ASX ANNOUNCEMENT **15 November 2017**

Enrolment of First Cohort Completed with Eighth Participant Dosed in Cynata's World First Clinical Trial

Melbourne, Australia; 15 November 2017: Australian stem cell and regenerative medicine company, Cynata Therapeutics Limited (ASX: CYP), is pleased to provide an update on the progress of the clinical trial of its lead Cymerus™ mesenchymal stem cell (MSC) product CYP-001.

Key Highlights

- Eighth participant dosed in Cynata's world first clinical trial of CYP-001 for the treatment of steroid-resistant graft-versus-host-disease (GvHD)
- Enrolment of Cohort A represents the half-way point in trial recruitment of a potential total of 16 participants
- The Company is pleased to reach this key milestone in the clinical development of MSCs produced using its Cymerus platform
- Independent Data Safety Monitoring Board (DSMB) review will be triggered once this patient reaches Day 28

Clinical Trial: Significant Milestone Achieved

Enrolment of the first cohort (Cohort A) is now complete. Participants in Cohort A received two CYP-001 infusions each at the lower dose level (1 million cells/kg, up to a maximum of 100 million cells per infusion). In accordance with the clinical trial protocol, once the final participant in Cohort A reaches Day 28 (28 days after the first CYP-001 infusion), it will trigger a review by the independent Data Safety and Monitoring Board (DSMB).

The DSMB is an expert advisory group, commissioned to ensure objective and independent review of participant safety during the conduct of this trial. The DSMB will review all available data, including response to treatment, usage of other medications, results of safety laboratory tests, adverse events and participant withdrawals (if applicable). The DSMB will then make one of the following recommendations:

(i) proceed with enrolment of participants into Cohort B, according to the current protocol, or;
(ii) amend the protocol prior to commencing enrolment of participants into Cohort B; or
(iii) end the study without enrolling participants into Cohort B.

The Company will announce the outcome of the DSMB review once it is known. In Cohort B, it is planned that a further eight participants would receive two CYP-001 infusions each at the higher dose level (2 million cells/kg, up to a maximum of 200 million cells per infusion).

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"The completion of enrolment of the first cohort of participants in this ground-breaking trial is a significant milestone for Cynata, and we're very much looking forward to receiving details of the interim data, and the DSMB's recommendation", said Dr Kilian Kelly, Cynata's Vice President, Product Development.

Ends

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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 that is developing a therapeutic stem cell platform technology, Cymerus™, originating from the University of Wisconsin-Madison, a world leader in stem cell research. The proprietary Cymerus™ technology addresses a critical shortcoming in existing methods of production of mesenchymal stem cells (MSCs) for therapeutic use, which is the ability to achieve economic manufacture at commercial scale. Cymerus™ utilises induced pluripotent stem cells (iPSCs) to produce a particular type of MSC precursor, called a mesenchymoangioblast (MCA). The Cymerus™ platform provides a source of MSCs that is independent of donor limitations and provides an "off-the-shelf" stem cell platform for therapeutic product use, with a pharmaceutical product business model and economies of scale. This has the potential to create a new standard in the emergent arena of stem cell therapeutics and provides both a unique differentiator and an important competitive position.

About the Phase 1 clinical trial (Protocol Number: CYP-GvHD-P1-01)

The trial is entitled "*An Open-Label Phase 1 Study to Investigate the Safety and Efficacy of CYP-001 for the Treatment of Adults With Steroid-Resistant Acute Graft Versus Host Disease*". Participants must be adults who have undergone an allogeneic haematopoietic stem cell transplant (HSCT) to treat a haematological (blood) disorder and subsequently been diagnosed with steroid-resistant Grade II-IV GvHD. The first eight participants will be enrolled in Cohort A and receive two infusions of CYP-001 at a dose of 1 million cells per kilogram of body weight (cells/kg), up to a maximum dose of 100 million cells. There will be one week between the two CYP-001 infusions in each participant. The next eight participants will be enrolled into Cohort B and receive two infusions of CYP 001 at a dose of 2 million cells/kg, up to a maximum dose of 200 million cells. The primary objective of the trial is to assess safety and tolerability, while the secondary objective is to evaluate the efficacy of two infusions of CYP-001 in adults with steroid-resistant GvHD. The primary evaluation period will conclude 100 days after the first dose in each participant. Efficacy will be assessed on the basis of response to treatment (as determined by change in GvHD Grade) and overall survival at 28 and 100 days after the administration of the first dose. After the completion of the primary evaluation period, participants will enter a longer term non-interventional follow-up period, which will continue for up to two years after the initial dose.