ASX ANNOUNCEMENT 12 April 2023

Cynata Receives Ethics Committee Approval for Proposed aGvHD Phase 2 Clinical Trial

Melbourne, Australia; 12 April 2023: Cynata Therapeutics Limited (ASX: **"CYP"**, **"Cynata"**, or the **"Company"**), a clinical-stage biotechnology company specialising in cell therapeutics, has today announced that it has received approval from the Australian Human Research Ethics Committee (HREC) to commence the proposed Phase 2 clinical trial in acute graft-versus-host disease (aGvHD).

Ethics committee approval is an essential step in the process of opening clinical study sites and to commencing a clinical trial in humans at the proposed Australian study sites. Cynata is currently finalising contractual and logistic arrangements with individual sites (hospitals) to prepare for patient recruitment. This approval follows the landmark clearance by the US FDA of Cynata's Investigational New Drug (IND) application in 2022, the grant of Orphan Drug Status for CYP-001 and Institutional Review Board (IRB) approval in the United States.

The proposed clinical trial titled "*A Multicenter, Randomized, Double-blind, Placebo-Controlled Phase 2 Study to Investigate the Efficacy and Safety of CYP-001 in Combination with Corticosteroids vs Corticosteroids Alone for the Treatment of High-Risk Acute Graft Versus Host Disease*" is expected to be conducted in approximately 60 patients at sites across the U.S., Europe and Australia.

Dr Jolanta Airey, Cynata's Chief Medical Officer, said:

"We continue to make good progress towards commencing a Phase 2 clinical trial in aGvHD, with our expectations being to commence patient recruitment this quarter and to complete our primary evaluation of the trial data in 2024. The proposed clinical trial has a strong foundation given the very promising results achieved in our phase 1 clinical trial of CYP-001 in steroid resistant aGvHD."

-ENDS-

Authorised for release by Dr Ross Macdonald, Managing Director & CEO

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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 (aGvHD) in a Phase 1 trial. Planning for a Phase 2 clinical trial in aGvHD under a cleared US FDA IND is presently underway. Clinical trials of Cymerus products in osteoarthritis (Phase 3) and diabetic foot ulcers (DFU) are currently ongoing. In addition, Cynata has demonstrated utility of its Cymerus technology in preclinical models of numerous diseases, including the clinical targets mentioned above, as well as 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.