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# European Medicines Agency Grants Atara Biotherapeutics Accelerated Assessment of tab-cel® for the Treatment of Epstein-Barr Virus Positive Post-Transplant Lymphoproliferative Disease (PTLD)

*Designation recognizes therapeutic innovation and potential to address significant unmet patient need*

*Atara on track to submit MAA in November 2021*

*Phase 3 ALLELE study analysis supporting tab-cel MAA to be presented in Q4 2021*

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)-- Atara Biotherapeutics, Inc. (Nasdaq: ATRA), a pioneer in T-cell immunotherapy, leveraging its novel allogeneic EBV T-cell platform to develop transformative therapies for patients with cancer and autoimmune diseases, today announced the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has granted accelerated assessment to the Company's lead product candidate, tabelecleucel (tab-cel®), for the treatment of Epstein-Barr virus positive post-transplant lymphoproliferative disease ($EBV^+$ PTLD).

$EBV^+$ PTLD is a rare and potentially life-threatening cancer that may occur following a solid organ transplant (SOT) or allogeneic hematopoietic cell transplant (HCT). For patients with $EBV^+$ PTLD, the median survival is only 2-3 months after failure of initial therapy. There are currently no EMA- or FDA-approved treatments indicated for these patients.

"We believe the granting of accelerated assessment by the EMA recognizes the potential of tab-cel as a first-in-kind new therapy addressing significant unmet need in $EBV^+$ PTLD patients facing poor prognosis with no approved treatment options," said Jakob Dupont, MD, Executive Vice President and Global Head of Research and Development at Atara. "We look forward to working closely with the EMA to bring tab-cel, the first ever allogeneic, off-the-shelf T-cell therapy to be reviewed by a regulatory agency, to patients as quickly as possible."

Accelerated assessment is granted by the CHMP when a medicinal product is expected to be of major public health interest and therapeutic innovation. The CHMP and Committee for Advanced Therapies (CAT) can reduce the time frame to review a marketing authorization application (MAA) to 150 days if the applicant provides sufficient justification for an accelerated assessment, although an application initially designated for accelerated assessment can revert to the standard procedure during the review for a variety of reasons. The decision to grant accelerated assessment has no impact on the eventual CHMP and

CAT opinion on whether a marketing authorization should be granted.

Tab-cel also has Orphan Drug status in Europe and was previously granted PRIME designation by the EMA. Following recent successful interactions with the EMA, Atara has completed the necessary regulatory and compliance steps needed to submit an MAA for tab-cel, which is on track for submission in November 2021. With the granting of accelerated assessment, Atara anticipates a decision regarding approval in the second half of 2022.

The MAA submission will include data from the ongoing Phase 3 ALLELE study assessing the efficacy and safety of tab-cel in patients with $EBV^+$ PTLD following solid organ transplant (SOT) or allogeneic hematopoietic cell transplant (HCT).

Atara will present a new analysis from the ALLELE study at an appropriate congress in Q4 2021. Top-line data with additional patients confirm a strong objective response rate (ORR) in line with prior results while demonstrating durability. There were no new safety signals, consistent with previously published findings.

**About tabelecleucel**

Tabelecleucel (tab-cel®) is an off-the-shelf, allogeneic T-cell immunotherapy in development for the treatment of Epstein-Barr virus-positive post-transplant lymphoproliferative disease ($EBV^+$ PTLD). $EBV^+$ PTLD is a type of lymphoma (cancer) that may occur after a solid organ transplant (SOT) or allogeneic hematopoietic cell transplant (HCT). There are currently no approved treatments indicated to treat PTLD and if left untreated, PTLD can have life-threatening consequences.

Tab-cel is currently being investigated in the Phase 3 ALLELE study to assess efficacy and safety for the treatment of $EBV^+$ PTLD in SOT and HCT after failure of standard of care.

Tab-cel has been granted Breakthrough Therapy Designation for $EBV^+$ PTLD following allogeneic HCT by the U.S. Food and Drug Administration (FDA) and PRIME designation by the EMA Priority Medicines for the same indication. Tab-cel has Orphan drug designation in the U.S. and E.U.

**About Atara Biotherapeutics, Inc.**

Atara Biotherapeutics, Inc. (@Atarabio) is a pioneer in T-cell immunotherapy leveraging its novel allogeneic EBV T-cell platform to develop transformative therapies for patients with serious diseases including solid tumors, hematologic cancers and autoimmune disease. With our lead program in Phase 3 clinical development, Atara is the most advanced allogeneic T-cell immunotherapy company and intends to rapidly deliver off-the-shelf treatments to patients with high unmet medical need. Our platform leverages the unique biology of EBV T cells and has the capability to treat a wide range of EBV-associated diseases, or other serious diseases through incorporation of engineered CARs (chimeric antigen receptors) or TCRs (T-cell receptors). Atara is applying this one platform to create a robust pipeline including: tab-cel® in Phase 3 development for Epstein-Barr virus-driven post-transplant lymphoproliferative disease (EBV+ PTLD) and other EBV-driven diseases; ATA188, a T-cell immunotherapy targeting EBV antigens as a potential treatment for multiple sclerosis; and multiple next-generation chimeric antigen receptor T-cell (CAR T)

immunotherapies for both solid tumors and hematologic malignancies. Improving patients' lives is our mission and we will never stop working to bring transformative therapies to those in need. Atara is headquartered in South San Francisco and our leading-edge research, development and manufacturing facility is based in Thousand Oaks, California. For additional information about the company, please visit atarabio.com and follow us on Twitter 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 potential benefits, safety and efficacy of tab-cel; the timing and progress of tab-cel, the timing of the submission of the MAA for tab-cel, the timing of a decision regarding approval of tab-cel in the EU; and Atara's ability to successfully advance the development of tab-cel in the EU. Because such statements deal with future events and are based on Atara Biotherapeutics' current expectations, they are subject to various risks and uncertainties and actual results, performance or achievements of Atara Biotherapeutics 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; the ongoing COVID-19 pandemic, which may significantly impact (i) our business, research, clinical development plans and operations, including our operations in South San Francisco and Southern California and at our clinical trial sites, as well as the business or operations of our third-party manufacturer, contract research organizations or other third parties with whom we conduct business, (ii) our ability to access capital, and (iii) the value of our common stock; the sufficiency of Atara's cash resources and need for additional capital; and other risks and uncertainties affecting Atara's and its development programs, including those discussed in Atara Biotherapeutics' filings with the Securities and Exchange Commission (SEC), 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 Biotherapeutics 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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