ASX ANNOUNCEMENT **13 December 2016**

Cynata Receives NHS HRA Approval for Clinical Study

- National Health Service (NHS) Health Research Authority (HRA) approves Cynata's graft-versus-host disease (GvHD) clinical study
- World first study using allogeneic, iPSC-derived therapeutic product

Melbourne, Australia; 13 December 2016: Australian stem cell and regenerative medicine company, Cynata Therapeutics Limited (ASX: CYP), has received approval from the NHS HRA for its Phase 1 clinical trial in patients with steroid-resistant acute GvHD.

Cynata has selected five leading NHS hospitals in England to participate in this clinical trial, which involves its lead Cymerus™ mesenchymal stem cell (MSC) product, CYP-001.

HRA Approval is a recently introduced process, which encompasses the assessment of governance and legal compliance for any clinical trial that will be conducted at NHS centres in England. As previously communicated, Cynata had already received authorisation from the UK Medicines and Healthcare products Regulatory Agency (MHRA) and Research Ethics Committee (REC), so all approvals required prior to the commencement of patient recruitment at NHS centres are now in place.

Cynata Vice President, Product Development Dr Kilian Kelly said, "We are very pleased to have completed the final administrative step required prior to patient recruitment at NHS centres. We are now working on initiating these centres and getting recruitment underway as soon as possible. Meanwhile, we anticipate being in a position to open Australian sites in the near future as well."

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About Cynata Therapeutics (ASX: CYP)

Cynata Therapeutics Limited (ASX: CYP) is an Australian 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 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 patient. 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. 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. Participants will also be followed up for up to two years under a separate non-interventional study protocol.

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