

Atara Bio Receives EMA Orphan Drug Designation for Allogeneic Epstein-Barr Virus Specific Cytotoxic T-lymphocytes to Treat Epstein-Barr Virus-Associated Post-Transplant Lymphoproliferative Disorder

SOUTH SAN FRANCISCO, Calif., March 23, 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) granted orphan drug designation for the Company's allogeneic Epstein-Barr Virus targeted cytotoxic T-lymphocyte (EBV-CTL) product candidate for the treatment of patients with EBV Post-Transplant Lymphoproliferative Disorder (EBV-PTLD).

"The EMA's decision to designate EBV-CTLs as an orphan medicinal product in the European Union (EU) for the treatment of EBV-PTLD, as well as the recent orphan drug designation granted by the FDA, highlights the compelling need for new treatments for PTLD following hematopoietic cell transplant or solid organ transplant," said Isaac Ciechanover, M.D., President and Chief Executive Officer of Atara Bio. "These designations also reinforce our ongoing commitment to expanding our T-cell platform in countries outside the US."

Orphan drug designation in the European Union provides regulatory and financial incentives for companies to develop and market therapies that treat a life-threatening or chronically debilitating condition 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 authorization procedure.

In February 2016, the FDA granted orphan drug designation for EBV-CTL for the treatment of patients with EBV-PTLD after hematopoietic cell transplant or solid organ transplant. Atara Bio anticipates it will commence a multi-center early access clinical trial for EBV-CTL in the middle of 2016 followed by the initiation of two Phase 3 pivotal trials in EBV-PTLD later this year.

About EBV-CTL

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 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 "off-the-shelf", allogeneic, cellular therapeutic option for patients. In the context of EBV-PTLD, Atara's EBV-CTL finds the cancer cells expressing EBV and kills them. EBV-CTL is currently being studied in ongoing Phase 2 clinical trials.

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 commitment to expand our T-cell platform in countries outside the US, commencement of a multi-center early access clinical trial for EBV-CTL in the middle of 2016, the initiation of two Phase 3 pivotal trials in EBV-PTLD later this year, the potential approval of EBV-CTL in PTLD, 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-K filed with the Securities and Exchange Commission (SEC) on March 4, 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.

INVESTOR & MEDIA CONTACT:

Investors:
Steve Klass
212-213-0006 x331
sklass@burnsmc.com

Media:
Justin Jackson
212-213-0006 x327
jjackson@burnsmc.com

Primary Logo							

Source: Atara Biotherapeutics, Inc.