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Atara Biotherapeutics Receives Rare Pediatric Disease Designation from FDA for ATA230 for Treatment of Congenital Cytomegalovirus (CMV) Infection

SOUTH SAN FRANCISCO, Calif., Oct. 26, 2017 (GLOBE NEWSWIRE) -- Atara Biotherapeutics, Inc. (Nasdaq:ATRA), a leading off-the-shelf T-cell immunotherapy company developing novel treatments for patients with cancer, autoimmune diseases and serious viral infections, today announced that ATA230 was granted Rare Pediatric Disease Designation for the treatment of congenital cytomegalovirus (CMV) infection 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 immunocompromised patients with CMV viremia or disease who are refractory or resistant to antiviral drug treatment in the post-transplant setting.

“FDA’s Rare Pediatric Disease Designation, following the recent orphan drug designation for ATA230, further underscores the high unmet medical need in treating congenital CMV infection,” said Isaac Ciechanover, M.D., Chief Executive Officer and President of Atara Biotherapeutics. “We will continue to work closely with FDA and other global health authorities to evaluate the development of ATA230 to address this potentially life-threating disease.”

The FDA grants Rare Pediatric Disease designation to drugs or biologics intended to treat serious or life-threatening rare diseases that primarily affect individuals aged from birth to 18 years and fewer than 200,000 persons in the U.S. Under this designation, should ATA230 be approved, Atara may be eligible to receive a rare pediatric disease priority review voucher for a biologics license or new drug application for a different product.

About CMV
In patients with weakened immune systems, including bone marrow and solid organ transplant recipients, newborns with immature immune systems and those with human immunodeficiency virus (HIV), CMV can cause potentially life-threatening disease or may result in blindness, brain damage and deafness. While small-molecule antiviral drugs are approved to treat and prevent CMV infection, there remains a high unmet need due to viral resistance, modest neurodevelopmental activity and adverse effects, such as toxicity and reduction in white blood cell count impairing the ability to fight other infections, with these agents.

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 immunocompromised patients with CMV viremia or disease who are refractory or resistant to antiviral drug treatment in the post-transplant setting. In September 2017, Atara announced that ATA230

received orphan drug designation from the FDA for the treatment of CMV viremia and disease in immunocompromised patients, and 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 intends 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 T-cell immunotherapy company developing novel treatments for patients with cancer, autoimmune diseases and serious viral infections. 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 (MATCH study) or solid organ transplant (ALLELE study) 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 hematopoietic cell transplant in the EU in 2018. Allogeneic ATA188 and autologous ATA190, the Company's next generation T-cell immunotherapies, selectively target specific EBV antigens believed to be important for the potential treatment of multiple sclerosis (MS). A Phase 1 clinical study of autologous ATA190 in patients with progressive MS is ongoing. Atara also initiated a multinational, multicenter Phase 1 allogeneic ATA188 clinical study in patients with progressive or relapsing-remitting MS in October 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 expectation that it will continue to work closely with FDA and other global health authorities to evaluate ATA230 development plans to address this potentially life-threating disease; the possibility that, should ATA230 be approved, Atara may be eligible to receive a rare pediatric disease priority review voucher for a biologics license or new drug application for a different product; the Company's plan to further evaluate ATA230 development plans 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 hematopoietic cell transplant or solid organ transplant in 2017 and 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 the Company's expected submission of a conditional marketing authorization

application in EBV-PTLD following hematopoietic cell transplant 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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