

# Atara Biotherapeutics Announces Six of Ten Progressive Multiple Sclerosis (MS) Patients Experienced Clinical Improvements in an Ongoing Phase 1 Study of Autologous ATA190

Three patients in the study improved their Expanded Disability Status Scale (EDSS) score

Reduction in fatigue was a consistent observation in responding patients, as highlighted in a presentation at the MSParis 2017 Congress

SOUTH SAN FRANCISCO, Calif., Oct. 25, 2017 (GLOBE NEWSWIRE) -- Atara Biotherapeutics, Inc. (Nasdaq:ATRA), a leading T-cell immunotherapy company developing novel treatments for patients with cancer and autoimmune diseases, announced today that the Company's collaborating investigators at QIMR Berghofer Medical Research Institute and The University of Queensland reported updated positive results for an ongoing Phase 1 study of autologous ATA190, an Epstein-Barr Virus (EBV) specific T-cell immunotherapy, in patients with progressive MS. The results will be presented at the MSParis 2017 Congress, the 7th Joint Meeting of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) and the Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS), that runs through October 28, 2017, at the Palais des Congrès de Paris, in Paris, France.

Six of ten progressive MS patients in the Phase 1 study of autologous ATA190 (formerly known as autologous ATA188) experienced clinical improvements, which were first observed 2-14 weeks after the initial infusion. Clinical improvements were reported in primary and secondary progressive MS patients from an established level of disability. Reduction in fatigue was a consistent observation in responding patients. Autologous ATA190 was well-tolerated, and no significant treatment-related adverse events were observed in the study.

A correlation between clinical improvement and the reactivity of autologous ATA190 against target EBV antigens (EBV reactivity) was also observed. Five of the six patients who showed clinical improvements received autologous ATA190 with 7% or greater EBV reactivity, including three patients who improved their EDSS scores. Of the four patients who received autologous ATA190 with 3% or lower EBV reactivity, one had a mild clinical improvement, one had EDSS worsening, and two reported no change. Clinical improvement also correlated with other mechanistic markers of ATA190 T-cell function in response to EBV.

"This study adds to the mounting evidence for a pathogenic role of EBV infection in MS," said Professors Michael Pender of The University of Queensland and Rajiv Khanna,

Coordinator of QIMR Berghofer's Centre for Immunotherapy and Vaccine Development in a joint statement. "Our work sets the stage for further clinical studies with autologous and allogeneic EBV-specific T-cell immunotherapy in MS and other autoimmune diseases. We are delighted that Atara Biotherapeutics recently initiated a multicenter, multinational allogeneic ATA188 Phase 1 clinical study in patients with progressive or relapsing-remitting MS."

"We are encouraged by the clinical data reported by Professor Pender, Professor Khanna, and their colleagues from the first prospective trial of an EBV-specific T-cell immunotherapy in progressive MS," said Chris Haqq M.D., Ph.D., Executive Vice President of Research and Development and Chief Scientific Officer of Atara Biotherapeutics. "The clinical improvements observed in six of ten progressive MS patients treated with autologous ATA190, including three patients who improved their EDSS score, highlights the potential that targeting EBV positive B-cells and plasma cells is a potential new treatment modality that could offer a novel alternative to available MS therapies. We look forward to continuing to develop both autologous ATA190 and allogeneic ATA188 in MS patients."

Atara and the Company's collaborating investigators at Stanford Medicine will also present new data tomorrow that demonstrate the presence of increased numbers of EBV-infected B-cells and plasma cells in the brains of MS patients, providing additional evidence that EBV plays an important role in MS disease pathogenesis.

Details for the poster presentations are as follows:

Abstract Title: Safety and clinical improvement in a phase 1 trial of autologous Epstein-Barr

virus-specific T cell therapy in patients with progressive multiple sclerosis

**Session Title:** Poster Session 1

Presentation Date & Time: Thursday, October 26, 2017; 15:30 CEST

Lead Authors: Professor Michael Pender, M.D., and Professor Rajiv Khanna, Ph.D.

Abstract Title: Molecular signature of Epstein-Barr virus infection in multiple sclerosis brain

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**Session Title:** Poster Session 2

**Presentation Date & Time:** Friday, October 27, 2017; 15:30 CEST **Lead Authors:** May Han, M.D., and Lawrence Steinman, M.D.

## **About Progressive Multiple Sclerosis**

MS is a chronic neurological autoimmune disease that affects an estimated 2.3 million people around the world. 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% 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.

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). Tcells are a critical component of the body's immune system and can selectively target specific EBV antigens believed to be important for the potential treatment of MS. Allogeneic ATA188 and autologous ATA190, the Company's next generation T-cell immunotherapies developed by Professor Rajiv Khanna at QIMR Berghofer, have the potential to precisely recognize and eliminate EBV-infected B-cells and plasma cells in the central nervous system that may catalyze autoimmune responses and MS pathophysiology. Professor Michael Pender from The University of Queensland presented initial interim results from the first autologous ATA190 study, which was partially funded by MS Research Australia, MS Queensland and Perpetual Foundation, at the American Academy of Neurology (AAN) meeting in April 2017. This study tested adoptive immunotherapy in patients with MS and showed that autologous ATA190, led to encouraging clinical improvements in MS symptoms that correlated with autologous ATA190's reactivity against target EBV antigens (EBV reactivity). In addition to the ongoing Phase 1 autologous ATA190 clinical study in patients with progressive MS, Atara also initiated a multinational, multicenter Phase 1 allogeneic ATA188 clinical study in patients with progressive or relapsing-remitting MS in October 2017.

## **About Atara Biotherapeutics, Inc.**

Atara Biotherapeutics, Inc. (@Atarabio) is a leading T-cell immunotherapy company developing novel treatments for patients with cancer and autoimmune diseases. The Company's "off-the-shelf", or allogeneic, T-cells are engineered from donors with healthy immune function and allow for rapid delivery from inventory to patients without a requirement for pretreatment. Atara's T-cell immunotherapies are designed to precisely recognize and eliminate cancerous or diseased cells without affecting normal, healthy cells. Atara's most advanced T-cell immunotherapy in development, ATA129, is being developed for the treatment of cancer patients with rituximab-refractory Epstein-Barr virus (EBV) associated post-transplant lymphoproliferative disorder (EBV-PTLD), as well as other EBV positive hematologic and solid tumors including nasopharyngeal carcinoma (NPC). Phase 3 studies of ATA129 in EBV-PTLD following a hematopoietic cell transplant (MATCH study) or solid organ transplant (ALLELE study) are expected to start in 2017, and a Phase 1/2 study of ATA129 in combination with Merck's anti-PD-1 (programmed death receptor-1) therapy, KEYTRUDA® (pembrolizumab), in patients with platinum-resistant or recurrent EBVassociated NPC is planned for 2018. ATA129 is also available to eligible patients with EBVpositive tumors through an ongoing multicenter expanded access protocol (EAP) clinical study. Atara expects to submit ATA129 for conditional marketing authorization in EBV-PTLD following HCT in the EU in 2018. Allogeneic ATA188 and autologous ATA190, the Company's next generation T-cell immunotherapies, selectively target specific EBV antigens believed to be important for the potential treatment of multiple sclerosis (MS). A Phase 1 clinical study of autologous ATA190 in patients with progressive MS is ongoing. Atara also initiated a multinational, multicenter Phase 1 allogeneic ATA188 clinical study in patients with progressive or relapsing-remitting MS in October 2017. Atara's clinical pipeline also includes ATA520 targeting Wilms Tumor 1 (WT1) and ATA230 directed against cytomegalovirus (CMV).

# **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: clinical

improvements correlated with the measures of T-cell function may support the development of clinical biomarkers; that the study adds to the mounting evidence for a pathogenic role of EBV infection in MS, that it sets the stage for further clinical studies with autologous and allogeneic EBV-specific T-cell immunotherapy in MS and other autoimmune diseases and that the Company looks forward to continuing development of both autologous ATA190 and allogeneic ATA188 in MS patients; that the clinical improvements observed supports the growing evidence that targeting EBV positive B-cells and plasma cells in the CNS is a potential new treatment modality that could offer favorable safety and efficacy compared to available MS therapies; ATA188 and ATA190 have the potential to precisely recognize and eliminate EBV-infected B-cells and plasma cells in the central nervous system that may catalyze autoimmune responses and MS pathophysiology; the Company's expected initiation of Phase 3 studies of ATA129 in EBV-PTLD following a hematopoietic cell transplant or solid organ transplant in 2017 and a Phase 1/2 study of ATA129 in combination with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in patients with platinum-resistant or recurrent EBV-associated NPC in 2018; and the Company's expected submission of a conditional marketing authorization application in EBV-PTLD following HCT in the EU in 2018. 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 forwardlooking statements are subject to risks and uncertainties, including those discussed under the heading "Risk Factors" in Atara Biotherapeutics' quarterly report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on August 7, 2017, including the documents incorporated by reference therein, and subsequent filings with the SEC. 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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