

Atara Biotherapeutics to Present Tab-cel® Long-Term Clinical Outcomes from a Multicenter Expanded Access Protocol (EAP) Study for Patients with Epstein-Barr Virus-Associated Post-Transplant Lymphoproliferative Disease (EBV+ PTLD) at the 61st American Society of Hematology (ASH) Annual Meeting

- *26 relapsed/refractory EBV+ PTLD patients were treated in a multicenter tab-cel® EAP study including a subgroup of 22 patients who would have likely met eligibility criteria for Atara's ongoing tab-cel® Phase 3 studies*
- *An overall response rate (ORR) of 55 and 82 percent was observed in this subgroup of patients with EBV+ PTLD following allogeneic hematopoietic cell transplant (HCT) and solid organ transplant (SOT), respectively*
- *Estimated 2-year overall survival (OS) in this subgroup was 79 and 81 percent for HCT and SOT, respectively*
- *Atara to present additional findings describing the hospitalization burden of patients with EBV+ PTLD*
- *Atara's Moffitt Cancer Center collaborators to present two ASH abstracts detailing next-generation CAR T technologies*

SOUTH SAN FRANCISCO, Calif., Nov. 06, 2019 (GLOBE NEWSWIRE) -- Atara Biotherapeutics, Inc. (Nasdaq: ATRA), a leading off-the-shelf, allogeneic T-cell immunotherapy company developing novel treatments for patients with cancer, autoimmune and viral diseases, today announced that it will present long-term tab-cel® (tabelecleucel) clinical outcomes from a multicenter Expanded Access Protocol (EAP) study for patients with Epstein-Barr virus-associated post-transplant lymphoproliferative disease (EBV+ PTLD). These results, along with findings described in three additional abstracts, will be presented at the 61st American Society of Hematology (ASH) Annual Meeting & Exposition, to be held December 7-10, 2019, in Orlando, Florida.

"I am pleased with the tab-cel® long-term clinical outcomes for patients with EBV+ PTLD we continue to observe in our EAP study," said Pascal Touchon, President and Chief Executive Officer of Atara Biotherapeutics. "The well-tolerated safety profile, high response rate and durable 2-year survival data are consistent with our previous tab-cel® clinical experience and reinforces our confidence in tab-cel® as a potentially transformative off-the-shelf, allogeneic

T-cell immunotherapy for this often-deadly ultra-rare cancer.”

Twenty-six EBV+ PTLD patients who failed prior rituximab treatment regimens were enrolled in a tab-cel[®] EAP study (EAP-201) as of June 2018, after which EAP-201 was amended to focus on expanded access for patients with EBV+ PTLD and other EBV+ diseases who are not eligible for Atara's ongoing tab-cel[®] Phase 3 studies (EAP-901, [NCT02822495](https://clinicaltrials.gov/ct2/show/study/NCT02822495)). The findings presented here are as of June 3, 2019. Consistent with prior studies, no tab-cel[®] related adverse events leading to discontinuation or death occurred.

A subgroup of 22 EAP-201 EBV+ PTLD patients with adequate ECOG performance status, no CNS disease and no PTLD-related ventilatory support, would have likely met the eligibility criteria for Atara's ongoing tab-cel[®] Phase 3 studies.

The overall response rate (ORR) for patients in this EAP-201 subgroup with EBV+ PTLD following HCT (n=11) and SOT (n=11) was 55 and 82 percent with an estimated two-year overall survival of 79 and 81 percent, respectively.

For all EBV+ PTLD patients enrolled in EAP-201, the ORR was 50 and 83 percent for HCT (n=14) and SOT (n=12), respectively.

Atara will also present additional findings describing the hospitalization burden of patients with EBV+ PTLD following SOT who failed first-line rituximab or rituximab plus chemotherapy.

In addition, Atara's Moffitt Cancer Center collaborators will present two abstracts detailing next-generation CAR T technologies, licensed exclusively to Atara, and designed to enhance persistence while reducing susceptibility to exhaustion and suppressive immune microenvironments.

Details of the ASH presentations and abstracts are as follows:

Abstract 4071: Long-Term Outcomes of Subjects with Epstein-Barr Virus-Driven Post-Transplant Lymphoproliferative Disorder (EBV+PTLD) Following Solid Organ (SOT) or Allogeneic Hematopoietic Cell Transplants (HCT) Treated with Tabelecleucel on an Expanded Access Program

Poster Presentation Date and Time: Monday, December 9, 6:00 - 8:00 p.m. EST

Session Title: 626. Aggressive Lymphoma (Diffuse Large B-Cell and Other Aggressive B-Cell Non-Hodgkin Lymphoma) – Results from Prospective Clinical Trials: Poster III

Location: Orange County Convention Center, Hall B

Authors: Susan Prockop, M.D.¹, Ran Reshef, M.D.², Donald E. Tsai, M.D., Ph.D.³, Nancy Bunin, M.D.⁴, Rolla Abu-Arja, M.D.⁵, Kris Michael Mahadeo, M.D.⁶, Wen-Kai Weng, M.D., Ph.D.⁷, Koen Van Besien, M.D., Ph.D.⁸, David Loeb, M.D., Ph.D.⁹, Sunita Dwivedy Nasta, M.D.¹⁰, Eneida R. Nemecek, M.D., M.B.A., M.S.¹¹, Minoti Hiremath, MBBS, Ph.D.¹², Susan Yue, M.D.¹³, Yan Sun, Ph.D.¹³, Willis H Navarro, M.D.¹² and Sarah Nikiforow, M.D., Ph.D.¹⁴

Affiliations: ¹Memorial Sloan Kettering Cancer Center, New York, NY; ²Columbia University Irving Medical Center, New York, NY; ³Loxo Oncology, Stamford, CT; ⁴Children's Hospital of Philadelphia, Philadelphia, PA; ⁵Nationwide Children's Hospital, Columbus, OH; ⁶MD Anderson Cancer Center, Houston, TX; ⁷Division of Blood and Marrow Transplantation,

Department of Medicine, Stanford Univ. School of Med., Stanford, CA; ⁸Division of Hematology and Oncology, Weill Cornell Medical College, New York, NY; ⁹Montefiore, Bronx, NY; ¹⁰University of Pennsylvania, Philadelphia; ¹¹Pediatric Hematology/Oncology & Bone Marrow Transplantation, OHSU Knight Cancer Institute Doernbecher Children's Hospital, Portland, OR; ¹²Atara Biotherapeutics, South San Francisco, CA; ¹³Atara Biotherapeutics, Thousand Oaks, CA; ¹⁴Dana-Farber Cancer Institute, Boston, MA

Abstract 65: Burden of Hospitalizations Due to Epstein-Barr Virus-Driven Post-Transplant Lymphoproliferative Disorder (EBV+ PTLD) in Patients Who Failed First Line Rituximab or Rituximab Plus Chemotherapy Following Solid Organ Transplant (Post-SOT): A Retrospective Chart Review Study of German PTLD Registry

Oral Presentation Date and Time: Saturday, December 7, 8:30 a.m. EST

Session Title: 902. Health Services Research – Malignant Conditions (Lymphoid Disease): Health Care Utilization and Quality of Life

Location: Orange County Convention Center, W308

Authors: Heiner Zimmermann, M.D.¹, Hairong Xu, M.D., Ph.D.², Arie Barlev, Pharm.D.³, Yang Zhang, Ph.D.², Dhanalakshmi Thirumala², Crystal Watson, M.S.³ and Ralf Ulrich Trappe, M.D.¹

Affiliations: ¹Internal Medicine II: Hematology and Oncology, Diako Hospital, Bremen, Germany; ²Atara Biotherapeutics, Inc, Thousand Oaks, CA; ³Atara Biotherapeutics, Inc, South San Francisco, CA

Summary: Approximately one-half of PTLD patients treated with rituximab, currently first-line therapy for PTLD, are relapsed or refractory to treatment. This review of the German PTLD registry database showed a substantial hospitalization burden for patients failing rituximab treatment, accounting for approximately 20% of patients' hospitalization time after initial PTLD diagnosis with approximately 10% of the time spent in the ICU.

Abstract 5826: The Economic Burden of Short-Term Adverse Events Associated with the CHOP Chemotherapy Regimen in Patients with Lymphoproliferative Disorders in the United States; A Comprehensive Literature Review

Presentation Date and Time: N/A; will appear in the November supplemental online-only issue of *Blood*

Authors: Crystal Watson, M.S.¹, Arie Barlev, Pharm.D.¹, Jodie Worrall¹, Steve Duff, M.S.³, Rachel Beckerman, Ph.D.²

Affiliations: ¹Atara Biotherapeutics, Inc, South San Francisco, CA; ²Maple Health Group, New York, NY; ³Veritas Health Economic Consulting, Carlsbad, CA

Abstract 867: Mutation of the CD28 Costimulatory Domain Confers Enhanced CAR T Cell Function

Oral Presentation Date and Time: Monday, December 9, 5:00 p.m. EST

Session Title: 703. Adoptive Immunotherapy: Mechanisms and New Approaches: New Approaches

Location: Orange County Convention Center, W224ABEF

Authors: Justin C Boucher¹, Gongbo Li¹, Hiroshi Kotani¹, Maria L Cabra², Dylan Morrissey³, Sae Bom Lee^{1,4}, Kristen Spitler¹, Nolan Beatty^{1,4}, Bishwas Shrestha¹, Bin Yu¹, Aslamuzzaman Kazi⁵, Xuefeng Wang⁶, Said M Sebt⁵, Marco L Davila^{1,3}

Affiliations: ¹Department of Blood & Marrow Transplant and Cellular Immunotherapy, Division of Clinical Science, H. Lee Moffitt Cancer Center, Tampa, FL; ²Department of Cell Biology, Microbiology, and Molecular Biology, College of Arts and Sciences, University of South Florida, Tampa, FL; ³Morsani College of Medicine, University of South Florida Health, Tampa, FL; ⁴Cancer Biology PhD Program, University of South Florida, Tampa, FL; ⁵Drug Discovery Program, H. Lee Moffitt Cancer Center, Tampa, FL; ⁶Department of Biostatistics and Bioinformatics, H. Lee Moffitt Cancer Center, Tampa, FL

Summary: Current generation Chimeric antigen receptors (CARs) utilizing CD28 co-stimulatory domains have been reported to drive high levels of T cell activation that also lead to exhaustion and shortened persistence. Three signaling subdomains present on CD28 differentially regulate this drive towards exhaustion. Using a combination of *in vitro* and *in vivo* genomic studies, this study demonstrates CAR T cells using a modified version of CD28, with tailored signaling driven through the PYAP (mut06) subdomain, optimizes CAR T cell signaling by lowering transcription factors that drive exhaustion.

Abstract 4438: MDSC Suppression of CAR T cell can be Reduced by Targeted Signaling Disruption

Poster Presentation Date and Time: Monday, December 9, 6:00 - 8:00 p.m. EST

Session Title: 703. Adoptive Immunotherapy: Mechanisms and New Approaches: Poster III

Location: Orange County Convention Center, Hall B

Authors: Estelle V Cervantes¹, Justin C Boucher², Sae Bom Lee^{2,3}, Kristen Spittler², Kayla Reid², Marco L Davila^{1,2}

Affiliations: ¹Morsani College of Medicine, University of South Florida, Tampa, FL, 33612; ²Department of Blood & Marrow Transplant and Cellular Immunotherapy, Division of Clinical Science, H. Lee Moffitt Cancer Center, Tampa, FL, 33612; ³Cancer Biology PhD Program, University of South Tampa, Tampa, FL, 33612

Summary: CAR T persistence is one of the challenges faced by CAR T cell therapy. Myeloid derived suppressor cells (MDSCs) function as key contributors to preventing persistence of CAR T cells. Data from this study show MDSCs can suppress CAR T cell function when present in vitro, including during CAR T production, as demonstrated by reductions in CAR T cell activation and cytotoxicity. CAR T cells expressing an optimized CD28 co-stimulatory domain (mut06) were less susceptible to the suppressive effects of MDSCs in vitro and in vivo. These data support that mut06 CARs may improve activity and persistence in the presence of MDSCs and may also improve CAR T production in vitro by overcoming the effects of MDSCs.

About Atara Biotherapeutics, Inc.

[Atara Biotherapeutics, Inc. \(@Atarabio\)](#) is a leading off-the-shelf, allogeneic T-cell immunotherapy company developing novel treatments for patients with cancer, autoimmune and viral diseases. Atara's technology platform leverages research collaborations with leading academic institutions with the Company's scientific, clinical, regulatory and manufacturing expertise. Atara's pipeline includes tab-cel[®] (tabelecleucel), which is in Phase 3 development for patients with Epstein-Barr virus-associated post-transplant lymphoproliferative disease (EBV+ PTLD) as well as in earlier stage development for other EBV-associated hematologic malignancies and solid tumors, including nasopharyngeal carcinoma (NPC); T-cell immunotherapies targeting EBV antigens believed to be important for the potential treatment of multiple sclerosis; and next-generation chimeric antigen

receptor T-cell (CAR T) immunotherapies. The company was founded in 2012 and is co-located in South San Francisco and Southern California. Our Southern California hub is anchored by the state-of-the-art Atara T-cell Operations and Manufacturing (ATOM) facility in Thousand Oaks, California. For additional information about the company, please visit atarabio.com.

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 impact of tab-cel[®]; and the results from Atara's ongoing tab-cel[®] EAP study. These forward-looking statements are subject to risks and uncertainties, 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.

INVESTOR & MEDIA CONTACT:

John Craighead, Ph.D.
Vice President, Investor Relations & Corporate Communications
Atara Biotherapeutics
650-410-3012
jcraighead@atarabio.com



Source: Atara Biotherapeutics, Inc.