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Atara Biotherapeutics Announces Plan to Initiate Tab-cel® FDA Biologics License Application Submission Next Year

SOUTH SAN FRANCISCO, Calif., July 16, 2019 (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 an updated development plan for the Phase 3 tab-cel® (tabelecleucel) program for patients with Epstein-Barr virus-associated post-transplant lymphoproliferative disease (EBV+ PTLD).

Based on Atara's recent discussions with the U.S. Food & Drug Administration (FDA), the Company plans to initiate a tab-cel® biologics license application (BLA) submission for patients with EBV+ PTLD in the second half of 2020.

"We believe focusing on the initiation of an FDA BLA submission next year is the best strategic development and value creation opportunity for tab-cel®," said Pascal Touchon, President and Chief Executive Officer of Atara Biotherapeutics. "We remain diligently committed to addressing the critical need for new transformative therapies to treat patients with EBV+ PTLD and bringing tab-cel® to patients as quickly as possible."

Accordingly, the initiation of the Company's BLA submission is now planned to occur prior to the Company's submission of an EU conditional marketing authorization (CMA) application. Atara remains in active discussions with the European Medicines Agency (EMA) regarding the development of tab-cel® for patients with EBV+ PTLD, and the outcome of these discussions will determine the timing of the CMA application submission.

As previously disclosed, the Company has combined the two ongoing tab-cel® Phase 3 clinical studies (MATCH and ALLELE) into a single study (ALLELE) that now consists of a hematopoietic cell transplants (HCT) cohort for EBV+ PTLD patients who have failed rituximab and a single solid organ transplant (SOT) cohort for EBV+ PTLD patients who have failed rituximab with both chemotherapy and non-chemotherapy prior treatment experience. As part of the amended ALLELE protocol, Atara plans to conduct an interim analysis prior to initiating the BLA submission. To ensure the integrity of the ongoing, open-label tab-cel® studies, Atara does not expect to disclose interim top-line EBV+ PTLD results until after acceptance of the FDA BLA filing.

About Atara Biotherapeutics, Inc.
Atara Biotherapeutics, Inc. (@Atarabio) is a leading off-the-shelf, allogeneic T-cell immunotherapy company developing novel treatments for patients with cancer, autoimmune and viral diseases. Atara's technology platform leverages research collaborations with leading academic institutions with the Company's scientific, clinical, regulatory and

manufacturing expertise. Atara's pipeline includes tab-cel® (tabelecleucel), which is in Phase 3 development for patients with Epstein-Barr virus-associated post-transplant lymphoproliferative disease (EBV+ PTLD) as well as in earlier stage development for other EBV-associated hematologic malignancies and solid tumors, including nasopharyngeal carcinoma (NPC); T-cell immunotherapies targeting EBV antigens believed to be important for the potential treatment of multiple sclerosis; and next-generation chimeric antigen receptor T-cell (CAR T) immunotherapies. The company was founded in 2012 and is co-located in South San Francisco and Southern California. Our Southern California hub is anchored by the state-of-the-art Atara T-cell Operations and Manufacturing (ATOM) facility in Thousand Oaks, California. For additional information about the company, please visit atarabio.com.

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: Atara's development plan for its Phase 3 tab-cel® program and its ability to bring tab-cel® to patients; the continued enrollment of patients in the Company's tab-cel® program; the timing of Atara's interim analysis of the ALLELE study; the timing of Atara's initiation of a BLA submission; the timing of Atara's CMA application submission; Atara's discussions with the FDA and EMA; and the timing of disclosure of interim top-line EBV+ PTLD results. 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.

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