

July 14, 2025



Atara Biotherapeutics Provides Regulatory and Business Updates on Tabelecleucel (Tab-cel®)

Atara Biotherapeutics Resubmits Tabelecleucel (Tab-cel®) Biologics License Application for Treatment of Epstein-Barr Virus Positive Post-Transplant Lymphoproliferative Disease to the U.S. FDA

Approval of BLA Would Trigger \$40 Million Milestone Payment from Pierre Fabre Laboratories

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 it has resubmitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for tabelecleucel (EBVALLO™ or tab-cel®) indicated as monotherapy for treatment of 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. There are no FDA approved therapies in this treatment setting.

“The BLA resubmission for tab-cel represents the collaborative efforts with our partner, Pierre Fabre Laboratories, to address the third-party manufacturing facility observations outlined in the January 2025 Complete Response Letter,” said Cokey Nguyen, President and Chief Executive Officer of Atara. “We look forward to continued engagement with the FDA throughout its review and with Pierre Fabre Laboratories as they actively prepare for the potential launch of this innovative therapy in the U.S.”

Tab-cel is an allogeneic, EBV-specific T-cell immunotherapy designed to target and eliminate EBV-infected cells. The BLA is supported by pivotal and supportive data covering more than 430 patients treated with tab-cel across multiple life-threatening diseases, including the latest pivotal ALLELE study data that demonstrated a statistically significant 48.8% Objective Response Rate (ORR) ($p < 0.0001$) and favorable safety profile consistent with previous analyses.

Tab-cel has been granted Breakthrough Therapy Designation for the treatment of rituximab-refractory EBV-associated lymphoproliferative disease by the U.S. FDA and has orphan drug designation for the treatment of Epstein-Barr virus-positive post-transplant lymphoproliferative disorders.

Corporate Updates

Tab-cel Transition Activities: The company is finalizing the transfer of the following clinical studies associated with tab-cel:

- NCT03394365: Tabelecleucel for Solid Organ or Allogeneic Hematopoietic Cell Transplant Participants with Epstein-Barr Virus-Associated Post-Transplant Lymphoproliferative Disease (EBV+ PTLD) After Failure of Rituximab or Rituximab and Chemotherapy (ALLELE)
- NCT04554914: A Study to Evaluate Tabelecleucel in Participants with Epstein-Barr Virus-associated Diseases. This study is a multicenter, multicohort, open-label, single-arm, Phase 2 study investigating the efficacy and safety of tabelecleucel for the treatment of EBV-associated diseases.

Upon completion substantially all operational activities and associated costs related to tab-cel will transfer to Pierre Fabre Laboratories.

The sponsorship of the BLA continues to be maintained by Atara.

Cash Runway and Future Tabelecleucel (Tab-cel®) Milestone and Royalty Income:

Atara projects that its cash, cash equivalents and short-term investments of approximately \$22M as of June 30, 2025, combined with the cost reduction initiatives implemented in the first half of 2025, will enable funding of all currently planned operations, including one-time restructuring costs, into the first quarter of 2026, that Atara believes will be sufficient to fund the ongoing activities required to achieve potential BLA approval.

Additionally, under its commercialization agreement with Pierre Fabre Laboratories, Atara is eligible to receive a \$40 million milestone payment upon FDA approval of the tab-cel BLA, as well as significant double-digit tiered royalties as a percentage of net sales, and milestones related to commercial sales of EBVALLO.

The estimate of our cash, cash equivalents and short-term investments as of June 30, 2025, is preliminary, has not been audited and it is subject to change upon completion of our financial statement closure procedures. Our independent registered public accounting firm has not audited or completed any procedures with respect to this estimate. Such estimates are based on assumptions and plans that are subject to change and such changes could materially impact our expected cash runway. These assumptions include the completion of specific development and regulatory activities by us and actions taken by third parties, and are, therefore, uncertain at this time. Any delay in these activities will create additional expenses and cash needs for us.

We have not yet completed our quarter-end financial close process for the quarter ended June 30, 2025. This estimate of our cash, cash equivalents and short-term investments as of June 30, 2025, is preliminary and is subject to change upon completion of our financial statement closing procedures. Additional information and disclosure would be required for a more complete understanding of our financial position and results of operations as of and for the quarter ended June 30, 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](https://www.atarabio.com) and follow [@Atarabio](https://twitter.com/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 resubmission of 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 Laboratories, including the receipt, timing and amount of any payments to be received by Atara thereunder; (2) Atara's estimate of its cash, cash equivalents, and short-term investments as of June 30, 2025, as well as Atara's cash runway, receipt of potential milestone payments, and operating expenses, including Atara's ability to fund its planned operations into the first quarter of 2026; and (3) Atara's planned transition of substantially all remaining activities relating to tab-cel to Pierre Fabre Laboratories and the timing thereof. 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 related with the timing of the transfer of substantially all operational activities related to tab-cel to Pierre Fabre Laboratories, with any potential delay creating additional expenses and cash needs for Atara; 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, Pierre Fabre Laboratories and Pierre Fabre Laboratories third-party manufacturer to address issues identified in the Complete Response Letter (CRL); 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 audit procedures; 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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Investor and Media Relations

Amber Daugherty

Sr. Director, Strategy and Operations

adaugherty@atarabio.com

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