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

Prescription Drug User Fee Act (PDUFA) Target Action Date of January 10, 2026

If Approved, Tab-cel Would Be First Approved Therapy in 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 the U.S. Food and Drug Administration (FDA) has accepted the filing of its Biologics License Application (BLA) for tabelecleucel (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 has been granted Priority Review with a Class 2 Resubmission Prescription Drug User Fee Act (PDUFA) target action date of January 10, 2026.

“The acceptance of the tab-cel resubmission moves us one step closer towards 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 continue to work closely with the Pierre Fabre Pharmaceuticals team to help prepare for the potential launch 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.

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 the development, timing and progress of tab-cel, including potential indications, the timing for FDA review of the 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. 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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