

MiNK's AgenT-797 Offers New Hope in Overcoming ICI Resistance in PD-1 Refractory Gastric Cancer - Published in Oncogene

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NEW YORK, Jan. 30, 2024 (GLOBE NEWSWIRE) -- MiNK Therapeutics, Inc. (NASDAQ: INKT), a clinical-stage biopharmaceutical company pioneering the discovery, development, and commercialization of allogeneic, off-the-shelf, invariant natural killer T (iNKT) cell therapies to treat cancer and other immune-mediated diseases, today announced the publication of a case report in *Oncogene* from its phase 1/2 study in patients with advanced solid tumors where one infusion of agenT-797 in gastric cancer refractory to anti-PD1 led to a durable confirmed partial response, highlighting the unique potential of iNKT cells to overcome resistance to immune checkpoint inhibitors (ICIs).

"Gastric cancer remains an area of high unmet need, where the majority of patients develop disease progression related to tumor resistance," said Dr. Benedito A. Carneiro, Director of Clinical Research, Director of Cancer Drug Development (Phase I), Associate Director of the Division of Hematology/Oncology, Legorreta Cancer Center at Brown University. "Novel therapeutic approaches, like allogeneic iNKT cells, are urgently needed to overcome resistance to immune checkpoint inhibitors in gastric cancers and other refractory solid tumors. The activity, tolerability, and ease of off-the-shelf administration of iNKT-based cell therapies position them as an attractive approach for overcoming cancer resistance."

Gastric cancer, the fifth most common malignancy globally, is incurable with only 12% responsive to ICIs^{1,2}. This phase study (NCT05108623) was designed to evaluate agenT-797, an unmodified iNKT cell therapy, in solid tumors refractory to ICIs. Patients received a single dose of agenT-797, without lymphodepletion, either alone or in combination with pembrolizumab or nivolumab.

This case report describes a durable response (by RECIST 1.1 criteria) in a patient with a challenging clinical profile—a PD-L1 positive, HER-2 negative, MSI-H adenocarcinoma with a high mutational burden (84 mut/MB). Prior treatments, including single-agent anti-PD-1 pembrolizumab, had failed to elicit a response, prompting a combination therapy approach involving chemotherapy (FOLFOX) and nivolumab. However, even this combined regimen proved ineffective before the patient's enrollment in MiNK's clinical trial. Following treatment with agenT-797, increased immune cell infiltration and proliferation were observed, which correlated with the radiographic partial response.

"These findings reinforce the distinct potential of iNKTs as a novel therapeutic approach to address refractory solid tumor cancers," said Dr. Jennifer Buell, Chief Executive Officer of MiNK. "Allogeneic iNKTs are an ideal approach for addressing refractory solid tumor cancers because of their unique ability to modulate the immune system, long-term persistence, scalability, and off-the-shelf administration without toxic pre-conditioning. We are continuing to advance iNKT cells in this setting and look forward to further updates on our solid tumor programs this year."

A randomized phase 2 trial, led by Dr. Yelena Janjigian, Chief of Gastrointestinal Oncology at Memorial Sloan Kettering Cancer Center, is underway.

References:

- 1. Rawla P, Barsouk A. Epidemiology of gastric cancer: global trends, risk factors and prevention. Prz Gastroenterol 2019; 14: 26-38.
- 2. Kono K, Nakajima S, Mimura K. Current status of immune checkpoint inhibitors for gastric cancer. Gastric Cancer 2020; 23: 565-578.

About MiNK Therapeutics

MiNK Therapeutics is a clinical-stage biopharmaceutical company pioneering the discovery, development, and commercialization of allogeneic invariant natural killer T (iNKT) cell therapies to treat cancer and other immune-mediated diseases. MiNK is advancing a pipeline of both native and next generation engineered iNKT programs, with a platform designed to facilitate scalable and reproducible manufacturing for off-the-shelf delivery. The company is headquartered in New York, NY. For more information, visit https://minktherapeutics.com/ or @MiNK_iNKT. Information that may be important to investors will be routinely posted on our website and social media channels.

Forward Looking Statements

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws, including statements regarding the therapeutic and curative potential of agenT-797 and iNKT cells the mechanism of action, potency and safety, interim or top-line data, including statements regarding clinical data of agenT-797 alone and in combination with anti-PD-1, the anticipated benefits of agenT-797 and clinical development plans and timelines. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially. These forward-looking statements are subject to risks and uncertainties, including the factors described under the Risk Factors section of the most recent Form 10-K, Form 10-Q and the S-1 Registration Statement filed with the SEC. MiNK cautions investors not to place considerable reliance on the forward-looking statements contained in this release. These statements speak only as of the date of this press release, and MiNK undertakes no obligation to update or revise the statements, other than to the extent required by law. All forward-looking statements are expressly qualified in their entirety by this cautionary statement.

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