ASX ANNOUNCEMENT **19 September 2016**

UK Regulatory Authority Approves Cynata GvHD Clinical Trial

- UK regulatory authority MHRA approves Phase 1 trial with Cymerus™ MSCs
- World first clinical trial with allogeneic iPSC-derived product
- Major milestone for stem cell therapeutics and regenerative medicine
- Cements Cynata's global leadership in second generation MSC therapeutics

Melbourne, Australia; 19 September 2016: Australian stem cell and regenerative medicine company, Cynata Therapeutics Limited (ASX: CYP) has received approval from the UK Medicines and Healthcare products Regulatory Agency (MHRA) to proceed with its Phase 1 clinical trial of CYP-001 in patients with steroid-resistant graft-versus-host disease (GvHD). CYP-001 is Cynata's lead Cymerus™ mesenchymal stem cell (MSC) product.

Cynata plans to conduct the Phase 1 clinical trial, which 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*", at a number of leading clinical centres in the UK and Australia. Additional centres in other jurisdictions are also being considered. The trial will aim to recruit approximately 16 participants who have undergone a bone marrow transplant or similar procedure, and were subsequently diagnosed with steroid-resistant Grade II-IV acute GvHD.

The Company believes that this will be the world's first clinical trial involving a therapeutic product derived from allogeneic induced pluripotent stem cells (iPSCs). Pluripotent stem cells are the most versatile cells of all, having the ability to reproduce themselves indefinitely, and also differentiate into any other type of cell in the body. iPSCs have very similar characteristics to embryonic stem cells (ESCs), but without the ethical controversies associated with ESCs, since they are derived from adult cells rather than from embryos. There has been enormous interest globally in the development of iPSC-derived therapies for a number of years. This trial represents a major milestone in the field of regenerative medicine. Results from the clinical trial will provide further insight into the use of Cynata's proprietary technology for the potential treatment of various diseases.

"We are delighted that the MHRA has approved our clinical trial. Not only does this enable us to start providing our highly promising therapy to patients with a particularly devastating disease, it also provides clear validation of our manufacturing process and preclinical development program, from one of the most highly regarded regulatory authorities worldwide," said Cynata Vice President of Product Development, Dr Kilian Kelly.

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Cynata's Chief Executive Officer and Managing Director, Dr Ross Macdonald, said, "The MHRA approval, combined with Cynata's developing business relationships with FUJIFILM and with apceth, cements the Company's commercial and technical leadership in second generation MSC technologies and it sets Cynata on a path to sustainable success."

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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.