

Atara Biotherapeutics Reports that the Tabelecleucel Biologics License Application Has Been Resubmitted to the U.S. Food and Drug Administration

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 that its partner, Pierre Fabre Pharmaceuticals, Inc. (PFP), has resubmitted the tabelecleucel Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA).

“We are grateful to the Agency for their continued guidance and engagement with our partner, PFP, and us,” said Cokey Nguyen, President and Chief Executive Officer of Atara. “We will continue to support PFP as it prepares for the review process and anticipate providing a revised anticipated PDUFA date as it becomes available.”

PFP, with Atara’s support, has resubmitted the BLA based on the feedback received from the Type A meeting held in April. The resubmission includes an updated data package with additional patients, plus longer follow up from the ongoing, pivotal Phase 3 single arm ALLELE study of tabelecleucel in adults and children two years of age and older with relapsed/refractory Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLD) following solid organ transplant (SOT) or hematopoietic cell transplant (HCT). The resubmission also includes additional supplemental data from the expanded access programs, a separate clinical study, and commercial experience in Europe.

Under its commercialization agreement with Pierre Fabre Laboratories, Atara is eligible to receive a \$31 million milestone payment upon FDA approval of the tabelecleucel BLA, as well as significant double-digit tiered royalties as a percentage of net sales, and milestones related to commercial sales.

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 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+ PTL. 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 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.

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Investor and Media Relations

Amber Daugherty

Sr. Director, Strategy and Operations

adaugherty@atarabio.com

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