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Atara Bio Announces Collaboration with Merck to Evaluate KEYTRUDA® (pembrolizumab) in Combination with ATA129 in Nasopharyngeal Carcinoma (NPC)

SOUTH SAN FRANCISCO, Calif., April 21, 2017 (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 entered into a clinical trial collaboration agreement with Merck (known as MSD outside the United States and Canada), to evaluate Atara Bio's allogeneic Epstein-Barr virus (EBV)-specific cytotoxic T lymphocytes (CTL), or ATA129, in combination with Merck's anti-PD-1 (programmed death receptor-1) therapy, KEYTRUDA® (pembrolizumab), in patients with platinum resistant or recurrent EBV-associated NPC. The Phase 1/2 trial will evaluate the safety, pharmacokinetics, pharmacodynamics, and preliminary efficacy of the combination and is planned for initiation in 2018.

Atara Bio's ATA129 is an investigational therapy in which a healthy donor's T-cells are stimulated to recognize EBV antigens, or viral proteins, expressed in the cells of certain liquid and solid tumors. ATA129 has previously been evaluated as a single agent in Phase 1 and 2 trials that enrolled patients with a variety of EBV-positive malignancies including 14 patients with chemotherapy refractory, metastatic NPC. In these trials, evidence of radiographic response was observed and EBV-CTLs were also shown to expand after administration without concomitant lymphodepleting chemotherapy. Recent studies suggest that EBV upregulates the transcription of PD-L1 in EBV-associated solid tumors such as NPC and gastric cancer, suggesting the potential for synergy in combination with anti-PD-1 therapies, such as KEYTRUDA.

KEYTRUDA is a humanized monoclonal antibody that works by increasing the ability of the body's immune system to help detect and fight tumor cells. KEYTRUDA blocks the interaction between PD-1 and its ligands, PD-L1 and PD-L2, thereby activating T lymphocytes which may affect both tumor cells and healthy cells.

"Both ATA129 and KEYTRUDA have shown evidence of objective radiographic responses in NPC, and there is a strong biologic rationale to combine these therapies as their complementary mechanisms of action may enhance the anti-tumor activity," said Chris Haqq, M.D., Ph.D., Executive Vice President of Research and Development and Chief Scientific Officer of Atara Bio.

The collaboration agreement is between Atara Biotherapeutics, Inc. and Merck Sharp & Dohme B.V. Under the agreement, the trial will be sponsored by Atara Bio. Additional details of the collaboration were not disclosed.

About ATA129

EBV is associated with a wide range of hematologic malignancies and solid tumors, as well as certain autoimmune conditions such as multiple sclerosis. 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 Bio's ATA129 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, ATA129 finds the cells expressing EBV and kills them. ATA129 is currently being studied in ongoing Phase 2 clinical trials in patients with EBV-associated cancers, including EBV-associated post-transplant lymphoproliferative disorders (EBV-PTLD) and NPC. ATA129 is also available to eligible patients with EBV-positive tumors through an ongoing multicenter expanded access protocol trial. Atara Bio is planning to initiate two Phase 3 trials of ATA129 in patients with rituximab-refractory EBV-PTLD following either hematopoietic cell transplant (HCT) or solid organ transplant (SOT).

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, ATA129, 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 allogeneic T-cell therapies for cancer, autoimmune, and infectious disease. Atara Bio's T-cell product candidates harness the power of the immune system to recognize and attack cancer cells and cells infected with certain viruses. The Company's initial clinical stage T-cell product candidates include ATA129, Cytomegalovirus targeted Cytotoxic T-cells (CMV-CTL), or ATA230, and Wilms Tumor 1 targeted Cytotoxic T-cells (WT1-CTL), or ATA520. These product candidates have demonstrated the potential to have therapeutic benefit in a number of clinical indications including hematologic malignancies, solid tumors, and refractory viral infections. The Company is also developing a next generation of allogeneic T-cell product candidates utilizing a technology to selectively enhance a T-cell's ability to target specific viral proteins implicated in disease. Initial clinical investigations employing this approach will focus on

multiple sclerosis and other virally mediated cancers and infections.

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 design of the Phase 1/2 trial to evaluate the safety, pharmacokinetics, pharmacodynamics, and preliminary efficacy of the combination; the planned initiation of the trial in 2018; and the complementary mechanisms of action which may enhance the anti-tumor activity. 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 SEC on March 9, 2017, 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.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA

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