

November 4, 2021



# Atara Biotherapeutics to Present Eight Abstracts at the 63rd American Society of Hematology (ASH) Annual Meeting, Including First Presentation of Tab-cel® Pivotal Phase 3 (ALLELE) Data

*Positive New ALLELE Results Show 50% Objective Response Rate (ORR) and Strong Safety Profile Reinforcing Transformative Potential of Tab-cel®*

*One-year Survival Rate of 89.2% for Patients Responding to Tab-cel Compared with 32.4% Among Non-Responders*

*Long-term Survival Benefit in Patients who Responded to Tab-cel Demonstrated in Separate Pooled Data Analysis from Phase 2 and Multicenter Expanded Access Protocol Studies*

SOUTH SAN FRANCISCO, 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 the upcoming first release of efficacy and safety results from its Phase 3 ALLELE study. The pivotal trial is investigating tabellecleucel (tab-cel®) for the treatment of Epstein-Barr virus-positive post-transplant lymphoproliferative disease (EBV+ PTLD) following solid organ transplant (SOT) or hematopoietic cell transplant (HCT). Detailed findings, along with combined data from investigator-sponsored Phase 2 and multicenter Expanded Access Program (EAP) studies, will be featured among eight abstracts, including two oral presentations, at the 63<sup>rd</sup> American Society of Hematology (ASH) Annual Meeting taking place December 11-14, 2021, in Atlanta.

“There is significant unmet need in patients with EBV+ PTLD, with poor overall survival measured in weeks to a few months after first-line treatment failure,” said Jakob Dupont, MD, Head of Global Research & Development at Atara. “Tab-cel demonstrated a clinically meaningful objective response rate and striking overall survival in a patient population with no approved treatment options, representing a first-in-kind allogeneic therapy with transformative potential. At ASH, we will share data from our Phase 3 ALLELE study, which further supports tab-cel as a potentially safe and effective treatment option for patients with EBV-driven diseases.”

As reported in the full abstract available today on the ASH [website](#), top-line data with additional patients and extended follow up confirm a strong ORR in line with prior Phase 2 and multicenter EAP results and demonstrate durability of response with no new safety signals.

In this ongoing Phase 3 study, 38 evaluable patients as of May 2021 — 24 EBV+ PTLD following SOT patients after failure of rituximab ± chemotherapy and 14 EBV+ PTLD following HCT patients after failure of rituximab monotherapy — were treated with tab-cel and had the opportunity for a six-month follow-up after response. An ORR, as measured by independent oncologic response adjudication (IORA) assessment, of 50% (19/38, 95% CI: 33.4, 66.6) was observed, with an ORR of 50.0% (12/24, 95% CI: 29.1, 70.9) in PTLD following SOT and 50.0% (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 median OS not evaluable (NE) (95% CI: 16.4, NE) and a 1-year survival rate of 89.2% (95% CI: 63.1, 97.2).

Safety findings were consistent with previously published data, with no new signals or concerns reported. 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 related to tab-cel.

Further detail on baseline demographics and disease characteristics, and additional safety data including tab-cel exposure details, will be presented on December 11 in the oral presentation.

Atara will present additional data on tab-cel and PTLD through several abstracts, including a second oral presentation on long term OS from Phase 2 and multicenter EAP studies with tab-cel in relapsed/refractory EBV+ PTLD showing median OS of 54.6 months in all patients and OS at two years reaching over 86% in responders whether patients experienced CR or PR. Treatment was well tolerated with no confirmed evidence for graft versus host disease, cytokine release syndrome, SOT rejection, or neurologic events attributable to tab-cel.

In total, five abstracts will be presented at the 63<sup>rd</sup> ASH Annual Meeting. An additional three accepted abstracts will be published online in the November supplemental issue of *Blood*.

#### **Oral Presentation Details:**

**Title:** Multicenter, Open-Label, Phase 3 Study of Tabelecleucel for Solid Organ or Allogeneic Hematopoietic Cell Transplant Recipients with Epstein-Barr Virus-Driven Post Transplant Lymphoproliferative Disease after Failure of Rituximab or Rituximab and Chemotherapy (ALLELE)

- **Presenting Author:** Susan Prockop, MD, Boston Children's Hospital/Dana Farber Cancer Institute, Boston, MA
- **Date & Time:** Saturday, December 11, 2021, at 4:00 p.m. EST/1:00 p.m. PST
- **Abstract Number:** 301
- **Session:** 626. Aggressive Lymphomas Prospective Therapeutic Trials: Challenging Populations
- **Location:** Georgia World Congress Center, B401-B402

**Title:** Overall Survival by Best Overall Response with Tabelecleucel in Patients with Epstein-

## Barr Virus-Driven Post-Transplant Lymphoproliferative Disease Following Solid Organ or Allogeneic Hematopoietic Cell Transplant

- **Presenting Author:** Susan Prockop, MD, Boston Children's Hospital/Dana Farber Cancer Institute, Boston, MA
- **Date & Time:** Monday, December 13, 2021, at 7:15 p.m. EST/4:15 p.m. PST
- **Abstract Number:** 887
- **Session:** 627. Aggressive Lymphomas: Clinical and Epidemiological: Real World Evidence for CAR-T Management II
- **Location:** Georgia World Congress Center, C101 Auditorium

### **Poster Presentation Details:**

**Title:** Clinical Outcomes of Patients with Epstein-Barr Virus-Driven Post-Transplant Lymphoproliferative Disease Following Hematopoietic Stem Cell Transplantation Who Fail Rituximab: A Multinational, Retrospective Chart Review Study

- **Presenting Author:** Jaime Sanz, MD, University Hospital La Fe in Valencia, Valencia, Spain
- **Date & Time:** Saturday, December 11, 2021, at 5:30-7:30 p.m. EST/2:30-4:30 p.m. PST
- **Abstract Number:** 1454
- **Session:** 627. Aggressive Lymphomas: Clinical and Epidemiological: Poster I
- **Location:** Georgia World Congress Center, Hall B5

**Title:** Clinical Outcomes of Solid Organ Transplant Patients with Epstein-Barr Virus-Driven (EBV+) Post-Transplant Lymphoproliferative Disorder (PTLD) Who Fail Rituximab Plus Chemotherapy: A Multinational, Retrospective Chart Review Study

- **Presenting Author:** Vikas Dharnidharka, MD, MPH, Washington University School of Medicine & St. Louis Children's Hospital, St Louis, MO
- **Date & Time:** Sunday, December 12, 2021, at 6:00-8:00 p.m. EST/3:00-5:00 p.m. PST
- **Abstract Number:** 2528
- **Session:** 627. Aggressive Lymphomas: Clinical and Epidemiological: Poster II
- **Location:** Georgia World Congress Center, Hall B5

**Title:** Comprehensive Activation Profiling of the Tabelecleucel Library, an Off-the-Shelf, Allogeneic EBV-Specific T-Cell Therapy

- **Presenting Author:** Joseph M Benoun, PhD, Atara Biotherapeutics, Thousand Oaks, CA
- **Date & Time:** Sunday, December 12, 2021, at 6:00-8:00 p.m. EST/3:00-5:00 p.m. PST
- **Abstract Number:** 2809
- **Session:** 703. Cellular Immunotherapies: Basic and Translational: Poster II
- **Location:** Georgia World Congress Center, Hall B5

### **About Tabelecleucel**

Tabelecleucel (tab-cel<sup>®</sup>) 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 [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<sup>®</sup> 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](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 ALLELE study, the investigator-initiated Phase 2 study, and the EAP; (ii) tab-cel<sup>®</sup> clinical trials, and (iii) 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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