

Atara Bio Receives Positive Opinion from EMA on Orphan Drug Designation for Allogeneic Cytomegalovirus (CMV)-specific Cytotoxic T Lymphocytes (CTL) for Treatment of CMV Infection in Patients with Impaired Immune Systems

SOUTH SAN FRANCISCO, Calif., Oct. 11, 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) issued a positive opinion for orphan drug designation for the Company's CMV-CTL product candidate for the treatment of CMV infection in patients with impaired cell-mediated immunity.

"The positive opinion from EMA to designate CMV-CTLs as an orphan medicinal product in the European Union (EU) demonstrates the compelling need for new treatments to combat this viral infection in patients with few therapeutic options," said Isaac Ciechanover, M.D., President and Chief Executive Officer of Atara Bio. "We look forward to the presentation of additional clinical data at upcoming scientific congresses on the use of CMV-CTL to treat refractory CMV infection in patients who have received an allogeneic hematopoietic cell transplant, and to continuing our discussions with both FDA and EMA on late phase development to support registration of CMV-CTL."

Orphan drug designation in the EU provides regulatory and financial incentives for companies to develop and market therapies that treat a life-threatening or chronically debilitating conditions affecting no more than five in 10,000 persons in the EU, and where no satisfactory treatment is available. In addition to a 10-year period of marketing exclusivity in the EU after product approval, orphan drug designation provides incentives for companies seeking protocol assistance from the EMA during the product development phase and direct access to the centralized procedure for authorizing medicinal products.

About CMV-CTL

In patients with weakened immune systems, CMV infection can result in a range of symptoms including blindness, brain damage, difficulty breathing, or even death, depending on which organ is affected. 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 cancers and infections, the power of the immune system can be employed to combat these diseases. Atara's CMV-CTL utilizes a technology in which T-cells are collected from the blood of third-party donors and then exposed to CMV

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 CMV infection, Atara's CMV-CTL finds the cells expressing CMV and kills them. CMV-CTL is currently being studied in an ongoing Phase 2 clinical 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 Epstein Barr virus targeted Cytotoxic T-cells (EBV-CTL), 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 presentation of additional clinical data at upcoming scientific congresses on the use of CMV-CTL to treat refractory CMV infection in patients who have received an allogeneic hematopoietic cell transplant, continued discussions with both FDA and EMA on late phase development to support registration of CMV-CTL and the marketing exclusivity derived from this orphan designation. 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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[Primary Logo](#)

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Source: Atara Biotherapeutics, Inc.