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Atara Biotherapeutics Announces FDA Clearance to Proceed with Enrollment at U.S. Sites for Ongoing Global Phase 1 Clinical Study to Evaluate ATA188 in Patients with Progressive or Relapsing-Remitting Multiple Sclerosis

SOUTH SAN FRANCISCO, Calif., Jan. 10, 2018 (GLOBE NEWSWIRE) -- Atara Biotherapeutics, Inc. (Nasdaq:ATRA), a leading off-the-shelf T-cell immunotherapy company developing novel treatments for patients with cancer, autoimmune and viral diseases, today announced that it received clearance of its Investigational New Drug (IND) application from the U.S. Food and Drug Administration (FDA) to proceed with patient enrollment at U.S. sites for its ongoing global Phase 1 clinical study to evaluate ATA188 in patients with progressive or relapsing-remitting multiple sclerosis (MS). ATA188, the Company's off-the-shelf T-cell immunotherapy using a complementary targeted antigen recognition technology licensed from QIMR Berghofer Medical Research Institute, selectively targets specific Epstein-Barr virus (EBV) antigens believed to play an important role in the pathogenesis of MS. Atara initiated the open-label, single arm Phase 1 study in MS patients in the fourth quarter of 2017 in Australia.

“We are pleased with FDA’s decision to allow off-the-shelf ATA188 to proceed into clinical development in patients with MS in the U.S.,” said Chris Haqq M.D., Ph.D., Executive Vice President of Research and Development and Chief Scientific Officer of Atara Biotherapeutics. “We believe that an off-the-shelf T-cell immunotherapy such as ATA188 may allow for a more consistent reactivity against target EBV antigens, which may be correlated with clinical improvements based on data from a previous autologous ATA190 Phase 1 study in patients with progressive MS. We look forward to the first results from the ATA188 Phase 1 study in patients with progressive MS in the first half of 2019.”

The primary objective of Atara’s ongoing Phase 1 clinical study is to assess the safety of ATA188 in patients followed for at least one year after the first dose. Key secondary endpoints in the study include measures of clinical improvement such as expanded disability status scale (EDSS) and annualized relapse rate (ARR) as well as MRI imaging. The study is expected to enroll a total of 60 patients across the U.S., Australia and Europe: 30 patients with progressive forms of MS, either primary progressive MS (PPMS) or secondary progressive MS (SPMS), and 30 patients with relapsing-remitting MS (RRMS). For more information about the study, please visit ClinicalTrials.gov (NCT03283826).

About Multiple Sclerosis
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% 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 ATA188 and ATA190

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 specific EBV antigens believed to be important for the potential treatment of MS. Off-the-shelf ATA188 and autologous ATA190, using the Company's complementary T-cell immunotherapy technology 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 updated results from the first autologous ATA190 study, which was partially funded by MS Research Australia, MS Queensland and Perpetual Foundation, at MSParis 2017 Congress, the 7th Joint ECTRIMS and ACTRIMS Meeting in October 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 global Phase 1 ATA188 clinical study in patients with progressive or relapsing-remitting MS in Australia in the fourth quarter of 2017 with patient enrollment at U.S. sites beginning in early 2018.

About Atara Biotherapeutics, Inc.

Atara Biotherapeutics, Inc. (@Atarabio) is a leading T-cell immunotherapy company developing novel treatments for patients with cancer, autoimmune and viral diseases. The Company's off-the-shelf, or allogeneic, T-cells are bioengineered 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, tabelecleucel (formerly known as ATA129), is being developed for the treatment of patients with rituximab-refractory Epstein-Barr virus (EBV) associated post-transplant lymphoproliferative disorder (EBV+PTLD), as well as other EBV associated hematologic and solid tumors, including nasopharyngeal carcinoma (NPC). Tabelecleucel is in Phase 3 clinical development for the treatment of EBV+PTLD following an allogeneic hematopoietic cell transplant (MATCH study) or solid organ transplant (ALLELE study), and a Phase 1/2 study of tabelecleucel in combination with Merck's anti-PD-1 (programmed death receptor-1) therapy, KEYTRUDA® (pembrolizumab), in patients

with platinum-resistant or recurrent EBV associated NPC is planned for 2018. Tabelecleucel is also available to eligible patients with EBV associated hematologic and solid tumors through an ongoing multicenter expanded access protocol (EAP) clinical study. Off-the-shelf ATA188 and autologous ATA190, the Company's T-cell immunotherapies using a complementary targeted antigen recognition technology, 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 global Phase 1 ATA188 clinical study in patients with progressive or relapsing-remitting MS in Australia in the fourth quarter of 2017 with patient enrollment at U.S. sites beginning in early 2018. 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: the Company's enrollment, expected results and completion of its Phase 1 study to evaluate allogeneic ATA188 in patients with progressive or relapsing-remitting MS; the expected opening of U.S. sites in early 2018; the expected start of a Phase 1/2 study of tabelecleucel in combination with Merck's anti-PD-1 (programmed death receptor-1) therapy, KEYTRUDA® (pembrolizumab), in patients with platinum-resistant or recurrent EBV associated NPC in 2018; and the potential advantages of its product candidates. 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 under the heading "Risk Factors" in Atara Biotherapeutics' quarterly report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 9, 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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