MiNK Therapeutics and University of Wisconsin–Madison Announce Phase 1 Clinical Trial of Allo-iNKT Cell Therapy (AgenT-797) to Evaluate Prevention of Graft-Versus-Host Disease

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- Non-dilutive public-private funded trial with NIAID STTR & Mary Gooze Clinical Trial and Translation Award
- Expands iNKT platform into transplantation with an off-the-shelf, HLA-independent, lymphodepletion-free experimental therapy in patients at risk for GvHD

NEW YORK, Jan. 08, 2026 (GLOBE NEWSWIRE) -- MiNK Therapeutics, Inc. (NASDAQ: INKT), a clinical-stage biopharmaceutical company pioneering off-the-shelf allogeneic invariant natural killer T (allo-iNKT) cell therapies, today announced the upcoming initiation of a Phase 1, investigator-sponsored clinical trial evaluating its lead therapy, agenT-797, in patients undergoing allogeneic hematopoietic stem cell transplantation (allo-HSCT).

The trial, led by Hongtao Liu, MD, PhD, Associate Professor of Medicine, University of Wisconsin School of Medicine and Public Health, with co-investigator Kalyan V. G. Nadiminti, MD, Assistant Professor of Medicine at the University of Wisconsin School of Medicine and Public Health, will evaluate the safety, tolerability, and preliminary efficacy of agenT-797 in reducing graft-versus-host disease (GvHD), relapse, and other post-transplant complications in patients with high-risk leukemias and other blood cancers.

Two complementary public-private funding awards support the advancement of agenT-797 development in HSCT and GvHD. First, an NIH STTR grant from the National Institute of Allergy and Infectious Diseases (NIAID) supports MiNK and the University of Wisconsin–Madison team to develop and evaluate agenT-797 in preclinical models. Second, a philanthropic clinical grant, the Mary Gooze Clinical Trial Award to the University of Wisconsin–Madison directly funds enrollment, immune monitoring, and operations for the Phase 1. Together, these awards enable the simultaneous execution of translational and clinical studies of iNKTs in GvHD prevention.

“This trial marks an important step in expanding our iNKT platform into GvHD, targeting one of the most serious and persistent complications of stem cell transplantation, where effective options remain limited,” said **Jennifer Buell, PhD, President and Chief Executive Officer of MiNK Therapeutics.** “Our objective is to reduce GvHD and relapse while supporting immune reconstitution, with the potential to improve survival and quality of life for transplant patients—without the cytotoxic burden of lymphodepleting conditioning regimens.”

GvHD is a leading cause of morbidity and mortality following HSCT, affecting up to half of recipients. iNKT cells are uniquely suited to this setting, as they can suppress inflammatory allo-immune responses while preserving anti-leukemia activity and immune competence. agenT-797, an off-the-shelf, donor-derived iNKT cell therapy, has demonstrated favorable safety and immune-modulating activity in solid tumors and ARDS—*without the need for lymphodepletion or human leukocyte antigen (HLA) matching*.

The University of Wisconsin Carbone Cancer Center's More for Stage IV philanthropic fund is providing support for the trial through the *Mary Gooze Clinical Trial and Translation Award* to the collaborative team also including Jenny Gumperz, PhD, Professor of Medical Microbiology & Immunology at the University of Wisconsin School of Medicine and Public Health. Beyond clinical testing, the award supports mechanistic research in the Gumperz laboratory to define how iNKT cells control leukemia. The work complements an ongoing collaboration between UW–Madison and MiNK under an NIAID-funded STTR grant, aimed at developing a universal, donor-independent iNKT platform for hematologic malignancies.

Dr. Hongtao Liu, MD, PhD, the study Principal Investigator, said, “As a transplant physician, I see firsthand the toll GvHD takes on patients and families. This study is designed not only to reduce this life-threatening complication but also to enhance immune reconstitution and reduce relapse risk, with the potential to change post-transplant outcomes.”

Professor Jenny Gumperz, leading researcher of iNKT biology, said, “Our research has shown that iNKT cells can restore immune balance and promote healthy engraftment. This trial brings years of translational work full circle by enabling clinical evaluation of an innovative immune-regulating therapy for patients in need.”

About MiNK Therapeutics

MiNK Therapeutics is a clinical-stage biopharmaceutical company pioneering allogeneic invariant natural killer T (iNKT) cell therapies and precision-targeted immune technologies. MiNK’s proprietary platform is designed to restore immune balance and drive cytotoxic responses across cancer, immune-mediated diseases, and pulmonary immune failure. MiNK’s lead candidate, agenT-797, is an off-the-shelf iNKT cell therapy currently in clinical development for GvHD, solid tumors, and severe pulmonary inflammation. With a scalable cryopreserved manufacturing process and differentiated biology bridging innate and adaptive immunity, MiNK is committed to developing next-generation immune reconstitution therapies. For more information, visit www.minktherapeutics.com or follow us on X @MiNK_iNKT.

About AgenT-797

AgenT-797 is an allogeneic invariant natural killer T (iNKT) cell therapy that harnesses the dual power of innate and adaptive immunity. iNKTs function as “master regulators,” combining the cytotoxic capabilities of NK cells with T-cell–like antigen recognition and memory. This unique biology enables a robust, pathogen-agnostic immune response that can be directed against hard-to-treat tumors. Manufactured by MiNK Therapeutics in Lexington, MA, agenT-797 is a scalable, off-the-shelf product designed to provide accessible, transformative treatment options. In clinical trials, agenT-797 can bolster

peripheral memory T-cell activation, enhance tumor infiltration, and potentially improve outcomes for patients with solid cancers (Cytryn et al. AACR IO 2024, Oncogene. 2024) and to combat inflammation in critically ill patients with severe respiratory pathology (*Nature Communications*. 2024).

About the University of Wisconsin School of Medicine and Public Health

The University of Wisconsin School of Medicine and Public Health is recognized as one of the nation's leading institutions in health sciences education, research, and service. Founded in 1907 as the medical school of the University of Wisconsin-Madison, in 2005 it became the nation's first school to integrate the disciplines of medicine and public health. With a deep commitment to a vision of healthy people and healthy communities, we translate discovery into application and interconnect clinical care, education and research. The school employs more than 5,600 faculty and staff and provides educational opportunities for nearly 3,000 students and postgraduate trainees. For federal fiscal year 2024, the school ranked #9 in the nation among public medical schools for NIH funding according to the Blue Ridge Institute for Medical Research. Some of the nation's leading researchers, educators, and clinicians are among the faculty, including several National Medal of Science recipients and National Academy of Science honorees.

About *Mary Gooze Clinical Trial and Translation Award*

Established by the University of Wisconsin Carbone Cancer Center in honor of advocate and philanthropist Mary Gooze, the Mary Gooze Clinical Trial and Translation Award supports early-stage clinical and translational research aimed at addressing critical unmet needs in advanced and life-threatening diseases. The award provides seed funding to accelerate the development of innovative therapies with the potential to transform patient care, particularly in areas where treatment options remain limited.

Forward-Looking Statements

This press release contains forward-looking statements made pursuant to the safe harbor provisions of the federal securities laws, including statements regarding the therapeutic potential, safety, and anticipated benefits of agenT-797; clinical trial design, timing, and enrollment; and MiNK's broader development plans. These statements are subject to risks and uncertainties detailed in MiNK's most recent filings with the Securities and Exchange Commission. MiNK cautions investors not to place undue reliance on these statements, which speak only as of the date of this release.

Contacts:

Investor Contact: 917-362-1370 | investor@minktherapeutics.com
Media Contact: 781-674-4428 | communications@minktherapeutics.com

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