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# Atara Biotherapeutics Provides Regulatory Updates on EBVALLO™ (tabelecleucel)

*FDA lifts clinical hold enabling resumption of clinical trials*

*FDA has granted a Type A Meeting to discuss path forward for BLA*

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 lifted the clinical hold on Atara's active Investigational New Drug (IND) applications for the EBVALLO™ (tabelecleucel) program.

"We are very pleased to have addressed the FDA's questions, and this has enabled the FDA to lift the clinical holds," said Cokey Nguyen Ph.D., President and Chief Executive Officer of Atara. "We are working closely with our partner Pierre Fabre Laboratories and our clinical trial sites and anticipate resuming enrollment and treatment of patients as soon as possible."

In January 2025, the EBVALLO™ (tabelecleucel) program was placed on clinical hold. The clinical hold was directly linked to 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.

The FDA has lifted the clinical hold on tabelecleucel after reviewing supplemental data on finished drug product. The Company is now allowed to restart the Phase 3 ALLELE clinical study for patients with Epstein-Barr Virus-associated post-transplant lymphoproliferative disease (EBV+ PTLD) and the Phase 2 label-expansion multi-cohort clinical study.

The FDA has also granted a date for a Type A meeting to discuss the plan to address the issues raised by the FDA in the CRL from January 2025, and the path forward for resubmission of the EBVALLO™ BLA.

"We are pleased that the FDA has granted our request for a Type A meeting and hope to gain clarity on the timing for resubmitting the tab-cel BLA for review by the FDA," said Dr. Nguyen.

## Corporate Update

**Strategic Option Evaluation:** As previously communicated, Atara engaged a well-known financial advisor to support a comprehensive process to explore and assess a range of potential strategic options for the Company. Alternatives may include, but are not limited to, an acquisition, merger, reverse merger, other business combinations, sale of assets, or other strategic transactions. We have temporarily paused this strategic option evaluation pending clarity with the FDA on timing of the resubmission of the EBVALLO™ BLA. It is

possible that Atara may not pursue a strategic alternative or transaction or that any strategic alternative or transaction, if pursued, will not be completed on attractive terms, or that a strategic alternative or transaction may not ultimately be consummated.

### **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](http://atarabio.com) and follow [@Atarabio](https://twitter.com/Atarabio) on [X](#) and [LinkedIn](#).

### **About tabellecleucel**

Tabellecleucel is an off-the-shelf allogeneic cell therapy composed of EBV specific cytotoxic T cell lymphocytes expanded from healthy donors and infused into partial HLA matched recipients suffering from EBV-driven malignancies such as post-transplant lymphoproliferative disease. Tab-cel is approved by the EMA, trademarked as EBVALLO™, for use in PTLD. Tab-cel is currently being evaluated in clinical studies and Atara is in the process of filing for approval by the FDA for commercial use in the United States. Pierre Fabre Laboratories holds worldwide Commercialization rights to EBVALLO™.

### **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 and the timing of resuming enrollment of the tab-cel clinical trials, the outcome of the Type A meeting with the FDA, the timing for FDA review of any resubmission of the BLA, and the potential characteristics and benefits of tab-cel; and (2) Atara's exploration of strategic alternatives and ability to consummate one or more strategic transactions. 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; 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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### **Investor and Media Relations**

Amber Daugherty

Sr. Director, Strategy and Operations

[adaugherty@atarabio.com](mailto:adaugherty@atarabio.com)

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