

Cynata Receives IRB Approval for Proposed aGvHD Phase 2 Clinical Trial

Melbourne, Australia; 30 January 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 to commence the proposed phase 2 clinical trial in acute graft-versus-host disease (aGvHD) from Advarra, Inc., a central Institutional Research Board (IRB) service provider in the USA.

IRB approval is an essential step in the process of opening clinical study sites and to commencing a clinical trial in humans in the United States. Cynata is now finalising contractual and logistic arrangements with individual sites (hospitals) to prepare for patient recruitment. This follows the landmark clearance of Cynata’s Investigational New Drug (IND) application in 2022 and grant of Orphan Drug Status for CYP-001.

The proposed clinical trial is 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*” and is expected to be conducted in around 60 patients at sites in the United States, Europe and Australia.

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

“We are very pleased with this important progress towards commencing a phase 2 clinical trial in this challenging condition. This new study will build on the very promising results achieved in our phase 1 clinical trial of CYP-001 in which all safety and efficacy endpoints were met. In addition to this milestone IRB achievement in the USA, we are continuing to make similar progress in Europe and Australia and are expecting to commence patient recruitment in the coming few months. We aim to complete primary evaluation of the trial data in 2024.”

-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 (GvHD) in a Phase 1 trial. Planning for a Phase 2 clinical trial in GvHD 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.