# MiNK Therapeutics Reports Durable Responses and Immune Reactivation with Allo-iNKT Cell Therapy agenT-797 in PD-1–Refractory Solid Tumors at SITC 2025

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- Durable survival and deep, lasting remissions in checkpoint-refractory, heavily pretreated cancers with median OS of ~23 months with agenT-797 plus anti-PD-1
- Evidence of immune activation and tumor-immune remodeling underscore agenT-797's potential to restore responsiveness in PD-1–resistant disease
- Favorable safety and reproducible activity reinforce MiNK's leadership in allogeneic iNKT cell therapy

NEW YORK, Nov. 07, 2025 (GLOBE NEWSWIRE) -- MiNK Therapeutics, Inc. (NASDAQ: INKT), a clinical-stage biopharmaceutical company pioneering allogeneic invariant natural killer T (allo-iNKT) cell therapies to reconstitute immunity to treat cancer and immune disorders, today announced updated clinical results evaluating agenT-797, alone and in combination with anti-PD-1 therapy, in patients with advanced solid tumors refractory to all approved treatments presented at the Society for Immunotherapy of Cancer (SITC) Annual Meeting 2025 (Late Breaking Abstract #1344).

The results demonstrate durable survival, deep and lasting responses, and broad immune restoration in patients with solid tumors that had progressed on checkpoint inhibitors and multiple prior therapies.

"We're seeing encouraging clinical activity with agenT-797 — including durable responses and deep remissions that have persisted beyond two years in some patients," **said Dr. Ben Garmezy, Associate Director of Genitourinary Research at Sarah Cannon Research Institute and presenting author at SITC.** "In my own patient with metastatic germ cell/testicular cancer, published in *Oncogene (2025)*, we observed a complete clinical, radiologic, and biochemical remission that has now lasted more than two years following treatment with agenT-797 in combination with anti–PD-1 therapy. What's particularly encouraging is the evidence of immune reprogramming within the tumor microenvironment — agenT-797 is not only killing tumor cells directly but also likely restoring the immune system's capacity to recognize and respond, even in settings of profound treatment resistance."

"agenT-797 continues to deliver what checkpoint inhibitors alone cannot — durable responses in resistant disease," **said Dr. Jennifer Buell, President and Chief Executive Officer of MiNK Therapeutics.** "The strength and consistency of these data support our belief that iNKT cells represent a new class of immune-restorative therapy. With a clean safety profile and reproducible activity across tumor types, agenT-797 is well positioned to move into Phase 2 studies and to redefine how we approach immune-resistant cancers."

**Key Study Findings**

**Durable and meaningful clinical benefit across tumor types:**

- agenT-797, alone or in combination with anti-PD-1, demonstrated durable responses and disease stabilization in multiple checkpoint-refractory solid tumors, including germ cell testicular (OS>33+mos), thymoma (OS>39+), 2L gastric (OS>27mos), cholangiocarcinoma (>21mos), renal and adenoid cystic cancers (OS>30+), highlighting its potential to overcome resistance and extend benefit across tumor types.
- Complete and sustained remission beyond two years in metastatic germ-cell/testicular cancer, with full resolution of hepatic lesions and normalization of tumor markers.
- Durable partial response in gastric cancer and prolonged disease control in thymoma (OS>36mos), adenoid cystic carcinoma (OS >18 mos), renal (OS>24) and cholangiocarcinoma, confirming broad applicability across solid tumors.

**Immune Reactivation and Tumor-Immune Remodeling**

- Dual killing pathways: agenT-797 eliminates tumor cells through TCR-dependent and TCR-independent mechanisms.
- Restores immune function by activating dendritic cells, converting suppressive macrophages to pro-inflammatory M1 states, and reactivating exhausted T cells. Enhanced $CD8^+$ and NK-cell infiltration and coordinated cytokine activation (IFN-γ, IL-8, VEGF-D) reflect a potent but controlled immune response without systemic toxicity.
- Favorable safety profile: agenT-797 was well tolerated across all treated patients, with no DLTs, no Grade ≥ 3 cytokine

release syndrome (CRS) or neurotoxicity observed. The most common treatment-related adverse events were fatigue (n = 7) and Grade 3 anemia (n = 1). The manageable safety profile, coupled with sustained clinical responses, supports the potential for combination and repeat-dose regimens in future development.

These results highlight agenT-797 as a first-in-class, off-the-shelf iNKT cell therapy that has the potential to transform treatment for patients with refractory solid tumors, including PD-1–resistant disease. By restoring immune balance and reversing T cell exhaustion, agenT-797 may help extend the benefits of immunotherapy to patients historically unresponsive to current checkpoint inhibitors. Collectively, these data validate iNKT cells as master regulators of immune orchestration, bridging innate and adaptive immunity, and underscores agenT-797's capacity to overcome immune resistance across diverse solid tumors.

**About MiNK Therapeutics**

MiNK Therapeutics is a clinical-stage biopharmaceutical company pioneering the development of allogeneic invariant natural killer T (iNKT) cell therapies and precision immune modulators designed to restore immune balance and drive durable cytotoxic responses. MiNK's proprietary iNKT platform bridges innate and adaptive immunity to address cancer, autoimmune disease, and immune collapse.

Its lead candidate, agenT-797, is an off-the-shelf, cryopreserved iNKT cell therapy currently in clinical trials for solid tumors, graft-versus-host disease (GvHD), and critical pulmonary immune failure. MiNK's pipeline also includes TCR-based and neoantigen-targeted iNKT programs that enable tissue-specific immune activation. With a scalable manufacturing process and broad therapeutic potential, MiNK is advancing a new class of immune reconstitution therapies designed to deliver durable, accessible, and globally deployable treatments.

**About the Study (NCT05108623)**
The SITC 2025 presentation builds on previous data demonstrating agenT-797's favorable safety and mechanistic profile in early-stage trials.

This ongoing Phase 1, open-label, multicenter study evaluates the safety, tolerability, pharmacodynamics, and preliminary efficacy of agenT-797 alone or in combination with anti-PD-1 therapy in patients with relapsed or refractory solid tumors who have progressed on standard therapies. Primary endpoints include safety and dose-finding; secondary endpoints include persistence and efficacy.

**Forward-Looking Statements**
This press release contains forward-looking statements within the meaning of the federal securities laws, including statements regarding the potential, safety, clinical benefit, and development plans for agenT-797 and other iNKT-based therapies. These statements involve risks and uncertainties, including those described under "Risk Factors" in MiNK's most recent SEC filings. MiNK undertakes no obligation to update these statements except as required by law.

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