



## MiNK Therapeutics Announces First Patient Dosed in Randomized Phase 2 Trial of agenT-797 in Acute Lung Injury and Critical Illness

May 28, 2026

- *First patient dosed marks rapid transition from trial activation to active treatment in patients with acute lung injury from all cause pneumonia meeting Global ARDS criteria*
- *Landmark advances a first-in-class immune therapy for critical illness where there are no approved mortality-reducing therapies*
- *Preliminary data expected in the second half of 2026*

NEW YORK and LVIV, Ukraine, May 28, 2026 (GLOBE NEWSWIRE) -- [MiNK Therapeutics](#) (NASDAQ: INKT), a clinical-stage biopharmaceutical company pioneering off-the-shelf allogeneic iNKT cell therapies for cancer and immune disorders, today announced that the first patient has been dosed in its randomized Phase 2 clinical trial evaluating agenT-797 with standard of care (SOC) vs placebo with SOC in patients with severe acute lung injury and critical illness.

The first patient was dosed at First Lviv Territorial Medical Union in Lviv, Ukraine, in collaboration with UNBROKEN Ukraine just days after approval from Ministry of health of Ukraine marking the rapid transition from trial activation to treatment administration in a real-world, high-acuity intensive care environment.

The randomized trial, designated C-1300-02, is evaluating agenT-797 plus standard of care compared with placebo plus standard of care in patients with acute lung injury meeting Global Acute Respiratory Distress Syndrome, or ARDS, criteria. The study is designed to evaluate clinically meaningful ICU outcomes, including survival, ventilator-free days, ICU recovery, and biologic measures associated with treatment activity and immune function.

"This milestone marks the advancement of a potentially new therapeutic paradigm for critical illness," said **Jennifer Buell, President and Chief Executive Officer of MiNK Therapeutics**. "Patients with severe lung injury and respiratory failure continue to face extraordinarily high mortality despite modern intensive care. These conditions remain among the largest unresolved challenges in medicine, with no approved therapies demonstrated to reduce mortality. agenT-797 was designed for these moments, delivering an immediately available, donor-derived iNKT cell therapy that can be delivered without patient-specific manufacturing, lymphodepletion, or HLA matching. This milestone also demonstrates the practical feasibility of delivering an off-the-shelf cell therapy into a real-world critical care environment. With treatment now underway, we remain focused on efficient study execution and generating preliminary data by second half of 2026."

Acute lung injury and ARDS remain among the most serious unresolved conditions in critical care, with mortality exceeding 40-50% and no approved therapies shown to reduce mortality.<sup>1</sup> Critically ill patients often deteriorate because severe lung injury can trigger broader immune dysfunction, including impaired pathogen control, infection susceptibility, and organ dysfunction.

"Patients with severe acute lung injury often deteriorate because inflammatory injury, immune exhaustion, infection risk, and respiratory failure become interconnected," said **Terese Hammond, M.D., Head of R&D at MiNK Therapeutics**. "The rapid activation of this trial allows us to evaluate agenT-797 in a real-world, critically ill population where immune restoration may be most meaningful. The study is designed to assess clinically important ICU outcomes, including survival, ventilator-free days, ICU recovery, pathogen control, and secondary infections."

First Lviv Territorial Medical Union serves a high-acuity critical care population, including patients with severe pneumonia, trauma-associated lung injury, infectious complications, and respiratory failure. Clinical care standards are aligned with modern Western intensive care practices, supporting generation of data intended to inform future regulatory pathways in the United States and Europe.

"Physicians in Ukraine are confronting some of the most severe forms of respiratory failure, trauma, infection, and immune dysfunction seen anywhere in the world," said **Dr. Khrystyna Orlynska, MD, Head of the Department of Anesthesiology and Intensive Care and Principal Investigator**. "The initiation of this study provides critically ill patients access to a novel investigational immunotherapy approach and marks the first clinical evaluation of iNKT cell therapy in Ukraine."

"This study reflects the reality of modern critical care medicine, where severe respiratory failure, infection, trauma, and immune dysfunction frequently converge," said **Demian Kalysh, MD, Anesthesiology, Pulmonary Critical Care and Sub-Investigator**. "For physicians caring for patients under these conditions, the ability to evaluate a rapidly deployable off-the-shelf immune restorative therapy in the ICU is both scientifically important and highly meaningful for patients with otherwise limited treatment options."

The trial has received authorization from the Ukraine Ministry of Health and is supported by an active U.S. IND with US site expansion underway. Preliminary data are expected in the second half of 2026.

### 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, agentT-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 to immune restoration applicable across a broad range of conditions. For more information, visit [www.minktherapeutics.com](http://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.

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### **References**

<sup>i</sup> Bellani G, Laffey JG, Pham T, et al. Epidemiology, Patterns of Care, and Mortality for Patients with Acute Respiratory Distress Syndrome in Intensive Care Units in 50 Countries. *JAMA*. 2016;315(8):788–800.



Source: MiNK Therapeutics