



ASX ANNOUNCEMENT

21 June 2016

Cynata Prepares for Phase 1 Clinical Trial

Melbourne, Australia; 21 June 2016: Australian stem cell and regenerative medicine company, Cynata Therapeutics Limited (ASX: CYP), announced that it intends to file an application for regulatory approval with the UK Medicines and Healthcare products Regulatory Agency (MHRA) for a Phase 1 clinical trial of CYP-001 in July 2016. Cynata's Phase 1 clinical trial application process advanced after a highly successful scientific advice meeting with the MHRA earlier this year. CYP-001 is Cynata's lead Cymerus™ mesenchymal stem cell (MSC) product and the Phase 1 trial will be conducted in patients with steroid-resistant graft-versus-host disease (GvHD).

The Company is currently preparing its clinical trial application and expects to receive additional data within the coming weeks from the proof of concept (PoC) study of CYP-001 progressing at the University of Massachusetts Amherst (UMass), USA. This PoC study is assessing the response to CYP-001 in animals with an experimental form of severe GvHD. Interim data announced in April demonstrated that CYP-001 treatment resulted in a strong, statistically significant, survival benefit in the study animals and confirmed biological activity of the Cymerus MSC product. The additional data for the MHRA application process is expected to provide a more robust data package for clinical trial approval.

"The pre-clinical product development program has been a success, with considerable credit due to Dr Kilian Kelly, Cynata's VP of Product Development," said Cynata CEO and Managing Director Dr Ross Macdonald. "We are on track with our plans to file the clinical trial application in the UK and with that, the Company is approaching a very important, value accretive milestone in the development of Cynata's unique and proprietary MSC technology, Cymerus". The Company intends to further update the market once the clinical trial application has been submitted.

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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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