

Marengo Therapeutics Receives Second U.S. FDA Fast Track Designation for Invikafusp Alfa, Expanding to a Tissue-Agnostic Indication Across Tumor Mutational Burden-High Solid Tumors That Progress After Prior Therapy, Including Checkpoint Inhibition

- New designation expands on first Fast Track Designation in TMB-H colorectal cancer and is supported by monotherapy responses across multiple tumor types in the START-001 study
- Invikafusp alfa believed to be first immuno-oncology T-cell agonist to receive Fast Track Designation in a biomarker-defined, tissue-agnostic indication
- New designation supported by updated Phase 2 data in this population, which will be featured in an oral presentation at the European Society for Medical Oncology (ESMO) Congress 2026 on October 23

CAMBRIDGE, Mass., October 15, 2026 /PRNewswire/ -- Marengo Therapeutics Inc., a clinical-stage biotechnology company pioneering precision immunotherapies for oncology and inflammation and immunology (I&I), today announced that the U.S. Food and Drug Administration (FDA) has granted a second Fast Track Designation (FTD) to invikafusp alfa for the treatment of unresectable, locally advanced, or metastatic, tumor mutational burden high (TMB-H) solid tumors that have progressed following prior treatment including immune checkpoint inhibition and who have no satisfactory treatment options.

The new designation expands invikafusp alfa's Fast Track status from a single tumor type, TMB-H colorectal cancer (granted January 2025), to TMB-H solid tumors regardless of their tissue of origin. It is supported by objective responses across multiple tumor types, including colorectal, gastric, breast, urothelial, endometrial, gastroesophageal, head and neck, and lung cancers, in the ongoing Phase 1/2 START-001 study, with initial data [presented at the Society for Immunotherapy of Cancer \(SITC\) 2025 Annual Meeting](#). Updated Phase 2 results will be presented in an oral session at ESMO 2026 in Madrid on October 23.

"Years ago, when we pursued the tumor-agnostic TMB-H approval for pembrolizumab, the premise was that a high mutational burden gives T cells more to recognize. Yet many patients with TMB-H tumors do not respond to PD-1 blockades, such as pembrolizumab, or progress after it and are left with few treatment options," said Eric Rubin, M.D., member of Marengo's Scientific Advisory Board and former Senior Vice President of Global Clinical Oncology at Merck, where he led the initial development of pembrolizumab. "Invikafusp alfa takes a fundamentally different approach: rather than releasing a checkpoint on exhausted T cells, it directly expands new T cells that can act on that antigen-rich landscape. That makes it a compelling candidate for patients whose tumors do not or no longer respond to PD-1-directed therapy, regardless of where the tumor arises."

"A second Fast Track Designation, now in a pan-tumor setting, reinforces our conviction that invikafusp alfa can become a next-generation, tissue-agnostic immuno-oncology backbone," said Ke Liu, M.D., Ph.D., Chief Development Officer of Marengo Therapeutics. "Across multiple clinical data sets, invikafusp alfa has shown encouraging monotherapy activity in heavily pretreated patients across tumor types that were either insensitive to checkpoint inhibitors or progressed after PD-1–directed therapy. In parallel, we are evaluating invikafusp alfa in combination with standard-of-care therapies, including an antibody-drug conjugate, to support its potential in earlier lines of therapy. We look forward to presenting Phase 2 STARt-001 data at ESMO later this month."

Invikafusp alfa [received its first FDA Fast Track Designation](#) for the treatment of unresectable, locally advanced or metastatic colorectal cancers with TMB-H in January 2025.

Invikafusp alfa is investigational and has not been approved by the FDA or any other regulatory authority.

About Fast Track Designation

Fast Track Designation is an FDA process designed to facilitate the development and expedite the review of drugs that treat serious conditions and fill an unmet medical need. It provides more frequent communication with the FDA and, for drugs that meet the relevant criteria, eligibility for rolling review, Accelerated Approval, and Priority Review.¹

About TMB-High Solid Tumors

Tumor mutational burden measures the number of somatic mutations in a tumor's genome. Tumors with high TMB (≥ 10 mutations/megabase) occur across many cancer types. Patients whose TMB-H tumors progress on or after checkpoint inhibitor therapy, or who are not candidates for it, have limited treatment options.

About Invikafusp alfa (STAR0602)

Invikafusp alfa (STAR0602), the lead candidate from Marengo's STAR™ platform, is a first-in-class, bispecific dual T-cell agonist. It is designed to selectively activate a common V β 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 V β 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.

¹ [Fast Track | FDA](#) (2025, September 28)

About the STARt-001 Clinical Study

STARt-001 is a global Phase 1/2 trial evaluating invikafusp alfa monotherapy in patients with advanced, antigen-rich solid tumors that are refractory or resistant to PD-1–directed therapy. 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](https://clinicaltrials.gov/ct2/show/study/NCT05592626)). Phase 2 expansion is ongoing to further investigate invikafusp for the treatment of ICB-resistant tumors.

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.

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