Military Health System Research Symposium – 06 August 2026

Randomized Phase 2 of agenT-797 as a Pathogen-Agnostic Treatment of Hypoxemic Pneumonia/ARDS in Austere and Conflict Environments

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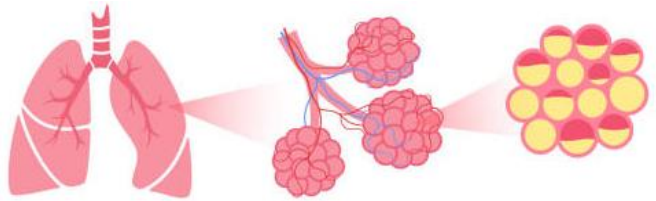
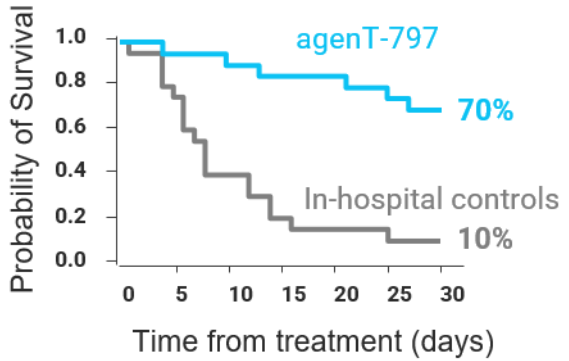
Critical and Pulmonary Illness: Concept of Operations

SMEAC: Situation. Mission. Execution. Administration & Logistics. Command & Signal.

Situation. Incidence of acute respiratory distress syndrome (**ARDS**) post-injury/trauma/illness in conflict zones (i.e. Ukraine) exacerbated by exposure to **MDRO** infections

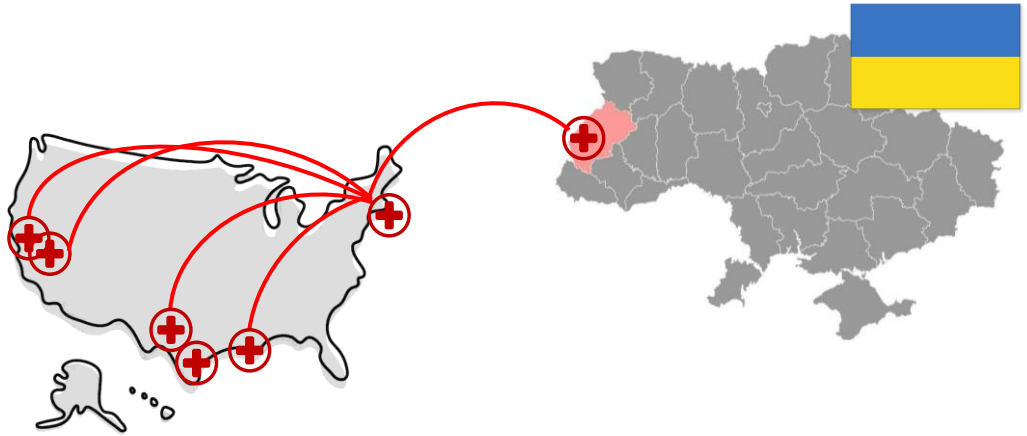


Mission. Restore immune competence with allogenic immune cell therapy, **agenT-797**: pathogen-agnostic, HLA-independent, lymphodepletion-independent therapy in ARDS & severe pneumonia (*Phase 1/2 clinical trial NCT04582201, 2024*)



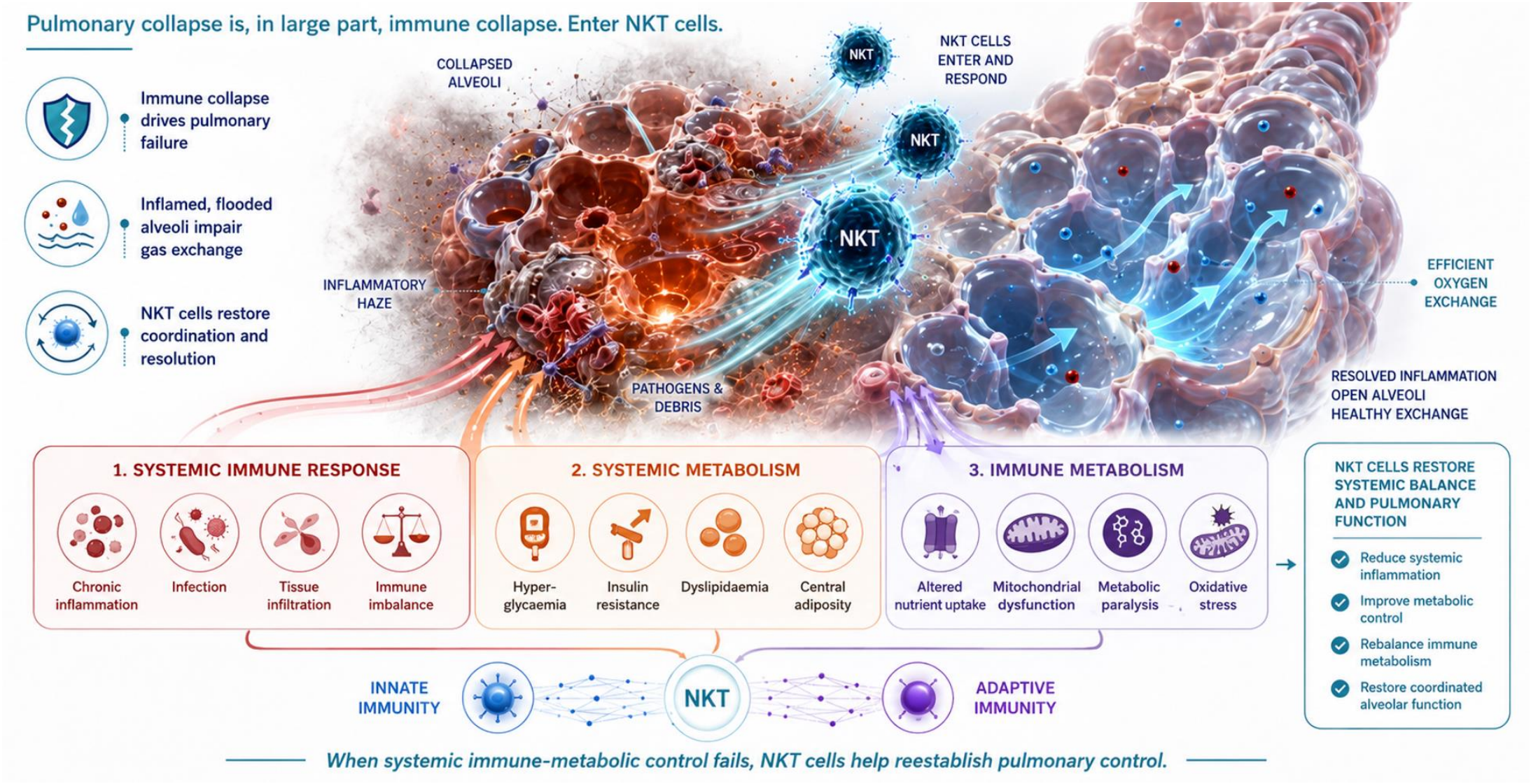
Execution. Phase 2b/3 Study: agenT-797 in severe hypoxemic pneumonia in patients at First Lviv Territorial Medical Union, Lviv, Ukraine

Administration & Logistics: Clinical benefit of agenT-797 shown in first dosed patients, study expansion into U.S. sites upcoming



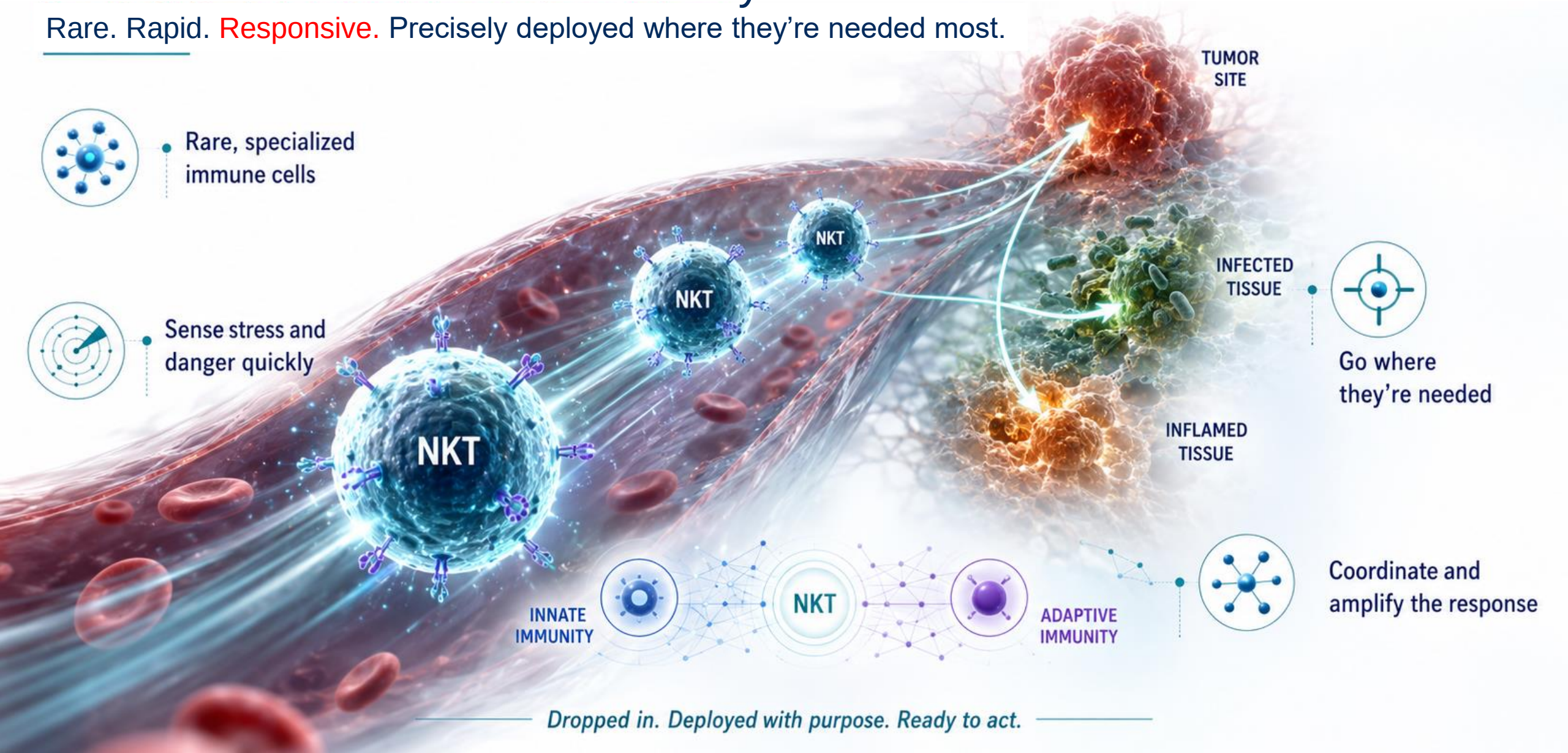
Command & Signal: Early observations and clinical signal clear path for seamless Phase III transition

Warzone in the Alveoli of the Lungs: Consequences of Austere Conditions on War Fighter Immune Systems



Invariant Natural Killer T (iNKT) Cells: Special Forces of the Immune System

Rare. Rapid. Responsive. Precisely deployed where they're needed most.



Trial Design Phase 2b/3 Study: agenT-797 in severe hypoxemic pneumonia

Design: Part 1: Unblinded (n=20); Part 2: Randomized, double-blind, placebo-controlled

Phase: 2b/3 Adaptive (n=80 → n=300)

Population: Severe CAP / ARDS / Fungal Pneumonia · P/F <200 mmHg

Arms: agenT-797 + SOC vs. Placebo + SOC (1:1)

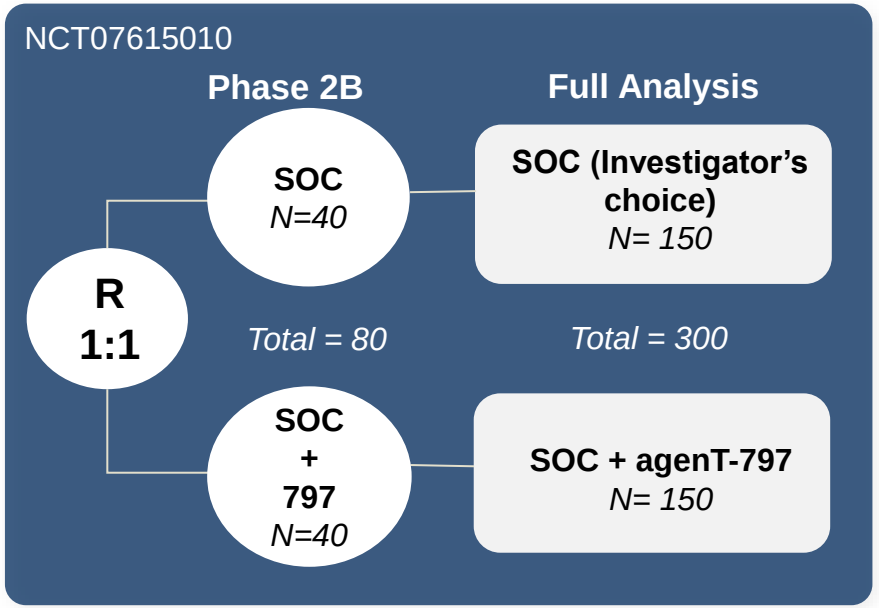
Primary: 28-day all-cause mortality (superiority)

Secondary: VFDs, vasopressor-free days, ICU-free days, SOFA trajectories, pathogen clearance

Interim: n=40: adaptive re-estimation; BTD if >10% absolute mortality reduction

Path: BTD → Phase 3 → BLA · Target filing 2028

NCT07615010
Study Number: C-1300-02



SAB Compromised of World Leaders in Critical Illness/Trauma


Michael Matthay


Michael Harhay


Shibani Pati

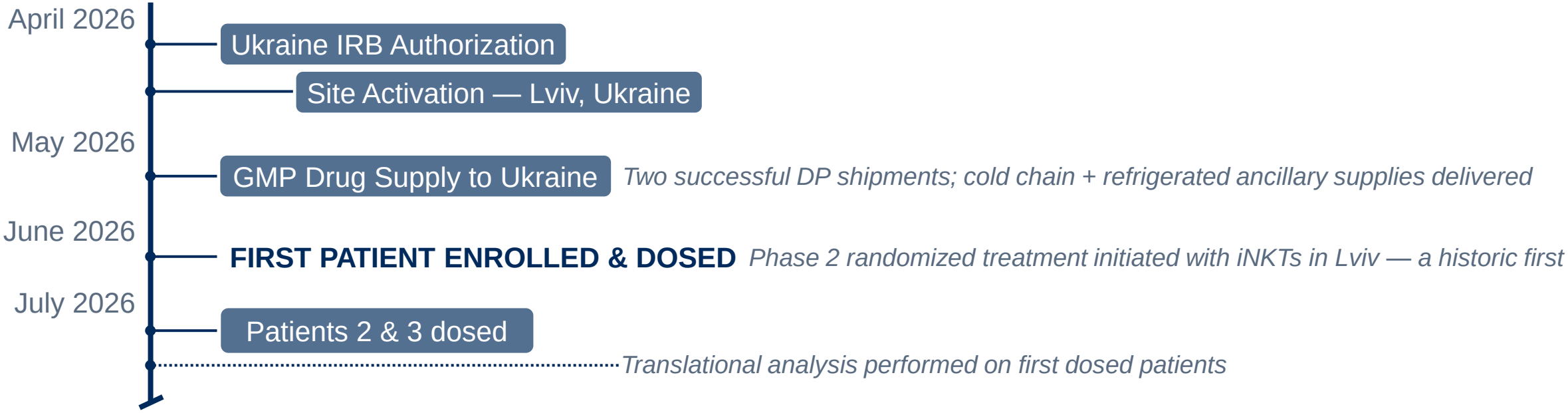

John Holcomb


Terese Hammond

NCT07615010 / C-1300-02

Phase 2b/3 ARDS Trial: Preparation to Execution

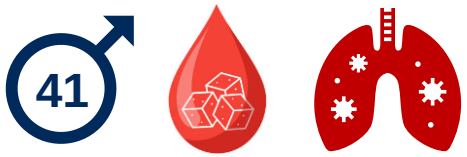
● ACTIVE & DOSING



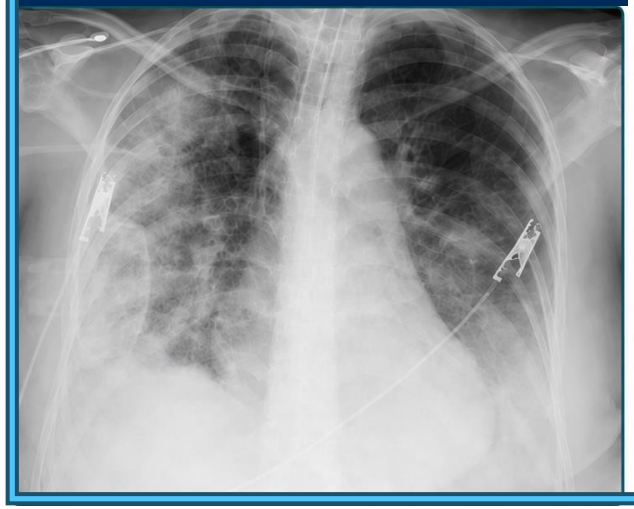
First Treated Patients at First Lviv Territorial Medical Union

Patient 101-001:

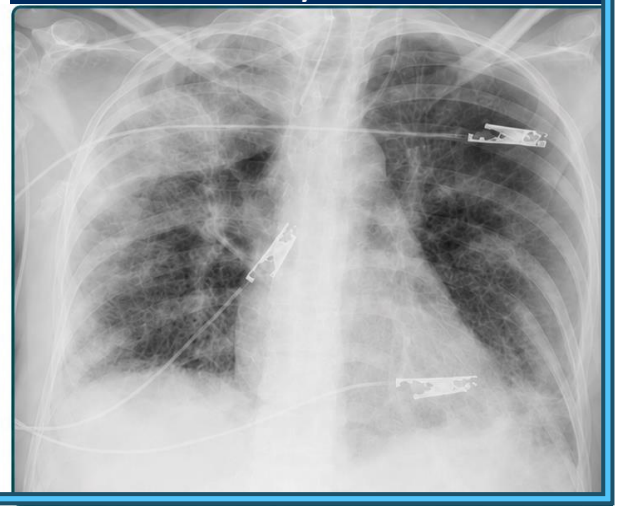
38.6°C



Day 1



Day 21



ICU admission:

- Sputum cultures: S. pneumonia + MDRO Klebsiella, Acinetobacter and pseudomonas
- Ventilator PEEP 12, PaO2 109, 80% FiO2 P/F ratio 136

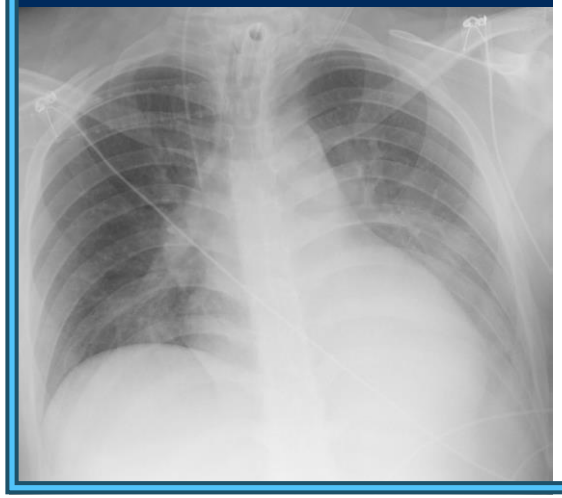
Day 28:

- Alive, afebrile, off pressors, P/F ratio 388

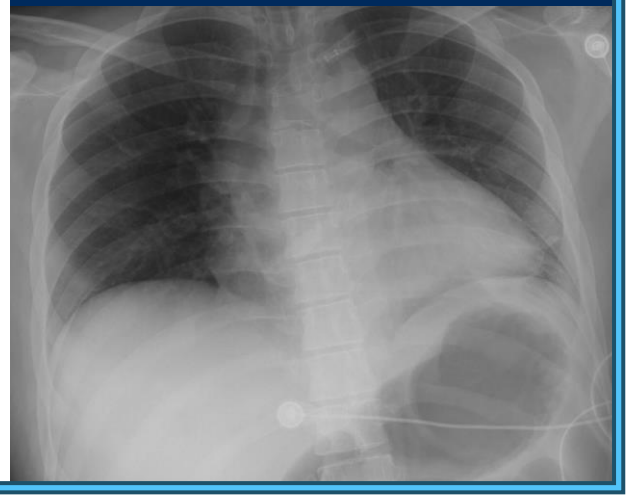
Patient 101-002:

40.1°C

Day 2



Day 26



ICU admission:

- Sputum cultures: MDRO Klebsiella + E. coli
- Ventilator PEEP 10, PaO2 86, 50% FiO2 P/F ratio 172

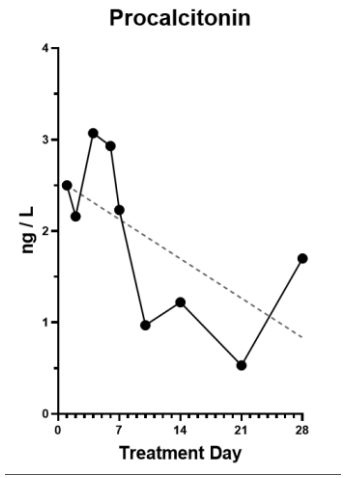
Day 28:

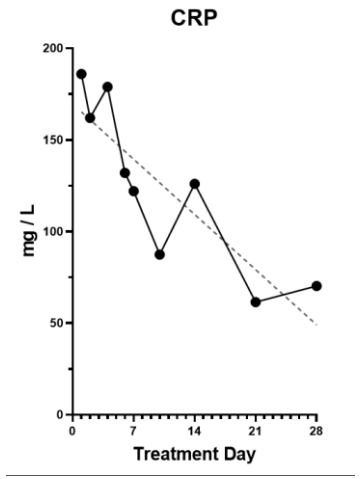
- Alive, afebrile, P/F ratio 467, off ventilator, no new infections → discharged to rehab (post-D28)

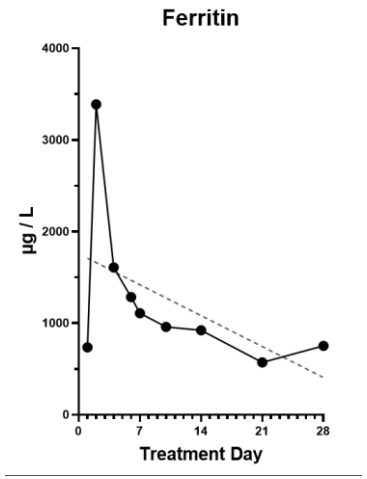
First Treated Patients at First Lviv Territorial Medical Union

101-001

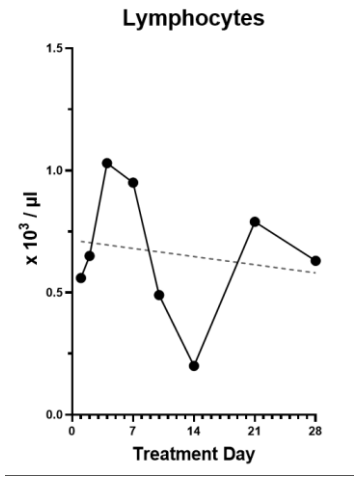
Inflammation resolution



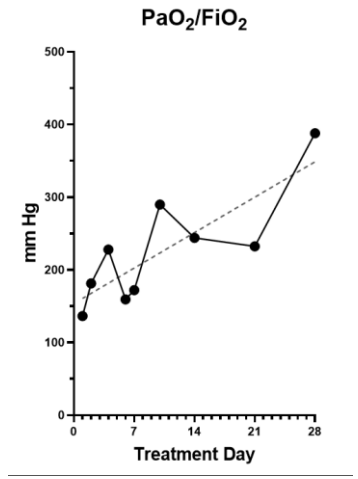




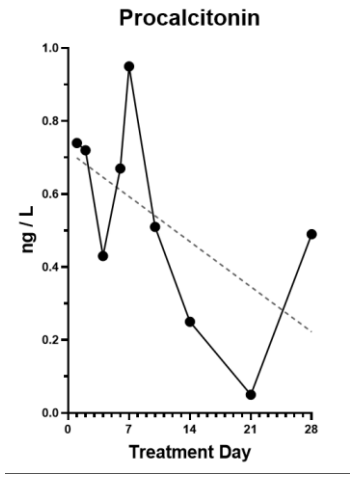
Immune reconstitution

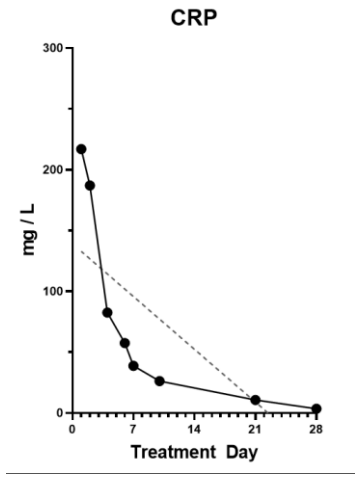


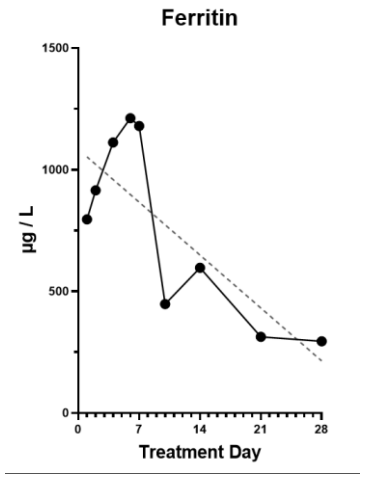
Lung reconstitution

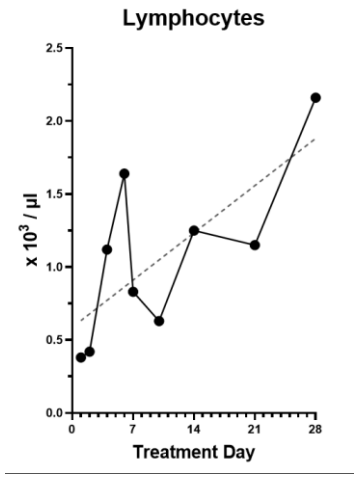


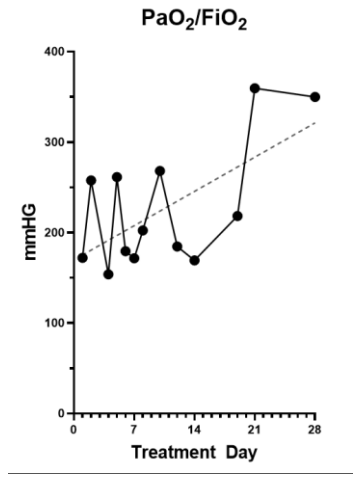
101-002







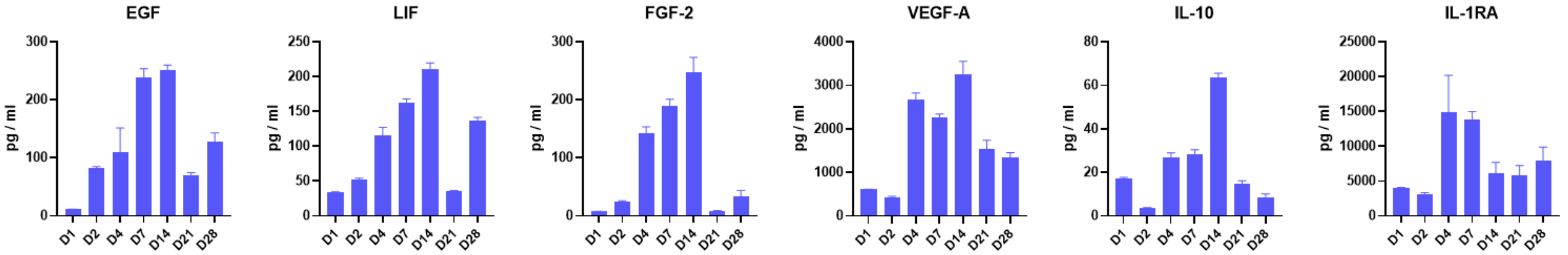




Baseline = Treatment Day 1, pre-infusion

Activation of Pulmonary Repair Pathways

101-001: BAL Biomarker Analysis indicates activation of multiple tissue repair pathways



Epithelial protection / regeneration

Angiogenesis / Post-injury vascularization

Inflammation control / Limiting tissue damage

NCT07615010 / C-1300-02

Phase 2b/3 ARDS Trial: Trial Expansion Ongoing

● ACTIVE & DOSING

April 2026
- Ukraine IRB Authorization
- Site Activation — Lviv, Ukraine

May 2026
- GMP Drug Supply to Ukraine — *Two successful DP shipments; cold chain + refrigerated ancillary supplies delivered*

June 2026
- **FIRST PATIENT ENROLLED & DOSED** — *Phase 2 randomized treatment initiated with iNKTs in Lviv — a historic first*

July 2026
- Patients 2 & 3 dosed
- *Translational analysis performed on first dosed patients*

August 2026
- Continued patient screening and dosing for Phase 2b (n=80)
- *All translational assessments completed for Phase 2b patients*

October 2026
- U.S. Sites begin enrolling patients

March 2027
- **TRANSITION INTO PHASE 3 (n=280)**
- *Interim assessments completed throughout study*

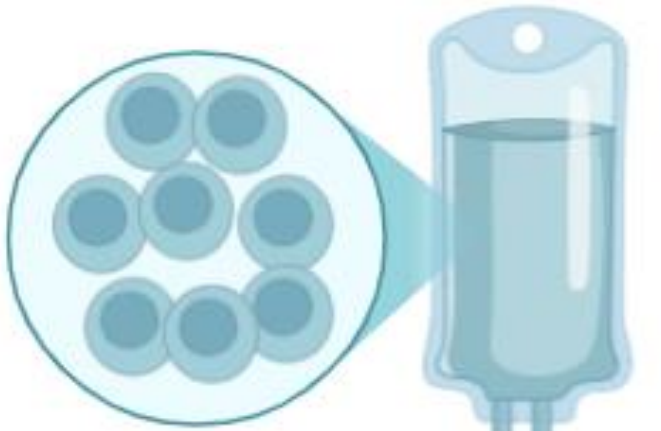
December 2027
- **ENROLLMENT ENDS**

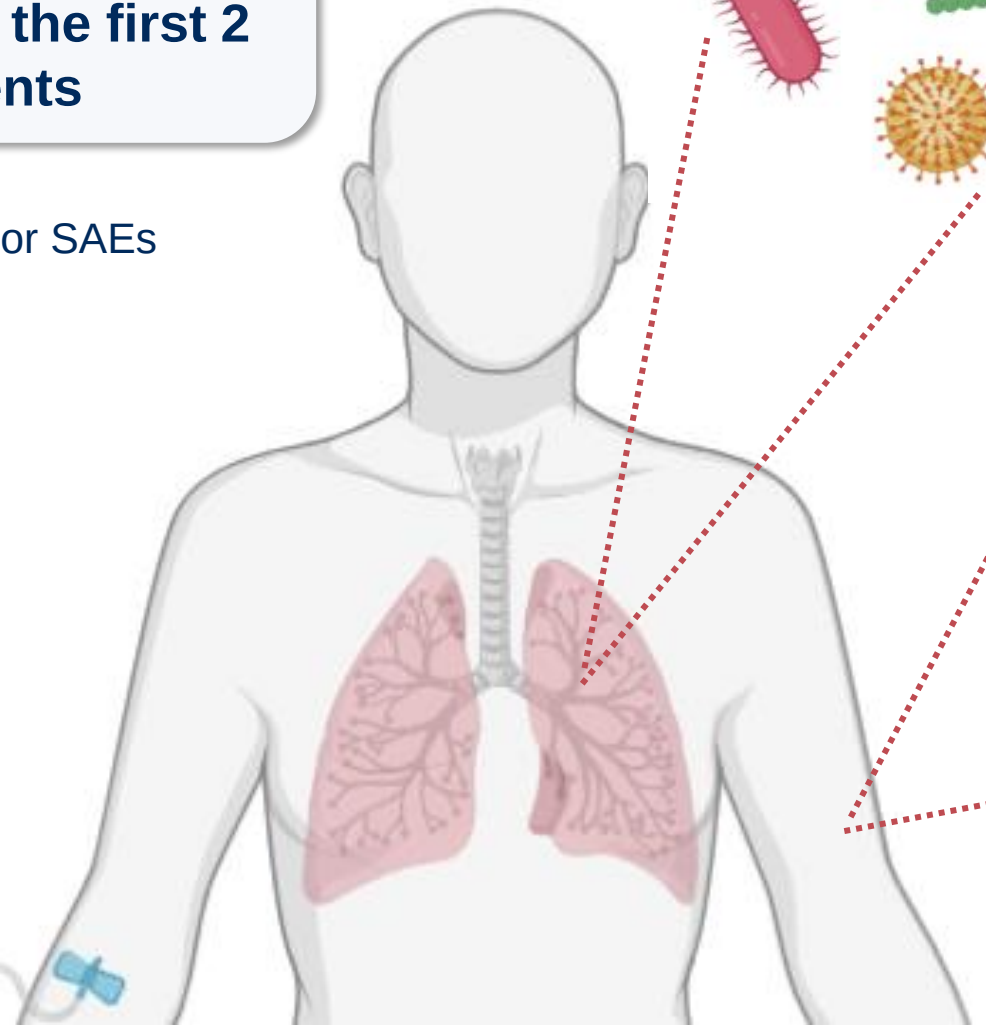
2028
- *All translational assessments completed for Phase 3 patients*

Early Observations of Phase 2b/3 ARDS Mission

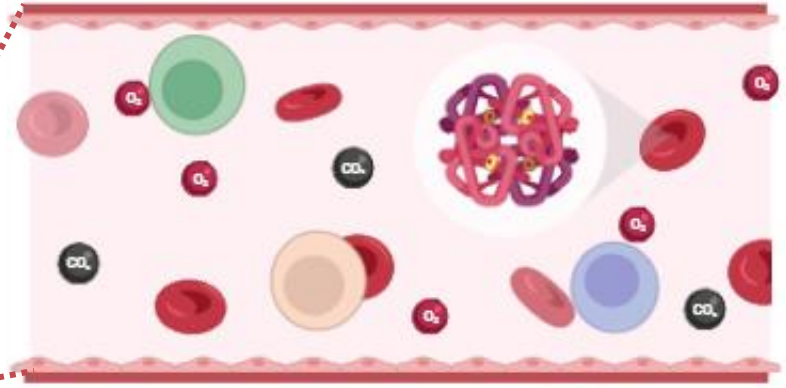
Progressive improvement observed with clear clinical signal & benefit in the first 2 dosed patients

- ✓ Safe, tolerable profile, no major SAEs





- ✓ No development of new infections following agenT-797 infusion
- ✓ Improvement in oxygenation reflected by increased PaO_2/FiO_2 ratios and reduced respiratory impairment
- ✓ Activation of pulmonary repair pathways



- ✓ Decreasing inflammatory markers and evidence of hematologic / lymphocyte recovery

Acknowledgments

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