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Atara Biotherapeutics Opens State-of-the-Art Operations and Manufacturing Facility to Support Robust Off-the-Shelf T-Cell Immunotherapy Pipeline

SOUTH SAN FRANCISCO, Calif., June 25, 2018 (GLOBE NEWSWIRE) -- Atara Biotherapeutics, Inc. (Nasdaq:ATRA), a leading off-the-shelf, allogeneic T-cell immunotherapy company developing novel treatments for patients with cancer, autoimmune and viral diseases, today announced the opening of its Atara T-Cell Operations and Manufacturing (ATOM) facility in Thousand Oaks, California. ATOM features approximately 90,000 square feet dedicated to manufacturing the Company's off-the-shelf T-cell immunotherapies, as well as additional space for R&D labs and offices for Atara's Southern California technical operations. The facility provides production capacity to support Atara's robust pipeline, and its flexible design allows for potential manufacturing expansion of tab-cel™ (tabelecleucel), Atara's most advanced off-the-shelf T-cell immunotherapy.

"The opening of ATOM in Thousand Oaks is a key milestone distinguishing Atara's leading off-the-shelf T-cell immunotherapy technology platform," said Isaac Ciechanover, M.D., Chief Executive Officer and President of Atara Biotherapeutics. "As the cornerstone of our Southern California R&D and manufacturing hub, this dedicated facility will allow us to expand and accelerate our robust pipeline. Our celebration today is also an opportunity to reflect on what we hope to accomplish for patients with serious medical conditions, as well as their families and communities."

At the ATOM grand opening ceremony taking place today, Richard J. O'Reilly, M.D., pioneer of tab-cel™ and Chief of the Pediatric Bone Marrow Transplant Service at Memorial Sloan Kettering Cancer Center (MSK), will join the Company to share his experiences treating post-transplant lymphoma patients. The program will also feature Doug Worthen, a bone marrow transplant recipient and post-transplant lymphoma survivor. Other guests will include Atara employees, board members, partners and investors, as well as local industry leaders and public officials.

"Memorial Sloan Kettering and Atara have been pioneers in developing off-the-shelf T-cell immunotherapies for the treatment of a number of virus-associated malignancies, including EBV-associated lymphomas, which are aggressive cancers associated with exceedingly poor outcomes", said Dr. O'Reilly. "The ATOM facility is a superb center that will help advance the development of promising T-cell immunotherapies that may transform many patients' lives."

Atara is a rapidly growing, 200+ employee company that is co-located by design in South San Francisco and Southern California, with a newly established European headquarters in Zug, Switzerland. Atara also has an R&D site in Aurora, Colorado and office in New York City. The ATOM facility is projected to create around 100 new highly skilled jobs in the City

of Thousand Oaks and Ventura County.

“ATOM encompasses all aspects of T-cell immunotherapy manufacturing and technical operations, and we designed the facility to provide flexibility to expand capacity as required,” stated Atara’s Joe Newell, Executive Vice President, Chief Technical Operations Officer and Steve Bertram, Senior Vice President of Global Human Resources. “ATOM is further demonstration of Atara’s dedication to supporting the growth of the innovative life sciences community in Southern California.”

Atara is advancing Phase 3 development of tab-cel™, the potential first commercially available off-the-shelf T-cell immunotherapy for the treatment of patients with Epstein-Barr virus associated post-transplant lymphoproliferative disorder (EBV+ PTLD). The Company recently announced positive long-term outcomes for tab-cel™ in Phase 2 studies of patients with EBV+ PTLD at the 23rd Congress of European Hematology Association held in Stockholm, Sweden.

“I am thrilled to welcome Atara and its state-of-the-art facilities to the Thousand Oaks biotech community,” said City Manager Drew Powers. “This company holds tremendous promise and brings cutting edge technology to our region. We are truly grateful they have selected Thousand Oaks for this important work.”

Atara plans to submit a conditional marketing authorization application in the EU for tab-cel™, as well as report initial efficacy results from its Phase 3 program, in the first half of 2019.

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 tab-cel™ (tabelecleucel; formerly known as ATA129)

Atara’s most advanced T-cell immunotherapy in development, tab-cel™, is a potential treatment for patients with Epstein-Barr virus (EBV) associated post-transplant lymphoproliferative disorder (EBV+ PTLD) who have failed rituximab, as well as other EBV-associated hematologic and solid tumors, including nasopharyngeal carcinoma (NPC). In February 2015, FDA granted tab-cel™ Breakthrough Therapy Designation for EBV+ PTLD following allogeneic hematopoietic cell transplant (HCT), and in October 2016, tab-cel™ 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 tab-cel™ for an expedited approval pathway. In addition, tab-cel™ has orphan status in the U.S. and EU. Tab-cel™ 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 Atara is planning a Phase 1/2 study in NPC. Tab-cel™ 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, 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, or tab-cel™ (formerly known as ATA129), is being developed for the treatment of patients with Epstein-Barr virus (EBV) associated post-transplant lymphoproliferative disorder (EBV+ PTLD) who have failed rituximab, as well as other EBV-associated hematologic and solid tumors, including nasopharyngeal carcinoma (NPC). Tab-cel™ 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). Atara is also developing off-the-shelf, allogeneic ATA188 and autologous ATA190 T-cell immunotherapies using a complementary targeted antigen recognition technology for 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 is advancing a Phase 1 ATA188 clinical study in patients with progressive or relapsing-remitting MS across clinical sites in the U.S. and Australia in March 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, expansion, expected results and completion of its Phase 3 studies of tab-cel™; the timing of the Company's submission of a CMA for tab-cel™ in the EU; the Company's ability to leverage its platform in other indications and initiate development of additional immunotherapies; 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 May 8, 2018, 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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Primary Logo

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Source: Atara Biotherapeutics, Inc.