

September 11, 2020



# **Atara Biotherapeutics Announces All Progressive Multiple Sclerosis Patients with Sustained Disability Improvement at Six Months Confirmed Improvement at 12 Months in the Phase 1a Study of ATA188**

*Patients Who Achieved SDI at Any Timepoint Maintained it at All Future Timepoints; Higher Proportion of Patients Showing SDI with Increasing Dose*

*Patients Achieving SDI Also Demonstrated Trend Toward Improvement in Fatigue and Physical Function at 12 Months*

*First Available Data from Open Label Expansion Show Patients with SDI at 12 Months, Maintained SDI at Later Time Points*

*Conference Call and Webcast Today, September 11, 2020 at 8:30 a.m. ET*

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 treatments for patients with severe diseases, including solid tumors, hematologic cancers and autoimmune disease, today announced the presentation of data from the first part of the ongoing Phase 1 study of ATA188 for the treatment of progressive forms of multiple sclerosis (MS). ATA188 is an off-the-shelf, allogeneic EBV-specific T-cell immunotherapy. These data demonstrate that ATA188 was well-tolerated across all four dose cohorts; patients who achieved sustained disability improvements at any timepoint maintained it at all future timepoints and a higher proportion of patients showed sustained disability improvements (SDI) with increasing dose. The results are featured in an e-poster at MSVirtual2020: 8<sup>th</sup> Joint ACTRIMS-ECTRIMS Meeting, held September 11-13, 2020.

“It is very encouraging to see that patients receiving ATA188 who achieved sustained disability improvement at any time point maintained it at all future time points and tended to also show improvements in fatigue and physical function at 12 months,” said Jakob Dupont, Global Head, Research and Development. “These results together with a favorable safety profile highlight the potential of ATA188 for patients with progressive MS and reinforce our excitement around advancing the randomized placebo-controlled portion of the study which is currently enrolling.”

This Phase 1a multicenter, open-label study of ATA188 in patients with progressive forms of MS was designed to establish safety and tolerability, to select the recommended dose for the randomized placebo-controlled Phase 1b study, which is currently actively recruiting, and to assess potential efficacy. Patients were treated across four dose-escalating cohorts (5 x 10<sup>6</sup>, 1 x 10<sup>7</sup>, 2 x 10<sup>7</sup> and 4 x 10<sup>7</sup> cells), with six patients each in cohorts 1-3 and seven

patients in cohort 4.

The e-poster presented at ACTRIMS-ECTRIMS assesses safety as well as sustained disability improvement (SDI), defined as improvement in Expanded Disability Status Scale (EDSS) or Timed 25-Foot Walk (T25W) at  $\geq 2$  consecutive time points. Other measures evaluated include Fatigue Severity Score (FSS), 12-item Multiple Sclerosis Walking Scale (MSWS-12), Multiple Sclerosis Impact Scale (MSIS-29), and whole brain volume (via magnetic resonance imaging, MRI).

All patients in cohorts 1-4 of this Phase 1 study showing SDI at six months, maintained improvement through 12 months. Additionally, a dose-related increase in the number of patients with SDI at 12 months was observed (42 percent in Cohorts 3 and 4 vs 17 percent in Cohorts 1 and 2) and EDSS was the main driver of SDI (vs T25FW) in five of the seven patients who achieved an SDI response at 12 months. These patients also showed a trend toward improvement in Fatigue Severity Scale, MS Impact Scale measuring physical function and the MS Walking Scale.

Data from the open-label extension (OLE) with redosing at 12 months show that all three patients that achieved SDI at 12 months maintained SDI at 15 months with the patient evaluated at 18 months maintaining SDI at that time point as well. A fourth patient achieved SDI during the OLE at 24 months.

The study found that across the four dose cohorts, ATA188 was well-tolerated in patients with progressive forms of MS. No dose-limiting toxicities and no fatal adverse events (AEs) have been reported. The safety profile has remained consistent with previously reported data.

A poster featured at ACTRIMS-ECTRIMS also details the Phase 1b double-blind randomized placebo-controlled study, which is actively recruiting. In addition to measuring disability progression, the study will evaluate other facets of 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. This study will be amended and expanded to allow for SDI to become the primary end point.

In addition to the clinical data reported, Atara also presented at ACTRIMS-ECTRIMS preclinical translational data that further support the proposed mechanism of action of ATA188 targeting EBV-infected B cells. These combined analyses of T cells comprising ATA188 are consistent with its proposed mechanism of targeting EBV-infected B cells by recognizing MS-relevant EBV antigens on these cells via defined T-cell receptors (TCRs).

“Our innovative approach of targeting EBV-infected B cells has led to very encouraging clinical results as we see sustained disability improvement consistently over time throughout this first study with ATA188,” said Pascal Touchon, President and Chief Executive Officer of Atara. “Although some treatments may delay disability progression in progressive MS, there are currently no treatment options in progressive MS that reverse the progression of disease. Therapies that improve disability would be very meaningful for patients with this progressive, debilitating, and life-altering disease. We are investing further in this valuable program in optimizing the protocol of our Randomized Control Trial, running new translational studies to further elucidate the Mode of Action and implementing novel process improvements using stirred-tank bioreactors to scale up manufacturing.”

## Atara Conference Call and Webcast Information

Atara will hold a conference call at 8:30 a.m. ET for analysts and investors to review the Phase 1a data and Atara's continued plans for the ATA188 program and provide an additional corporate update. The call will include:

- Pascal Touchon, President and Chief Executive Officer, Atara Biotherapeutics
- Jakob Dupont, MD, Executive Vice President, Global Head of Research and Development, Atara Biotherapeutics
- AJ Joshi, MD, Senior Vice President and Chief Medical Officer, Atara Biotherapeutics

Analysts and investors can participate in the conference call by dialing (888) 540-6216 for domestic callers and (734) 385-2715 for international callers, using the conference ID 6694633. A live audio webcast can be accessed by visiting the [Investors & Media – News & Events](#) section of [atarabio.com](#). An archived replay will be available on the Company's website for 30 days following the live webcast.

### Details of the MSVirtual2020 e-Poster Presentations:

**Title:** Phase I study of ATA188, an off-the-shelf, allogeneic Epstein-Barr virus-targeted T-cell immunotherapy for progressive forms of multiple sclerosis

**Poster #:** P0226

**Abstract #:** 1635

**Title:** Phase I, multicenter, two-part study of ATA188, an open-label, dose-escalation and double-blind, placebo-controlled dose-expansion study

**Poster #:** P0227

**Abstract #:** 1691

**Title:** Gene expression profiling and TCR diversity of ATA188, an off-the-shelf, allogeneic EBV-targeted T-cell immunotherapy for progressive MS (encore from AAN 2020)

**Poster #:** P0084

**Abstract #:** 1770

### About EBV in MS

Though the development of MS likely requires more than a single causative factor, EBV is the only risk factor identified to date that appears to be necessary for MS.<sup>4</sup> Evidence demonstrates that 100 percent of patients with MS have been exposed to EBV.<sup>1-4,7</sup> EBV-infected cells, particularly B memory cells which have become immortalized with EBV infection, are thought to play an important role in the immune cascade responsible for both relapsing and progressive forms of MS. The success of interventions that deplete all peripheral B cells underscores the importance of these cells in MS pathophysiology. ATA188 offers a unique approach with the advantage of selectively targeting EBV-infected B cells and plasma cells in the circulation and in the central nervous system (CNS).

### 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, placebo-controlled clinical study 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 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<sup>®</sup> (tabelecleucel) in Phase 3 development for Epstein-Barr virus-driven post-transplant lymphoproliferative disease (EBV+ PTLTD); 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](#).

### **References**

<sup>1</sup>Dobson R, et al. Epstein-Barr-negative MS: a true phenomenon? *Neurol Neuroimmunol Neuroinflamm.* 2017;4:1-4.

<sup>2</sup>Pakpoor J, et al. The risk of developing multiple sclerosis in individuals seronegative for Epstein-Barr virus: a meta-analysis. *Mult Scler.* 2012;19:162-166.

<sup>3</sup>Ruprecht K. Absence of Epstein-Barr virus seronegativity in a large cohort of patients with early multiple sclerosis. Presented at: ECTRIMS; October 10-12, 2018; Berlin, Germany. Abstract 320.

<sup>4</sup>Abrahamyan S, et al. Complete Epstein-Barr virus seropositivity in a large cohort of patients with early multiple sclerosis. *J Neurol Neurosurg Psychiatry.* 2020 May 5. [Epub ahead of print]

<sup>5</sup>Bar-Or A, et al. Epstein-Barr Virus in Multiple Sclerosis: Theory and Emerging Immunotherapies. *Trends Mol Med.* 2020;26:296-310.

<sup>6</sup> Pender MP. Infection of autoreactive B lymphocytes with EBV, causing chronic autoimmune diseases. *Trends Immunol.* 2003;24:584-588.

<sup>7</sup> Bar-Or A, et al. Phase 1 Study of the Safety and Efficacy of ATA188, an Off-the-shelf, Allogeneic Epstein-Barr Virus-targeted T-cell Immunotherapy to Treat Progressive Forms of Multiple Sclerosis. Presented at: EAN; May 23-26, 2020; Virtual from Vienna, Austria. EPO130.

## **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 functional characteristics and potential safety and efficacy of ATA188; the enrollment of patients in the Phase 1b study of ATA188, the timing and progress of clinical trials of ATA188; and Atara Biotherapeutics' ability to successfully advance, and the potential timelines for, 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 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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