

# Atara Biotherapeutics Presents Updated Clinical Data from Pivotal Phase 3 Trial (ALLELE) of Tab-cel® at the 64th American Society of Hematology (ASH) Annual Meeting

*Phase 3 ALLELE Study Shows 51.2% Objective Response Rate (ORR) in 43 EBV+ PTLD Patients*

*Median Duration of Response (DOR) of 23.0 Months*

*Median Overall Survival of 18.4 Months with Patients Who Responded Having Longer Survival Than Non-Responders*

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 updated interim analysis and safety results from its Phase 3 multicenter ALLELE study investigating tabelecleucel (tab-cel®) for the treatment of relapsed/refractory (r/r) Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLD) following solid organ transplant (SOT) or hematopoietic cell transplant (HCT).

The Phase 3 ALLELE study findings, along with updated efficacy and safety data from two single-center, open-label studies as well as a multicenter expanded access program investigating tab-cel including patients with Epstein-Barr virus positive leiomyosarcomas (EBV+ LMS), were featured among four poster presentations at the 64<sup>th</sup> American Society of Hematology (ASH) Annual Meeting taking place December 10-13, 2022, in New Orleans.

“The updated efficacy and safety results of the Phase 3 ALLELE study including additional patients and longer follow-up are consistent with the transformative potential of tab-cel in EBV+ PTLD patients with no approved treatment options available,” said Jakob Dupont, MD, Head of Global Research & Development at Atara. “Similar to EBV+ PTLD, patients with EBV+ LMS face a poor prognosis with limited treatment options, underscoring the significant need for effective and safe new therapeutic options. We report exciting new data that suggest tab-cel may provide a clinical benefit in these hard-to-treat patients with LMS and, together with other EBV-driven diseases like PTLD, represent the potential of tab-cel to transform the lives of thousands of patients across multiple indications and geographies.”

In the ongoing Phase 3 ALLELE study, 43 patients — 14 HCT recipients and 29 SOT recipients — were treated with tab-cel and were included in the analysis. Patients received a median of 2 cycles (range: 1-6) of tab-cel. The median age of evaluable patients for both

SOT and HCT was 48.5 years (3.2–81.5) who had received a median of 1 (range: 1–5) prior systemic treatments. Responses per clinical and radiographic assessment were measured by independent oncologic response adjudication (IORA) assessment.

Results as of November 2021 data cutoff showed:

- An objective response rate (ORR) of 51.2% (22/43) was observed for both HCT and SOT groups (95% CI: 35.5, 66.7), 51.7% (15/29) for patients following SOT (95% CI: 32.5, 70.6) and 50.0% (7/14) for HCT patients (95% CI: 23.0, 77.0) with a best overall response of Complete Response (CR; 27.9%; n=12; n=6, SOT, n=6, HCT) or Partial Response (PR; 23.3%; n=10; n=9, SOT, n=1, HCT).
- The median time to response (TTR) in all patients was 1.0 month (range: 0.7–4.7) and median duration of response (DOR) in 22 responders was 23.0 months (95% CI: 6.8, not estimable [NE]), with 12/22 responders having a DOR >6 months.
- Median overall survival (OS) of 18.4 months (95% CI: 6.9, NE) in all patients, 16.4 months in SOT (95% CI: 5.0, NE) and not yet reached in HCT (95% CI: 5.7, NE).
- One-year survival rates were 61.1% (95% CI: 43.7, 74.5), 56.2% in SOT (95% CI: 34.6, 73.2) and 70.1% in HCT (95% CI: 38.5, 87.6).
- Patients responding to tab-cel had longer one-year survival compared to the non-responders, with a one-year survival rate of 84.4% (95% CI: 58.9, 94.7) versus 34.8% (95% CI: 14.6, 56.1) for non-responders.

In addition, Atara presented updated efficacy and safety data investigating the potential of tab-cel in patients with EBV+ LMS who have received at least one therapy. EBV+ LMS is a rare, aggressive, and potentially fatal solid tumor that responds poorly to radiation and chemotherapy. Among 18 patient-treatments, median age was 8.9 years (range: 3–35) and 44.4% of patients were male.

Results showed:

- A clinical benefit rate (CR, PR, and stable disease) of 77.8% (14/18) (95% CI: 56.6, 96.2), and ORR of 22.2% (95% CI: 6.4, 47.6; PR in all cases) was observed. Median follow-up for all patients was 18.9 months (95% CI: 1.5, 109.3).
- The estimated median OS was 77.4 months (95% CI: 18.0, NE) and the median progression-free survival (PFS) was 12.5 months (95% CI: 5.5, NE).
- Median DOR was 6.2 months (95% CI: 4.8, NE) with a one-year DOR rate of 37.5% (95% CI: 1.1, 80.8). The one-year survival rate was 86.7% (95% CI: 56.4, 96.5) and the estimated two-year survival rate was 78.0% (95% CI: 45.5, 92.5).

In both the ALLELE and LMS studies, tab-cel was well tolerated and the safety profile consistent with previous data. There was no evidence of tumor flare reaction, infusion reactions, cytokine release syndrome, transmission of infectious diseases, and no events of graft versus host disease (GvHD) or organ rejection related to tab-cel.

In separate posters, Atara also presented the methodology of using T-cell receptor  $\beta$  (TCR $\beta$ ) sequencing to identify allogeneic cell product clones post-infusion and data confirming the absence of clinical manifestation of immunogenicity following tab-cel administration in patients enrolled in the ALLELE study.

### **Poster Presentation Details:**

**Title:** New and Updated Results from a Multicenter, Open-Label, Global Phase 3 Study of Tabelecleucel (Tab-cel) for Epstein–Barr Virus-Positive Post-Transplant Lymphoproliferative Disease (EBV<sup>+</sup> PTLD) Following Allogeneic Hematopoietic Cell (HCT) or Solid Organ Transplant (SOT) after Failure of Rituximab or Rituximab and Chemotherapy (ALLELE)

- **Presenting Author:** Kris Michael Mahadeo, MD, MPH, MD Anderson Cancer Center, Houston, TX
- **Date & Time:** Monday, December 12, 2022, 6-8 p.m. CST / 5-7 p.m. PST
- **Abstract Number:** 4658
- **Poster Session:** 705. Cellular Immunotherapies: Late Phase and Commercially Available Therapies: Poster III
- **Location:** Ernest N. Morial Convention Center, Hall D

**Title:** Updated Efficacy and Safety of Tabelecleucel in Patients with Epstein-Barr Virus-Positive (EBV+) Leiomyosarcomas (LMS)

- **Presenting Author:** Lauren S. Jiménez-Kurlander, MD, Boston Children's Hospital/Dana Farber Cancer Institute, Boston, MA
- **Date & Time:** Sunday, December 11, 2022, 6-8 p.m. CST / 5-7 p.m. PST
- **Abstract Number:** 3349
- **Poster Session:** 705. Cellular Immunotherapies: Late Phase and Commercially Available Therapies: Poster II
- **Location:** Ernest N. Morial Convention Center, Hall D

**Title:** Utilizing TCRseq to Detect Tabelecleucel, an Allogeneic Epstein-Barr Virus (EBV)-Specific T-Cell Therapy, Post-Infusion

- **Presenting Author:** Fiona Ruiz, PhD, Atara Biotherapeutics, Thousand Oaks, CA
- **Date & Time:** Saturday, December 10, 2022, 5:30-7:30 p.m. CST / 4:30-6:30 p.m. PST
- **Abstract Number:** 2169
- **Poster Session:** 803. Emerging Tools, Techniques and Artificial Intelligence in Hematology: Poster I
- **Location:** Ernest N. Morial Convention Center, Hall D

**Title:** Exploring the Impact of Humoral Immunogenicity with Tabelecleucel for the Treatment of EBV+ PTLD Following HCT and SOT

- **Presenting Author:** Tassja J. Spindler, Atara Biotherapeutics, Thousand Oaks, CA
- **Date & Time:** Sunday, December 11, 2022, 6-8 p.m. CST / 5-7 p.m. PST
- **Abstract Number:** 3351
- **Poster Session:** 705. Cellular Immunotherapies: Late Phase and Commercially Available Therapies: Poster II
- **Location:** Ernest N. Morial Convention Center, Hall D

## About Tabelecleucel

Tabelecleucel (tab-cel) is an allogeneic, EBV-specific T-cell immunotherapy which targets and eliminates EBV-infected cells in an HLA-restricted manner. Tab-cel 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. 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.

## **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 a CHMP positive opinion for a 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 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 Southern 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 tab-cel®: the development, timing and progress of tab-cel®, including data from tab-cel® clinical trials, the potential characteristics and benefits of tab-cel®, and Atara's ability to successfully advance the development of tab-cel® and its programs. 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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