

Atara Biotherapeutics To Present Clinical Data in Epstein-Barr Virus-Driven (EBV+) Acquired & Primary Immunodeficiency Lymphoproliferative Diseases (AID-LPD and PID-LPD) from Tab-Cel® Expanded Access Program in e-Poster at ESMO 2020 Virtual Congress

Tab-cel® was well-tolerated and demonstrated encouraging clinical efficacy in previously treated patients with EBV⁺ AID-LPD and PID-LPD

Data provide rationale for cohort selection in tab-ce® Phase 2 multi-cohort study with registrational intent which remains on track to initiate enrollment in 2H 2020

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)-- [Atara Biotherapeutics, Inc.](#) (Nasdaq: ATRA), a pioneer in T-cell immunotherapy, leveraging its novel allogeneic EBV T-cell platform to develop transformative therapies for patients with severe diseases including solid tumors, hematologic cancers and autoimmune disease, today announced the presentation of safety and efficacy data in Epstein-Barr virus-driven (EBV⁺) acquired and primary immunodeficiency lymphoproliferative diseases (AID-LPD and PID-LPD) from the tabelecleucel (tab-cel®) Expanded Access Program (EAP) (NCT02822495). These data demonstrate that tab-cel® was well-tolerated and showed encouraging clinical activity in patients with EBV⁺ AID-LPD and PID-LPD. The results will be featured in an e-poster at the European Society for Medical Oncology (ESMO) 2020 Virtual Congress, held September 17-21, 2020.

Data being presented for the first time at ESMO will detail the clinical experience of tab-cel® in patients with EBV⁺ AID- and PID-LPD from an EAP. Results provide evidence of clinical safety and activity of tab-cel® in patients with EBV⁺ AID-LPD and PID-LPD.

“There are an estimated few thousand cases of EBV⁺ AID-LPD and PID-LPD annually in the U.S., often presenting as aggressive lymphomas,” said Jakob Dupont, Global Head of Research and Development at Atara. “Currently there are no approved therapies, with initial treatments usually including chemotherapy with or without rituximab. Failure of initial treatment results in poor prognosis. As previously reported in other EBV⁺ cancers these data demonstrate tab-cel® may provide a treatment option with a favorable benefit-risk profile for these very sick patients with significant unmet medical need for whom there are limited therapeutic options.”

In the EAP, patients with EBV⁺ AID-LPD (n=9) and PID-LPD (n=8) received tab-cel[®] at 1.6-2.0 x10⁶ cells/kg/dose on Days 1, 8 and 15 with investigator-assessed response per Lugano criteria on Day 28 of each 5-week cycle. Patients classified as non-responders (progressive disease or stable disease) were allowed to switch to tab-cel[®] with a different human leukocyte antigen (HLA) restriction (restriction switch). Patients continued treatment until unacceptable toxicity, maximal response or up to four different HLA restrictions.

Specifically, objective response rates (ORR) were 33.3 percent (three out of nine patients) in AID-LPD and 37.5 percent (three out of eight patients) in PID-LPD groups demonstrating clinical activity of tab-cel[®]. Tab-cel[®] was generally well-tolerated with a favorable safety profile consistent with previously published clinical studies. A total of five patients had treatment-related treatment-emergent serious adverse events (TESAEs) in the AID-LPD (n=2) and PID-LPD (n=3) cohorts (all less than grade 3; two grade 3, one grade 2 and two grade 1). No fatal events were reported as treatment-related. Additional data will be included in the poster, available later this week, detailing overall survival and prior treatments.

“Given the preliminary efficacy we are seeing in these patient populations, combined with the favorable safety profile we have observed across the entire tab-cel[®] program, we are more encouraged than ever to expand our study of tab-cel[®] across various EBV⁺ cancers,” said AJ Joshi, M.D., Senior Vice President and Chief Medical Officer at Atara. “These data provide a strong rationale for further clinical investigation of tab-cel[®] in EBV⁺ AID- and PID-LPD in our Phase 2 multi-cohort study which will begin enrolling in the second half of 2020, and may significantly expand the opportunity for tab-cel[®].”

Atara is focusing on extending further into IA-LPDs (immunodeficiency-associated lymphoproliferative diseases) as the next step in the tab-cel[®] potential label expansion given the commonality of their EBV-driven mechanism of disease in immunocompromised patients, high unmet medical need and positive clinical data to date with tab-cel[®].

The multi-cohort study will evaluate both treatment-naïve and previously treated patients in six patient populations with significant unmet need, including within IA-LPDs, two cohorts addressing EBV⁺ LPDs arising out of primary or acquired immune deficiencies including AID-LPD and PID-LPD and two cohorts addressing front-line EBV⁺ PTLD (post-transplant lymphoproliferative disease). Altogether these populations represent an additional few thousand patients with addressable EBV-driven diseases in the U.S. alone.

Abstracts were made available on the ESMO Website as of 6:05 p.m. ET on Sunday, September 13. E-posters will be made available on Thursday, September 17 3:00 a.m. ET/9:00 a.m. CEST.

About EBV+ Immunodeficiency-Associated Lymphoproliferative Disorders (IALPD), Including AID-LPD and PID-LPD

EBV⁺ IALPD represents a group of diseases that include PTLD, AID-LPD, and PID-LPD. All are characterized by immunodeficiency which can allow EBV to reactivate. This reactivation leads to uncontrolled proliferation and transformation of cells and the development of lymphoproliferative disease that often manifests as aggressive B-cell lymphoma. Though there are no approved therapies in these conditions, initial treatment approaches are

generally similar with poor prognosis when initial treatments fail.

AID-LPD can arise due to immune suppression in patients with autoimmune diseases such as Rheumatoid Arthritis, Primary Sjogren's Syndrome, Systemic Lupus Erythematosus, or as a result of an infection such as HIV causing AIDS. PID-LPD arises in patients who have Primary Immunodeficiency Diseases, a group of more than 400 rare, chronic disorders in which part of the body's immune system is missing or functions improperly, including both Humoral Deficiencies and Combined Immune Deficiencies.

Currently no therapies are approved for the treatment of AID-LPD and PID-LPD and treatment options are limited for those with relapsed or refractory diseases. PID-LPD patients tend to have especially poor prognosis as they often cannot tolerate standard doses of chemotherapy and are at high risk for infection.

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 severe 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 severe 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+ PTLN); 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[®]; 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 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.

View source version on businesswire.com:

<https://www.businesswire.com/news/home/20200914005272/en/>

INVESTOR & MEDIA:

Media

Kerry Beth Daly
Head, Corporate Communications
Atara Biotherapeutics
516-982-9328
kdaly@atarabio.com

Investors

Eric Hyllengren
Vice President, Investor Relations & Finance
Atara Biotherapeutics
805-395-9669
ehyllengren@atarabio.com

Source: Atara Biotherapeutics, Inc.