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Atara Biotherapeutics Announces FDA Clearance of IND for ATA2271, a Next-Generation Autologous Mesothelin-Targeted CAR T with Novel PD1DNR and 1XX Technologies Combined to Treat Solid Tumors

First CAR T therapy leveraging combination of cell intrinsic PD1DNR checkpoint inhibition and 1XX CAR signaling technologies to enter the clinic

Atara's next-generation CAR T program targets Mesothelin, a highly-expressed antigen on the cell surface of many aggressive solid tumors

Evidence of preclinical safety, improved functional characteristics and enhanced antitumor efficacy of ATA2271 from IND-enabling studies were recently presented at the 2020 American Association for Cancer Research (AACR) Virtual Annual Meeting II

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)-- [Atara Biotherapeutics, Inc.](https://www.atara.bio) (Nasdaq: ATRA), a pioneer in T-cell immunotherapy leveraging its novel allogeneic EBV T-cell platform to develop treatments for patients with severe diseases including solid tumors, hematologic cancers and autoimmune disease, today announced that the U.S. Food and Drug Administration (FDA) has accepted the Investigational New Drug (IND) application providing clearance to initiate an open-label, single-arm Phase 1 clinical study of ATA2271, the Company's next-generation autologous CAR T therapy targeting mesothelin under development in collaboration with Memorial Sloan Kettering Cancer Center (MSK), for the treatment of advanced mesothelioma.

"We are pleased the FDA has cleared the IND for ATA2271 for the treatment of advanced mesothelioma," said Jakob Dupont, Global Head of Research and Development, Atara Biotherapeutics. "This milestone marks an important moment in the advancement of cell and gene immunotherapy for patients, for the field and for Atara. As the first-ever CAR T therapy leveraging the combination of PD1DNR checkpoint inhibition and 1XX CAR signaling technologies to enter the clinic, we are advancing such a unique CAR T program with the goal of developing transformative therapies for patients with solid tumors."

This novel next-generation autologous, mesothelin-targeted CAR T therapy was developed in collaboration with researchers at MSK, Dr. Prasad Adusumilli, who led two trials with first-generation mesothelin CAR T therapy and engineered T-cell intrinsic checkpoint blockade by PD1DNR to overcome the immune suppression of PDL1, and Dr. Michel Sadelain, a leader in the CAR T-cell field who developed the 1XX co-stimulatory domain technology to extend T-cell effector function while limiting cell exhaustion.

At the 2020 American Association for Cancer Research (AACR) Virtual Annual Meeting II, preclinical data were presented from ATA2271 IND-enabling studies conducted collaboratively in Dr. Adusumilli's laboratory, showing the effects of combining multiple novel technologies in this next-gen CAR T therapy, which includes both 1XX co-stimulatory domain signaling and an engineered PD1DNR. ATA2271 was associated with less cell exhaustion, improvements in functional persistence, serial cell killing, and enhanced *in vivo* efficacy when compared with first-generation mesothelin CAR T therapy. These effects were maintained through multiple redosings with ATA2271 and are consistent with emerging views in the field regarding preferred characteristics of CAR Ts when targeting solid tumors, including mesothelioma. This improved profile of ATA2271 will now be assessed in a Ph1 clinical trial led by principal investigator, Dr. Roisin O'Cearbhaill.

Although CAR T cell therapies have been approved for certain hematologic malignancies, they have not yet proven effective in solid tumor settings. Mesothelin is a tumor-specific antigen that is commonly expressed at high levels on the cell surface in many aggressive solid tumors including mesothelioma, ovarian cancer, pancreatic cancer, and non-small cell lung cancer. Atara has selected mesothelin as the target for both the ATA2271 autologous and the ATA3271 allogeneic programs along with novel CAR T-cell technologies that have the potential to further enhance activity and resulting clinical benefits. ATA3271, the allogeneic version of this CAR T, leverages Atara's EBV T-cell platform and is currently in IND-enabling studies.

About ATA2271

In collaboration with MSK, Atara is developing ATA2271, a next-generation autologous mesothelin-targeted CAR T using novel 1XX CAR signaling and programmed death-1 (PD-1) dominant negative receptor (PD1DNR) checkpoint inhibition technologies (M28z1XX PD1DNR CAR T cells). This technology is supported by the safety and anti-tumor efficacy that was exhibited in prior studies evaluating a mesothelin-directed CAR utilizing a CD28 co-stimulatory signaling domain. This autologous mesothelin-targeted construct (using M28z CAR T cells) combined with PD-1 antibody is being studied in two ongoing MSK Phase 1 studies in patients with malignant pleural disease and mesothelioma, non-small cell lung cancer, and breast cancer (NCT02414269 and NCT02792114).

Michel Sadelain, MD, Ph.D., Director, Center for Cell Engineering, and Head, Gene Expression and Gene Transfer Laboratory at MSK and Prasad Adusumilli, MD, Deputy Chief of Thoracic Service, Vice Chair of Department of Surgery, and Head Solid Tumors, Cell Therapy, Cellular Therapeutics Center at MSK have intellectual property interests in technology licensed by Memorial Sloan Kettering (MSK) to Atara, related to this program. Dr. Adusumilli also has compensated consulting relationships with Atara. MSK has institutional financial interests related to Atara in the form of intellectual property rights and associated interests by virtue of licensing agreements between MSK and Atara.

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 severe 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 severe 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[®] (tabelecleucel) in Phase 3 development for Epstein-Barr virus-driven post-transplant lymphoproliferative disease (EBV+ PTLN); 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 safety, functional characteristics and efficacy of ATA2271; and Atara's ability to successfully advance, and the potential timelines for, the development of ATA2271 and ATA3271. 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 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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