

Atara Biotherapeutics Announces Positive Results from Pivotal Phase 3 Trial (ALLELE) of Tab-cel® at the 63rd American Society of Hematology (ASH) Annual Meeting

Phase 3 ALLELE Study in EBV+ PTLD Demonstrates 50% Objective Response Rate, Consistent with Previous Results

At Least 11 of 19 Responders had a Duration of Response (DOR) Lasting More Than Six Months with Median Time to Response in All Patients of Just 1.1 Months

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

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 Epstein-Barr virus (EBV) T-cell platform to develop transformative therapies for patients with cancer and autoimmune diseases, today announced efficacy and safety results from its Phase 3 multicenter ALLELE study 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). These findings, along with combined long-term survival data from Phase 2 and multicenter Expanded Access Protocol (EAP) studies of tab-cel were featured as oral presentations at the 63rd American Society of Hematology (ASH) Annual Meeting.

“Patients with EBV+ PTLD face a poor prognosis with survival measured in weeks to months if initial treatment is unsuccessful. There are no approved treatment options for this devastating disease, underscoring the critical unmet need that exists,” said Jakob Dupont, MD, Head of Global Research & Development at Atara. “Our conviction that tab-cel, recently filed with the EMA, is a potential first-in-class treatment option for transplant recipients that develop EBV+ PTLD is validated by almost 90% of patients responding to treatment surviving after one year, and a similar two-year survival benefit of over 86% in patients who achieved a complete or partial response from Phase 2 and EAP studies.”

Poor patient survival in relapsed or refractory EBV+ PTLD underscores the significant need for effective, safe, and fast-acting new therapeutic options as highlighted in two additional posters presented at ASH. Patients suffer from poor median survival of 0.7 months (n=81) and 4.1 months (n=86) for HCT and SOT, respectively, reported in EBV+ PTLD patients for whom rituximab ± chemotherapy failed.

In the ongoing Phase 3 ALLELE study, 38 evaluable patients as of May 2021 — 24 EBV+

PTLD patients following SOT after failure of rituximab ± chemotherapy and 14 EBV+ PTLD patients following HCT after failure of rituximab monotherapy — were treated with tab-cel and had the opportunity for a six-month follow-up after response. The median age of evaluable patients for both SOT and HCT was 52.9 years (3.2–81.5) who had tried a median of 1 (range: 1-5) prior systemic treatments including rituximab monotherapy, chemotherapy or immunotherapy.

As measured by independent oncologic response adjudication (IORA) assessment, an ORR of 50% (19/38, 95% CI: 33.4, 66.6) was observed for both HCT and SOT groups. For patients with EBV+ PTLD following SOT, an ORR of 50.0% (12/24, 95% CI: 29.1, 70.9) was observed and similarly, for patients with EBV+ PTLD following HCT, an ORR of 50.0% (7/14, 95% CI: 23.0, 77.0) was observed, with a best overall response of Complete Response (CR; 26.3%; n=10; n=5, SOT, n=5, HCT) or Partial Response (PR; 23.7%; n=9; n=7, SOT, n=2, HCT). The median time to response (TTR) in all patients was 1.1 months (0.7-4.7). In the study, 11 of 19 responders had a duration of response (DOR) lasting more than six months and median DOR has not yet been reached. Of the remaining eight responders, four had events due to IORA-assessed progressive disease (PD) or death and four patients were alive and censored for the DOR at the time of the data cut.

Patients responding to tab-cel had longer survival compared to the non-responders, with a median overall survival (OS) not evaluable (NE) (95% CI: 16.4, NE) and a one-year survival rate of 89.2% (95% CI: 63.1, 97.2) versus non-responders' OS of 5.7 months (95% CI: 1.8, 12.1) and one-year survival rate of 32.4% (95% CI: 12.1, 54.9).

Safety was consistent with previously published data, and no new safety signals or concerns were reported. There were no reports of tumor flare reaction, infusion reactions, cytokine release syndrome, transmission of infectious diseases, including cytomegalovirus, and no events of graft versus host disease (GvHD) or organ rejection related to tab-cel. Overall, tab-cel was well-tolerated in treatment-refractory and immunocompromised patients.

Atara also reported combined long-term survival data from Phase 2 and multicenter EAP studies of tab-cel in a second oral presentation. Results show that across studies, patients who responded to tab-cel for treatment of EBV+ PTLD experienced a long-term survival benefit with a median OS of 54.6 months (95% CI: 14.8, 115.0) reported in all patients (n=76). An ORR of 63.2% (48/76) was observed in all patients with a best overall response of CR (42.1%; n=32) or PR (21.1%; n=16). Two-year survival rates were 86.2% (95% CI: 67.0, 94.6) and 86.5% (95% CI: 55.8, 96.5) for patients with CR and PR, respectively. Importantly, patients who achieved a PR with tab-cel derived similar OS benefit to those who achieved a CR. Treatment was well tolerated in refractory and immunocompromised patients and there were no fatal events reported related to tab-cel. There were no reports of tumor flare reaction, cytokine release syndrome, organ/marrow rejection, or transmission of infectious diseases and cytomegalovirus. There is no evidence of GvHD or infusion-related reaction risks attributable to tabellecleucel based on current data.

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. These data support the recent EMA-validated Marketing Authorization Application for tab-cel as the first off-the-shelf allogeneic T-cell therapy ever to be reviewed by a regulatory agency. The EMA's Committee for Medicinal Products for Human Use (CHMP) granted tab-cel Accelerated Assessment and an EU approval decision is anticipated for second half of 2022.

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 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 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](#) 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[®]; the timing and progress of tab-cel[®], including (i) data and analyses from ALLELE study, the investigator-initiated Phase 2 study, and the EAP; (ii) tab-cel[®] clinical trials, and (iii) Atara's ability to successfully advance the development of tab-cel[®]. 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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