Atara Biotherapeutics Announces Initiation of Two Phase 3 Clinical Studies to Evaluate Tabelecleucel in Patients with Rituximab-Refractory Epstein-Barr Virus Associated Post-Transplant Lymphoproliferative Disorder (EBV+PTLD)

– Three clinical sites for both the MATCH and ALLELE pivotal studies now open for enrollment in the U.S. –

SOUTH SAN FRANCISCO, Calif., Jan. 02, 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 initiation of two Phase 3 clinical studies to evaluate tabelecleucel (formerly known as ATA129) in patients with rituximab-refractory Epstein-Barr virus (EBV) associated post-transplant lymphoproliferative disorder (EBV+PTLD). Three clinical sites for both the MATCH and ALLELE pivotal studies are now open for enrollment in the U.S. and the studies will later expand to additional U.S. sites as well as sites in the EU, Canada and Australia. Tabelecleucel is Atara’s off-the-shelf T-cell immunotherapy in development for the treatment of EBV+PTLD, as well as other EBV associated hematologic and solid tumors.

“Today we started 2018 on a strong path by initiating tabelecleucel Phase 3 clinical studies at multiple centers in the U.S.,” said Isaac Ciechanover M.D., Chief Executive Officer and President of Atara Biotherapeutics. “We are ready to enroll patients and look forward to bringing a novel treatment option to people in need with EBV+PTLD. We will continue to work closely with the FDA and other global health authorities to make tabelecleucel available to patients as expeditiously as possible.”

Atara’s tabelecleucel Phase 3 program consists of two global, multicenter, open-label studies:

- for the treatment of patients with EBV+PTLD following allogeneic hematopoietic cell transplant (HCT) after failure of rituximab (MATCH), and
- for the treatment of patients with EBV+PTLD following solid organ transplant (SOT) after failure of rituximab or after failure of rituximab plus chemotherapy (ALLELE).

About EBV+PTLD
Since its discovery as the first human oncovirus, Epstein-Barr virus (EBV) has been implicated in the development of a wide range of lymphoproliferative disorders, including lymphomas and other cancers. EBV is widespread in all human populations and persists as a lifelong, asymptomatic infection. In immunocompromised patients, such as those
undergoing allogeneic hematopoietic cell transplants (HCT) or solid organ transplants (SOT), EBV associated post-transplant lymphoproliferative disorder (EBV+PTLD), represents a life-threatening condition. Median overall survival in patients with EBV+PTLD following HCT who have failed rituximab-based first line therapy is 16-56 days. In EBV+PTLD following SOT, patients failing rituximab experience increased chemotherapy-induced treatment-related mortality compared to other lymphoma patients. One- and two-year survival in patients with high-risk EBV+PTLD following SOT is 36% and 0%, respectively.

About tabelecleucel (formerly known as ATA129)
Atara’s most advanced T-cell immunotherapy in development, tabelecleucel, is a potential treatment for 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). In February 2015, FDA granted tabelecleucel Breakthrough Therapy Designation for EBV+PTLD following allogeneic hematopoietic cell transplant (HCT) and in October 2016, tabelecleucel was accepted into the EMA Priority Medicines (PRIME) regulatory pathway for the same indication, providing enhanced regulatory support. Atara also received positive regulatory feedback from Health Canada in September 2017 supporting the submission of tabelecleucel for an expedited approval pathway. In addition, tabelecleucel has orphan status in the U.S. and EU. 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 in 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 clinical study, positive interim results of which were presented in December 2017 at the 59th American Society of Hematology (ASH) Annual Meeting.

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. Allogeneic 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 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: the Company's enrollment, later expansion of additional sites in the U.S. and sites in the EU, Canada and Australia, expected results and completion of its Phase 3 studies of tabelecleucel, (formerly known as ATA129); 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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