ASX ANNOUNCEMENT **19 April 2017**

Cynata Advances to Pre-IND Meeting with US FDA

- Initiates formal regulatory engagement for the US market
- Follows earlier informal FDA interactions and builds on approvals in the UK and Australia to commence Phase I Clinical Trials for graft-versus-host disease (GvHD)
- Potential for accelerated product approval under USA "21st Century Cures Act"

Melbourne, Australia; 19 April 2017: Australian stem cell and regenerative medicine company, Cynata Therapeutics Limited (ASX: CYP), has been granted a pre-Investigational New Drug (IND) meeting with the United States Food and Drug Administration (FDA) Office of Cell, Tissue and Gene Therapy products, to discuss the regulatory approval path for Cynata's proprietary Cymerus™ mesenchymal stem cell (MSC) products in the USA.

The meeting will also include a discussion on the process for seeking "Regenerative Medicine Advanced Therapy" (RMAT) designation for Cynata's lead MSC product, CYP-001, in the treatment of graft-versus-host disease (GvHD).

RMAT designation is an initiative that arose from the 21st Century Cures Act, which recently came into law in the USA. Companies with RMAT designated products are entitled to avail of additional and earlier interactions with the FDA and to seek priority review and accelerated approval for the relevant product(s). Cynata expects to receive the FDA's written advice arising from the pre-IND meeting by July 2017.

"This formal meeting with the FDA gives us a valuable opportunity to ensure that our development programs address US regulatory expectations. This will build on the numerous constructive discussions we have had with key regulatory agencies worldwide before now, including previous informal interactions with the FDA. Our recently commenced Phase 1 clinical trial is currently recruiting patients in the UK and Australia, and we plan to include clinical centres in other countries, including the USA, as our development programs progress. Consequently, it is important for us to continue to engage with the FDA and other regulatory authorities in parallel to the conduct of our initial trial," said Dr Kilian Kelly, Cynata's Vice President, Product Development.

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About Cynata Therapeutics (ASX: CYP)

Cynata Therapeutics Limited (ASX: CYP) is an Australian clinical stage 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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