



ASX ANNOUNCEMENT

5 May 2016

Cynata Commences Manufacture of Clinical Trial Product; Files Further Patent Application

- Commencement of manufacture of CYP-001 product supplies for upcoming clinical trial
- Follows series of successful manufacturing qualification runs
- Further patent protection for proprietary Cymerus™ mesenchymal stem cell (MSC) technology

Melbourne, Australia; 5 May 2016: Australian stem cell and regenerative medicine company, Cynata Therapeutics Limited (ASX: CYP), announced today that its contract manufacturer in the USA, Waisman Biomanufacturing, has commenced manufacture of supplies of CYP-001 product for specific use in the clinical trial in graft-versus-host disease (GvHD), expected to commence within the next few months.

Manufacture of the clinical trial batch of CYP-001 was initiated following the successful conclusion of a lengthy and intensive series of good manufacturing practice (GMP) manufacturing qualification runs. These qualification runs were conducted multiple times over the course of the past year in a rigorous program which determined that product of consistent, high quality could be derived using the Company's unique Cymerus process.

The Company also announced that it had filed a further patent application describing certain novel aspects of the Cymerus technology. This patent application is owned by Cynata and, should it mature to a granted patent, will provide additional commercial exclusivity in key markets around the world. The new discovery will add further value to the Cymerus technology that clears a path toward low cost, cutting edge MSC therapy.

"The production of the clinical trial batch of CYP-001 is a very important step for Cynata. It follows the major achievement last year of transferring the original laboratory process to Waisman and up-scaling it in a GMP environment. The product derived from the qualification runs has provided abundant material for the pre-clinical program that has been underway for around 12 months; now we will complete that phase with the manufacture of our clinical trial batch", said Dr Kilian Kelly, Cynata's Vice President of Product Development.

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About CYP-001

CYP-001 is Cynata's lead therapeutic product, an allogeneic, induced pluripotent stem cell (iPSC)-derived MSC. Cynata plans to undertake a Phase 1 clinical trial with CYP-001 in graft-versus-host disease (GvHD) before undertaking development for further disease targets, ideally in collaboration with commercial partners.

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.

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