ASX ANNOUNCEMENT **13 December 2023**

Recruitment Completed in Phase 3 SCUlpTOR Osteoarthritis Clinical Trial

Melbourne, Australia; 13 December 2023: Cynata Therapeutics Limited (ASX: "**CYP", "Cynata",** or the **"Company"**), a clinical-stage biotechnology company specialising in cell therapeutics, has been advised by the University of Sydney (USYD) that enrolment of participants in the Phase 3 SCUlpTOR[1] clinical trial of CYP-004 has been completed.

The revised target sample size was surpassed last month, with a total of 321 participants enrolled. In accordance with the study protocol, patients will be followed up for two years, to allow sufficient time for a potential disease modifying effect to be assessed. Consequently, Cynata now anticipates that the last participant visit in this trial will occur around November 2025, with results expected in the first half of 2026.

CYP-004 is Cynata's Cymerus™ off-the-shelf iPSC[2]-derived MSC[3] product candidate for intra-articular injection.[4] This randomised and placebo-controlled trial is being conducted by USYD, with funding provided under an Australian Government National Health and Medical Research Council (NHMRC) project grant. The co-primary endpoints of the trial are (i) the proportion of participants achieving patient-acceptable symptom state (PASS) for knee pain at 24 months; and (ii) central medial femorotibial (cMFT) cartilage thickness change from baseline to 24 months, as assessed by magnetic resonance imaging (MRI).

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

"*We are delighted that recruitment in this trial has been completed. There is a pressing need for safe and effective disease-modifying treatments for osteoarthritis, a debilitating condition affecting a large global adult population with no cure. As such, this trial was designed to evaluate the ability of Cymerus MSCs to affect the two most important outcomes in osteoarthritis: reduction in pain and disease modification. We look forward to receiving the results, which could have substantial influence on clinical practice in the future.*"

Dr Kilian Kelly, Cynata's CEO and MD, said*:*

"The completion of recruitment is a major milestone in any clinical trial, and especially so in a trial of this magnitude and importance. Our Cymerus iPSC-based platform uniquely enables the scalable manufacture of consistent quality off-the-shelf MSCs on an ongoing basis from a single donor, and we are optimistic that this trial will build on the very encouraging body of preclinical and clinical data that we have generated in a range of indications to date."

-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.

[1] SCUlpTOR = Stem Cells as a symptom- and strUcture-modifying Treatment for medial tibiofemoral OsteoaRthritis
[2] iPSC = induced pluripotent stem cell
[3] MSC = mesenchymal stem (or stromal) cell
[4] Intra-articular injection = injection into a joint

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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