

# Atara Bio Announces Positive Interim Results from Ongoing Phase 1 Trial of the Autologous Version of ATA188 in Patients with Primary and Secondary Progressive Multiple Sclerosis (MS) at the American Academy of Neurology (AAN) Annual Meeting 2017

**Encouraging Clinical Improvements Correlate with EBV Reactivity** 

### Presentation Selected for Emerging Science and Conference Press Programs by AAN

SOUTH SAN FRANCISCO, Calif., April 20, 2017 (GLOBE NEWSWIRE) -- Atara Biotherapeutics, Inc. (Nasdaq:ATRA), a biopharmaceutical company focused on developing meaningful therapies for patients with unmet medical needs in diseases that have seen limited therapeutic innovation, today announced that its collaborating investigators at the Queensland Institute of Medical Research (QIMR Berghofer) and The University of Queensland are reporting interim Phase 1 trial results from the autologous version of ATA188, or autologous ATA188, in patients with primary or secondary progressive MS (PPMS and SPMS, respectively), at the 69<sup>th</sup> AAN Annual Meeting in Boston, Massachusetts from April 22-28, 2017. Autologous ATA188 is a targeted Epstein-Barr virus (EBV)-specific cytotoxic T lymphocyte (CTL) product candidate that selectively targets specific antigens of EBV that are believed to be important for the potential treatment of MS. Studies suggest that EBV positive B-cells and plasma cells in the central nervous system (CNS) have the potential to catalyze an autoimmune response and MS pathophysiology. Atara Bio believes that selectively targeting and eliminating EBV positive B-cells and plasma cells has the potential to benefit patients with MS.

The Phase 1 trial is designed to enroll ten patients, including five with PPMS and five with SPMS. In the trial, patients receive four escalating doses of autologous ATA188 over six weeks and are followed for an additional twenty weeks after the last dose. The objectives of the trial were first, to assess the safety and tolerability of autologous ATA188 in patients with progressive MS; second, document preliminary evidence of efficacy through the evaluation of both clinically measured and patient reported changes in MS symptoms during and following treatment; and third, to generate autologous ATA188 at clinical scale from the blood of patients with progressive MS.

Dr. Michael Pender, M.D., an honorary senior principal research fellow at QIMR Berghofer, and his colleagues are reporting the following interim clinical results from the trial:

- Six patients treated to date four with SPMS, two with PPMS
- Three of six patients, including two with SPMS and one with PPMS, experienced improvements in MS symptoms as measured by patient reported and objective clinical evaluations
- All three patients with observed clinical improvement showed commencement of improvement two to eight weeks after initiation of T-cell therapy, including reductions in fatigue and gains in quality of life, ability to perform activities of daily living, and manual dexterity
- No patient in the trial experienced progression of disability; there was no worsening in EDSS
- Encouraging clinical improvements through 26 weeks correlate with CTL reactivity against target EBV antigens (EBV reactivity)
  - A patient with SPMS (EBV reactivity of 47%) experienced improvements in disability, mobility, musculoskeletal function, and fatigue:
    - Expanded Disability Status Scale (EDSS) score improved from 6.5 at baseline to 6.0 following treatment
    - Increased walking distance with walker from 100 meters at baseline to 1,500 meters; Able to walk 100 meters with unilateral assistance following treatment
    - Improvement in lower extremity muscle tone
    - Reduction in fatigue from 60 at baseline to 9 on the fatigue severity scale (FSS) following last study visit (the FSS provides scores in the range from 9-63)
    - Nocturia episodes reduced by 80%
  - A patient with PPMS (EBV reactivity of 15%) experienced improvements in vision, bladder function, and musculoskeletal function:
    - Improved color vision and visual acuity
    - Nocturia episodes reduced by 75%
    - Clonus with sudden movement resolved and lower extremity spasms improved
    - Vertigo resolved
    - One gadolinium (Gd) enhancing lesion at baseline to 2 following treatment
  - A patient with SPMS (EBV reactivity less than 1%) showed improvements in radiographic and biochemical markers as well as proprioception:
    - Reduction in intrathecal immunoglobulin G
    - Elimination of Gd-enhancing lesions present at baseline
    - Positive to negative Romberg test
- Of the three patients without clinically observed improvements, two had EBV reactivity of less than 1% and the third patient, with EBV reactivity of 10%, reported increased productivity, which could not be confirmed objectively
- No significant adverse events were observed; one patient experienced transient dysgeusia

The AAN 2017 poster presentation, titled "Symptomatic and objective clinical improvement in progressive multiple sclerosis patients treated with autologous Epstein–Barr virus-specific T cell therapy: Interim results of a phase I trial," will take place Wednesday, April 26, from 8:30 am to 7:00 pm ET in Exhibit Hall B1 at the Boston Exhibition and Convention Center in Boston, Massachusetts.

"The clinical data reported by Dr. Pender, Dr. Khanna and their colleagues from the first prospective trial of EBV-specific T-cell therapy in MS suggest that it is possible to achieve objective clinical improvements in MS patients with advanced disease by targeting EBV," said Chris Haqq M.D., Ph.D., Executive Vice President of Research and Development and Chief Scientific Officer of Atara Bio. "The observed clinical improvements in patients with the highest levels of EBV reactivity support the hypothesis that targeting EBV positive B-cells and plasma cells may be an effective therapeutic strategy in the treatment of MS. We look forward to additional development with both the autologous and allogeneic versions of ATA188 to further evaluate the potential therapeutic utility of targeting EBV in the treatment of MS."

"This clinical trial directly follows our previously reported findings from a patient with SPMS who showed a durable response to autologous EBV-CTL therapy that lasted for more than three years," said Professor Rajiv Khanna, Coordinator of QIMR Berghofer's Centre for Immunotherapy and Vaccine Development. "At QIMR Berghofer, we have focused for years on elucidating the role of EBV in human disease, and we are excited to be working with Atara Bio to help realize the promise of expanding immunotherapy beyond oncology to autoimmune conditions."

"We believe that 2017 will be a pivotal year for Atara Bio," said Isaac Ciechanover, President and CEO of Atara Bio. "We look forward to the further development of autologous ATA188 for patients with MS and to our expected initiation of both the Phase 1 allogeneic ATA188 trial as well as our Phase 3 trials of ATA129 in the second half of the year."

In October 2015, Atara Bio obtained an exclusive, worldwide license to develop and commercialize allogeneic CTLs directed against EBV that utilize the QIMR Berghofer technology, including ATA188. Under the license agreement, Atara Bio also received an option to exclusively license the autologous version of ATA188.

#### **About ATA188**

EBV is associated with a wide range of hematologic malignancies and solid tumors, as well as certain autoimmune conditions such as multiple sclerosis. T-cells are a critical component of the body's immune system and can be harnessed to counteract viral infections, cancers, and certain autoimmune disorders. By focusing the T-cells on specific proteins involved in the disease, the power of the immune system can be employed to combat the condition. ATA188 utilizes a technology in which T-cells are educated to recognize specific antigens of EBV that are implicated in MS. In the context of MS, ATA188 finds and eliminates EBV-infected B-cells and plasma cells in the central nervous system that may catalyze autoimmune response and MS pathophysiology.

#### **About Progressive Multiple Sclerosis**

Progressive Multiple Sclerosis (PMS) is a severe disease with few therapeutic options. PMS comprises two conditions, both characterized by persistent progression and worsening of MS symptoms and physical disability over time. This is distinct from Relapsing Remitting MS (RRMS) where people have flares of the disease that are followed by periods of recovery and quiescence during which the disease does not progress. The first form of PMS, Primary Progressive MS (PPMS) occurs when people have a progressive disease course from the day of diagnosis. The second condition is Secondary Progressive MS (SPMS) that initially

begins as RRMS but once patients start to have continuous progression of their disease, they have developed SPMS. There is substantial unmet medical need for new and effective therapies for patients with PMS. Most of the treatment options that work well in reducing the flares in RRMS have not been shown to be effective in slowing or reversing the progression of disability in PMS.

#### About Atara Biotherapeutics' Allogeneic Cellular Therapy Platform

Atara Bio's cellular therapy platform provides healthy immune capability to a patient and arms the immune system to precisely target and combat disease. Cells derived from healthy donors are manufactured in advance and stored as inventory so that a customized unit of cells can be chosen for each patient. The cells are ready to infuse in approximately 3 to 5 days. Once administered, the cells home to their target, expand in-vivo to eliminate diseased cells, and eventually recede. This versatile platform can be directed towards a broad array of disease causing targets and has demonstrated clinical proof of concept across both viral and non-viral targets in conditions ranging from liquid and solid tumors to infectious and autoimmune diseases. The Company has pursued prospective feedback from health authorities on both manufacturing and clinical trial design. Atara Bio's lead product candidate, ATA129, has the potential to be the first commercial allogeneic T-cell therapy for a viral target implicated in cancer.

### About Atara Biotherapeutics, Inc.

Atara Biotherapeutics, Inc. is a biopharmaceutical company developing meaningful therapies for patients with severe and life-threatening diseases that have been underserved by scientific innovation, with an initial focus on allogeneic T-cell therapies for cancer, autoimmune, and infectious disease. Atara Bio's T-cell product candidates harness the power of the immune system to recognize and attack cancer cells and cells infected with certain viruses. The Company's initial clinical stage T-cell product candidates include Epstein-Barr virus targeted Cytotoxic T-cells (EBV-CTL), or ATA129, Cytomegalovirus targeted Cytotoxic T-cells (CMV-CTL), or ATA230, and Wilms Tumor 1 targeted Cytotoxic Tcells (WT1-CTL), or ATA520. These product candidates have demonstrated the potential to have therapeutic benefit in a number of clinical indications including hematologic malignancies, solid tumors, and refractory viral infections. The Company is also developing a next generation of T-cell product candidates utilizing a technology to selectively enhance a T-cell's ability to target specific viral proteins implicated in a disease. The Company's ATA188 product candidate leverages this technology. Initial clinical investigations employing this approach will focus on multiple sclerosis and other virally mediated cancers and infections.

## **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 clinical development of ATA188 and Atara Bio's other product candidates, Atara Bio's collaboration with QIMR Berghofer and the timing, design and results of clinical trials, including the Phase 1 trial sponsored by QIMR Berghofer, further development of autologous ATA188 and Atara Bio's proposed Phase 1 trial of allogeneic ATA188 for patients with MS and Phase 3 trials utilizing ATA129. Because such statements deal with future events and are based on Atara

Bio's current expectations, they are subject to various risks and uncertainties and actual results, performance or achievements of Atara Bio 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 under the heading "Risk Factors" in Atara Bio's annual report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 9, 2017, including the documents incorporated by reference therein, and subsequent filings with the SEC. Except as otherwise required by law, Atara Bio 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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