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## FDA Grants Breakthrough Therapy Designation to Epstein-Barr Virus (EBV) Targeted T-Cells for Treatment of EBV-Associated Lymphoproliferative Disease

SOUTH SAN FRANCISCO, Calif., March 2, 2015 (GLOBE NEWSWIRE) -- Atara Biotherapeutics, Inc. (Nasdaq:ATRA) today announced that its collaborative partner, Memorial Sloan Kettering Cancer Center (MSK) has received breakthrough therapy designation from the U.S. Food and Drug Administration (FDA) for Atara's optioned cytotoxic T lymphocytes activated against Epstein-Barr Virus (EBV-CTL) in the treatment of patients with rituximab-refractory, EBV-associated lymphoproliferative disease (EBV-LPD), a type of malignancy occurring after allogeneic hematopoietic cell transplantation (HCT). Allogeneic HCT is also commonly called a bone marrow transplant.

EBV-CTL may provide an "off-the-shelf", allogeneic, cellular therapeutic option for patients with EBV-LPD. EBV-CTL are made from T-cells collected from the blood of third-party donors. Once collected, the T-cells are exposed to certain antigens. The resulting activated T-cells are expanded, characterized and stored for future therapeutic use in an appropriate partially human leukocyte antigen matched patient. In the context of EBV-LPD, the EBV-CTL find the cancer cells expressing EBV and kill them.

Richard O'Reilly, M.D., Chair of the Department of Pediatrics and Chief of the Pediatric Bone Marrow Transplant Service at MSK, noted, "The receipt of breakthrough therapy designation brings us one step closer to our ultimate goal of making EBV-CTL available to all patients with EBV-LPD, a serious and life threatening condition with limited treatment options. We are excited to have the resources and expertise of the Atara team on board to help us achieve our goals."

Isaac Ciechanover, M.D., President and Chief Executive Officer of Atara, said, "We are very pleased that our collaboration partner, MSK, has received breakthrough therapy designation, and we look forward to continuing our collective work to further develop this promising approach. The designation underscores an urgent need to bring novel treatments to patients with EBV-LPD after HCT. We believe that this off-the-shelf, adoptive T-cell therapy has the potential to be an important option for patients for whom there are no approved treatments."

Breakthrough therapy designation for EBV-CTL was based on data from two separate clinical trials of EBV-CTL conducted by MSK. Data from these studies have been submitted for presentation at an upcoming medical conference in 2015.

The FDA's breakthrough therapy designation is designed to expedite the development and review of new drugs for the treatment of serious or life-threatening conditions. To qualify for this designation, a drug must show credible evidence of a substantial improvement on a

clinically significant endpoint over available therapies, or over placebo if there is no available therapy, or in a study that compares the new treatment plus standard of care to the standard of care alone. The designation confers several benefits, including intensive FDA guidance and discussion and eligibility for submission of a rolling biologic license application.

## **About Atara Biotherapeutics**

Atara Biotherapeutics, Inc. is a biopharmaceutical company focused on developing innovative therapies for patients with debilitating diseases. Atara's lead programs target myostatin and activin, members of the TGF-beta family of proteins that have demonstrated the potential to have therapeutic benefit in a number of clinical indications. In September 2014, Atara Biotherapeutics entered into an exclusive option agreement with MSK under which it has the right to license (pursuant to a negotiated form of license agreement) the exclusive, worldwide rights to three clinical stage T-cell programs, as well as other T-cell programs that are discovered or developed by MSK pursuant to sponsored research funded by the company.

## **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. Because such statements deal with future events and are based on Atara's current expectations, they are subject to various risks and uncertainties and actual results, performance or achievements of Atara could differ materially from those described in or implied by the statements in this press release. For example, forward-looking statements include statements regarding the clinical development of product candidates, the possible impact of accelerated approval and whether the receipt of breakthrough therapy designation for EBV-CTL in patients with EBV-LPD will meaningfully impact the development and review of EBV-CTL by the FDA or the likelihood that the product will be found to be safe and effective. These forward-looking statements are subject to other risks and uncertainties, including those discussed under the heading "Risk Factors" in Atara's annual report on Form 10-K for the year ended December 31, 2014 and subsequent filings with the Securities and Exchange Commission. Except as otherwise required by law, Atara 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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