ASX ANNOUNCEMENT 30 December 2020

2020 Review and Outlook

Melbourne, Australia; 30 December 2020: Cynata Therapeutics Limited (ASX: "**CYP", "Cynata",** or the **"Company"**), a clinical-stage biotechnology company specialising in cell therapeutics, is pleased to provide investors with an end-of-year review and an outlook update, from Dr Ross Macdonald, CEO and MD of Cynata:

Dear Shareholders,

2020 has been a significant year for Cynata, and I would like to take the time to reflect on the progress made and provide an outlook for the year ahead. At Cynata, we are very pleased with the achievements made and excited by our expanded clinical development pipeline and the promising opportunities in the year ahead.

While the healthcare industry faced significant challenges from the global COVID-19 pandemic, I am pleased that Cynata has significantly advanced its leadership position in regenerative medicine and in particular the development of cell therapies derived from induced pluripotent stem cells (iPSCs).

2020 Key Highlights:

- Received ethics approval and expedited regulatory pathway of our Phase 3 osteoarthritis trial, which recently commenced in November 2020
- Received rapid ethics approval to commence a clinical trial in intensive care patients with COVID-19 in Australia – currently open for enrolment
- Received UK / AUS regulatory approval to commence a Phase 2 trial in critical limb ischemia
- Completed 2-year follow up with excellent results in the Phase 1 graft-versus-host disease (GvHD) trial, with Phase 1 clinical trial results published in prestigious journal, *Nature Medicine* and our Cymerus™ technology featured on the front cover
- Continued to work with licensee FUJIFILM towards a further GvHD clinical trial
- Successfully raised funds to expand the clinical development pipeline, enhance process development and progress regulatory strategy for commercialisation
- Significant validation of our platform and expanded pipeline from healthcare investor BioScience Managers, who corner-stoned the recent institutional share placement through the BioScience Managers Translation Fund I
- Completed further pre-clinical programs with positive results, providing a broad pipeline of future opportunities and further validating the potential therapeutic utility of the Cymerus technology

In addition, this year we have further strengthened our Board, bolstered our financial position, and have now emerged in a robust position to progress key clinical trials with the lifting of pandemic restrictions.

Looking forward, we have a broad and attractive pipeline of clinical development plans. The multiple trials currently active will advance, including those led by Cynata, by FUJIFILM (for GvHD), and in collaboration with universities. In addition, we will focus on developing clinical programs for the new

high priority targets of idiopathic pulmonary fibrosis, renal transplantation, and diabetic foot ulcers, leveraging the encouraging pre-clinical data generated.

The osteoarthritis phase 3 trial is currently underway with initial subjects having received their first doses of study treatments. This will be a 440-patient study in patients with osteoarthritis of the knee, and it will showcase Cynata's ability to consistently manufacture potent MSCs at scale. The market opportunity in osteoarthritis alone is huge, estimated at US$11.6bn. We look forward to progressing this trial through 2021 with our collaborator, the University of Sydney.

The clinical trial in COVID-19 patients is open for recruitment in Australia. This is targeting patients with COVID-19 admitted to the Intensive Care Unit (ICU) with compromised lung function, such as respiratory distress. Respiratory distress represents a significant unmet need as a consequence of a severe COVID-19 infection, as well as other causes well beyond COVID-19. The underlying disorders that we are ultimately looking to address include acute respiratory distress syndrome (ARDS), cytokine release syndrome (CRS) and sepsis – all of which may occur in serious COVID-19 disease, and disorders for which we have previously generated highly encouraging pre-clinical results. This year provided an opportunity to rapidly receive ethics approval to commence a clinical trial in an area of significant unmet need in COVID-19 patients and beyond, and we are now actively progressing opportunities to accelerate recruitment.

We remain confident our platform iPSC-derived mesenchymal stem cell (MSC) manufacturing technology, Cymerus, is a truly commercially viable solution to the current MSC manufacturing challenges. The commercial opportunity for MSCs is compelling, with a growing amount of pre-clinical and clinical evidence supporting the role of MSCs in tissue repair and regeneration, and as well as in mitigating disease severity. Further regulatory approvals for MSC therapeutic products are expected in the coming years, thereby increasing the demand for MSCs, which will focus attention on the current manufacturing issues faced by all other MSC-based companies in their efforts to produce commercial quantities of product.

Cymerus provides consistently high quality and potent MSCs from a single blood donation. The absolute requirement for product consistency has been brought into focus by the US Food and Drug Administration (FDA) this year, further cementing Cynata's unique competitive advantage and underpinning our confidence in the platform.

In summary, we conclude 2020 being incredibly well positioned, with multiple active clinical trials, a broad clinical development pipeline, and significant validation and endorsement having been achieved during the year. We look forward to achieving further milestones in 2021, and updating you on the developments in due course.

On behalf of the Cynata Board and Management, thank you all for your continued interest and support in Cynata and we wish you all a happy holiday season.

Yours sincerely,

Ross Macdonald
CEO & MD

-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. Cynata has active clinical trials, using its Cymerus™ MSCs for a Phase 3 trial is osteoarthritis and a Phase 2 trial in severe complications arising from COVID-19. Cynata plans to advance into trials for GvHD (through licensee Fujifilm) and critical limb ischemia. Cynata is planning for additional clinical programs in further indications (including idiopathic pulmonary fibrosis, renal transplantation, and diabetic foot ulcers), following encouraging pre-clinical data. In addition, Cynata has demonstrated utility of its Cymerus™ MSC technology in preclinical models of asthma, diabetic wounds, heart attack, sepsis, acute respiratory distress syndrome (ARDS) and cytokine release syndrome.

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