

Patient Enrolment Opens in COVID-19 Clinical Trial

Melbourne, Australia; 24 August 2020: Cynata Therapeutics Limited (ASX: CYP), a leading clinical-stage biotechnology company specialising in cell therapeutics, is pleased to announce that the MEND (MEseNchymal covid-19) Trial is now open for patient enrolment. Following ethics committee approval (as announced on 8 May 2020), this important step represents the formal commencement of this clinical trial. The MEND Trial will investigate early efficacy of Cynata's proprietary Cymerus™ mesenchymal stem cells (MSCs) in adults admitted to intensive care with COVID-19.

Dr. Kilian Kelly, Cynata's COO, said:

"The opening of enrolment of this clinical trial is a major achievement for Cynata. The trial builds on the solid pre-clinical foundations for the use of our Cymerus MSC technology in respiratory diseases, including acute respiratory distress syndrome (ARDS), as well as cytokine release syndrome and sepsis, all of which are hallmarks of critically ill COVID-19 patients."

"Cynata's proprietary Cymerus technology uniquely enables the manufacture at scale of a consistent and robust MSC product without the substantial functional heterogeneity, i.e. lack of consistency, that has been observed between MSC batches derived from different donors. We look forward to advancing this clinical trial to investigate the potential benefits our MSCs could have to treat patients in dire need during this global pandemic."

-ENDS-

Authorised for release by Dr Ross Macdonald, Managing Director & CEO

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About the MEND Trial

The MEND Trial is to be conducted at centres in New South Wales in collaboration with the Cerebral Palsy Alliance Research Institute and investigators from the COVID-19 Stem Cell Treatment (CSCT) Group. The study will be an open-label, randomised controlled clinical trial to investigate early efficacy of Cymerus MSCs in 24 adult patients admitted to intensive care with COVID-19 and 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. The primary efficacy endpoint will be improvement in PaO₂/FiO₂ 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.

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 plans to advance its Cymerus™ MSCs into Phase 2 trials for severe complications arising from COVID-19, GvHD, critical limb ischemia and into a Phase 3 trial for osteoarthritis. 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.