January 12, 2026

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

U.S. Food and Drug Administration has issued a 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 issued a Complete Response Letter (CRL) 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 indicates that the FDA is unable to approve the EBVALLO™ BLA in its present form. The BLA was resubmitted in 2025 after reaching alignment with the FDA on the acceptability of the resubmission criteria and fulfilment of the conditions as identified in the first Complete Response Letter dated 15 January 2025 (First CRL). As we previously disclosed, in the First CRL, the FDA identified a single deficiency regarding Good Manufacturing Practice (GMP) compliance and did not raise any concerns with respect to the safety, efficacy or trial design.

In the current CRL, received after market close on 9 January 2026, the FDA confirmed that the GMP compliance issues had been satisfactorily resolved, and importantly, no safety issues were raised. However, in a complete reversal of position by the FDA, the CRL claims that the single arm ALLELE trial, which was previously confirmed by the FDA as adequate to support the BLA filing, is no longer considered to be adequate to provide evidence of effectiveness for accelerated approval. Furthermore, the FDA stated that the trial's interpretability is confounded due to trial study design, conduct, and analysis.

The FDA's new position is contrary to the FDA's prior guidance to Atara, the FDA's alignment with Atara on the clinical trial data set, and the acceptance of the trial design as a single arm study as relevant for this patient population at BLA submission. This prior alignment had been reached by Atara and the FDA through multiple, documented meetings held over the past five plus years.

In November 2025, Atara transferred the BLA to Pierre Fabre Pharmaceuticals (PFP), Inc., the U.S. pharmaceutical subsidiary of Pierre Fabre Laboratories. As a first step towards resolution, PFP intends to request a Type A meeting and expects it to be granted within 45 days. PFP and Atara plan to urgently interact with the FDA to find a path forward for the timely accelerated approval of EBVALLO without which patients with EBV+ PTLD have extremely limited treatment options and a life expectancy often measured in weeks to

months.

“We are surprised and disappointed by this FDA decision for EBV+ PTLD patients who have a significant unmet need, highlighted by tabelecleucel’s Orphan Drug designation and by the granting of Breakthrough status at the time we submitted the ALLELE primary data,” said Cokey Nguyen, President and Chief Executive Officer of Atara. “The issues highlighted in the CRL were issues Atara and the FDA aligned on in previous reviews or communications. We had aligned with the agency to accept an Accelerated Approval and to perform a post marketing confirmatory study to support full approval. We proceeded with the BLA submission on this basis and continued all remediation efforts after the resubmission in 2025, in full reliance of the confirmation provided by the FDA. We strongly believe that tabelecleucel can bring substantial benefit to post-transplant lymphoproliferative disease patients, and look forward to addressing the concerns of the FDA clinical review team newly in place alongside our partners.”

Corporate and Financial Updates

In December 2025, Atara amended the commercialization agreement with Pierre Fabre Medicament (PFM) to, among other things, mitigate the impact of the cost of rebuilding commercial inventory in the United States. Under the terms of the amendment, Atara agreed to reduce the milestone payment due upon BLA approval to $31 million in exchange for the right to receive an additional $15 million potential milestone payment upon achieving a certain commercial milestone.

Cash, cash equivalents and short-term investments as of December 31, 2025, totaled approximately $8.5 million.

In 2025, Atara implemented significant operational efficiencies, including an approximately 90% reduction in headcount year over year, and transitioned substantially all tab-cel activities and associated costs to Pierre Fabre Laboratories including all regulatory, clinical and CMC responsibilities.

Additionally, in November 2025, we amended our Atara Research Center (ARC) lease agreement reducing our square footage and remaining lease liability by approximately 65%.

This estimate of our cash, cash equivalents, short-term investments and accounts receivable as of December 31, 2025, is preliminary, and 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, 2025.

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. 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 PFP's request for a Type A meeting and PFP's and Atara's plans to urgently interact with the FDA to find a path forward for the timely accelerated approval of EBVALLO, the potential characteristics and benefits of tab-cel, and the results of, and prospects for, the global partnership with PFM involving tab-cel, and the potential financial benefits to Atara as a result of the global partnership with PFM, including the receipt, timing and amount of any payments to be received by Atara thereunder; (2) Atara's estimated cash, cash equivalents and short term investments, as well as accounts receivable, at December 31, 2025, as well as Atara's cash runway, receipt of potential milestone payments, and estimated reduction in operating expenses; and (3) the prospect of bringing tab-cel to U.S. patients with EBV+ PTLD. 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 our year-end the costly and time-consuming pharmaceutical product development process and the uncertainty of clinical success; risks related to FDA's review of tab-cel; our ability to access capital, and the sufficiency of Atara's cash resources and access to additional capital on favorable terms or at all; risks and uncertainties related to Atara's financial close and year-end 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 stockholders; whether the process will have an adverse impact on Atara and other risks and uncertainties affecting Atara, 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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