

# Atara Biotherapeutics Presents New MRI and Updated Open-Label Extension Data from Phase 1 Study of ATA188 in Progressive Multiple Sclerosis at ECTRIMS 2022

*Sustained Improvement Observed in ATA188 Treated Patients Achieving Confirmed Disability Improvement (CDI) in Open Label Extension (OLE) with up to 46 Months Follow up*

*Patients Treated with ATA188 that Achieved CDI Demonstrate Significantly Less Brain Atrophy in Longitudinal Analysis Through 42 Months*

*All Patients in the OLE with Stable Disease Remained Stable for up to 48 Months*

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 new magnetic resonance imaging (MRI) biomarker and open-label extension (OLE) clinical data from the study of ATA188, an investigational Epstein-Barr virus (EBV)-targeted T-cell immunotherapy, in progressive multiple sclerosis (MS). These findings will be presented as a late-breaking ePoster at the 38<sup>th</sup> Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) taking place October 26-28, 2022, in Amsterdam, the Netherlands.

During the initial 12 months, or in the OLE, seven of the 24 patients achieved confirmed disability improvement (CDI), by expanded disability status scale (EDSS), defined as EDSS improvement versus baseline that is confirmed at two consecutive timepoints; 13 had stable EDSS and four had confirmed disability progression (CDP). Additionally, nine met sustained disability improvement (SDI) criteria, a composite scale combining confirmed improvement in either the EDSS score or timed 25-foot walk test in the initial 12-month period (n=7) or in the OLE (n=2). These data demonstrate that ATA188 continues to be well-tolerated, and safety is consistent with previous reports with no Grade >3 events, dose limiting toxicities, cytokine release syndrome, or graft versus host disease.

“New biomarker imaging data presented at ECTRIMS suggest brain structural changes and potential remyelination may underlie clinical disability improvements observed with ATA188 treatment,” said AJ Joshi, MD, Chief Medical Officer at Atara. “We are pleased to see a majority of patients experiencing either long term durability of CDI based on EDSS improvement or long-term stability in EDSS, which would also represent a transformational profile relative to the expected natural course of the disease.”

As of September 2022, patients achieving CDI continuing in the OLE have been followed for up to 46.5 months. Five of five patients continued to maintain CDI for a median of 27.5 (range, 23.8–36.7) months. Eight of eight participants with stable EDSS remaining in the OLE continued to have a stable EDSS for a median of 41.2 (36.3–48.5) months.

In the study, changes in whole-brain and regional brain volumes were assessed longitudinally utilizing T1-weighted and FLAIR MRI images. Specific measures of atrophy included percentage brain volume change (PBVC), percentage ventricular volume change (PVVC, where increasing ventricular volume is indicative of increased atrophy in general, and specifically subcortical atrophy), and thalamic volume change (TVC) assessed on T1-weighted MRI. Myelin density was assessed longitudinally through nMTR images in T2 unenhancing lesions and in the normal-appearing brain tissue.

During the initial 12 months:

- Patients who achieved SDI (n=7) had significantly less ventricular enlargement (PVVC,  $p=0.019$ ), reflecting less brain atrophy, and similar PBVC ( $p=0.538$ ) and TVC ( $p=0.529$ ) versus those who did not (n=16).
- Similar trends were observed in patients achieving CDI, who tended to have less ventricular enlargement (PVVC;  $p=0.108$ ) at 12 months while PBVC ( $p=0.437$ ) and TVC ( $p=0.742$ ) were similar.

In a longitudinal analysis through 42 months, patients achieving CDI (versus not) had:

- Significantly less decrease in PBVC over time ([95% CI: 0.02–0.66],  $p=0.037$ ) and there was a trend for less ventricular volume enlargement over time ([95% CI: –0.6–0.03],  $p=0.074$ ), both reflecting less brain atrophy; TVC did not differ by CDI status.
- Significantly increased signal on nMTR in unenhancing T2 lesions (reflective of possible increased myelin density) ([95% CI: 0.05–0.24],  $p=0.005$ ) suggesting that brain structural changes, potentially including remyelination, persist over time and may underlie the durable CDI associated with ATA188.
- A trend for increased myelin density (nMTR) in normal appearing brain tissue over time ([95% CI: –0.04–0.35],  $p=0.112$ ).

Further detail on MRI and nMTR data as well as updated safety and efficacy data will be presented in the October 26 ePoster presentation, EP1242.

In separate ePosters (EP1070 & EP1190), Atara will also present health economics and outcomes research data on the unmet need in patients with non-active secondary progressive multiple sclerosis (SPMS) in the U.S. and the study design, patient demographics, and healthcare resource utilization of patients with active and non-active PMS in a novel, patient-centered real-world evidence study.

### **Poster Presentation Details:**

**EP1242:** Long-term disability improvement during EBV-targeted T-cell immunotherapy ATA188 is related to brain volume change and normalised magnetisation transfer ratio in T2 lesions

- **Presenting Author:** Samantha Noteboom, MS Center Amsterdam, Anatomy and

Neurosciences, Vrije Universiteit Amsterdam, Amsterdam Neuroscience, Amsterdam UMC location VUmc, Amsterdam, Netherlands

- **Date & Time:** Wednesday, October 26, 2022, at 8 a.m. CEST / 2 a.m. EDT / 11 p.m. PDT on Tuesday, October 25, 2022

**EP1070:** Unmet Need of Current Disease-modifying Treatments Reported by Physicians in Patients with Non-active Secondary Progressive Multiple Sclerosis in the United States

- **Presenting Author:** Kiren Kresa-Reahl, MD, Atara Biotherapeutics, South San Francisco, CA, United States
- **Date & Time:** Wednesday, October 26, 2022, at 8 a.m. CEST / 2 a.m. EDT / 11 p.m. PDT on Tuesday, October 25, 2022

**EP1190:** A Novel, Patient-Centred Real-World Evidence Study Designed to Better Understand Active and Non-active Progressive Multiple Sclerosis Using Health Records in the United States

- **Presenting Author:** Kiren Kresa-Reahl, MD, Atara Biotherapeutics, South San Francisco, CA, United States
- **Date & Time:** Wednesday, October 26, 2022, at 8 a.m. CEST / 2 a.m. EDT / 11 p.m. PDT on Tuesday, October 25, 2022

## About ATA188

Epstein-Barr virus (EBV) is the leading cause of multiple sclerosis (MS) from onset to progression of the disease and is both necessary for and precedes diagnosis of MS, with prior EBV infection increasing susceptible individuals' risk of developing MS 32-fold. EBV-infected B cells drive pathology in MS by stimulating autoreactive T cells, and by differentiating into autoreactive plasma cells. These EBV-infected B cells present in the central nervous system (CNS), driving chronic inflammation and the generation of reactive antibodies against some brain proteins. Specifically targeting EBV infected immune cells represents a new targeted approach. ATA188, Atara's investigational off-the-shelf, allogeneic T-cell immunotherapy aims to specifically target EBV-infected B cells and plasma cells for progressive forms of MS. ATA188 is currently in a Phase 2 **EMBOLD** clinical study for the treatment of patients with progressive forms of MS and has met target enrollment, with final data and communication expected in October 2023.

## 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 receiving a CHMP positive opinion for a marketing authorization 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, USA. For additional information about the company, please visit [atarabio.com](https://www.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 ATA188, the development, timing and progress of ATA188, the potential characteristics and benefits of ATA188, the potential safety, efficacy, duration of response and tolerability of ATA188, including as measured by SDI or EDSS, clinical trials and data relating to ATA188, and the potential link between ATA188 and brain structural changes or remyelination. 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 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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