

Successful Completion of Planned DSMB Review of Cynata's MEND Clinical Trial

Key highlights

- A planned Data Safety Monitoring Board (DSMB) review of Cynata's MEND clinical trial has been successfully completed
- DSMB recommends MEND clinical trial continue unchanged
- The MEND clinical trial is investigating the safety and early efficacy of Cynata's mesenchymal stem cell (MSC) product in patients admitted to an ICU with respiratory failure, who meet the 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

Melbourne, Australia; 8 October 2021: Cynata Therapeutics Limited (ASX: "CYP" or "Cynata"), a clinical-stage biotechnology company specialising in cell therapeutics, has today announced the successful completion of a planned, routine review of the MEND clinical trial by the independent DSMB. The DSMB has recommended that the clinical trial continue as planned.

A review by an independent DSMB is consistent with good clinical practice in clinical trials. The primary responsibilities of the DSMB are to review and evaluate the available study data for participant safety, study conduct and progress, and to make recommendations concerning the continuation, modification, or termination of the trial. The study protocol for the MEND clinical trial includes oversight by a DSMB as well as provision for an interim review, which has now been successfully completed.

Dr Kilian Kelly, Cynata's Chief Operating Officer, said:

"We thank the members of the independent DSMB for completing this important review. The DSMB's positive recommendation is an important milestone, which enables us to continue patient enrolment in the MEND clinical trial and advance toward our goal of completing the trial later this year."

-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 is presently underway. Clinical trials of Cymerus products in osteoarthritis (Phase 3) and in patients with respiratory failure 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 asthma, heart attack, sepsis, acute respiratory distress syndrome (ARDS) and cytokine release syndrome.

About the MEND Clinical Trial

The MEND Trial is 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 24 adult patients admitted to intensive care with respiratory failure. 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.

Cynata Therapeutics encourages all current investors to go paperless by registering their details with the designated registry service provider, Automic Group.