ASX ANNOUNCEMENT **5 March 2024**

First Patient Treated in Phase 2 GvHD Trial

Melbourne, Australia; 5 March 2024: Cynata Therapeutics Limited (ASX: "**CYP", "Cynata",** or the **"Company"**), a clinical-stage biotechnology company specialising in cell therapeutics, confirms that the first patient has been enrolled and treated in its Phase 2 clinical trial of CYP-001 in high-risk acute graft versus host disease (aGvHD).

CYP-001 is Cynata's Cymerus™ off-the-shelf iPSC[1]-derived MSC[2] product candidate for intravenous infusion, which previously generated very encouraging safety and efficacy results in a Phase 1 clinical trial in steroid-resistant aGvHD.[3] The US FDA has cleared an Investigational New Drug (IND) application for CYP-001 and granted the product Orphan Drug Designation[4] for the treatment of aGvHD.

aGvHD is a potentially life-threatening complication of bone marrow transplants or similar procedures. It arises when immune cells in the transplant (the graft) attack the recipient's tissues (the host) as "foreign". In this trial, CYP-001 is being investigated as a potential immune modulating treatment for aGvHD.

This global Phase 2 trial aims to enrol approximately 60 patients with high-risk aGvHD, who will be randomised to receive either steroids plus CYP-001, or steroids plus placebo. Additional details on the trial may be found at clinicaltrials.gov using identifier NCT05643638. The trial has been approved to commence in Australia, the USA and Turkey, and numerous clinical centres across those jurisdictions are now open for recruitment. The first patient was enrolled in the USA.

Dr Kilian Kelly, Cynata's Chief Executive Officer, said:
"The treatment of the first patient in this Phase 2 trial marks a milestone moment in the clinical development journey of CYP-001 for aGVHD. We are continuing to open additional clinical centres, and we anticipate completion of enrolment by the end of this calendar year, with primary results available in the second half of 2025."

-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 of other production methods by using induced pluripotent stem cells (iPSCs) and a precursor cell known as mesenchymoangioblast (MCA) to achieve economic manufacture of cell therapy products, including mesenchymal stem cells (MSCs), at commercial scale without the limitation of multiple donors.

Cynata's lead product candidate CYP-001 met all clinical endpoints and demonstrated positive safety and efficacy data for the treatment of steroid-resistant acute graft-versus-host disease (GvHD) in a Phase 1 trial. A Phase 2 clinical trial in GvHD under a cleared US FDA IND, as well as trials of Cymerus products in osteoarthritis (Phase 3) and diabetic foot ulcers (DFU) are currently ongoing, while a trial in renal transplant is expected to commence in the near future. In addition, Cynata has also demonstrated utility of its Cymerus technology in preclinical models of numerous 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] Bloor AJC, et al. Production, safety and efficacy of iPSC-derived mesenchymal stromal cells in acute steroid-resistant graft versus host disease: a phase I, multicenter, open-label, dose-escalation study. Nat Med. 2020;26(11):1720-1725.
[4] Orphan Drug Designation qualifies Cynata for incentives including extended marketing exclusivity, tax credits and fee waivers.