ASX ANNOUNCEMENT **6 November 2023**

Phase 3 SCUlpTOR Osteoarthritis Clinical Trial Progress

Patient Recruitment Expected to Complete This Month (November 2023)

Melbourne, Australia; 6 November 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) of the following updates on the ongoing Phase 3 SCUlpTOR[1] clinical trial of CYP-004:

Key Highlights

- The independent Data Safety and Monitoring Board (DSMB) for the trial has completed a review of the study progress and interim accumulating safety data. It concluded that there are no ongoing concerns and recommended that the trial continue.
- Following a review by the study statistician, which took into account the lower than expected dropout rate observed thus far, the target sample size has been reduced to a minimum of 320 patients. The independent DSMB confirmed that it considers this decision to be acceptable.
- The revised target sample size has already been reached, and consequently patient recruitment is expected to close by the end of this month (November 2023).

CYP-004 is Cynata's Cymerus™ off-the-shelf iPSC[2]-derived MSC[3] product candidate for intra-articular injection,[4] and this randomised and placebo-controlled trial is being conducted in patients suffering from osteoarthritis of the knee.

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

"*We believe the revised sample size provides sufficient statistical power to achieve the objectives of this study, and is commensurate with other trials of this nature, so we endorse this decision by the USYD team. Importantly, this means that completion of recruitment – and by extension expected delivery of results – should occur sooner than previously anticipated. It is also reassuring that the DSMB has no concerns with the data, a finding that is consistent with our prior experience with Cymerus MSCs.*"

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. The trial is being undertaken by USYD, with funding provided under an Australian Government National Health and Medical Research Council (NHMRC) project grant.

-ENDS-

Authorised for release by Dr Kilian Kelly, 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.

[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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