Marengo Presents Interim Phase 2 STARt-002 Results for First-in-Class Selective T-Cell Agonist Invikafusp Alfa Plus Sacituzumab Govitecan Across Two Metastatic Breast Cancer Cohorts in Oral Presentation at SITC 2026

- First clinical trial combining a Vβ-directed selective T-cell agonist with an ADC supports invikafusp alfa's potential as a precision immune amplifier and IO backbone for broader cancer patient populations
- Encouraging clinical activity observed across two different metastatic breast cancer populations including HR-positive/HER2-negative metastatic breast cancer, where most patients derive limited benefit from checkpoint inhibition, and metastatic TNBC
- Maturing results demonstrate reductions in target lesions in 71% of efficacy-evaluable patients, with confirmed complete responses in both breast cancer subtypes and disease control in 74% overall

CAMBRIDGE, Mass., November 9, 2026 – Marengo Therapeutics, Inc., a clinical-stage biotechnology company pioneering precision immunotherapies for oncology and inflammation and immunology (I&I), today announced interim results from the Phase 1b/2 STARt-002 trial evaluating invikafusp alfa, a first-in-class dual T-cell agonist, in combination with sacituzumab govitecan-hziy (Trodelvy®; SG). Results from patients with metastatic triple-negative breast cancer (mTNBC) and HR-positive/HER2-negative metastatic breast cancer (HR+/HER2− mBC) were presented in an oral session at the Society for Immunotherapy of Cancer (SITC) 2026 Annual Meeting.

The presentation, titled "Initial clinical results from STARt-002: A Phase 1b/2 study of invikafusp alfa, a first-in-class dual T-cell agonist, in combination with sacituzumab govitecan in triple-negative or HR+/HER2− mBC," highlighted interim results from the first clinical trial evaluating a Vβ-directed selective T-cell agonist in combination with an antibody-drug conjugate (ADC), advancing a next-generation precision IO–ADC combination approach.

STARt-002 is evaluating the combination across two biologically distinct metastatic breast cancer populations: TNBC and HR-positive/HER2-negative disease. The combination is designed to bring together two complementary mechanisms. SG provides Trop-2-directed tumor-cell killing and antigen release, which may prime less immunogenic tumors, while invikafusp alfa selectively activates and expands functional Vβ T cells to amplify the resulting antitumor immune response.

"The interim STARt-002 findings provide encouraging evidence that invikafusp alfa retains its selective immunologic mechanism when combined with SG while generating antitumor activity across two difficult-to-treat metastatic breast cancer populations," said Steven J. Isakoff, M.D., Ph.D., Director of Breast Cancer Clinical Research at Mass General Brigham Cancer Institute and presenter of the study. "Most notably, confirmed complete responses were observed in both triple-negative and HR-positive/HER2-negative metastatic breast cancer, including a response continuing beyond one year in a patient with PD-L1-negative metastatic TNBC. These findings

support further evaluation of this novel combination for patients who need new treatment options."

Highlights from the STARt-002 Presentation

As of the October 16, 2026, data cutoff, 48 patients had been enrolled across the metastatic TNBC and HR+/HER2− mBC cohorts, representing heavily pretreated populations. Fifty percent of patients had received three or more prior lines of therapy in the metastatic setting, including 67% of patients in the HR+/HER2− cohort. Key findings include:

- Reductions in target lesions were observed in 71% (27/38) of efficacy-evaluable patients, with disease control achieved in 74% (28/38) overall and 83% among ADC-naïve patients across mTNBC and HR+/HER2− mBC.
- Confirmed complete responses were observed in both the mTNBC and HR+/HER2− mBC cohorts, including a response continuing beyond 12 months in a patient with PD-L1-negative mTNBC.
- Objective responses were observed in both breast cancer subtypes:
    - 25% ORR (5/20) and 80% DCR (16/20) in HR+/HER2− mBC.
    - 28% ORR (5/18) and 67% DCR (12/18) in mTNBC.
    - 36% ORR (5/14) and 79% DCR (11/14) in ADC-naïve mTNBC.
- Translational analyses demonstrated selective expansion of Vβ6-positive T cells in all eight patients assessed during the first treatment cycle, consistent with observations previously reported for invikafusp alfa monotherapy[1,2].
- The combination demonstrated a manageable safety profile consistent with the known profiles of each agent:
    - Cytokine release syndrome was primarily low-grade and medically manageable.
    - Adverse events commonly associated with SG were managed using established supportive-care measures and dose modifications.
    - No unexpected toxicities or treatment-related deaths were observed.

"These interim results reinforce our conviction that selective activation of Vβ T-cell populations can broaden the reach of immunotherapy, particularly in less immunogenic tumors that derive limited benefit from checkpoint inhibition," said Zhen Su, M.D., President and Chief Executive Officer of Marengo Therapeutics. "The confirmed complete responses in both metastatic breast cancer cohorts, together with reductions in target lesions in 71% of efficacy-evaluable patients, are particularly encouraging. STARt-002 is the first clinical study to combine a dual T-cell agonist with an ADC, and these data provide important clinical support for invikafusp alfa's potential as a precision immune amplifier and IO backbone for rational combinations in broader patient populations."

The STARt-002 results highlighted here expand upon the initial Phase 2a findings presented at the 2026 American Association for Cancer Research (AACR) Annual Meeting, providing a larger and more mature dataset with quantified activity across both metastatic breast cancer cohorts. The data also complement Phase 2 STARt-001 findings recently presented at the European Society for Medical Oncology (ESMO) 2026 Congress, which demonstrated tissue-agnostic, single-agent efficacy signals for invikafusp alfa across eight distinct TMB-H solid tumor types.

First-in-human data supporting this approach were recently published in *Nature Medicine*[2], demonstrating that invikafusp alfa can selectively activate and expand Vβ-positive T-cell populations in the blood and tumor and generate antitumor activity across advanced solid tumors. Together, STARt-001 and STARt-002 provide converging clinical and translational evidence supporting invikafusp alfa as a precision immune amplifier with potential applicability across tumor types and therapeutic combinations.

Marengo continues to advance invikafusp alfa through a focused development strategy that translates the broad potential of selective T-cell activation into prioritized programs, spanning biomarker-selected monotherapy and rational combinations in broader all-comer populations.

The use of invikafusp alfa and sacituzumab govitecan in patients with metastatic TNBC and HR+/HER2- metastatic breast cancer is investigational, and the safety and efficacy of this combination has not been established.

[1] Garralda et al. Annals of Oncology (2026) 37 (suppl_3): S1180-S1228. 10.1016/annonc/annonc2204
[2] Sullivan et al. Nat Med 2026. https://doi.org/10.1038/s41591-026-04711-0

About Marengo Therapeutics
Marengo Therapeutics, Inc. is a clinical-stage biotech company developing novel TCR-targeting antibodies that selectively modulate common and disease-specific T-cell subsets of the germline TCR repertoire to provide durable 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 (TriSTAR™) 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 Invikafusp Alfa (STAR0602)
Invikafusp alfa (STAR0602), the lead candidate from Marengo’s STAR™ platform, is a first-in-class dual T-cell agonist designed to function as a precision immune amplifier. It selectively activates a common Vβ T-cell subset shared across many cancers by combining a non-clonal mode of TCR activation with a T-cell costimulatory signal in a single molecule. This approach promotes the expansion of clonally diverse effector and memory Vβ T cells designed to amplify antitumor immunity. Invikafusp alfa is being developed as a potential immuno-oncology

backbone for patients whose tumors have progressed on, or are insensitive to, prior immune checkpoint blockade and for rational combinations intended to extend immunotherapy benefit into broader patient populations. Invikafusp alfa has received two Fast Track Designations from the U.S. Food and Drug Administration: the first for TMB-H colorectal cancer, granted in January 2025, and the second for TMB-H solid tumors regardless of tissue of origin following prior therapy, including checkpoint inhibition, granted in October 2026.

About the STARt-002 Clinical Trial
STARt-002 is a Phase 1b/2, open-label clinical trial (NCT06827613) evaluating invikafusp alfa in combination with sacituzumab govitecan in patients with metastatic triple-negative breast cancer and HR-positive/HER2-negative metastatic breast cancer. The trial is designed to assess safety, tolerability and preliminary efficacy while exploring the complementary effects of selective Vβ T-cell activation and ADC-mediated tumor-cell killing.

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