

Marengo Therapeutics Announces First Patient Dosed in Phase 1/2 Clinical Trial of its Novel TCR V β Directed Antibody-Fusion Molecule STAR0602, in Cancer Patients Refractory to Anti-PD1 Therapy

- ***START-001 study leverages a biomarker-enriched tissue-agnostic approach to evaluate the activity of STAR0602 monotherapy in checkpoint inhibitor refractory advanced solid tumors***

Cambridge, Mass. January 27, 2023 – Marengo Therapeutics, Inc., a company pioneering novel therapeutics targeting the T cell receptor (TCR) V β to selectively activate the right T cell subsets to fight cancer, today announced that the first patient has been dosed in its ongoing clinical trial of STAR0602 (START-001). Marengo's START-001 trial is a seamless Phase 1/2 clinical trial evaluating the safety and clinical activity of STAR0602 as monotherapy in a biomarker-enriched cohort of patients with PD-1 refractory advanced solid tumors.

The START-001 trial ([NCT05592626](https://clinicaltrials.gov/ct2/show/study/NCT05592626)) is currently enrolling patients at two top US cancer research institutes, National Institutes of Health (NIH)'s National Cancer Institute (NCI) and Mass General Hospital (MGH)/Harvard Medical School, co-led by seasoned clinical and translational researchers James Gulley, M.D., Ph.D., of NCI and Ryan Sullivan, M.D., of MGH. Additional top cancer centers are planned to join these clinical sites to support the further expansion of the study.

"The Center for Cancer Research's Center for Immuno-Oncology at the NCI was recently established to explore fundamental questions of cancer immunotherapy through rigorous preclinical studies and translate these findings into clinical trials with the goal of developing novel therapies for a spectrum of cancers with high unmet medical needs. We look forward to studying this novel TCR agonist that selectively activates a subset of $\alpha\beta$ T cells in cancer patients at the NCI," said Dr. Gulley, Co-Director of the Center for Immuno-Oncology (CIO), Deputy Director of the Center for Cancer Research (CCR) at the NCI, and acting Clinical Director, NCI.

"The initiation of our first clinical trial with STAR0602 is an important milestone for Marengo and our selective T cell-targeted STAR platform," said Zhen Su, M.D., MBA, Chief Executive Officer of Marengo. "The START-001 trial leverages a deep biology-driven study design to address high unmet clinical needs in patients for whom PD-1 therapies are no longer effective. Our clinical development approach utilizes a biomarker-enriched, tumor-agnostic strategy that offers a much-needed novel approach to cancer drug development. We are confident that



evaluating STAR0602 in well-defined populations will allow us to efficiently investigate biological and clinical activity, paving the way for further investigation.”

“Cancer immunotherapy has transformed standard of care across many tumor settings and has significantly improved overall survival for patients with cancer. Despite these innovative therapies, most patients progress following treatment creating an urgent need to develop the next wave of novel therapeutics,” said Dr. Sullivan, Associate Director, Melanoma Program, MGH Cancer Center. “We are excited to test this novel biology via reinvigorating the T cell compartment in tumors to promote an antitumor immune response distinct from the PD-1 mechanism.”

About Marengo Therapeutics

Marengo Therapeutics, Inc, an ATP company, is pioneering first-in-class therapeutics that activate the right immune response to promote lifelong protection against cancer. With a passionate team of dedicated scientists experienced in immunology and oncology, Marengo’s proprietary Selective T Cell Activation Repertoire (STAR) platform leverages an extensive biological understanding of T cell function and receptor signaling to create a world in which everyone’s immune system can defeat cancer. To learn more, visit marengotx.com.

About STAR0602

STAR0602 is Marengo’s lead program, the first T cell activator generated from Marengo’s STAR platform; a library of antibodies targeting non-clonal variable (V) β regions of the TCR fused to different co-stimulatory moieties. STAR0602 selectively targets a common V β T cell subset present in all cancers and, by combining a novel non-clonal mode of TCR activation with a T cell co-stimulator in the same molecule, promotes expansion of a new population of clonally enriched, effector memory V β T cells that turbo-charge tumor immune responses and promote durable clearance of tumors. STAR0602 has undergone extensive preclinical testing, which demonstrates potent anti-tumor activity in both mouse and human ex vivo tumor models attributed to a distinct mechanism of action from existing cancer immunotherapies.

About the START-001 Clinical Study

START-001 is a Phase 1/2 clinical trial evaluating the safety, tolerability, and preliminary clinical activity of STAR0602 as a single agent in patients with advanced antigen-rich solid tumors including PD-1 refractory and rare tumors. This open-label, multi-center trial consists of two



parts: Phase 1 dose escalation and Phase 2 dose expansion. For more information, please visit clinicaltrials.gov (trial identifier: [NCT05592626](https://clinicaltrials.gov/ct2/show/study?term=NCT05592626)).

For patients interested in enrolling in this study at NCI, please contact NCI's toll-free number 1-800-4-Cancer (1-800-422-6237) (TTY: 1-800-332-8615) and/or the website <https://trials.cancer.gov> and/or email NCIMO_referrals@mail.nih.gov.

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