January 4, 2021

Atara Biotherapeutics Provides Regulatory Update for Tab-Cel® for Epstein-Barr Virus-Positive Post-Transplant Lymphoproliferative Disease

Company to Host Conference Call on January 4th at 8:30 a.m. EST

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)-- Atara Biotherapeutics, Inc. (Nasdaq: ATRA; the "Company"), a pioneer in T-cell immunotherapy leveraging its novel allogeneic EBV T-cell platform to develop transformative therapies for patients with severe diseases including solid tumors, hematologic cancers and autoimmune diseases, today noted that it has not yet initiated the Biologics License Application (BLA) submission for tab-cel® (tabelecleucel), currently in Phase 3 development for Epstein-Barr virus-positive post-transplant lymphoproliferative disease (EBV^+ PTLD). The Company remains on track to complete the BLA filing in Q3 2021, based on several key points of agreement with FDA as previously announced.

To initiate the BLA, Atara is awaiting a procedural decision from the FDA related to how the historical non-pivotal data should be presented in the BLA submission. Following the FDA agreement in October 2020 that the pivotal 302 ALLELE data will be the primary basis for approval, and that historical non-pivotal clinical data will be supportive, FDA needs to decide whether they view the drug product manufactured by our academic partner used in historical, non-pivotal studies as comparable to the drug product manufactured by Atara used in the pivotal ALLELE study. This decision will then determine if the Company will submit in the clinical module the pivotal and non-pivotal data combined in pooled analyses or separately in parallel analyses. The type of analysis does not change expectations regarding the proposed product indication for previously treated patients with EBV^+ PTLD.

The initial module for the rolling BLA for tab-cel® has been ready for submission since early December, and its content is not impacted by this decision. The Company remains on track to complete the BLA filing in Q3 2021 and is simply awaiting this procedural decision from FDA to initiate the BLA.

"Based on prior conversation with FDA, we had the understanding that this procedural decision would be made by the end of 2020 so we could initiate the BLA as planned. This procedural decision has not yet been communicated by FDA, and we look forward to continuing our constructive dialogue with the agency as part of our BTD status," said Pascal Touchon, President and Chief Executive Officer of Atara. "We remain on track to complete the BLA filing in Q3 2021."

The Company expects this procedural decision to be taken soon by FDA, based on the ongoing, constructive dialogue with the agency, which has already resulted in several key

points of agreement, including: a rolling submission is acceptable for the BLA; Atara can complete the BLA submission with currently enrolled patients in the pivotal ALLELE study with at least six-months follow-up of duration of response; and, FDA will consider historical data as supportive data to the pivotal study in the BLA clinical module. Based on these discussions, the critical path to completion of the BLA remains unchanged, and the Company remains on track to complete the BLA submission in Q3 2021.

As previously announced, Atara successfully completed an interim analysis (IA) in the pivotal study for tab-cel® in Q3 2020 and found the data supportive of engaging with the FDA in line with stated plans to initiate a rolling BLA filing by end of 2020. The IA showed a 50 percent objective response rate (ORR) to tab-cel® with independent oncologic and radiographic assessment (IORA) in patients with relapsed-refractory EBV^+ PTLD following hematopoietic cell transplants (HCT) or solid organ transplants (SOT), that had reached at least six months follow-up after the ORR assessment. This ORR is consistent with previously published investigator assessed data. The tab-cel® safety profile is also consistent with previously published data, with no new safety signals.

Atara Conference Call and Webcast Information

Atara will hold a conference call today, January 4th at 8:30 a.m. EST. Analysts and investors can participate in the conference call by dialing (888) 540-6216 for domestic callers and (734) 385-2715 for international callers, using the conference ID 9370747. A live audio webcast can be accessed by visiting the Investors & Media – News & Events section of atarabio.com. An archived replay will be available on the Company's website for 30 days following the live webcast.

About Atara Biotherapeutics

Atara Biotherapeutics, Inc. (@Atarabio) is a pioneer in T-cell immunotherapy leveraging its novel allogeneic EBV T-cell platform to develop transformative therapies for patients with severe diseases including solid tumors, hematologic cancers and autoimmune disease. With our lead program in Phase 3 clinical development, Atara is the most advanced allogeneic T-cell immunotherapy company and intends to rapidly deliver off-the-shelf treatments to patients with high unmet medical need. Our platform leverages the unique biology of EBV T cells and has the capability to treat a wide range of EBV-associated diseases, or other severe diseases through incorporation of engineered CARs (chimeric antigen receptors) or TCRs (T-cell receptors). Atara is applying this one platform to create a robust pipeline including: tab-cel® (tabelecleucel) in Phase 3 development for Epstein-Barr virus-positive post-transplant lymphoproliferative disease (EBV^+ PTLD); ATA188, a T-cell immunotherapy targeting EBV antigens as a potential treatment for multiple sclerosis; and multiple next-generation chimeric antigen receptor T-cell (CAR T) immunotherapies for both solid tumors and hematologic malignancies. Improving patients' lives is our mission and we will never stop working to bring transformative therapies to those in need. Atara is headquartered in South San Francisco and our leading-edge research, development and manufacturing facility is based in Thousand Oaks, California. For additional information about the company, please visit atarabio.com and follow us on Twitter and LinkedIn.

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 tab-cel®, including Atara's discussions with, and potential decisions by, the FDA regarding the BLA submission for EBV^+ patients with PTLD, the timing and results of additional clinical data, and the timing of, and Atara's plans for, initiation and completion of the BLA. 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 in Atara Biotherapeutics' filings with the Securities and Exchange Commission (SEC), including in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of the Company's most recently filed periodic reports on Form 10-K and Form 10-Q and subsequent filings and in the documents incorporated by reference therein. 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.

View source version on businesswire.com:
https://www.businesswire.com/news/home/20210104005393/en/

INVESTOR & MEDIA:
Media
Kerry Beth Daly
Head, Corporate Communications
Atara Biotherapeutics
516-982-9328
kdaly@atarabio.com

Investors
Eric Hyllengren
Vice President, Investor Relations and Finance
Atara Biotherapeutics
805-395-9669
ehyllengren@atarabio.com

Source: Atara Biotherapeutics, Inc.