



**ASX ANNOUNCEMENT**

**1 August 2016**

## **Cynata Files Application to Commence Phase 1 Clinical Trial**

**Melbourne, Australia; 1 August 2016:** Australian stem cell and regenerative medicine company, Cynata Therapeutics Limited (ASX: CYP), announced that it has filed a Clinical Trial Authorisation application for its lead Cymerus™ mesenchymal stem cell (MSC) product, with the UK Medicines and Healthcare products Regulatory Agency (MHRA). The proposed Phase 1 study will be conducted in patients with graft-versus-host disease (GvHD), a potentially fatal disease that often follows a bone marrow transplant procedure and occurs when the immune cells in the donor material (the graft) attack the recipient's tissues (the host) as "foreign". Bone marrow transplants are used in the treatment of certain cancers including leukaemia. The application to the MHRA follows a successful scientific advice meeting which took place earlier this year.

"The application to commence our Phase 1 study with the MHRA represents the culmination of an intensive program of manufacturing process development, safety evaluation and proof-of-concept studies. The successful outcomes from our product development activities over the past two-and-a-half years have allowed us to move things forward," said Cynata Vice President of Product Development, Dr Kilian Kelly. "We have been very pleased with the result of our pre-clinical program and are eager to advance to an initial clinical study with our induced pluripotent stem cell (iPSC) derived MSC therapeutic product, CYP-001."

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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.

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