Cymerus™ MSCs Effective in Preclinical Model of Sepsis

Melbourne, Australia; 5 December 2019: Australian stem cell and regenerative medicine company, Cynata Therapeutics Limited (ASX: CYP), announced today that it has received positive efficacy data from preclinical studies of its Cymerus™ mesenchymal stem cells (MSCs) in a model of sepsis. Sepsis, sometimes referred to as blood poisoning, is a life-threatening condition that arises from the body’s response to an infection or injury.

**Key Highlights**

- In a preclinical model of severe pneumonia-induced sepsis, Cymerus MSC treatment:
  - Increased blood oxygen levels
  - Increased lung compliance (the ability of lungs to stretch and expand)
  - Decreased alveolar neutrophil infiltration (which can lead to lung injury)
  - Decreased barrier permeability (which allows harmful proteins into the lungs)
  - Decreased inflammation

- The extent of each of the above benefits was statistically significant in comparison to a placebo control.

- Positive trends were also observed in a preclinical model of mild pneumonia-induced sepsis.

- Cymerus MSCs were also shown to enhance phagocytosis, both directly and indirectly. Phagocytosis is the process by which white blood cells ingest and remove bacteria and other harmful agents from the body.

The studies were performed under Cynata’s development partnership with RCSI (the Royal College of Surgeons in Ireland), under the leadership of Professor Gerard Curley, Chair of the Department of Anaesthesia and Critical Care at RCSI, and Consultant in Intensive Care Medicine at Beaumont Hospital, Dublin. This partnership, which was announced in July 2018, is co-funded by Cynata and RCSI under the RCSI Strategic Industry Partnership Seed Fund.

Sepsis is a major medical challenge and is the most common cause of death in hospital Intensive Care Units – implicated in 1 in 20 deaths in the population as a whole and up to 50 percent of all hospital deaths.1

Professor Curley said, “There is a critical need for new therapies to treat sepsis, which is a devastating condition that can affect people at any stage of life without warning. These exciting results give us grounds for optimism that Cymerus MSCs could provide a new treatment option for these patients.”

Dr Kilian Kelly, Cynata’s Chief Operating Officer, said, “There is an enormous unmet medical need associated with sepsis, which existing treatments are not capable of addressing. Professor Curley’s results are highly encouraging, and we believe the data can support progression to a clinical trial in patients with sepsis. These latest results build on our broad preclinical database across a range of commercial opportunities, including asthma, heart disease and diabetes complications, in addition to our very successful clinical trial in GvHD.”
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 GvHD, critical limb ischemia and osteoarthritis. In addition, Cynata has demonstrated utility of its Cymerus MSC technology in preclinical models of asthma, diabetic wounds, heart attack and cytokine release syndrome, a life-threatening condition stemming from cancer immunotherapy.