**Marengo's First-in-Class Invikafusp Alfa (STAR0602) Receives U.S. FDA Fast Track Designation for Treatment of Unresectable, Locally Advanced, or Metastatic Colorectal Cancers with High Tumor Mutational Burden (TMB-H)**

- *Initial safety and efficacy data from Phase 1 STARt-001 trial showed promising single agent clinical activity in patients with different types of PD-1 resistant tumors including TMB-H colorectal cancer*

- *Global Phase 2 clinical study for invikafusp alfa monotherapy in PD-1 resistant tumors is ongoing*

**Cambridge, Mass., January 8, 2024** – Marengo Therapeutics, Inc., a clinical-stage biotechnology company pioneering novel approaches for precision T cell activation, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation (FTD) to invikafusp alfa (STAR0602), Marengo's first-in-class selective dual T cell agonist being studied as a potential new treatment for advanced colorectal cancer with TMB-H. Fast Track designation is designed to facilitate the development and expedite the review of therapies intended to treat serious or life-threatening conditions with unmet medical needs.

"The FDA's Fast Track designation is an important milestone for the STAR0602 program and further positions our unique selective dual T cell agonist platform as a promising solution to address key challenges that perpetuate significant unmet needs in oncology," said Zhen Su, M.D., MBA, Chief Executive Officer of Marengo Therapeutics. "This recognition specifically validates the promise of STAR0602 as a novel treatment option for patients with TMB-H metastatic colorectal cancer, which is insensitive to PD-1 treatment."

The FDA's decision is informed by the encouraging results from Marengo's first-in-human Phase 1 clinical study of invikafusp alfa in heavily pretreated cancer patients, which were recently presented during a plenary oral session at the 2024 SITC Annual Meeting and an oral presentation at the 2024 ESMO Immuno-Oncology Congress. The data reinforce invikafusp alfa's anti-tumor activity and favorable safety profile.

"Marengo's selective Vβ T cell activation approach targeting specific T cell subsets enriched in Tumor-infiltrating lymphocytes to enhance anti-tumor activity is unique and highly promising," said Bruce Chabner, M.D., Clinical Director Emeritus for the Massachusetts General Hospital Cancer Center and Professor of Medicine at Harvard Medical School. "The Phase 2 clinical investigation of invikafusp alfa is ongoing and this novel treatment could lead to a new class of therapeutics for tumor types that are PD-1 insensitive or resistant, especially in colorectal cancer where current treatment options remain limited."

Marengo is committed to advancing STAR0602 – the asset entered Phase 2 clinical trials at the end of 2024, and the company expects to report additional efficacy results later this year.

**About Marengo Therapeutics**

Marengo Therapeutics, Inc, a clinical-stage biotech company, develops novel TCR-targeting antibodies that selectively modulate common and disease-specific T cell subsets of the germline TCR repertoire to provide lifelong protection against cancer and other diseases. 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 the STAR™ Platform**
Marengo's STAR™ Platform is a multi-specific antibody-fusion platform derived from Marengo's proprietary library of antibodies targeting germline-encoded variable Vβ regions of the TCR fused to different T cell co-stimulatory moieties. Combining a novel non-clonal mode of TCR activation with a T cell co-stimulator in the same molecule, promotes a distinct mechanism of action that promotes durable anti-tumor Vβ T cell responses.

**About invikafusp alfa (STAR0602)**
Invikafusp alfa (STAR0602) is Marengo's lead program, and the first T cell activator generated from Marengo's STAR platform; a library of antibodies targeting non-clonal variable Vβ regions of the TCR fused to different co-stimulatory moieties. STAR0602 selectively targets a common Vβ 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 Vβ T cells that turbo-charge tumor immune responses and promote durable clearance of tumors. STAR0602 has undergone extensive preclinical testing and is currently being studied in a Phase 1/2 clinical trial.

**About the STARt-001 trial**
Clinical Study STARt-001 is a Phase 1/2 clinical trial evaluating the safety, tolerability, and preliminary clinical activity of invikafusp alfa (STAR0602) as a single agent in biomarker selected patients with advanced antigen-rich solid tumors including PD-1 refractory and rare tumors. This open-label, multi-center trial consists 2 of two parts: Phase 1 dose escalation and Phase 2 dose expansion. For more information, please visit clinicaltrials.gov (trial identifier: NCT05592626).

For patients interested in enrolling in this study at NCI, please contact NCI's toll-free number 1800-4-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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