

June 17, 2020



Atara Biotherapeutics Announces First Patient Enrolled in Randomized Placebo-Controlled Study of Allogeneic T-cell Therapy ATA188 in Progressive Forms of Multiple Sclerosis

Based on promising results from the Phase 1a study including sustained disability improvements among progressive MS patients, the Phase 1b study will assess clinical outcomes including measures of disability, physical and cognitive function, biomarkers and MRI imaging as well as safety

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 first patient has been enrolled in a Phase 1b study of ATA188, an off-the-shelf, allogeneic EBV-specific T-cell immunotherapy, in patients with progressive forms of multiple sclerosis (MS).

The Phase 1b study ([NCT03283826](#)) is a double-blind randomized placebo-controlled study evaluating the efficacy and safety of ATA188. In addition to measuring change in disability measures compared to baseline, especially sustained improvement over time, the Phase 1b study will also include multiple measures of patients' function as well as various biomarkers. Types of data to be collected include: standard disability measures (EDSS, timed 25 foot walk test, 9 hole peg test); cognition and outpatient ambulatory activity; patient-reported fatigue; visual acuity; biomarkers in blood and cerebrospinal fluid (CSF); and, MRI imaging.

"We are thrilled at the investigator and patient interest in our randomized placebo-controlled Phase 1b study assessing the efficacy and safety of ATA188," said AJ Joshi, MD, Senior Vice President and Chief Medical Officer of Atara Biotherapeutics. "The initiation of this study, including first-patient-enrolled, is an important step in further assessing the potential of ATA188 in progressive MS, a complex disease of high unmet medical need where disability continues to progress despite approved treatment options. Based on the promising results of safety and sustained disability improvements seen to date in the Phase 1a study, we look forward to continuing enrollment in this randomized placebo-controlled study with the goal of developing a transformative therapy for patients that could halt or reverse the progression of this severe disease."

Participants in clinical sites across the U.S. and Australia will be randomized to receive ATA188 or matching placebo at the cohort 3 dose selected from the Phase 1a portion of the study. The primary end point will be evaluated at 12 months, after which, all subjects will be switched to active treatment and followed for an additional 12 months. All subjects will have the opportunity to enter into a three-year open-label extension after the first two years of

treatment.

Progression into the randomized, placebo-controlled study of ATA188 is supported by data from the Phase 1a study that were featured in a late-breaking e-poster at the 6th Congress of the European Academy of Neurology (EAN) virtual meeting, held May 23-26, 2020. These data demonstrate that ATA188 was safe and well-tolerated across all four dose cohorts. Importantly, there was a higher proportion of patients showing sustained disability improvements with increasing dose, and sustained disability improvements seen at six months were maintained at 12 months in all three cohorts that have reached the 12-month time point in the study.

In addition to the clinical data reported at EAN, preclinical translational data recently published online at the 2020 Academy of Neurology (AAN) 72nd Annual Meeting further support the proposed mechanism of action of ATA188. These analyses of the T-cells comprising ATA188 demonstrate that they recognize MS-relevant EBV antigens via defined T-cell receptors. This supports the proposed mechanism of action of ATA188 in targeting the MS-relevant antigens on EBV-infected B cells believed to play an important role in propagating the autoimmune cascade that causes MS.

About Multiple Sclerosis (MS)

MS is a chronic neurological autoimmune disease that affects an estimated 2.3 million people around the world. Relapsing-remitting MS (RRMS) is the most common form of MS and is characterized by episodes of new or worsening signs or symptoms (relapses) followed by periods of recovery. Despite available disease-modifying treatments, most individuals with RRMS continue to experience disease activity and disability progression.

Progressive MS (PMS) is a severe form of the disease with few therapeutic options. PMS comprises two conditions, both characterized by persistent progression and worsening of MS symptoms and physical disability over time. Primary progressive MS (PPMS) occurs when continuous progressive disease is present at diagnosis and occurs in approximately 15% of newly diagnosed cases. Secondary progressive MS (SPMS) initially begins as RRMS and develops into a progressive form. Up to 80 percent of people with RRMS will eventually develop SPMS. There is substantial unmet medical need for new and effective therapies for patients with PPMS and SPMS. Most treatment options that work well in reducing flares in RRMS have not been shown to be effective in slowing or reversing disability in PMS.

About EBV in MS

Two decades of converging epidemiological, histological, and molecular evidence strongly support the role of EBV infection as a prerequisite for MS—MS likely does not develop in the absence of EBV infection.¹ While several hypotheses have been proposed to explain the pathophysiology of EBV in MS, the autoreactive B-cell hypothesis provides unifying principles based on the concept that defective elimination of EBV-infected autoreactive B cells by CD8⁺ T cells results in their accumulation in lymphoid structures and target organs implicated in MS, including the central nervous system leading to inflammation.² This aberrant inflammation eventually leads to demyelination and axon destruction. For progressive MS, there is a significant unmet need for high-efficacy neuroprotective therapies that work directly in the central nervous system, and have the potential to delay, stop, or

reverse disease progression, as well as the accumulation of permanent disability. It is hypothesized that the depletion of autoreactive EBV-infected B cells and plasma cells in the central nervous system may address a key factor involved in the development of progressive MS and result in clinically meaningful results for patients.

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 a Phase 1 ATA188 clinical study in patients with progressive MS across clinical sites in the U.S. and Australia.

For more information about the ATA188 randomized placebo-controlled Phase 1b study, please visit [ClinicalTrials.gov \(NCT03283826\)](https://clinicaltrials.gov/ct2/show/study/NCT03283826).

About Atara Biotherapeutics, Inc.

[Atara Biotherapeutics, Inc. \(@Atarabio\)](https://www.atarabio.com) 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+ 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](https://www.atarabio.com) and follow us on [Twitter](https://twitter.com/Atarabio) and [LinkedIn](https://www.linkedin.com/company/atarabio).

References

¹ Bar-Or A, et al. Epstein-Barr Virus in Multiple Sclerosis: Theory and Emerging Immunotherapies. *Trends Mol Med*. 2020;26:296-310.

² Pender MP. Infection of autoreactive B lymphocytes with EBV, causing chronic autoimmune diseases. *Trends Immunol*. 2003;24:584-588.

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 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 our 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 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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