

## Phase 2 Trial of CYP-001 in aGvHD Open for Recruitment

**Melbourne, Australia; 10 August 2023:** As foreshadowed following the recent strategic review, Cynata Therapeutics Limited (ASX: “CYP”, “Cynata”, or the “Company”), a clinical-stage biotechnology company specialising in cell therapeutics, has opened recruitment in its Phase 2 clinical trial of CYP-001, in patients with High-Risk acute Graft versus Host Disease (HR-aGvHD).

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. This trial is being managed and funded by Cynata.

The first clinical centre to open for recruitment in this trial is Westmead Hospital, Sydney, Australia, under the leadership of Professor David Gottlieb (Director, Blood Transplant & Cell Therapies Program, Westmead Hospital; and Professor of Haematology, The University of Sydney).

**Prof Gottlieb said:**

*“We are very excited to be participating in this important clinical trial and delighted to be the first centre worldwide to open for recruitment. Graft versus host disease is a devastating condition, with limited existing treatment options and often very poor outcomes. We are determined to find more effective and safer treatments for these patients, and we hope that this trial will help us achieve that aim.”*

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

*“Now that we have opened the first clinical centre, our attention turns to opening the rest of the participating centres, and of course enrolling patients as soon as possible. As previously announced, we anticipate completion of enrolment by the end of next year, with primary results expected in the second half of 2025.”*

**Dr Kilian Kelly, Cynata’s Chief Executive Officer & Managing Director, said:**

*“The commencement of this randomised controlled trial – which is being conducted under a US FDA IND – is a major milestone for Cynata. The results of the Phase 1 trial of our unique Cymerus iPSC-derived MSCs in GvHD were outstanding, with very encouraging response and survival rates, and no safety concerns identified. As such, we are optimistic that this new trial will build on the substantial body of data we have generated so far, and ultimately make a difference to the lives of patients suffering from this terrible disease.”*

-ENDS-

**Authorised for release by Dr Kilian Kelly, CEO & Managing Director**

**CONTACTS:** Dr Kilian Kelly, CEO & MD, Cynata Therapeutics, +61 (03) 7067 6940, [kilian.kelly@cynata.com](mailto:kilian.kelly@cynata.com)  
Lauren Nowak, Media Contact, +61 (0)400 434 299, [littlebigdealconsulting@gmail.com](mailto:littlebigdealconsulting@gmail.com)

**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 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, Automatic Group.**