ASX ANNOUNCEMENT **28 January 2016**

Cynata Receives Favourable Advice from UK Regulatory Authority

- *Clear path to commence clinical program determined*
- *World-first allogenic iPSC-derived mesenchymal stem cell product*
- *Initial clinical trial with Cymerus™ MSCs to take place in EU/Australia*
- *Ground-breaking trial on track to commence in second quarter 2016*

Melbourne, Australia; 28 January 2016: Australian stem cell and regenerative medicine company, Cynata Therapeutics Limited (ASX: CYP), has received favourable advice from the UK Medicines and Healthcare products Regulatory Agency (MHRA), following a successful scientific advice meeting, which took place earlier this month.

The MHRA confirmed that Cynata's proprietary Cymerus™ mesenchymal stem cell (MSC) product, CYP-001, is considered to be suitable for use in a proposed Phase 1 clinical trial in patients with graft versus host disease. Additionally, the MHRA advised that Cynata's existing program of preclinical studies is expected to be sufficient to support the approval of the proposed clinical trial, and that no additional preclinical studies are required. The MHRA also agreed with the general design of the proposed clinical trial.

On the basis of this advice, Cynata can now confirm that it intends to conduct the clinical trial at centres in the European Union, including the United Kingdom, and Australia. Additional countries in the EU will be confirmed following the completion of further interactions with the relevant regulatory authorities in those jurisdictions. The trial remains on track to commence during the second quarter of 2016.

In parallel to these regulatory interactions, the process of identifying and selecting clinical centres for the study has been ongoing. A number of high profile investigators at leading institutions have expressed interest in participating in the study, and Cynata expects to formally select the investigators/centres by the end of the first quarter of this year.

"We are delighted that one of the world's most respected and experienced regulatory authorities has provided such a favourable assessment of the Cymerus™ technology. This reinforces the view that we had formed previously, that regulators in key jurisdictions are comfortable in principle with the progression of iPSC-derived therapies into human clinical trials", said Dr Kilian Kelly, Cynata's Vice President, Product Development. "We look forward to confirming the participating sites and proceeding with Clinical Trial Applications (CTA) for this ground-breaking clinical trial in the near future."

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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™ does so through the production of a particular type of MSC precursor, called a mesenchymoangioblast (MCA). The Cymerus™ MCA platform provides a source of MSCs that is independent of donor limitations and provides a potential "off-the-shelf" stem cell platform for therapeutic product use, with a pharmaceutical 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 EU Regulatory Process

CYP-001 is regulated as an Advanced Therapy Medicinal Product (ATMP) in the EU. Responsibility for approving a Marketing Authorisation for ATMPs lies with the European Medicines Agency (EMA), but responsibility for approving clinical trials lies with the national regulatory authorities within the individual EU Member States where the clinical trial will take place. Cynata has previously received Scientific Advice from the EMA, which focussed on the longer term development of the product in the context of expectations for Marketing Authorisation. This latest regulatory advice from the UK national regulatory authority (MHRA) was focussed on the proposed Phase 1 clinical trial.