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Atara Bio Concludes EMA Scientific Advice and Plans to Submit Conditional Marketing Authorization Application (MAA) in Europe for Allogeneic Epstein-Barr Virus (EBV)-Specific Cytotoxic T Lymphocytes (CTL), or ATA 129, for the Treatment of EBV-Associated Post Transplant Lymphoproliferative Disorder (EBV-PTLD)

Reimbursement Discussions with Health Technology Assessment Agencies Being Conducted in Parallel

SOUTH SAN FRANCISCO, Calif., Jan. 03, 2017 (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 pursuant to parallel scientific advice from the European Medicines Agency's (EMA's) Scientific Advice Working Group and several national Health Technology Assessment (HTA) Agencies in the EU, the Company plans to submit in 2018 an application for Conditional Marketing Authorization Approval (Conditional MAA) of ATA 129 in the treatment of patients with rituximab refractory EBV-PTLD following hematopoietic cell transplant (HCT). The Conditional MAA will be based on clinical data from Phase 1 and 2 trials conducted at Memorial Sloan Kettering Cancer Center (MSK) and supported by available data from the Company's Phase 3 studies in rituximab refractory EBV-PTLD after HCT and solid organ transplantation (SOT), which will be ongoing at the time of filing.

Participating in the Scientific Advice meeting were HTAs representing England and Wales, (National Institute for Clinical Excellence [NICE]), Germany (Gemeinsamen Bundesausschuss [G-BA]), and France (Haute Autorité de Santé [HAS]). A separate meeting was also held with G-BA. Based on the feedback received in these discussions, the Company is moving forward to compile information in support of potential product reimbursement.

"We are very pleased with the outcome of our discussions with the EMA's Scientific Advice Working Group and the HTAs," noted Isaac Ciechanover, M.D., President, and Chief Executive Officer of Atara Bio. "We look forward to submitting our Conditional MAA in 2018."

The European Medicines Agency (EMA) supports the development of medicines that address unmet medical needs of patients. In the interest of public health, medicines may be eligible for conditional marketing authorization if they are aimed at treating, preventing or diagnosing seriously debilitating or life-threatening diseases, intended for use in emergency situations, or designated as orphan medicines. Applicants may be granted a conditional marketing authorization if the CHMP finds that the benefit-risk balance of the product is positive; it is likely that the applicant will be able to provide comprehensive data at a later date; unmet medical needs will be fulfilled; and the benefit to public health of the medicinal product's immediate availability on the market outweighs the risks due to the request for further data.

In October 2016, ATA 129 was granted access to the EMA's newly established Priority Medicines (PRIME) regulatory initiative for the treatment of patients with rituximab refractory EBV-PTLD following HCT. 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 U.S. Food and Drug Administration granted Breakthrough Therapy Designation to ATA 129 for the treatment of patients with rituximab refractory EBV-PTLD after HCT in February 2015.

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 PTLD and nasopharyngeal carcinoma. EBV-CTL is also available to eligible patients with PTLD 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 to 5 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 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, or ATA 129, Cytomegalovirus targeted Cytotoxic T-cells (CMV-CTL), or ATA 230, and Wilms Tumor 1 targeted Cytotoxic T-cells (WT1-CTL), or ATA 520, 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 Company's plans to submit a Conditional MAA for ATA 129 in the treatment of patients with rituximab refractory EBV-PTLD following hematopoietic cell transplant (HCT) based on clinical data from Phase 1 and 2 trials conducted at Memorial Sloan Kettering Cancer Center (MSK) and supported by available data from the Company's Phase 3 studies in rituximab refractory EBV-PTLD after HCT and solid organ transplantation (SOT), which will be ongoing at the time of filing; and the Company's plan to file the Conditional MAA in 2018. 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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