ASX ANNOUNCEMENT **15 December 2025**

Patient Enrolment Complete in Phase 2 aGvHD Clinical Trial

Announcement Highlights:

- *Patient enrolment has been completed in Cynata's Phase 2 clinical trial of CYP-001 in acute graft versus host disease.*
- *The study has enrolled a total of 65 participants in the US, Europe and Australia, each of whom was randomised to receive either steroids plus CYP-001, or steroids plus placebo.*
- *Primary evaluation period expected to complete in March 2026, with results in June 2026.*
- *CYP-001 has potential to address a major unmet need for the treatment of aGvHD, a life-threatening condition.*

Melbourne, Australia; 15 December 2025: Cynata Therapeutics Limited (ASX: **"CYP"** or **"Cynata"**), a clinical-stage biotechnology company specialising in cell therapeutics, is pleased to announce that patient enrolment has been completed in its Phase 2 clinical trial of CYP-001 in adults with newly diagnosed, high risk acute graft versus host disease (aGvHD).

A total of 65 participants have been enrolled in the trial across numerous clinical centres in Australia, the USA, and Europe. Each participant was randomised to receive either steroids plus CYP-001, or steroids plus placebo.

The trial involves a 100-day primary evaluation period, which is expected to conclude in March 2026, with results anticipated around June 2026. The primary endpoint is Overall Response Rate at Day 28.

Dr Kilian Kelly, Cynata's Chief Executive Officer and Managing Director, said*: "We are delighted to complete patient enrolment in this trial, which has huge importance to Cynata, as well as to patients afflicted with aGvHD, an extremely debilitating and potentially life-threatening disorder. There remains a significant unmet need for safer and more effective treatments, given that existing treatments often fail to prevent poor outcomes, as well as potentially causing serious safety concerns. We are optimistic that the results of this trial will build on the very encouraging results we saw in Phase 1."*

About aGvHD and CYP-001

Acute graft versus host disease (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). aGvHD 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™ iPSC[2]-derived MSC[3] 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] CYP-001 has been granted Orphan Drug Designation[6] by the US FDA for the treatment of aGvHD.

Investors are encouraged to visit the Company's InvestorHub, where they can view a video of Dr Kelly summarising this announcement.

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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.

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[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.