

May 7, 2026



# Atara Biotherapeutics Provides Regulatory Update on Tabelecleucel

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 provided an update following the recent Type A meeting with the U.S. Food and Drug Administration (FDA) to discuss the Complete Response Letter (CRL) to the Biologics License Application (BLA) for tabelecleucel (tab-cel) held by our partner Pierre Fabre Pharmaceuticals, Inc. (PFP).

PFP, with Atara's support, had a productive meeting with the FDA and discussed a potential path forward to resubmitting the tab-cel BLA. The FDA agreed that a single arm study using an appropriate historical control applicable to the trial population, conducted in a pre-specified manner, could serve as an adequate and well controlled study and provide safety and efficacy data in support of a future marketing application of tab-cel for the proposed indication. PFP has indicated they intend to submit an updated dataset with additional patients and longer follow up from the pivotal Phase 3 single arm ALLELE study of tabelecleucel in adults and children two years of age and older with R/R EBV+ PTLD following solid organ transplant or hematopoietic cell transplant as well as supportive data, as a part of the resubmission plan being defined with the FDA.

"We are grateful to the agency for engaging in a collaborative conversation with our partners, Pierre Fabre, and us. We appreciate the FDA's continued engagement with PFP and Atara, and we believe the Type A Meeting provided helpful alignment on the regulatory framework to resubmit," said Cokey Nguyen, President and Chief Executive Officer of Atara. "We will continue to support Pierre Fabre as it prepares the resubmission and anticipate providing a further regulatory update in the third quarter."

## 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](http://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 the timing of PFP's resubmission of the tab-cel BLA, the potential characteristics and benefits of tab-cel; and (2) 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 a resubmission of the tab-cel BLA may not address the deficiencies identified in the CRL or other issues that may be raised by the FDA on review; the fact that PFP, and not Atara, holds the tab-cel BLA and controls the timing, content and strategy of any 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/20260507608246/en/>

### **Investor and Media Relations**

Amber Daugherty

Sr. Director, Strategy and Operations

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

Source: Atara Biotherapeutics, Inc.