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Atara Biotherapeutics Receives FDA Orphan Drug Designation for ATA230

SOUTH SAN FRANCISCO, Calif., Sept. 05, 2017 (GLOBE NEWSWIRE) -- Atara Biotherapeutics, Inc. (Nasdaq:ATRA), a leading "off-the-shelf" T-cell immunotherapy company developing novel treatments for patients with cancer and autoimmune diseases, today announced that ATA230 was granted orphan drug designation for the treatment of cytomegalovirus (CMV) viremia and disease in immunocompromised patients by the U.S. Food and Drug Administration (FDA). ATA230, an allogeneic T-cell immunotherapy targeting antigens expressed by CMV, has been investigated in one Phase 1 and two Phase 2 clinical studies in patients with CMV viremia and disease who are refractory or resistant to antiviral drug treatment.

"We are delighted that the therapeutic potential of our allogeneic T-cell immunotherapies in orphan diseases continues to be recognized by the FDA," said Isaac Ciechanover, M.D., Chief Executive Officer and President of Atara Biotherapeutics. "We believe that the high unmet medical need of immunocompromised patients with antiviral refractory or resistant CMV and compelling ATA230 clinical data provide a strong rationale for continued development. We look forward to further evaluating ATA230 development plans with the FDA and other global health authorities following the initiation of our ATA129 EBV-PTLD Phase 3 studies."

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 to a seven-year period of marketing exclusivity in the United States for ATA230 should Atara receive FDA approval for the treatment of CMV viremia and disease in immunocompromised patients.

About CMV
In patients with weakened immune systems, including bone marrow and solid organ transplant recipients as well as those with human immunodeficiency virus (HIV) and symptomatic congenital CMV infections, CMV causes potentially life-threatening disease that can result in blindness, brain damage and difficulty breathing. While small-molecule antiviral drugs are approved to treat and prevent CMV infection, viral resistance and adverse effects, such as kidney toxicity and a reduction in white blood cell count impairing the ability to fight other infections, remain a challenge.

About ATA230
ATA230, an allogeneic T-cell immunotherapy targeting antigens expressed by CMV, has been investigated in one Phase 1 and two Phase 2 clinical studies in patients with CMV viremia and disease who are refractory or resistant to antiviral drug treatment. In October 2016, the European Medicines Agency (EMA) issued a positive orphan drug designation opinion for ATA230 for the treatment of CMV infection in patients with impaired cell-mediated immunity. Atara plans to further evaluate ATA230 development plans with the FDA and other global health authorities following the initiation of ATA129 EBV-PTLD Phase 3 studies.

About Atara Biotherapeutics, Inc.
Atara Biotherapeutics, Inc. (@Atarabio) is a leading cell therapy company developing novel treatments for patients with cancer and autoimmune diseases. The Company's "off-the-shelf", or allogeneic, T-cells are engineered from donors with healthy immune function and allow for rapid delivery from inventory to patients without a requirement for pretreatment. Atara's T-cell immunotherapies are designed to precisely recognize and eliminate cancerous or diseased cells without affecting normal, healthy cells. Atara's most advanced T-cell immunotherapy in development, ATA129, is being developed for the treatment of cancer patients with rituximab refractory Epstein-Barr virus (EBV) associated post-transplant lymphoproliferative disorder (EBV-PTLD), as well as other EBV positive hematologic and solid tumors including nasopharyngeal carcinoma (NPC). Phase 3 studies of ATA129 in EBV-PTLD following a hematopoietic cell transplant (HCT) or solid organ transplant (SOT) are expected to start in 2017, and a Phase 1/2 study of 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 is planned for 2018. ATA129 is also available to eligible patients with EBV-positive tumors through an ongoing multicenter expanded access protocol (EAP) clinical study. Atara expects to submit ATA129 for conditional marketing authorization in EBV-PTLD following HCT in the EU in 2018. ATA188, the Company's next generation T-cell immunotherapy for autoimmune diseases, selectively targets specific EBV antigens believed to be important for the potential treatment of multiple sclerosis (MS). A Phase 1 clinical study of autologous ATA188 in progressive forms of MS is

ongoing, and a Phase 1 allogeneic ATA188 clinical study is expected to begin in the second half of 2017. Atara's clinical pipeline also includes ATA520 targeting Wilms Tumor 1 (WT1) and ATA230 directed against cytomegalovirus (CMV).

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 Company's belief that the high unmet medical need of immunocompromised patients with antiviral refractory or resistant CMV and compelling ATA230 clinical data provide a strong rationale for the continued development of ATA230; the Company's plan to further evaluate ATA230 development and study designs with the FDA and other global health authorities following the initiation of the ATA129 EBV-PTLD Phase 3 studies; the Company's expected initiation of Phase 3 studies of ATA129 in EBV-PTLD following a HCT or SOT in 2017, a Phase 1/2 study of ATA129 in combination with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in patients with platinum-resistant or recurrent EBV-associated NPC in 2018 and a Phase 1 allogeneic ATA188 clinical study in the second half of 2017; and the Company's expected submission of a conditional marketing authorization application in EBV-PTLD following HCT in the EU in 2018. Because such statements deal with future events and are based on Atara Biotherapeutics' current expectations, they are subject to various risks and uncertainties and actual results, performance or achievements of Atara Biotherapeutics 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 Biotherapeutics' quarterly report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on August 7, 2017, including the documents incorporated by reference therein, and subsequent filings with the SEC. Except as otherwise required by law, Atara Biotherapeutics 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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