

October 14, 2026



Atara Biotherapeutics Reports that the Resubmitted Tabelecleucel (Tab-cel®) Biologics License Application Has Been Accepted by the U.S. Food and Drug Administration

Prescription Drug User Fee Act (PDUFA) Target Action Date of March 31, 2027

If Approved, Tab-cel Would Be the First Therapy Available in the U.S. for EBV+ PTLD

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 its partner, Pierre Fabre Pharmaceuticals, Inc. (PFP), has received acceptance by the U.S. Food and Drug Administration (FDA) of the Biologics License Application (BLA) resubmission for tabelecleucel, with a proposed indication 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.

The BLA has a Class 2 Resubmission Prescription Drug User Fee Act (PDUFA) target action date of March 31, 2027.

"The acceptance of the tabelecleucel resubmission brings us one step closer to making this first-of-its-kind treatment available to patients in the U.S.," said Cokey Nguyen, President and Chief Executive Officer of Atara. "We appreciate the Agency's guidance and look forward to a collaborative review process. We will continue supporting PFP as it prepares for a potential U.S. launch."

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.

If tabelecleucel is approved, Atara would be eligible to receive a \$31 million milestone payment under its commercialization agreement with Pierre Fabre Laboratories. Atara would also be eligible to receive significant double-digit tiered royalties on net sales and additional commercial sales milestones.

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](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 timing of FDA's review of the resubmitted BLA and the PDUFA target action date and the potential characteristics and benefits of tab-cel; (2) the receipt of milestone and royalty payments, including the potential milestone payment upon FDA approval of the tab-cel BLA, 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 the costly and time-consuming pharmaceutical product development process and the uncertainty of clinical success; risks related to FDA's review of tab-cel, including the risk that the resubmission of the tab-cel BLA may not address the deficiencies identified in the second complete response letter received on January 9, 2026 or other issues that may be raised by the FDA on review; and that the FDA may not act by the PDUFA target action date, may extend its review period, or may issue another complete response letter; the fact that PFP, and not Atara, holds the tab-cel BLA and controls the content and strategy of the resubmission and related FDA interactions, and Atara's ability to influence the resubmission process is limited; our ability to access capital, and the sufficiency of Atara's cash resources and access to additional capital on favorable terms or at all; 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 Atara'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.

View source version on businesswire.com:

<https://www.businesswire.com/news/home/20261014012366/en/>

Investor and Media Relations

Amber Daugherty

Sr. Director, Strategy and Operations

adaugherty@atarabio.com

Source: Atara Biotherapeutics, Inc.

