ASX ANNOUNCEMENT 24 May 2021

First Patient Enrolled in Cynata's MEND Clinical Trial

Melbourne, Australia; 24 May 2021: Cynata Therapeutics Limited (ASX: "**CYP", "Cynata",** or the **"Company"**), a clinical-stage biotechnology company specialising in cell therapeutics, has today announced that the first patient has been enrolled in its MEND (MEseNchymal coviD-19) clinical trial. Originally designed to recruit COVID-19 patients admitted to intensive care with respiratory distress the study was expanded in late March this year to include patients in intensive care with respiratory failure resulting from causes beyond COVID-19.

Key highlights

- **First patient with respiratory failure enrolled in Cynata's MEND clinical trial**
- **Trial to investigate early efficacy of Cynata's Cymerus™ mesenchymal stem cells (MSCs) in patients with respiratory failure, who meet the well-established criteria for Acute Respiratory Distress Syndrome (ARDS)**
- **Respiratory failure/distress (including ARDS) is a severe and life-threatening illness, representing a major unmet medical need**
- **Trial cements Cynata's world-leading position in the development of next generation commercially scalable stem cell products**

Dr. Kilian Kelly, Cynata's COO, said:
"Commencing this clinical trial is a major milestone for Cynata and our proprietary Cymerus MSC technology. The trial will allow us to investigate the potential benefits our MSCs could have in the treatment of these severely ill patients in dire need.

Our proprietary Cymerus manufacturing platform, which utilises an induced pluripotent stem cell (iPSC) bank sourced from a single blood donation from one donor, eliminates the reliance upon multiple donors and the need to excessively expand MSCs derived from them. Cynata is truly at the forefront of the industry with a sustainable and scalable manufacturing process for therapeutic MCS products."

A total of 24 adult patients are expected to participate in the trial being conducted at centres in New South Wales and Victoria in collaboration with the Cerebral Palsy Alliance Research Institute and investigators from the COVID-19 Stem Cell Treatment (CSCT) Group.

The study is an open-label, randomised controlled clinical trial to investigate early efficacy of Cymerus MSCs in patients admitted to intensive care with respiratory distress. Twelve patients will be randomised to receive Cymerus MSC infusions, in addition to standard of care, while 12 patients will be randomised to the control group and will receive current standard of care only. The primary efficacy endpoint will be trajectory of PaO_2/FiO_2 ratio (a measure of hypoxemia, a low level of oxygen in the blood caused by compromised lung function) by Day 7. Safety and tolerability up to Day 28 will also be a primary endpoint. Results from the trial could demonstrate potential relevance in several diseases including ARDS, Cytokine Release Syndrome (CRS) and sepsis.

Respiratory failure or distress (including ARDS) is a severe and life-threatening illness, representing a major unmet medical need. ARDS is an inflammatory process leading to build-up of fluid in the lungs due to infection, trauma and inhalation of noxious substances, with no specific pharmacological treatment options currently available. ARDS accounts for 10% of all ICU admissions and ~25% of patients require mechanical

ventilation, with hospital mortality up to 46%[1]. The combined market opportunity of ARDS, together with CRS and Sepsis, is estimated to be over US$8 billion[2].

-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. Clinical trials of Cymerus MSC products in osteoarthritis (Phase 3) and in patients with respiratory failure are currently ongoing. Planning is also underway for further clinical trials of Cymerus MSC products in GvHD (through licensee Fujifilm), critical limb ischemia, idiopathic pulmonary fibrosis, renal transplantation, and diabetic foot ulcers. In addition, Cynata has demonstrated utility of its Cymerus MSC technology in preclinical models of numerous diseases, including the clinical targets mentioned above, as well as asthma, heart attack, sepsis, acute respiratory distress syndrome (ARDS) and cytokine release syndrome.

[1] Bellani G, Laffey JG, Pham T, et al. Epidemiology, Patterns of Care, and Mortality for Patients With Acute Respiratory Distress Syndrome in Intensive Care Units in 50 Countries. Jama. 2016;315(8):788

[2] Vasomune Therapeutics company announcement, 2018 (Reflects ARDS global market opportunity of US$2.5bn); GlobeNewswire, 2020 (Represents CRS global market opportunity of US$0.16m in 2017); GlobalData 2017 (Reflects Sepsis global market opportunity of US$5.9bn in 2026).