

## Clinical Pipeline Update Following Strategic Portfolio Review

**Melbourne, Australia; 12 August 2022:** Cynata Therapeutics Limited (ASX: “CYP”, “Cynata”, or the “Company”), a clinical-stage biotechnology company specialising in cell therapeutics, has conducted a strategic review of its clinical development pipeline to ensure the portfolio maximises the commercial opportunities and is optimised to deliver shareholder value. Given the ongoing recruitment activities in the Phase 3 osteoarthritis trial and Phase 2 diabetic foot ulcer (DFU) trial, as well as the recent IND clearance for a proposed Phase 2 acute graft-versus-host disease (aGvHD), the Company has decided to prioritise resources towards these initiatives and conclude the current MEND respiratory distress clinical trial.

The MEND clinical trial commenced in August 2020 and enrolled the first patient in May 2021, initially targeting patients admitted to ICU with COVID-19 (later expanded to respiratory distress). Although patient recruitment was strong at first, the changing nature of the COVID-19 pandemic together with continuous pressure on healthcare systems, created delays in recruitment as hospitals experienced staffing shortages and prioritised conventional standards of care over clinical trials. In addition, the introduction of new antiviral drugs and rapid uptake of COVID vaccines meant fewer patients migrating to ICU, further reducing the pool of eligible patients. Cynata proactively implemented several initiatives since the trial opened to adapt to changing clinical circumstances in an effort to achieve timely completion (such as including additional clinical sites). With substantial changes in patient outcomes among the target population and an evolving clinical environment impacting eligible patient numbers, together with broader challenges in the healthcare system in Australia, it has become apparent that recruitment would remain unpredictable and behind target rate. Given the uncertainty surrounding timely patient recruitment, continuation was considered to be imprudent, particularly in light of the other promising indications within the portfolio. The trial will therefore be concluded with minimal further expenditure relating only to trial close-out activities.

**Dr Ross Macdonald, Cynata’s Chief Executive Officer, said:**

*“We operate in a highly dynamic environment and the situation around the MEND clinical trial has certainly exhibited a fast-moving landscape. The widespread uptake of COVID-19 and influenza vaccines, availability of new antiviral drugs, along with vastly improved patient management practices in our target population, have had very significant effects on the trial and the availability of eligible patients. These effects have had to be factored into our plans to ensure an optimal risk profile and allocation of resources across our clinical pipeline. Our strategic portfolio review was intended to ensure that we focus the application of resources on only the most viable opportunities and continuing to pursue the MEND trial no longer had alignment with that goal. The decision allows us to refocus our resources on, and maintain our commitment to, our other promising clinical programs.”*

-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.**