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Atara Bio Receives FDA Orphan Drug Designation for EBV-CTL to Treat Epstein-Barr Virus-Associated Post-Transplant Lymphoproliferative Disorder (EBV-PTLD)

SOUTH SAN FRANCISCO, Calif., Feb. 08, 2016 (GLOBE NEWSWIRE) -- Atara Biotherapeutics, Inc. (Nasdaq:ATRA), a biopharmaceutical company focused on developing meaningful therapies for patients with severe and life-threatening diseases that have been underserved by scientific innovation, today announced that the U.S. Food and Drug Administration (FDA) granted orphan drug designation for the Company's T-lymphocyte product candidate activated against Epstein-Barr Virus (EBV-CTL) for the treatment of patients with EBV Post-Transplant Lymphoproliferative Disorder (EBV-PTLD) following hematopoietic cell transplant (HCT) or solid organ transplant (SOT).

"Atara is a leader in developing 'off-the-shelf', allogeneic cellular therapies, and we are very pleased to have achieved this key milestone for our EBV-CTL program," said Isaac Ciechanover, M.D., President and Chief Executive Officer of Atara Bio. "Orphan drug designation is an important step as we progress towards the initiation of our Phase 3 pivotal trials in EBV-PTLD in HCT and SOT."

Orphan drug designation is granted by the FDA to novel drugs and biologics which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 people in the U.S. The designation provides incentives for sponsors to develop products for rare diseases, which may include tax credits towards the cost of clinical trials and prescription drug user fee waivers. The orphan drug designation also would entitle Atara Bio to a seven-year period of marketing exclusivity in the United States for the Company's EBV-CTL candidate should Atara receive FDA approval for the treatment of EBV-PTLD.

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 unmet medical needs in diseases that have seen limited therapeutic 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 initiation of pivotal trials with EBV-CTL in HCT and SOT patients, the potential approval of EBV-CTL in PTLD as well as any 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 quarterly report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 6, 2015, 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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