



Marengo Therapeutics Completes Enrollment in Phase 1/2 START-001 Monotherapy Cohorts and Strengthens Leadership to Advance Invikafusp Alfa Toward Late-Stage Development

- **Enrollment completed in cohorts evaluating invikafusp alfa monotherapy in PD-1-resistant, antigen-rich solid tumors; updated START-001 results selected for oral presentation at the ESMO 2026 Congress**
- **Amy Otto appointed Senior Vice President, Program Leadership, bringing more than 20 years of oncology development leadership at Amgen, Seagen and Gilead**
- **Zhenming Shun, Ph.D., appointed Senior Vice President, Data Science, brings more than 30 years of drug-development leadership, including Sanofi and Daiichi Sankyo, to guide statistical strategy supporting invikafusp alfa's late-stage development**

CAMBRIDGE, Mass., September 9, 2026 – Marengo Therapeutics, Inc., a clinical-stage biotechnology company pioneering precision immunotherapy approaches for cancer and autoimmune diseases, today announced the completion of enrollment in the monotherapy cohorts of START-001, its Phase 1/2 clinical trial evaluating invikafusp alfa in patients with PD-1-resistant, antigen-rich solid tumors. Enrollment continues in standard of care combination cohorts. In addition, updated results from the study have been selected for an oral presentation at the European Society for Medical Oncology (ESMO) 2026 Congress, taking place October 23–27 in Madrid, Spain.

The company also announced the appointments of Amy Otto as Senior Vice President, Program Leadership, and Zhenming Shun, Ph.D., as Senior Vice President, Data Science. Together, they will strengthen Marengo's integrated development, execution and data capabilities as the company prepares invikafusp alfa for its next stage of clinical development.

"Completing enrollment in the START-001 monotherapy cohorts represents an important step in establishing invikafusp alfa's single-agent activity across eight distinct PD-1-resistant tumor types, including MSS colorectal cancer, PD-L1-negative non-small cell lung cancer and triple-negative breast cancer," said Zhen Su, M.D., MBA, President and Chief Executive Officer of Marengo Therapeutics. "The signals observed across these diverse tumor types highlight invikafusp's long-term potential as a pan-tumor immuno-oncology backbone. Our near-term priority is a focused development path in lead indications selected from these monotherapy cohorts, in areas of high unmet need for patients whose tumors are unresponsive to PD-1-directed therapies, which we expect to announce alongside the updated data at ESMO."

Following the ESMO presentation, the company expects to complete planned interactions with the U.S. Food and Drug Administration (FDA) to align on the development plan for invikafusp alfa, with the next stage of development expected to begin in 2027.

Appointment of Amy Otto, Senior Vice President, Program Leadership

Amy joins Marengo as Senior Vice President, Program Leadership. In this role, she will lead integrated development strategy and cross-functional execution for invikafusp alfa, partnering closely with Marengo's leadership and functional teams to advance the program's clinical, regulatory and operational priorities.



Amy brings more than 20 years of oncology development leadership experience across Amgen, Seagen and Gilead, with deep expertise guiding programs from early development through regulatory approval, global launch and lifecycle expansion. Most recently, she served as Vice President and Head of Oncology Program Strategy Leadership at Gilead, where she grew the oncology program strategy function and shaped portfolio and program decisions across the pipeline of oncology investigational assets, including TRODELVY®. Previously, Amy served as Product Team Leader for PADCEV® at Seagen, leading the program through late-stage development, FDA approval, global launch and lifecycle expansion.

“Invikafusp alfa has generated compelling clinical momentum and has the potential to become an important new immuno-oncology backbone,” said Amy. “I am excited to join Marengo at this important stage and work with its highly experienced team to integrate the evidence, strategy and execution required to realize the program’s full potential for patients.”

Appointment of Zhenming Shun, Ph.D., to Senior Vice President, Data Science

Zhenming has been appointed Senior Vice President, Data Science, to lead biostatistics and data management across Marengo’s clinical portfolio, which will play a central role in shaping trial design, statistical strategy and evidence generation.

Zhenming brings more than 30 years of experience across the pharmaceutical industry and academia. Before joining Marengo, he served as Vice President, Global Head of Biostatistics and Data Management at Daiichi Sankyo and previously as Global Head of Biostatistics in Oncology at Sanofi. Across these roles, Zhenming led global teams responsible for clinical trial design, statistical analysis and regulatory submissions and contributed to multiple successful drug approvals in oncology and cardiovascular medicine.

“The breadth and maturity of the emerging invikafusp dataset create an important opportunity to apply rigorous statistical and data science approaches to its next stage of development,” said Zhenming. “I look forward to working with our clinical, regulatory and program teams to translate these findings into an efficient, evidence-driven late-stage development strategy.”

“As invikafusp advances toward its next critical inflection point, Amy’s extensive experience guiding oncology programs from early development through approval and commercialization and Zhenming’s deep statistical and data science expertise significantly strengthen our ability to translate emerging clinical evidence into a focused, integrated late-stage development strategy,” said Dr. Su.

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 Invikafusp alfa (STAR0602)

Invikafusp alfa (STAR0602) is the lead candidate from Marengo's STAR™ platform and a first-in-class, bispecific dual T-cell agonist. 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 approach promotes the expansion of clonally diverse, effector memory Vβ T cells, enhancing antitumor immunity and enabling durable tumor clearance. Invikafusp alfa was designed to restore and amplify antitumor immunity in patients who have progressed on, or are insensitive to, prior immune checkpoint blockade.

About the STARt-001 Clinical Study

STARt-001 is a global Phase 1/2 clinical trial evaluating the safety, tolerability and preliminary efficacy of invikafusp alfa as a monotherapy in biomarker-selected patients with advanced, antigen-rich solid tumors that are refractory or resistant to PD-1–directed therapy, including rare tumor types. The Phase 2 portion uses biomarker-enriched cohorts, including TMB-H and MSI-H, to assess activity across multiple tumor types and help identify patients most likely to benefit. For more information, visit ClinicalTrials.gov (NCT05592626).

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