

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

– Pivotal studies to commence imminently –

– Primary endpoint results and EU conditional marketing authorization submission expected in the first half of 2019 –

– Company to host conference call and webcast today at 8:00 a.m. EST –

SOUTH SAN FRANCISCO, Calif., Dec. 29, 2017 (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 from the U.S. Food and Drug Administration (FDA) to initiate two Phase 3 clinical studies with tabelecleucel (formerly known as ATA129) in patients with rituximab-refractory Epstein-Barr virus (EBV) associated post-transplant lymphoproliferative disorder (EBV+PTLD). The Company plans to initiate these studies imminently. 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.

“We are delighted to have received FDA clearance to start the tabelecleucel Phase 3 clinical studies,” said Isaac Ciechanover M.D., Chief Executive Officer and President of Atara Biotherapeutics. “This achievement included extensive collaboration with the FDA under Breakthrough Therapy Designation and we expect tabelecleucel to be the first off-the-shelf T-cell immunotherapy to begin Phase 3 clinical development in the U.S. Receiving clearance to initiate these studies is a significant milestone for Atara, and we expect to open our initial clinical sites imminently to serve the substantial unmet need for patients with this life-threatening condition.”

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 patients with EBV+PTLD following solid organ transplant (SOT) after failure of

rituximab or after failure of rituximab plus chemotherapy (ALLELE).

The Phase 3 studies are expected to open for enrollment in the U.S. imminently and will later expand to include sites in the EU, Canada and Australia.

Results from the first tabelecleucel Phase 3 study to reach the primary endpoint are expected to be announced in the first half of 2019. Atara also plans to submit a tabelecleucel Conditional Marketing Authorization (CMA) application in the EU for patients with rituximab-refractory EBV+PTLD following HCT during the first half of 2019. In addition, Atara plans to continue working closely with the FDA, Health Canada and other global health authorities to make tabelecleucel available to patients as expeditiously as possible.

The primary endpoint of both the MATCH and ALLELE studies is the confirmed objective response rate (ORR), defined as the percent of patients achieving either a complete or partial response to tabelecleucel treatment confirmed after the initial tumor assessment showing a response. The protocols are designed to rule out 20% ORR as the null hypothesis. For example, assuming anticipated enrollment of 35 patients in MATCH, an ORR above approximately 37% would be expected to meet the primary endpoint. In ALLELE, each of two cohorts with an anticipated enrollment of 35 patients will be analyzed independently using the same statistical methodology. Secondary endpoints for both the MATCH and ALLELE studies include duration of response, overall survival, safety, quality of life metrics, and other data in support of potential health economic benefits.

Atara also recently announced positive interim results from an ongoing multicenter expanded access protocol (EAP) study of tabelecleucel for patients with EBV associated cancers, which were presented at the 59th American Society of Hematology (ASH) Annual Meeting. The EAP study findings presented at ASH in patients from the Phase 3 EBV+PTLD study populations were consistent with the tabelecleucel profile observed in previously reported Phase 2 studies conducted by Memorial Sloan Kettering Cancer Center. With the EAP study, Atara has also displayed the ability to rapidly deploy banked, off-the-shelf T-cells to transplant patients in a multicenter setting, and the Company will continue to leverage this experience in the tabelecleucel Phase 3 studies.

Conference Call Information

Atara will host a conference call and webcast today, December 29, 2017, at 8:00 a.m. EST. Analysts and investors can participate in the conference call by dialing (888) 540-6216 for domestic callers and (734) 385-2715 for international callers, using the conference ID 2395468. The live webcast can be accessed on the Events and Presentations page in the Investors and Media section of the Atara website, www.atarabio.com. A replay of the webcast will be available on the Company's website for 90 days following the live conference call.

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 tabellecleucel (formerly known as ATA129)

Atara's most advanced T-cell immunotherapy in development, tabellecleucel, 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 tabellecleucel Breakthrough Therapy Designation for EBV+PTLD following allogeneic hematopoietic cell transplant (HCT) and in October 2016, tabellecleucel 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 tabellecleucel for an expedited approval pathway. In addition, tabellecleucel has orphan status in the U.S. and EU. Phase 3 studies of tabellecleucel in EBV+PTLD following HCT (MATCH study) or solid organ transplant (ALLELE study) are expected to start imminently, and a Phase 1/2 study in NPC is planned for 2018. Tabellecleucel 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, tabellecleucel (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). Phase 3 studies of tabellecleucel in EBV+PTLD following an allogeneic hematopoietic cell transplant (MATCH study) or solid organ transplant (ALLELE study) are expected to start imminently, and a Phase 1/2 study of tabellecleucel 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. Tabellecleucel 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 imminent initiation, enrollment, expansion of sites in the EU, Canada and Australia, results and completion of its Phase 3 studies of tabelecleucel, (formerly known as ATA129) in patients with rituximab-refractory Epstein-Barr virus associated post-transplant lymphoproliferative disorder following allogeneic hematopoietic cell transplant or solid organ transplant; plans to continue working closely with the FDA, Health Canada and other global health authorities to make tabelecleucel available to patients as expeditiously as possible; 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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