Marengo to Present Initial Results from Invikafusp Alfa and TRODELVY® Combination Study, STARt-002, at the 2025 San Antonio Breast Cancer Symposium

- ***Safety profile of Invikafusp alfa + TRODELVY® is consistent with the known profiles of each agent***
- ***Invikafusp alfa demonstrates selective expansion of Vβ6/10 T cells when combined with TRODELVY® in previously treated metastatic breast cancer***
- ***Early anti-tumor activity observed in majority of patients, recommended dose selected for phase 2 expansion cohorts currenting enrolling at select North American cancer centers***

Cambridge, Mass., December 12, 2025 – Marengo Therapeutics, Inc., a clinical-stage biotechnology company pioneering precision immunotherapy for oncology and inflammation & immunology (I&I), today unveiled initial clinical results from its ongoing STARt-002 phase 1b/2 trial during a late breaking presentation at the 2025 San Antonio Breast Cancer Symposium (SABCS) taking place December 9-12.

Early findings from the combination study of Invikafusp alfa (Invika) and TRODELVY® (sacituzumab govitecan-hziy; SG) suggest that this novel regimen, which leverages two key modalities (immunotherapy and ADCs), is well tolerated and biologically active across all dose levels evaluated. The safety profile of the combination was consistent with the known profiles of each agent.

“The early safety and pharmacodynamic data from STARt-002 are highly encouraging,” said Steven Isakoff, M.D., Ph.D., Director of Breast Cancer Clinical Research at the Massachusetts General Hospital Cancer Center. “The combination of Invika with TRODELVY® is scientifically compelling — pairing targeted T cell activation with ADC-mediated tumor killing. Seeing consistent Vβ6/10 expansion alongside early tumor responses reinforces the potential of this regimen to meaningfully benefit patients with metastatic breast cancer, and I look forward to the results from the ongoing phase 2 cohorts.”

Pharmacodynamic analyses confirmed that Invika maintains its mechanism of action in combination with Trodelvy, inducing robust and selective expansion of Vβ6/10 T cells in patients with previously treated metastatic triple-negative breast cancer (TNBC) and HR+/HER2– metastatic breast cancer. Evidence of early anti-tumor activity was observed in almost all patients treated with this combination, including two confirmed partial responses.

A recommended phase 2 dose (RP2D) has now been established, and enrollment is ongoing in two phase 2 expansion cohorts for people with metastatic triple-negative breast cancer (TNBC) and HR+/HER2– metastatic breast cancer at select cancer centers across North America.

“Invikafusp has already demonstrated promising single-agent activity in PD-1-resistant tumors, including breast cancer,” said Kevin Chin, M.D., Chief Medical Officer of Marengo Therapeutics. “These initial findings further support Invika as a potential immunotherapy backbone, particularly when paired with ADCs to treat immunologically ‘cold’ tumors such as breast cancer. We are encouraged by the safety, pharmacology, and early signs of clinical activity observed with the Invika and SG regimen and look forward to understanding the full clinical potential of this treatment regimen as STARt-002 advances through Phase 2.”

Additional presentation details are as follows:

- **Presentation:** *Initial clinical and pharmacology results from START-002*
    - **Abstract Number:** LBA 3714
    - **Presentation Number:** PS4-06-28
    - **Poster Presentation Date/Time:** Thursday, December 11, 2025, 5:00 PM - 6:30 PM
- **Presentation:** *Trial-in-progress: START-002*
    - **Abstract Number:** 2124
    - **Presentation Number:** PS5-09-16
    - **Poster Presentation Date/Time:** Friday, December 12, 2025, 12:30 PM - 2:00 PM

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 autoimmune diseases. With a passionate team of dedicated scientists experienced in immunology and oncology, and three proprietary platforms: Selective T Cell Activation Repertoire (STAR), Trispecific T Cell Engager (Tri-STAR) and T cell Depletor (MSTAR), Marengo is working to selectively target the right T cells in the right patients to create a world in which everyone’s immune system can defeat cancer and autoimmune diseases. 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 the lead candidate from Marengo's STAR™ platform. It is designed to selectively activate a common Vβ T cell subset found in all cancers by combining a non-clonal mode of TCR activation with a T cell co-stimulatory signal in a single molecule. This innovative approach promotes the expansion of clonally diverse, effector memory Vβ T cells, enhancing anti-tumor immunity and enabling durable tumor clearance. Extensive preclinical studies demonstrate STAR0602's potent anti-tumor activity in both mouse and human ex vivo models via a novel mechanism of action.

About the STARt-002 Clinical Study
STARt-002 (NCT06827613) is a Phase 1b/2, open-label, multicenter study investigating the combination of invikafusp alfa and TRODELVY® in patients with unresectable, locally advanced, or metastatic breast cancer. The trial consists of a safety lead-in phase followed by two dose expansion cohorts: one in triple-negative breast cancer (mTNBC) and one in HR+/HER2− metastatic breast cancer. More information is available at clinicaltrials.gov.

Marengo Contacts:

Media
Peg Rusconi I peg.rusconi@deerfieldgroup.com

Investors
Svetlana Makhni | smakhni@marengotx.com