ASX ANNOUNCEMENT **2 November 2023**

First Site Initiation Visit in USA Completed in Phase 2 Trial of CYP-001 in aGvHD

Melbourne, Australia; 2 November 2023: Cynata Therapeutics Limited (ASX: "**CYP", "Cynata",** or the **"Company"**), a clinical-stage biotechnology company specialising in cell therapeutics, has initiated the first site in the USA in its Phase 2 clinical trial of CYP-001, in patients with High-Risk acute Graft versus Host Disease (HR-aGvHD).

The Site Initiation Visit has been completed at Weill Cornell Medical Center, New York, which is participating in the trial under the leadership of Professor Tsiporah Shore (Associate Director, Bone Marrow Transplant and Cellular Therapy Program; Vice Chair, Compliance, Department of Medicine; Clinical Director, Inpatient Oncology Operations; and Professor of Clinical Medicine).

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. The trial opened for recruitment in Australia in August 2023. 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]

Dr Jolanta Airey, Cynata's Chief Medical Officer, said:
"In addition to the opening of the initial clinical centres announced so far, we expect to open several more centres in Australia and the USA by the end of this calendar year. In 2024, we plan to open further centres across Europe, Australia and the USA. Our goals are to complete 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.

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[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.