics and disease characteristics of patients with EBV+ diseases treated with tab-cel under the EAP. Secondary objectives are to describe the tab-cel dosing pattern, to evaluate clinically relevant treatment outcomes, and to describe the safety of tab-cel in patients with EBV+ diseases treated under the EAP.

Of the 16 EBV+ PTLD patients, 15 received at least one dose of tab-cel. Overall, nine out of 15 (60%) tab-cel treated patients achieved a response as assessed by the treating physician, with six complete responses (CRs) and three partial responses (PRs). Of the nine responses, eight were observed after the first treatment cycle of tab-cel.

Safety findings were consistent with previously published data. All treatment-emergent events were assessed as unrelated to tab-cel by the treating physician and were consistent with patients' underlying diseases. Further detail on baseline demographics and disease

characteristics, and additional safety data including tab-cel exposure details, will be presented at the conference.

“We are pleased to share the latest data from our EAP in Europe demonstrating clinically meaningful outcomes for patients with EBV+ PTLD, a rare and aggressive disease with no approved treatment options, in line with the favorable safety and efficacy profile from previously reported studies including the pivotal Phase 3 ALLELE study,” said Jakob Dupont, M.D., Head of Global Research & Development at Atara. “In addition, we now welcome the completion of our pre-approval inspections as a key milestone on our road to achieving approval in the EU.”

Separately, Atara announced completion of all six pre-approval inspections required to support the Marketing Authorization Application for tab-cel in Europe, with the Good Manufacturing Practice (GMP) compliance certificates required to support the filing expected by July. Combined with the recent Day 120 critical assessment report, where the European Medicines Agency (EMA) considered the comparability data between clinical and commercial manufacturing versions as sufficient to demonstrate comparability, Atara continues to expect European Commission approval in Q4 2022.

ASCO presentation details:

- **Title:** Demographics and treatment outcomes in patients with EBV+ PTLD treated with off-the-shelf EBV-specific CTL (tabelecleucel) under an ongoing expanded access program in Europe: First analyses.
- **Presenting Author:** Ralf Trappe, M.D., DIAKO Evangelisches Diakonie-Krankenhaus Bremen, Bremen, Germany
- **Date & Time:** Saturday, June 4, 2022, at 8-11 a.m. CDT/6-9 a.m. PDT
- **Abstract Number:** 7530
- **Poster Number:** 184
- **Session:** Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia
- **Location:** McCormick Place Convention Center Chicago, Hall A

### 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 and currently under review to support registration 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<sup>®</sup> (tabelecleucel) in Phase 3 development for Epstein-Barr virus-driven post-transplant lymphoproliferative disease (EBV+ PTLD); 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](http://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: the potential benefits, safety and efficacy of tab-cel<sup>®</sup>; the timing and progress of tab-cel<sup>®</sup>, including (i) data and analyses from the EAP; (ii) the timing and outcome of the MAA for tab-cel, (iii) the timing of the EMA's review of the MAA for tab-cel; and (iv) Atara's ability to successfully advance the development of tab-cel<sup>®</sup>. 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, 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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