

Positive DSMB Review in Phase 1/2 Kidney Transplant Trial

Announcement Highlights:

- Independent DSMB review of trial Cohort 1 completed with no safety concerns identified and clearance to proceed to Cohort 2.
- Demonstrates initial safety and tolerability of Cynata's Cymerus™ MSC therapy (CYP-001) in kidney transplant recipients.
- This Phase 1/2 study is managed and funded by Leiden University Medical Centre (LUMC), a global leader in kidney transplantation.
- CYP-001 has potential to address a major unmet need for safer therapies in the kidney transplantation setting.

Melbourne, Australia; 4 December 2025: [Cynata Therapeutics Limited](#) (ASX: "CYP" or "Cynata"), a clinical-stage biotechnology company specialising in cell therapeutics, is pleased to announce that an independent Data and Safety Monitoring Board (DSMB) has completed its planned review of the first cohort of patients treated in the Phase 1/2 NEREID kidney transplant trial.

Independent DSMB oversight plays a critical role in overseeing patient safety and the integrity of ongoing clinical trials.

Summary of DSMB review:

- The first cohort of patients in this trial each received a single intravenous infusion of CYP-001 (Cynata's Cymerus™ iPSC¹-derived MSC² product candidate for intravenous use) approximately six weeks after receiving a kidney transplant, in addition to standard treatment.
- There have been no episodes of kidney transplant rejection in this cohort.
- No safety concerns have been identified:
 - No serious adverse events related to CYP-001 have been reported
 - No donor-specific antibodies have been detected⁵

Dr Jolanta Airey, Cynata's Chief Medical Officer, said: "We are very pleased to receive confirmation from our partners at LUMC that CYP-001 has been safe and well-tolerated in this first cohort of kidney transplant patients. The successful outcome of this first cohort represents the first step in our clinical development program of CYP-001 in kidney transplant recipients. The ultimate aim of this program is to establish CYP-001 treatment as a safe and efficacious alternative to the drugs currently used to prevent rejection of transplanted organs. While these established drugs are quite effective in preventing rejection, they are associated with significant toxicity, including increased risk of serious infections, cancer, diabetes, and kidney damage^{6,7} In light of this, our objective is to determine if CYP-001 can facilitate a safer way to prevent organ transplant rejection."

Kidney transplantation is the preferred treatment for end-stage renal disease, with more than 100,000 procedures performed globally each year.³ Long-term success depends on preventing immune rejection

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— yet existing anti-rejection drugs, while effective, are toxic and can contribute to chronic graft failure, infections, cancer and metabolic complications.^{4,5}

The Phase 1/2 NEREID trial is evaluating CYP-001 as a potential treatment to reduce reliance on long-term immunosuppressant drugs in kidney transplant recipients.

The trial is managed and fully funded by LUMC in the Netherlands — one of Europe’s leading academic hospitals and a recognised global centre of excellence in kidney transplantation and regenerative medicine. The study is led by Professor Ton Rabelink⁶ and Dr Siebe Spijker,⁷ internationally regarded clinical researchers in renal and regenerative medicine.

Following the successful DSMB review, LUMC now plans to progress with Cohort 2 in this trial. This will involve a further three patients, each of whom will receive two infusions of CYP-001, in addition to standard treatment.

-ENDS-

Authorised for release by Dr Kilian Kelly, CEO & Managing Director

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About Cynata Therapeutics (ASX: CYP)

Cynata Therapeutics Limited (ASX: CYP) is an Australian clinical-stage stem cell and regenerative medicine company focused on the development of therapies based on Cymerus™, a proprietary therapeutic stem cell platform technology. Cymerus™ overcomes the challenges and limitations of conventional MSC production by using induced pluripotent stem cells (iPSCs) to achieve economic manufacture of cell therapy products, including mesenchymal stem cells (MSCs), at commercial scale without the necessity to obtain tissue from multiple donors on an ongoing basis, and without the complexity and product inconsistency resulting from conventional methods.

Cynata has demonstrated positive safety and efficacy data for its Cymerus™ product candidates CYP-001 and CYP-006TK in Phase 1 clinical trials in steroid-resistant acute graft versus host disease (GvHD) and diabetic foot ulcers (DFU), respectively. Further clinical trials are now ongoing: a Phase 2 trial of CYP-001 in GvHD under a cleared US FDA IND; a Phase 1/2 trial of CYP-001 in patients undergoing kidney transplantation; and a Phase 3 trial of CYP-004 in osteoarthritis. In addition, Cynata has demonstrated utility of its Cymerus™ technology in preclinical models of numerous other diseases, including critical limb ischaemia, idiopathic pulmonary fibrosis, asthma, heart attack, sepsis, acute respiratory distress syndrome (ARDS) and cytokine release syndrome.

Cynata Therapeutics encourages all current investors to go paperless by registering their details with the designated registry service provider, [Automic Group](#).

¹ iPSC = induced pluripotent stem cell.

² MSC = mesenchymal stem (or stromal) cell.

³ World Health Organization Global Database on Donation and Transplantation.

⁴ Schagen et al. Expert Opinion on Drug Metabolism & Toxicology. 19(7), 429-445 (2023).

⁵ Rodríguez-Perálvarez et al. Am J Transplant. 22(6):1671-1682 (2022).

⁶ Professor of Internal Medicine and Head of the Division of Nephrology and the Department of Internal Medicine at LUMC.

⁷ Internist-nephrologist at LUMC.