



## **Atara Biotherapeutics' Tab-cel™ Achieves Positive Long-Term Outcomes in Phase 2 Studies of Patients with Epstein-Barr Virus Associated Post-Transplant Lymphomas**

June 15, 2018

*Findings presented at 23rd Congress of European Hematology Association*

***Tab-cel™ demonstrated durable remissions and encouraging safety profile in patients with EBV+ PTLD who failed first line therapy***

***Median survival in SOT patients was 21.3 months and was not reached in the HCT population after 23.3 months***

***None of the responders (CR or PR) to tab-cel™ died of EBV+ PTLD; Two-year overall survival for these responding patients was 83% and 86% following HCT and SOT, respectively***

SOUTH SAN FRANCISCO, Calif., June 15, 2018 (GLOBE NEWSWIRE) -- Atara Biotherapeutics, Inc. (Nasdaq:ATRA), a leading off-the-shelf, allogeneic T-cell immunotherapy company developing novel treatments for patients with cancer, autoimmune and viral diseases, today announced positive long-term outcomes including durable remissions and encouraging safety findings from two Phase 2 studies of tab-cel™ (tabelecleucel), Atara's most advanced off-the-shelf T-cell immunotherapy. These single center, open-label studies enrolled patients with Epstein-Barr virus associated post-transplant lymphoproliferative disorder (EBV+ PTLD) following allogeneic hematopoietic cell transplant (HCT) or solid organ transplant (SOT) who failed first-line therapy. Atara and its collaborating investigators at Memorial Sloan Kettering Cancer Center (MSK) reported the Phase 2 results in a poster presentation at the 23rd Congress of the European Hematology Association (EHA), being held in Stockholm, Sweden, June 14-17, 2018.

"Tab-cel™ demonstrated durable remissions and an encouraging safety profile after substantial follow-up time for patients with EBV-associated lymphomas who have limited treatment options and often experience poor outcomes," said Dietmar Berger, M.D., Ph.D., Global Head of Research and Development of Atara Biotherapeutics. "No patient who responded to tab-cel™ in these studies died of EBV+ PTLD after treatment with this off-the-shelf, allogeneic T-cell immunotherapy. We are progressing two tab-cel™ Phase 3 clinical studies to confirm the Phase 2 findings in patients with EBV+ PTLD following HCT and SOT who have failed first line therapy."

### *Overall Survival (OS)*

- One- and three-year OS for tab-cel™ treated patients with EBV+ PTLD following HCT who failed rituximab (n=35) was 68% and 55%, respectively. Median OS was not reached after 23.3 months of follow-up in this patient group. The expected median survival for patients with EBV+ PTLD following HCT who have failed rituximab first line therapy is 16 to 56 days.<sup>1,2</sup>
- In patients with EBV+ PTLD following SOT who failed rituximab, the one- and three-year OS after treatment with tab-cel™ (n=14) was 64% and 43%, respectively. Median survival in this patient group was 21.3 months, which compares favorably to the expected 12- to 13-month median survival in patients with EBV+ PTLD following SOT who fail to achieve a complete response to first-line therapy with single-agent rituximab.<sup>3</sup>
- None of the EBV+ PTLD patients who had complete or partial responses (CR or PR) after treatment with tab-cel™ died of EBV+ PTLD. Two-year OS for these responding patients was 83% and 86% following HCT (n=24) and SOT (n=7), respectively.

### *Overall response rates (ORR)*

- Tab-cel™ was associated with durable ORR (CR plus PR) of 69% and 50% in patients with EBV+ PTLD following HCT and SOT, respectively, who have failed rituximab.

### *Safety*

- Tab-cel™ was generally well-tolerated. Safety findings were consistent with previous reports of these studies with no new signals noted with additional follow up.

Atara anticipates results from the first tab-cel™ Phase 3 study and submission of an EU conditional marketing authorization application in the first half of 2019.

Details for the poster presentation at the [EHA Congress](#) are as follows:

**Abstract PF401:** Long Term Outcomes of Tabelecleucel (Allogeneic Third-Party EBV-Targeted Cytotoxic T Lymphocytes) for Rituximab-Refractory Post-Transplant EBV+ Lymphomas: A Single Center Experience

**Session Title:** Gene therapy, cellular immunotherapy and vaccination - Clinical

**Presentation Date & Time:** Friday, June 15; 5:30 p.m. to 7:00 p.m. CEST

**Authors:** Susan Prockop, Ekaterina Doubrovina, Amy Feng, Guenther Koehne, Parastoo Dahi, Esperanza Papadopoulos, Craig Sauter, Stephanie Suser, Willis Navarro, Akshay Sudhindra, Richard O'Reilly

**Location:** Poster area, Älvsjö building, Stockholm International Fairs and Congress Centre (Stockholmsmässan)

#### **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 allogeneic 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 patients with EBV+ PTLD following 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 patients with high-risk EBV+ PTLD following SOT is 36% and 0%, respectively.

#### **About tab-cel™ (tabelecleucel; formerly known as ATA129)**

Atara's most advanced T-cell immunotherapy in development, tab-cel™, is a potential treatment for patients with Epstein-Barr virus (EBV) associated post-transplant lymphoproliferative disorder (EBV+ PTLD) who have failed rituximab, as well as other EBV-associated hematologic and solid tumors, including nasopharyngeal carcinoma (NPC). In February 2015, FDA granted tab-cel™ Breakthrough Therapy Designation for EBV+ PTLD following allogeneic hematopoietic cell transplant (HCT), and in October 2016, tab-cel™ was accepted into the EMA Priority Medicines (PRIME) regulatory pathway for the same indication, providing enhanced regulatory support. Atara also received positive regulatory feedback from Health Canada in September 2017 supporting the submission of tab-cel™ for an expedited approval pathway. In addition, tab-cel™ has orphan status in the U.S. and EU. Tab-cel™ is in Phase 3 clinical development for the treatment of EBV+ PTLD following an allogeneic hematopoietic cell transplant (MATCH study) or solid organ transplant (ALLELE study), and Atara is planning a Phase 1/2 study in NPC. Tab-cel™ is also available to eligible patients with EBV-associated hematologic and solid tumors through an ongoing multicenter expanded access protocol clinical study, positive interim results of which were presented in December 2017 at the 59th American Society of Hematology (ASH) Annual Meeting.

#### **About Atara Biotherapeutics, Inc.**

[Atara Biotherapeutics, Inc. \(@Atarabio\)](#) is a leading T-cell immunotherapy company developing novel treatments for patients with cancer, autoimmune and viral diseases. The Company's off-the-shelf, allogeneic T-cells are bioengineered 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, tabeclucel, or tab-cel™ (formerly known as ATA129), is being developed for the treatment of patients with Epstein-Barr virus (EBV) associated post-transplant lymphoproliferative disorder (EBV+ PTLD) who have failed rituximab, as well as other EBV-associated hematologic and solid tumors, including nasopharyngeal carcinoma (NPC). Tab-cel™ is in Phase 3 clinical development for the treatment of EBV+ PTLD following an allogeneic hematopoietic cell transplant (MATCH study) or solid organ transplant (ALLELE study). Atara is also developing off-the-shelf, allogeneic ATA188 and autologous ATA190 T-cell immunotherapies using a complementary targeted antigen recognition technology for 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 is advancing a Phase 1 ATA188 clinical study in patients with progressive or relapsing-remitting MS across clinical sites in the U.S. and Australia in March 2018. Atara's clinical pipeline also includes ATA520 targeting Wilms Tumor 1 (WT1) and ATA230 directed against cytomegalovirus (CMV).

#### **References**

<sup>1</sup>Atara estimated 1-year survival based on analysis of Ocheni S, *et al.* EBV reactivation and post transplant lymphoproliferative disorders following allogeneic SCT. *Bone Marrow Transplantation*. 2008 Aug;42(3):181-6.

<sup>2</sup>Fox CP, *et al.* EBV-associated post-transplant lymphoproliferative disorder following in vivo T-cell-depleted allogeneic transplantation: Clinical features, viral load correlates and prognostic factors in the rituximab era. *Bone Marrow Transplant*. 2014;49(2):280-6.

<sup>3</sup>Choquet S, *et al.* Rituximab in the management of post-transplantation lymphoproliferative disorder after solid organ transplantation: proceed with caution. *Ann Hematol*. 2007 Aug;86(8):599-607.

#### **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 enrollment, expansion, expected results and completion of its Phase 3 studies of tab-cel™; the timing of the Company's submission of a CMA for tab-cel™ in the EU; the Company's ability to leverage its platform in other indications and initiate development of additional immunotherapies; and the potential advantages of its product candidates. 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 May 8, 2018, 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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