

# Atara Biotherapeutics Presents First Preclinical Evaluation of ATA3219, a Next-Generation Allogeneic CD19 CAR T Cell Therapy, at the 62nd American Society of Hematology (ASH) Annual Meeting

Atara's allogeneic EBV CAR T-cell platform is designed to improve upon current CAR T therapy; ATA3219 leverages this novel platform and incorporates 1XX CAR signaling technologies

Preclinical findings with ATA3219 show potent antitumor activity both in vitro and in vivo, with long-term persistence and no evidence of allocytoxicity in vivo

Atara is also featuring four posters supporting its lead product candidate tab-ce (tabelecleucel), including the first-ever presentation of data on patients with life-threatening complications associated with EBV viremia and significant cost burden associated with post-transplant lymphoproliferative disease (PTLD) in kidney transplant patients

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)-- <u>Atara Biotherapeutics</u>, <u>Inc.</u> (Nasdaq: ATRA), 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, today announced the presentation of the first preclinical evaluation of ATA3219, a next-generation, off-the-shelf, allogeneic CAR T-cell therapy targeting CD19, as well as data supporting its multicohort Phase II study with tab-cel<sup>®</sup> (tabelecleucel) for the treatment of rare EBV-driven diseases (ATA129-EBV-205). These data are being featured in five poster presentations at the 62<sup>nd</sup> American Society of Hematology (ASH) Annual Meeting, December 5-8, 2020.

"Though the current generation of CD19 CAR T immunotherapies has transformed how we treat hematologic malignancies, a significant opportunity remains to improve outcomes and make the power of CAR T accessible to more patients using allogeneic cells with our differentiated EBV T-cell platform," said Jakob Dupont, M.D., Executive Vice President and Global Head of Research and Development at Atara. "As a leader in allogeneic CAR T-cell therapy, Atara is developing ATA3219 to be best-in-class, improving upon established CD19 targeting by leveraging both our EBV T-cell platform and novel 1XX co-stimulation signaling technology. We are pleased to share, for the first time, preclinical data demonstrating the antitumor activity, persistence, polyfunctional phenotype and safety of ATA3219."

Preclinical results presented at ASH detail findings from *in vitro* and *in vivo* evaluations of ATA3219. Specifically, *in vitro* functional studies demonstrate potent antitumor activity of ATA3219 against CD19-expressing target lines, with durable CD19 antigen-specific and

HLA-independent killing of CD19 targets. In addition, both *in vivo* and *in vitro* assessments of ATA3219 alloreactivity support a potentially favorable safety profile that would be required for an allogeneic, off-the-shelf CAR-T therapy.

Furthermore, *in vivo*, ATA3219 demonstrates potent antitumor activity in an established disseminated tumor model of acute lymphoblastic leukemia and is associated with long-term persistence and survival benefit. No treatment-related toxicities were observed in this animal model. Together, these findings support advancing ATA3219 to clinical evaluation.

ATA3219 combines an allogeneic EBV T-cell approach with a CAR signaling domain designed to improve upon current and clinically validated CD19 targeted CAR therapies without the need for gene editing. ATA3219 utilizes next-generation 1XX co-stimulatory domain technology, designed to extend functional persistence without compromising potency.

Following a successful pre-investigational new drug (IND) meeting with the U.S. Food and Drug Administration (FDA) in early Q4 2020, Atara plans to submit an IND for ATA3219 in 2021.

Additionally, Atara will report several data sets related to lead product candidate tab-cel<sup>®</sup> including the first-ever presentation of data on patients with life-threatening complications associated with EBV viremia.

In this heterogeneous group of patients with life-threatening complications stemming from EBV viremia including some with hemophagocytic lymphohistiocytosis (HLH), a condition with poor prognosis for which treatment options are limited, 80 percent (n=4/5) of patients in the EAP-201 study with persistent EBV viremia (not HLH or chronic active EBV (CAEBV) were responders, and 50 percent (n=2/4) of the patients in EAP-901 with EBV viremia and HLH were responders. The overall survival (OS) rate at one year in patients with EBV viremia treated in the EAP-201 study was 100 percent for a median follow-up of 14.6 months (min 12.2, max 17.8).

Tab-cel<sup>®</sup> was generally well-tolerated with no new safety signals in this study and data support the continued overall safety profile of the product. The EAP-901 study reported a fatal SAE of chronic hepatic failure that was assessed as unrelated to treatment; one patient experienced a grade 3 TESAE of facial nerve disorder that was assessed as possibly related to treatment and recovered in one month. There were no other fatal or treatment-related TESAEs reported in this patient population.

The Company has now presented clinical data for tab-cel <sup>®</sup> in all six of the patient populations of the multi-cohort study, showing meaningful efficacy and consistent favorable safety profile.

In a poster evaluating the Healthcare Resource Utilization (HRU) and cost for patients with post-transplant lymphoproliferative disease (PTLD) following kidney transplant, it was found that PTLD is associated with substantial HRU and cost (>\$200k PPY in the year diagnosed), regardless of the year diagnosed post-transplant, while patients without PTLD and patients who haven't developed PTLD had a cost of ~\$83k per-person year (PPY) in year one, and ~\$26k PPY for year two and three post-transplant. Patients who developed PTLD continued to incur higher healthcare costs than patients who did not develop PTLD in years beyond the

# PTLD diagnosis year.

"We are pleased to see the growing body of evidence showing that tab-cel<sup>®</sup> was well-tolerated and demonstrated strong objective response rates and overall survival in patients with life-threatening EBV-driven diseases beyond EBV<sup>+</sup> PTLD," said AJ Joshi, M.D., Senior Vice President and Chief Medical Officer at Atara. "These data support the continued study of tab-cel<sup>®</sup> in the multicohort trial aligned with our mission of bringing potentially transformative therapies to patients with serious diseases of high unmet medical need. Additionally, the characterization of the significant cost burden of PTLD begins to clarify important aspects of the significant value that a transformative treatment could provide to patients and the healthcare system."

## **Atara Poster Presentations at ASH:**

**Title:** ATA3219: A Potent Next-Generation Allogeneic Off-the-Shelf CD19-CAR T Therapy without the Need for Gene-Editing

**Abstract #:** 3259

**Session:** 703. Adoptive Immunotherapy: Mechanisms and New Approaches: Poster III **Time and Location:** Monday, December 7, 2020: 7:00 AM-3:30 PM ET, Poster Hall (Virtual Meeting)

**Title:** <u>Clinical Experience of Tabelecleucel in Patients with Life-Threatening Complications of</u> Epstein-Barr Virus Viremia

**Abstract #: 2554** 

**Session:** 905. Outcomes Research—Malignant Conditions (Lymphoid Disease): Poster II **Time and Location:** Sunday, December 6, 2020: 7:00 AM-3:30 PM ET, Poster Hall (Virtual Meeting)

Title: Clinical Experience of Tabelecleucel in Patients with EBV+ Primary (PID) or Acquired Immunodeficiency (AID) Associated Lymphoproliferative Disease

**Abstract #:** 1658

**Session:** 905. Outcomes Research—Malignant Conditions (Lymphoid Disease): Poster I **Time and Location:** Saturday, December 5, 2020: 7:00 AM-3:30 PM ET, Poster Hall (Virtual Meeting)

**Title:** <u>High Healthcare Resource Utilization and Cost for PTLD Patients Following Kidney</u> Transplants

**Abstract #:** 3482

**Session:** 905. Outcomes Research—Malignant Conditions (Lymphoid Disease): Poster III **Time and Location:** Monday, December 7, 2020: 7:00 AM-3:30 PM ET, Poster Hall (Virtual Meeting)

Title: A Multicenter, Multicohort, Open-Label, Single-Arm per Cohort, Phase II Study to Assess the Efficacy and Safety of Tabelecleucel in Patients with EBV-Associated Diseases Using an Adaptive Two-Stage Study Design

**Abstract #: 2551** 

**Session:** 905. Outcomes Research—Malignant Conditions (Lymphoid Disease): Poster II **Time and Location:** Sunday, December 6, 2020: 7:00 AM-3:30 PM ET, Poster Hall (Virtual Meeting)

# 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 to create a robust pipeline including: tab-cel® (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 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: preclinical results and data from the IND-enabling studies for ATA3219; the timing and progress of ATA3219, Atara's ability to successfully advance the development of its CAR T programs, the potential benefits, safety and efficacy of tab-cel®; data from the tab-cel® EAP; the timing and progress of clinical trials of tab-cel®, and Atara's ability to successfully advance the development of tab-cel®. Because such statements deal with future events and are based on Atara Biotherapeutics' current expectations, they are subject to various risks and uncertainties and actual results, performance or achievements of Atara Biotherapeutics 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 Biotherapeutics' 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 Biotherapeutics 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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