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Atara Biotherapeutics Provides Update on Clinical Programs Related to EBVALLO™ (tabelecleucel) and ATA3219

U.S. FDA issues clinical hold on EBVALLO™ (tabelecleucel) and ATA3219 studies linked to EBVALLO Complete Response Letter (CRL)

THOUSAND OAKS, Calif.--(BUSINESS WIRE)-- Atara Biotherapeutics, Inc. (Nasdaq: ATRA), a leader in T-cell immunotherapy, leveraging its novel allogeneic Epstein-Barr virus (EBV) T-cell platform to develop transformative therapies for patients with cancer and autoimmune diseases, today announced that the U.S. Food and Drug Administration (FDA) has placed a clinical hold on Atara's active Investigational New Drug (IND) applications. These INDs include the EBVALLO™ (tabelecleucel) program as monotherapy treatment for adult and pediatric patients two years of age and older with Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLD), as well as ATA3219, an allogeneic CD19-targeted CAR-T therapy, for the treatment of non-Hodgkin's lymphoma and systemic lupus erythematosus. Specifically identified subjects currently enrolled in the clinical studies who have the potential to derive clinical benefit may continue to receive treatment in accordance with the ongoing study protocols. Screening and enrollment of new participants in both programs have been paused.

The clinical hold for EBVALLO is directly linked to inadequately addressed GMP compliance issues identified during the pre-license inspection of the third-party manufacturing facility referenced in the Complete Response Letter (CRL) for EBVALLO that was announced on January 16, 2025. While ATA3219 drug product is manufactured at a separate, fully compliant GMP-certified facility, the starting materials used in its production are affected by the compliance issues at the same third-party facility referenced in the CRL. These issues, which underlie both the CRL and the clinical hold, are specific to the referenced third-party manufacturing facility and do not affect Atara's second third-party manufacturer, FUJIFILM Diosynth Biotechnologies (FDB) facility in Thousand Oaks, California. The FDB facility remains a critical component of Atara's long-term manufacturing strategy for both assets.

Atara and FDA have discussed and agreed upon the actions necessary to release the clinical holds. The FDA has confirmed its commitment to working collaboratively and expeditiously with Atara to resolve the clinical holds.

"We intend to work closely with the FDA to address these issues as expeditiously as possible," said Cokey Nguyen, Ph.D., President and Chief Executive Officer of Atara. "We are encouraged with ongoing correspondence with the Agency and a potential path to submitting the necessary data to release the clinical hold. Patient safety remains our priority and maintaining the highest standards for our programs."

About Atara Biotherapeutics, Inc.

Atara is harnessing the natural power of the immune system to develop off-the-shelf cell therapies for difficult-to-treat cancers and autoimmune conditions that can be rapidly delivered to patients from inventory. With cutting-edge science and differentiated approach, Atara is the first company in the world to receive regulatory approval of an allogeneic T-cell immunotherapy. Our advanced and versatile T-cell platform does not require T-cell receptor or HLA gene editing and forms the basis of a diverse portfolio of investigational therapies that target EBV, the root cause of certain diseases, in addition to next-generation AlloCAR-Ts designed for best-in-class opportunities across a broad range of hematological malignancies and B-cell driven autoimmune diseases. Atara is headquartered in Southern California. For more information, visit atarabio.com and follow @Atarabio on X 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: (1) the development, timing and progress of tab-cel, including the BLA and potential indications, the timing for FDA review of any resubmission of the BLA, the potential characteristics and benefits of tab-cel, the tab-cel clinical trials; (2) the development, timing and progress of Atara's AlloCAR-T programs (including ATA3219 and ATA3431), including the clinical trials; and (3) Atara's ability to address the FDA's concerns and to complete the activities necessary to release the clinical hold. Because such statements deal with future events and are based on Atara's current expectations, they are subject to various risks and uncertainties and actual results, performance or achievements of Atara 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, without limitation, risks and uncertainties associated with the costly and time-consuming pharmaceutical product development process and the uncertainty of clinical success; risks related to FDA feedback and the ability of Atara and its third-party manufacturer to address the issues identified in the CRL and the clinical hold; our ability to access capital; the sufficiency of Atara's cash resources and need for and ability to obtain additional capital on favorable terms or at all; risks and uncertainties related to Atara's financial close and audit procedures; the timing of the strategic review process; whether Atara will pursue any strategic alternatives; in the event Atara pursues a strategic alternative, that the strategic alternative may not be attractive or ultimately consummated; whether any strategic alternative will result in additional value for Atara and its shareholders; whether the process will have an adverse impact on Atara; and other risks and uncertainties affecting Atara's and its development programs, including those discussed in Atara's filings with the Securities and Exchange Commission , 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 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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