

# **Atara Bio Reaches Agreement with FDA on Design of Phase 3 Trials for its Lead Anti-Cancer Immunotherapy Program, Allogeneic Epstein-Barr Virus (EBV)-Specific Cytotoxic T Lymphocytes (CTL), or ATA 129, to Support Potential Approval in Two Separate Indications**

## **Plan to Review Comparability Data with FDA Prior to Initiating Phase 3 Trials**

SOUTH SAN FRANCISCO, Calif., Dec. 12, 2016 (GLOBE NEWSWIRE) -- Atara Biotherapeutics, Inc. (Nasdaq:ATRA), a biopharmaceutical company focused on developing meaningful therapies for patients with severe and life-threatening diseases, today announced that it has reached agreement with the U.S. Food and Drug Administration (FDA) on the designs of two Phase 3 trials for ATA 129 intended to support approval in the treatment of rituximab-refractory EBV-Associated Post Transplant Lymphoproliferative Disorder (EBV-PTLD) after hematopoietic cell transplant (HCT) or solid organ transplant (SOT). These two Phase 3 trials will support potential approvals in two separate indications.

### MATCH Trial (EBV-PTLD after HCT)

- Multicenter, open label
- Single arm study
- Designed to enroll approximately 35 patients previously treated with rituximab

### ALLELE Trial (EBV-PTLD after SOT)

- Multicenter, open label
- Two non-comparative cohorts
- Each cohort is designed to enroll approximately 35 patients
  - The first cohort includes patients who previously received rituximab monotherapy
  - The second cohort includes patients who previously received rituximab plus chemotherapy
  - Both cohorts will enroll concurrently

The primary endpoint of both the MATCH and ALLELE trials is objective response rate, defined as the percent of patients achieving either a complete or partial response to treatment with ATA 129. Secondary endpoints for both trials include duration of response, overall survival, safety, quality of life metrics, and other data in support of potential health

economic benefits. The trials are expected to open initially in the U.S. and later expand to include ex-U.S. sites.

Atara has manufactured ATA 129 lots intended for use in the Phase 3 trials, and Atara is continuing to generate and review data comparing this new material with that previously produced by Memorial Sloan Kettering (MSK). Atara's review of the comparability data generated to date suggests that additional analysis is required. As a result, Atara intends to conduct these analyses and meet with FDA in early 2017 to review these data and gain alignment prior to initiating the Phase 3 trials.

"Agreement on the Phase 3 trial designs is an important step in the development of ATA 129," said Isaac Ciechanover, Chief Executive Officer and President of Atara Bio. "We look forward to bringing this potentially important new therapy to patients with such significant unmet need."

### **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 ATA 129 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 these patients. In the context of EBV infection, Atara's ATA 129 finds the cells expressing EBV and kills them. ATA 129 is currently being studied in ongoing Phase 2 clinical trials in patients with EBV-associated cancers, including PTLD and nasopharyngeal carcinoma. ATA 129 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. Atara Bio's 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 the statements regarding the designs and initiation of the ATA 129 Phase 3 trials in EBV-PTLD, the results of the Company's analysis of comparability data for ATA 129, the Company's plans to review comparability data with the FDA in early 2017 to gain alignment prior to initiating the Phase 3 trials, the Company's plan to initially open the Phase 3 trials in the U.S. and later expand to include ex-U.S. sites and bringing this potentially important new therapy to patients with such significant unmet need. 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 SEC on November 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.