MiNK Therapeutics and First Lviv Territorial Medical Union Initiate Randomized Phase 2 Trial of agenT-797 in Acute Lung Injury and Critical Illness

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- *Randomized Phase 2 trial evaluates off-the-shelf invariant natural killer T (iNKT) cell therapy in patients with acute lung injury and hypoxemic respiratory failure*
- *Study initiates in Lviv, Ukraine, in partnership with First Lviv Medical and UNBROKEN Ukraine, expands development into a high-acuity critical care setting with U.S. sites in parallel*
- *Trial is designed to evaluate clinically meaningful ICU endpoints including survival, ventilator-free days, and secondary infections, with preliminary data expected in the second half of 2026*
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NEW YORK and LVIV, Ukraine, May 14, 2026 (GLOBE NEWSWIRE) -- MiNK Therapeutics, a clinical-stage biopharmaceutical company pioneering off-the-shelf allogeneic iNKT cell therapies for cancer and immune disorders, and First Lviv Territorial Medical Union today announced the initiation of a randomized Phase 2 clinical trial evaluating agenT-797, MiNK's off-the-shelf allogeneic invariant natural killer T cell therapy (iNKTs), in patients with severe acute lung injury (ALI). The study has received authorization from the Ministry of Health of Ukraine and is supported by an active U.S. IND.

The trial, designated C-1300-02, is a randomized, placebo-controlled study evaluating agenT-797 plus standard of care compared with placebo plus standard of care in patients with ALI meeting Global ARDS criteria. The study is designed to evaluate whether treatment with donor-derived iNKT cells may improve clinically meaningful outcomes in critically ill patients, including survival, ventilator-free days, ICU recovery, pathogen control, and reduction of secondary infections.

Inflammatory Lung Disease

ALI and ARDS remain among the most serious unresolved conditions in critical care. ARDS affects an estimated 3 million people globally and approximately 200,000 people annually in the United States, accounting for nearly one-quarter of mechanically ventilated ICU patients[i]. Mortality remains high, particularly in severe disease[ii], and there are currently no approved therapies shown to reduce mortality.

Prior therapeutic approaches in ARDS have struggled in part because they targeted isolated inflammatory pathways rather than the broader immune dysfunction that emerges during critical illness, including impaired pathogen control, secondary infection susceptibility, myeloid dysregulation, and progressive organ failure.

iNKT cells are a rare immune subset that recognize lipid antigens presented through CD1d and rapidly coordinate innate and adaptive immune responses. Unlike prior supportive cellular approaches, iNKT cells possess direct immune effector capability and may actively restore immune coordination during severe inflammatory injury. ***agenT-797 is designed to deliver functional donor-derived iNKT cells during a critical window of disease progression characterized by immune dysregulation, respiratory failure, and susceptibility to secondary complications.***

In prior clinical studies (Hammond et al. *Nat Comms*[i]) in virally induced ARDS, agenT-797 demonstrated activity consistent with improved clinical outcomes, such as improved survival, reduced secondary infections, and accelerated recovery relative to contemporaneous standard-of-care controls.

"Critical illness is often driven not only by the initial insult, but by the subsequent collapse of coordinated immune function," said **Jennifer Buell, Ph.D., President and Chief Executive Officer, MiNK Therapeutics.** "By leveraging CD1d-mediated activation of iNKT cells, trafficking to inflamed tissues, and the ability to coordinate pathogen control and immune recovery during critical illness, we believe this study may generate the prospective data needed to support future registrational pathways in acute lung injury and related critical care conditions."

Because agenT-797 is an off-the-shelf allogeneic therapy administered without patient-specific manufacturing, the product may be particularly well suited for rapid deployment in acute critical care settings where timing and scalability are essential.

High-Acuity Critical Care with Global Relevance

The study is being conducted in partnership with First Lviv Territorial Medical Union, one of Ukraine's leading trauma and critical care institutions, and UNBROKEN Ukraine, a nationally recognized medical and rehabilitation ecosystem. The institution manages a high-acuity patient population with severe pneumonia, trauma, infection-related complications, and respiratory failure, creating an environment well suited for evaluation of immune-directed therapies in critical illness.

Importantly, the biologic mechanisms underlying immune dysfunction in critical illness are globally relevant. Whether acute lung injury is triggered by pneumonia, sepsis, trauma, or other severe inflammatory insults, progression to respiratory failure and organ dysfunction is frequently driven by profound immune dysregulation.

"Our teams are caring for patients with some of the most severe forms of critical illness seen anywhere in the world," said **Mariana Svirchuk, Chief Operating Officer, First Lviv Territorial Medical Union.** "Through this collaboration with MiNK Therapeutics and UNBROKEN Ukraine, we are contributing to the development of therapies that may change outcomes for patients with severe lung injury — here, and in ICUs everywhere."

Clinical care practices in Lviv are aligned with Western intensive care standards, and the study is designed to generate data applicable to future regulatory pathways in the United States and Europe, with expansion into U.S. sites underway.

"Patients with acute lung injury and critical illness often deteriorate because the initial insult triggers a broader immune cascade. Respiratory failure, secondary infection, and organ dysfunction are deeply interconnected in critical illness. The growing evidence in this field points toward the importance of restoring coordinated immune function, rather than targeting only isolated inflammatory pathways. The evidence from prior studies points toward the importance of addressing the immune component of this disease," said **John B. Holcomb, M.D., Professor of Surgery, University of Alabama at Birmingham, Trauma Surgeon, Advisor to the Department of Defense on Battlefield and Mass Casualty Medicine, Board Member, MiNK Therapeutics.**

About C-1300-02 Trial

The C-1300-02 trial is a randomized Phase 2 study evaluating agenT-797 plus standard of care compared with placebo plus standard of care in adults with acute lung injury and critical illness, including moderate to severe acute hypoxemic respiratory failure, who meet Global ARDS criteria. The study is being initiated at First Lviv Territorial Medical Union in Lviv, Ukraine along with U.S. sites. The trial has received authorization from the Ukraine Ministry of Health, is supported by an active U.S. IND.. Preliminary data are expected in the second half of 2026.

About MiNK Therapeutics

MiNK Therapeutics is a clinical-stage biopharmaceutical company developing off-the-shelf allogeneic iNKT cell therapies for life-threatening conditions driven by immune dysfunction. The company's lead program, agenT-797, is being evaluated in acute lung injury and critical illness, with a pipeline that extends across immuno-oncology, transplant medicine, and other settings where dysregulated immunity is a driver of morbidity and mortality. MiNK believes that iNKT cell biology — because of its regulatory role across innate and adaptive immunity — may represent a foundational approach tc immune restoration applicable across a broad range of conditions. For more information, visit www.minktherapeutics.com.

About First Lviv Territorial Medical Union and UNBROKEN

First Lviv Territorial Medical Union is one of Ukraine's largest and most advanced integrated healthcare systems, serving as a regional referral center for western Ukraine. The institution provides comprehensive care across trauma, critical illness, infectious disease, and complex surgery, with specialized capabilities in intensive care and post-acute recovery. Since the onset of the full-scale war, it has been at the forefront of treating both civilians and service members with severe injuries and infection-related complications, operating at a scale and acuity comparable to major Western medical care. For more information, visit First Lviv Territorial Medical Union.

UNBROKEN Ukraine is a nationally recognized medical and rehabilitation ecosystem based in Lviv, dedicated to the treatment and recovery of individuals affected by war. The program integrates acute care, reconstructive surgery, prosthetics, physical and psychological rehabilitation, housing, and long-term reintegration services. Since the start of the full-scale invasion, UNBROKEN has treated more than 24,000 wounded Ukrainians, including children, and has become a leading model for coordinated, multidisciplinary recovery in conflict settings. For more information, visit UNBROKEN Ukraine.

Contacts

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Source: MiNK Therapeutics