Marengo Therapeutics Announces Clinical Study Collaboration with Gilead Sciences to Evaluate Invikafusp alfa (STAR0602) and Trodelvy® in both Metastatic TNBC and Metastatic HR+/HER2- Breast Cancers

- Invikafusp alfa has recently demonstrated single agent clinical activity across different PD-1 resistant cancers in the ongoing START-001 Phase1/2 clinical study
- The collaboration plans to evaluate the combination of Marengo's first-in-class TCR Vβ selective dual T cell agonist, STAR0602 (Invikafusp alfa), with Trodelvy (sacituzumab govitecan-hziy) Gilead's Trop-2 directed ADC in a new multi-center Phase I/II clinical study (START-002)
- Marengo will sponsor the clinical trial and Gilead will provide Trodelvy

Cambridge, Mass., September 13, 2024 – Marengo Therapeutics, Inc., a clinical-stage biotech company pioneering a new way to activate T cells targeting the Vβ chain of the T cell receptor to select the optimal T cell subsets against cancer, today announced that it has entered into a clinical study collaboration and supply agreement with Gilead Sciences, Inc. to study the combination of STAR0602 (Invikafusp alfa) with Trodelvy® (sacituzumab govitecan-hziy), a Trop-2-directed antibody-drug conjugate (ADC), as a potential treatment for adult patients with metastatic hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) breast cancer and metastatic triple-negative breast cancer (TNBC).

The planned combination trial, sponsored by Marengo, is expected to commence soon. This study will evaluate the safety, tolerability, and preliminary efficacy of STAR0602 (Invikafusp alfa) in combination with Trodelvy in patients with metastatic TNBC or metastatic HR+/HER2- breast cancer, aiming to explore a novel therapeutic strategy that could offer new treatment options for patients.

"We are excited about the clinical potential of combining our novel selective dual T cell activator with Gilead's antibody-drug conjugate, Trodelvy," said Kevin Chin, M.D., Chief Medical Officer of Marengo Therapeutics. "This innovative approach leverages the strengths of two unique modalities to target and potentially eradicate cancer cells more effectively. With the possibility to deliver target cytotoxic agents directly to tumors, which release more tumor antigens for selectively activated and expanded Vβ6/10 T cells to recognize and build long-term immune memory, we believe this combination may have the potential to improve cancer patient outcomes."

Under the clinical study collaboration and supply agreement, Gilead will provide Trodelvy to Marengo, who will conduct and sponsor the combination study. Marengo and Gilead will retain all development and commercial rights to their respective compounds, including as monotherapy or as combination therapies.

The combination of invikafusp alfa and sacituzumab govitecan-hziy is investigational and not approved by any health authority globally. The safety and efficacy of this combination has not been established.

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 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 (V)β 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 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 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, 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 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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