ASX ANNOUNCEMENT **7 December 2023**

Phase 2 Trial of CYP-001 in aGvHD Approved in Turkey

Melbourne, Australia; 7 December 2023: Cynata Therapeutics Limited (ASX: "**CYP", "Cynata",** or the **"Company"**), a clinical-stage biotechnology company specialising in cell therapeutics, has received regulatory and ethics approval to commence its Phase 2 clinical trial of CYP-001 in patients with High-Risk acute Graft versus Host Disease (HR-aGvHD) at clinical centres in Turkey (Türkiye).

This global trial aims to enrol approximately 60 patients with HR-aGvHD, who will be randomised to receive either steroids plus CYP-001, or steroids plus placebo. 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.[3]

Cynata intends to open multiple clinical centres in Turkey, with the first site initiation visits anticipated within the next 1-2 months. The trial has already opened for recruitment in Australia and the USA.

Dr Jolanta Airey, Cynata's Chief Medical Officer, said:
"We are delighted to receive approval to commence this trial in Turkey, which is a country that we expect will make a substantial contribution to this trial. Start-up activities for this trial continue to progress well, and we remain focussed on our goals of completing patient recruitment by the end of 2024, with primary results expected 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.