ASX ANNOUNCEMENT **20 March 2024**

EU Regulatory and Ethics Approval for Phase 2 Trial of CYP-001 in GvHD

Melbourne, Australia; 20 March 2024: Cynata Therapeutics Limited (ASX: "**CYP**", "**Cynata**", or the "**Company**"), a clinical-stage biotechnology company specialising in cell therapeutics, has received regulatory and ethics approval in the European Union (EU) for 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. The trial has been granted approval under the recently implemented EU Clinical Trials Regulation. Approximately half of the clinical sites selected for the trial are based in the EU (in Spain, France, Italy and Lithuania).

This is the final step in the regulatory and ethics approval process for the trial, which was previously cleared to proceed in the USA, Australia and Turkey. Numerous clinical sites have already opened for recruitment in those jurisdictions, with the first patient enrolled earlier this month.

The 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.

Dr Kilian Kelly, Cynata's Chief Executive Officer, said:
"The successful outcome of this application further underlines the strength of the Company's regulatory dossier, and the global applicability of our technology. As we near the completion of the start-up stage of the project, our team is now focussed on meeting our goals for recruitment."

-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