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Atara Bio Granted Access to Priority Medicines (PRIME) Regulatory Support for Allogeneic Epstein-Barr Virus (EBV)-Specific Cytotoxic T Lymphocytes (CTL) for Treatment of EBV-Associated Post Transplant Lymphoproliferative Disorder (EBV-PTLD)

PRIME, A European Medicines Agency Initiative, Provides Enhanced Scientific Guidance and Supports Accelerated Review of Investigational Therapies Addressing Unmet Medical Need

SOUTH SAN FRANCISCO, Calif., Oct. 18, 2016 (GLOBE NEWSWIRE) -- Atara Biotherapeutics, Inc. (Nasdaq:ATRA), a biopharmaceutical company developing meaningful therapies for patients with severe and life-threatening diseases that have been underserved by scientific innovation, today announced that the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) and Committee for Advanced Therapies (CAT) have granted access to the EMA's newly established Priority Medicines (PRIME) regulatory initiative for EBV-CTL in the treatment of patients with rituximab refractory EBV-PTLD following hematopoietic cell transplant (HCT). PRIME provides early and enhanced regulatory support to optimize regulatory applications and accelerate the review of medicines that address a high unmet need. EBV-CTL is an investigational therapy in which a healthy donor's T-cells are stimulated to recognize EBV antigens, or viral proteins, expressed in the cells of certain liquid and solid tumors, as well as in autoimmune diseases.

"We are pleased to be selected by the CHMP and CAT to participate in this innovative program designed to spur development of therapies for patients with serious diseases that have few therapeutic options," noted Isaac Ciechanover, M.D., President, and Chief Executive Officer of Atara Bio. "We look forward to working closely with the CHMP and CAT, and to seeking Scientific Advice in the fourth quarter of this year to continue to advance our development efforts in Europe."

Access to the Priority Medicines initiative is granted by the EMA to support the development and accelerate the review of new therapies to treat patients with unmet medical need. The criteria for the Priority Medicines initiative require early clinical evidence that the therapy offers a therapeutic advantage over existing treatments or benefits patients without treatment options. This designation provides appointment of a rapporteur, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review earlier in the application process.

The U.S. Food and Drug Administration granted Breakthrough Therapy Designation to EBV-CTL for the treatment of patients with rituximab refractory EBV-PTLD after HCT in February 2015. The company anticipates the initiation of two Phase 3 trials in rituximab refractory EBV-PTLD after HCT or solid organ transplant (SOT) later this year.

About EBV-CTL

EBV is associated with a wide range of hematologic malignancies and solid tumors, as well as certain autoimmune conditions such as multiple sclerosis. In patients with weakened immune systems, including those who have received an HCT or SOT, EBV infection can result in an aggressive B-cell lymphoma called EBV-PTLD. T-cells are a critical component of the body's immune system and can be harnessed to counteract viral infections and some cancers. By focusing the T-cells on specific proteins involved in the cancers and infections, the power of the immune system can be employed to combat these diseases. Atara's EBV-CTL utilizes a technology in which T-cells are collected from the blood of third-party donors and then exposed to EBV antigens. The resulting activated T-cells are then expanded, characterized, and stored for future therapeutic use in an appropriate partially human leukocyte antigen, or HLA, matched patient, providing an allogeneic, cellular therapeutic option for patients. In the context of EBV infection, Atara's EBV-CTL finds the cells expressing EBV and kills them. EBV-CTL is currently being studied in ongoing Phase 2 clinical trials in patients with EBV-associated cancers, including PTL and nasopharyngeal carcinoma. EBV-CTL is also available to eligible patients with PTL through an ongoing multicenter expanded access protocol trial.

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 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's lead product candidate derived from this platform is expected to enter pivotal trials in 2016. The company has pursued prospective feedback from health authorities on both manufacturing and clinical trial design. Its lead product candidate 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 immunotherapy and oncology. Atara Bio's programs include T-cell product candidates and molecularly targeted product candidates. The T-cell product candidates include EBV-CTL, Cytomegalovirus targeted Cytotoxic T-cells (CMV-CTL), and Wilms Tumor 1 targeted Cytotoxic T-cells (WT1-CTL) and harness the power of the immune system to recognize and attack cancer cells and cells infected with certain viruses. The molecularly targeted product candidates include STM 434. These

product candidates target activin and myostatin, members of the TGF-beta family of proteins, and have demonstrated the potential to have therapeutic benefit in a number of clinical indications.

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 early and enhanced regulatory support to optimize regulatory applications and accelerate the review of medicines that address a high unmet need derived from this PRIME designation, working closely with the CHMP and CAT, seeking Scientific Advice in the fourth quarter of this year to continue to advance our development efforts in Europe, and the initiation of two Phase 3 trials in rituximab refractory EBV-PTLD after HCT or solid organ transplant (SOT) later this year. 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-Q filed with the Securities and Exchange Commission (SEC) on August 8, 2016, 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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