

January 16, 2025



Atara Biotherapeutics Provides Regulatory and Business Update on EBVALLO™ (tabelecleucel)

Atara received FDA Complete Response Letter (CRL) solely related to inspection findings at third-party manufacturer

CRL did not identify deficiencies related to clinical efficacy or safety data in the Biologics License Application (BLA), and the FDA did not request any new clinical studies to support approval

Atara remains committed to working with the FDA, Pierre Fabre Laboratories, and the third-party manufacturer to bring EBVALLO to patients in the U.S.

Atara has engaged a well-known financial advisor to support exploration of all strategic options

Atara remains focused on preserving future EBVALLO financial value for the benefit of all stockholders

Atara has entered into a non-binding term sheet with Redmile Group to provide up to \$15 million in funding, which Atara believes is sufficient to fund the ongoing activities required to achieve BLA approval

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 it received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) for the EBVALLO™ (tabelecleucel) Biologics License Application (BLA) 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), who have received at least one prior therapy including an anti-CD20 containing regimen.

The CRL was solely related to observations as part of a standard pre-license inspection of a third-party manufacturing facility for EBVALLO. The CRL did not identify any deficiencies related to the manufacturing process, the clinical efficacy, or clinical safety data in the BLA, and the FDA did not request any new clinical trials to support the approval of EBVALLO.

“We are working closely with our partner Pierre Fabre Laboratories, the FDA, and the third-party manufacturer to address the feedback to support marketing approval for EBVALLO,” said Cokey Nguyen, Ph.D., President and Chief Executive Officer of Atara. “Once the third-party manufacturer GMP compliance issues have been adequately addressed, we will file for a resubmission, which we would expect to be potentially approved within six months of

resubmission. Atara and its partner Pierre Fabre remain confident in the potential of EBVALLO and are committed to bringing this potential first-in-class medicine to U.S. patients with EBV+ PTLD who have limited treatment options and significant unmet need.”

“We are disappointed by the delay and are willing to work with Atara on appropriate next steps to bring EBVALLO to U.S. patients that suffer from this deadly rare disease with no approved therapies,” said Eric Ducournau, CEO of Pierre Fabre Laboratories.

EBVALLO, which was granted marketing authorization by the European Commission in December of 2022, is an allogeneic, EBV-specific T-cell immunotherapy designed to target and eliminate EBV-infected cells. The BLA in the U.S. is based on results from the pivotal ALLELE study demonstrating a statistically significant 50% Objective Response Rate (ORR) and a favorable safety profile.

A second third-party manufacturer, FUJIFILM Diosynth Biotechnologies (FDB) manufacturing facility in Thousand Oaks, CA, has recently been approved to manufacture EBVALLO by the EMA, making it a critical component of the planned long-term global manufacturing strategy for EBVALLO.

Corporate Updates

Review of Strategic Alternatives: The Board regularly reviews Atara’s strategic plan, priorities, and opportunities as part of its commitment to act in the best interest of Atara and its stockholders. Atara had previously engaged a well-known financial advisor to support the assessment of opportunities to advance and realize value from Atara’s CAR-T assets. The advisor’s scope has recently expanded to include a wider range of additional strategic alternatives which may include, but are not limited to, an acquisition, merger, reverse merger, other business combinations, sale of assets, or other strategic transactions. Through this process, Atara is already in active discussions with several potential parties. However, there can be no assurance regarding the results or outcome of this process. It is possible that Atara may not pursue a strategic alternative or transaction or that any strategic alternative or transaction, if pursued, will be completed on attractive terms, or that a strategic alternative or transaction may not ultimately be consummated.

Preservation of Future EBVALLO Milestone and Royalty Income Value to Shareholders: Atara remains eligible to receive a \$60 million milestone payment from Pierre Fabre upon FDA approval of the EBVALLO BLA, as well as significant double-digit tiered royalties as a percentage of net sales, and milestones related to commercial sales of EBVALLO. Atara remains committed to preserving this potential future value for all stockholders.

If a strategic resolution is not reached to provide funding for its CAR-T development programs in Q1 2025, Atara intends to suspend all CAR-T activities, and significantly reduce company expenses and activities to only those that support the approval of EBVALLO, including through a near-term progressive transfer of all operational activities related to EBVALLO to Pierre Fabre.

Atara has entered into a non-binding term sheet with Redmile Group to provide up to \$15 million in funding through an equity line of credit, which Atara believes is sufficient to fund the ongoing activities required to achieve BLA approval. Atara is also exploring alternative

financing options, including non-dilutive sources of capital.

“We are pleased to have the strong confidence from a key stockholder in the future of EBVALLO and access to the capital to support the transfer of EBVALLO activities to Pierre Fabre, creating opportunities for value creation through the anticipated U.S. approval and launch,” said Cokey Nguyen, Ph.D., President and Chief Executive Officer of Atara.

Financial Update

- Cash, cash equivalents and short-term investments as of year-end 2024 totaled approximately \$43 million
- Entered into non-binding term sheet with Redmile Group to provide up to \$15 million in available capital through an equity line of credit
- Several additional options are under consideration as part of the exploration of financial and strategic alternatives

This estimate of our cash, cash equivalents and short-term investments as of December 31, 2024 is preliminary, has not been audited and is subject to change upon completion of our financial statement closing procedures. Our independent registered public accounting firm has not audited or performed any procedures with respect to this estimate. Additional information and disclosure would be required for a more complete understanding of our financial position and results of operations as of December 31, 2024.

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](https://twitter.com/Atarabio) on X and [LinkedIn](https://www.linkedin.com/company/atarabio).

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, and the results of, and prospects for, the global partnership with Pierre Fabre Laboratories involving tab-cel, and the potential financial benefits to Atara as a result of the global partnership with Pierre Fabre, including the receipt, timing and amount of any payments to be received by Atara thereunder; (2) the development, timing and progress of Atara's AlloCAR-T programs (including ATA3219 and ATA3431), including potentially suspending such programs; (3) Atara's cash, cash equivalents and short-term investments as of December 31, 2024, as well as Atara's cash runway, the timing and receipt of potential

milestone and other payments, and operating expenses; (4) Atara's fundraising needs and the sufficiency of additional funding to support operations, and the availability of such funding, including the non-binding term sheet and Atara's ability to enter into definitive documentation for such funding; (5) Atara's planned transition of substantially all activities relating to EBVALLO to Pierre Fabre and the timing thereof; (6) Atara's planned cost reduction strategies; and (7) 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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