ASX ANNOUNCEMENT **15 December 2016**

Cynata's Clinical Study Approved in Australia

- Australian Human Research Ethics Committee (HREC) approves Cynata's graft-versus-host disease (GvHD) clinical study
- World first study using allogeneic, iPSC-derived therapeutic product

Melbourne, Australia; 15 December 2016: Australian stem cell and regenerative medicine company, Cynata Therapeutics Limited (ASX: CYP), has received approval from the Royal Adelaide Hospital HREC for its Phase 1 clinical trial of CYP-001 in patients with steroid-resistant acute GvHD.

Royal Adelaide Hospital is one of two leading hospitals in Australia that Cynata has selected to participate in this clinical trial with its lead Cymerus™ mesenchymal stem cell (MSC) product.

The Royal Adelaide Hospital HREC is acting as the lead HREC for both Australian centres in this trial, which has been approved under the Australian Clinical Trial Notification (CTN) scheme. The CTN process involves review and approval by a HREC, along with notification to the Therapeutic Goods Administration (TGA). The notification for this trial has already been submitted and acknowledged by the TGA, so the regulatory and ethics approval process for this trial in Australia is now complete.

Cynata Vice President, Product Development Dr Kilian Kelly said, "We are delighted to have received approval for this trial in Australia, to add to the previously announced approval in the UK. We are now working on the initiation of recruitment in both countries."

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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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