

# **Atara Biotherapeutics to Present New Open-Label Extension Data, Including 15-Month Safety and Efficacy Data from Highest Dose Cohorts, in the Phase 1a Study of ATA188 for Progressive Forms of Multiple Sclerosis at the ECF 28th Annual Meeting**

*Long-term follow-up shows all patients who demonstrated sustained disability improvement (SDI) maintained it at all subsequent timepoints*

*50 percent of patients in the two highest dose Cohorts (3 and 4) demonstrated SDI at 15 months*

*Cohort 4 dose selected for the ongoing randomized placebo-controlled clinical trial (RCT) based on higher proportion of patients showing sustained EDSS improvements and consistent safety profile over 15 months*

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 serious diseases including solid tumors, hematologic cancers and autoimmune disease, today announced the Company will present for the first time 15-month safety and efficacy data from all patients in the two highest dose cohorts of the Phase 1a open-label extension (OLE) study of ATA188 for the treatment of progressive forms of multiple sclerosis (MS). The results are featured in a poster presentation at the European Charcot Foundation (ECF) 28<sup>th</sup> Annual Meeting, held November 15-19, 2020.

“We are very pleased to see dose-related and durable responses maintained long-term which likely indicate a treatment effect with ATA188,” said Jakob Dupont, Global Head, Research and Development at Atara. “Seeing 50 percent of patients achieve long-term sustained disability improvement out to 15 months is remarkable in progressive forms of MS and supports the continued clinical investigation of ATA188 for this devastating disease for which there are currently no treatment options that substantially alter the course of disease.”

Findings presented include data on 24 patients from the 12-month dose escalation portion of the trial, 16 of whom entered the OLE and have ≥15-month data available as of October 2020. Throughout the entire Phase 1a and OLE study, nine of the 16 patients who entered the OLE demonstrated sustained disability improvement (SDI) with ATA188 treatment (seven achieved SDI in the first twelve months and two during the OLE). In seven out of the

nine patients, SDI was driven by sustained improvement in Expanded Disability Status Score (EDSS).

A dose-related increase in the number of patients meeting SDI criteria was observed. Similar safety profile with no dose-limiting toxicities was shown in the highest dose cohorts (Cohorts 3 and 4). In the two highest dose cohorts, five out of 12 total patients (42%) and six out of 12 total patients (50%) demonstrated SDI at 12 and 15 months, respectively. SDI was driven by EDSS in all but one of the patients in Cohorts 3 and 4; all SDI observed in Cohort 4 was based on EDSS improvement. The Cohort 3 and 4 doses demonstrated similar efficacy profile based on SDI, with the Cohort 4 dose trending toward greater effect on EDSS.

Given encouraging clinical results to date in ATA188 studies and the significant unmet medical need in progressive forms of MS, the Company is increasing its investment in the ATA188 program. Atara is expanding the size of the RCT to at least 64 patients, changing the primary endpoint of the study to disability improvement, and maintaining biological and functional endpoints.

“With a higher proportion of patients demonstrating sustained EDSS improvements and a continued favorable safety profile, we will start treating newly enrolled patients with the Cohort 4 dose per the amended protocol in the randomized placebo-controlled study,” said AJ Joshi, M.D., Senior Vice President and Chief Medical Officer of Atara Biotherapeutics. “Additionally, we are making great progress enrolling the randomized trial and advancing the overall development program. We look forward to continuing to periodically provide meaningful data updates from the OLE.”

The Company recently submitted material to the U.S. Food and Drug Administration (FDA), that includes the Phase 1a data, planned updated design of the RCT and discussion of potential opportunities for expedited development of ATA188 for patients living with progressive forms of MS. Feedback from the agency is expected at the end of 2020.

## **About ATA188**

Epstein-Barr Virus (EBV) is associated with a wide range of hematologic malignancies and solid tumors, as well as certain autoimmune conditions such as multiple sclerosis (MS). T cells are a critical component of the body’s immune system and can selectively target EBV believed to be important in the pathogenesis of MS.

Off-the-shelf, investigational ATA188, has the potential to target EBV-infected B cells and plasma cells in the central nervous system that may catalyze autoimmune responses and MS pathophysiology.

Atara is advancing the clinical development of ATA188 with a double-blind, randomized, placebo-controlled clinical trial (RCT) in patients with progressive MS across clinical sites in the U.S. and Australia. In addition to measuring disability progression, the study will also evaluate many facets of the disease, including: cognition and outpatient ambulatory activity; fatigue, and biological end points in blood and cerebrospinal fluid/CSF (IgG, synthesis and index, OCBs, product kinetics); and MRI imaging.

## **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<sup>®</sup> (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](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 ATA188; data from the Phase 1a study of ATA188; planned updates to the design of the ATA188 RCT; the timing and progress of clinical trials of ATA188, and Atara's ability to successfully advance the development of ATA188. 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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