

CYP-001 Graft Versus Host Disease Trial: Primary Evaluation Results

Melbourne, Australia; 17 June 2026: [Cynata Therapeutics Limited](#) (ASX: “CYP”, “Cynata”, or the “Company”), a clinical-stage biotechnology company specialising in cell therapeutics, has received the primary evaluation results of the Phase 2 clinical trial of CYP-001 in patients with high-risk acute graft versus host disease (HR-aGvHD).

Key Findings:

- There were no safety concerns identified, with a similar adverse event profile between groups.
- There were no significant differences between groups in the primary or key secondary endpoints:

Primary endpoint	Active	Control	P Value ¹
Day 28 Overall Response Rate (ORR)	57.7%	54.8%	>0.9999
Secondary endpoints			
Day 28 Complete Response Rate (CRR)	38.5%	35.5%	>0.9999
Day 100 ORR	23.1%	32.3%	0.5581
Day 100 CRR	19.2%	29.0%	0.5392
Durable ORR (patients with OR at each of Day 28, Day 60 and Day 100)	19.2%	32.3%	0.3681
Day 100 overall survival rate	88.1%	82.3%	0.5137

CYP-001 is Cynata’s Cymerus™ iPSC²-derived MSC³ product for intravenous use. The Phase 2 trial enrolled a total of 65 patients with HR-aGvHD across clinical centres in Australia, the USA and Europe. Patients were randomised to receive either steroids plus CYP-001 (active group) or steroids plus placebo (control group).⁴ A total of 57 patients (26 in the active group and 31 in the control group) were included in the analysis, while the remaining eight randomised patients withdrew from the trial before receiving any investigational product.

The trial includes a 100-day primary evaluation period, which has been completed, and a follow-up period that was anticipated to end in December 2027 (two years after the final patient was enrolled). In light of the primary evaluation results, the Company has made the decision to terminate the trial early.

The Company will remain under voluntary suspension from the ASX pending the results of the Phase 3 SCULpTOR⁵ trial of CYP-004 in patients with osteoarthritis of the knee, which are expected to be announced later this week.

Dr Kilian Kelly, Cynata’s CEO and Managing Director, said:

“We are exceptionally disappointed with this outcome. The results of our Phase 1 clinical trial of CYP-001 in aGvHD were very positive, which had given us strong grounds for optimism, but sadly the Phase 2 results have fallen well short of what we were hoping for. I would like to acknowledge the huge amount of work that went into this trial, by Cynata employees, our service providers, clinical investigators and their teams. Above all, I would like to thank the patients who participated in the trial, and wish all aGvHD patients the very best.”

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

¹ P values were calculated using Fisher's Exact Test for ORR and CRR endpoints, and the Log Rank Test for overall survival.

² iPSC = induced pluripotent stem cell.

³ MSC = mesenchymal stem (or stromal) cell.

⁴ More information on the trial is available at <https://clinicaltrials.gov/study/NCT05643638>

⁵ SCUptOR = Stem Cells as a symptom- and strUcture-modifying Treatment for medial tibiofemoral OsteoaRthritis

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