

Atara Biotherapeutics Receives Positive Health Canada Regulatory Feedback for ATA129

- Health Canada New Drug Submission (NDS) planned based on Phase 1 and 2 clinical results and supported by available data from anticipated MATCH and ALLELE Phase 3 studies, which are expected to be ongoing at the time of NDS filing
- Health Canada regulatory feedback similar to scientific advice from European Medicines Agency's (EMA's) Scientific Advice Working Group

SOUTH SAN FRANCISCO, Calif., Sept. 11, 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 receipt of positive regulatory feedback from Health Canada for ATA129, the Company's most advanced T-cell immunotherapy in development for the treatment of cancer patients with rituximab-refractory Epstein-Barr virus (EBV) associated post-transplant lymphoproliferative disorder (EBV-PTLD) following a hematopoietic cell transplant (HCT) or solid organ transplant (SOT).

Based on feedback from a meeting with Health Canada's Biologics and Genetic Therapies Directorate (BGTD), Atara plans to request advance consideration under the Notice of Compliance with Conditions (NOC/c) policy for ATA129 in the treatment of patients with rituximab-refractory EBV-PTLD after HCT. A Notice of Compliance issued under the NOC/c policy is an authorization to market a drug in Canada with the condition that the sponsor undertake additional studies to verify the clinical benefit, and is analogous to a conditional marketing authorization in the EU.

Consistent with Atara's previously communicated regulatory plan in Europe, the Canadian filing is expected to be based on results from the Phase 1 and 2 clinical studies conducted at Memorial Sloan Kettering Cancer Center (MSK) and supported by available data from the Company's planned MATCH and ALLELE Phase 3 studies, which are anticipated to be ongoing at the time of the NDS filing.

"Health Canada represents the second major regulatory body to provide feedback supporting the submission of ATA129 for an expedited approval pathway based on the compelling results of the prior Phase 1 and 2 studies," said Isaac Ciechanover, M.D., Chief Executive Officer and President of Atara Biotherapeutics. "We look forward to working closely with Health Canada and other global health authorities to make ATA129 available to patients as expeditiously as possible."

Following completion of the Phase 3 studies, Atara also expects to file a ATA129 supplemental NDS for the treatment of cancer patients with rituximab-refractory EBV-PTLD after SOT, as well as request to remove the conditions of the NOC/c for the HCT indication.

About EBV-PTLD

Since its discovery as the first human oncovirus, Epstein-Barr virus (EBV) has been implicated in the development of a wide range of lymphoproliferative disorders, including lymphomas and other cancers. EBV is widespread in all human populations and persists as a lifelong, asymptomatic infection. In immunocompromised patients, such as those undergoing hematopoietic cell transplants (HCT) or solid organ transplants (SOT), EBV-associated post-transplant lymphoproliferative disorder (EBV-PTLD), represents a life-threatening condition. Median overall survival in EBV-PTLD patients after HCT who have failed rituximab-based first line therapy is 16-56 days. In EBV-PTLD following SOT, patients failing rituximab experience increased chemotherapy-induced treatment-related mortality compared to other lymphoma patients. One and two-year survival in high-risk EBV-PTLD patients after SOT is 36% and 0%, respectively.

About ATA129

Atara's most advanced T-cell immunotherapy in development, ATA129, is a potential treatment for cancer patients with rituximab-refractory EBV-PTLD as well as other EBV positive hematologic and solid tumors including nasopharyngeal carcinoma (NPC). In February 2015, FDA granted ATA129 Breakthrough Therapy Designation for EBV-PTLD following allogeneic hematopoietic cell transplant (HCT) and in October 2016, ATA129 was accepted into the EMA Priority Medicines (PRIME) regulatory pathway for the same indication, providing enhanced regulatory support. In addition, ATA129 also has orphan status in the U.S. and EU. Phase 3 studies of ATA129 in EBV-PTLD after HCT (MATCH study) or solid organ transplant (ALLELE study) are expected to start in 2017, and a Phase 1/2 study in 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.

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 (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 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: that the Canadian filing is expected to be based on results from the Phase 1 and 2 clinical studies conducted at MSK and supported by available data from the Company's planned MATCH and ALLELE Phase 3 studies, which are anticipated to be ongoing at the time of the NDS filing; the Company's expectation that it will work closely with Health Canada and other global health authorities to make ATA129 available to patients as expeditiously as possible; the Company's expectation that it will file a ATA129 supplemental NDS for the treatment of cancer patients with rituximab-refractory EBV-PTLD after SOT, as well as request to remove the conditions of the NOC/c for the HCT indication; 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.

INVESTOR & MEDIA CONTACTS:

Investors:

John Craighead, Atara Biotherapeutics
650-491-5806
jcraighead@atarabio.com

Steve Klass, Burns McClellan
212-213-0006 x331
sklass@burnsmc.com

Media:

Justin Jackson, Burns McClellan
212-213-0006 x327
jjackson@burnsmc.com



Source: Atara Biotherapeutics, Inc.