

100-Day Primary Evaluation Period Complete in Phase 2 aGvHD Clinical Trial

Melbourne, Australia; 30 March 2026: [Cynata Therapeutics Limited](#) (ASX: "CYP", "Cynata", or the "Company"), a clinical-stage biotechnology company specialising in cell therapeutics, is pleased to announce that the 100-day primary evaluation period has been completed for the last participant enrolled in its Phase 2 clinical trial of CYP-001 in adults with acute graft versus host disease (aGvHD).

As previously announced, a total of 65 participants were enrolled in the randomised, double-blind, placebo-controlled trial, across clinical centres in Australia, the USA and Europe. Each participant was randomised to receive either steroids plus CYP-001, or steroids plus placebo. With the 100-day primary evaluation period now complete for all participants, the trial data is being compiled and analysed. The primary endpoint is Overall Response Rate at Day 28, with results anticipated in June 2026.

Dr Kilian Kelly, Cynata's Chief Executive Officer and Managing Director, said:

"The last patient, last visit in this trial is a significant milestone for the Company. aGvHD remains a devastating condition with very limited treatment options, and we are driven by the hope that CYP-001 can make a meaningful difference to the lives of patients and their families. With the primary evaluation period now complete, we look forward to the data analysis and results readout ahead."

About aGvHD and CYP-001

aGvHD is a serious and often life-threatening complication of bone marrow transplantation and similar procedures, where the donor's immune cells (the graft) attack the recipient's tissues (the host). It affects up to 50% of patients who receive transplants from other donors. Standard first-line treatment with steroids fails in around half of all aGvHD cases, which are known as "steroid-resistant" or SR-aGvHD cases. Historical two-year survival rates in patients with SR-aGvHD are less than 20%.¹

Cynata's Cymerus™ iPSC²-derived MSC³ product for intravenous use, CYP-001, is designed to modulate the immune system and improve both response rates and survival outcomes in aGvHD. In a successful Phase 1 trial in patients with SR-aGvHD, 87% of patients showed an Overall Response, 53% showed a Complete Response, and 60% survived for at least two years. Importantly, there were no serious adverse events or safety concerns related to CYP-001 treatment. This ground-breaking trial led to two publications in the prestigious journal *Nature Medicine*.^{4,5} The US FDA has granted Orphan Drug Designation⁶ to CYP-001 for the treatment of aGvHD.

Clinical Programs Update

Alongside this milestone in the aGvHD program, the Company's broader clinical portfolio continues to advance as planned. Results from the Phase 3 SCULpTOR trial of CYP-004 in osteoarthritis of the knee, which enrolled 321 patients and is being conducted by the University of Sydney, also remain on track for release in Q2 CY 2026. The Phase 1/2 NEREID kidney transplantation trial at Leiden University Medical Centre in the Netherlands is progressing, following a positive independent DSMB review of the first cohort of patients.

Investors are encouraged to visit the Company's [InvestorHub](#), where they can view further information on this announcement.

-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 Westin JR et al. Adv Hematol. 2011;2011:601953

² iPSC = induced pluripotent stem cell.

³ MSC = mesenchymal stem (or stromal) cell.

⁴ Bloor AJC, et al. Nat Med. 2020;26:1720–1725

⁵ Kelly K, et al. Nat Med. 2024;30:1556–1558

⁶ Orphan Drug Designation qualifies Cynata for incentives including extended marketing exclusivity, tax credits and fee waivers.