ASX ANNOUNCEMENT **5 July 2017**

FDA Meeting Provides Clear Path for Cynata US Development Plans

- Cynata Pre-IND meeting with the US FDA completed successfully
- FDA confirms Cymerus™ manufacturing dossier meets expectations
- Clear path determined for preclinical and clinical protocol requirements for product development in US
- Potential to take advantage of fast-track provisions under the new 21st Century Cures Act

Melbourne, Australia; 5 July 2017: Australian stem cell and regenerative medicine company, Cynata Therapeutics Limited (ASX: CYP), has received written advice from the United States Food and Drug Administration (FDA) regarding the regulatory approval path for Cynata's proprietary Cymerus™ mesenchymal stem cell (MSC) products in the US. This advice follows a pre-Investigational New Drug (pre-IND) meeting (announced 19 April 2017), which Cynata recently held with the FDA's Office of Cellular, Tissue and Gene Therapies.

The FDA confirmed that the scope and substance of Cynata's "Chemistry, Manufacturing and Controls" (CMC) dossier is commensurate with its expectations, which indicates that Cymerus™ MSC products are expected to be of suitable quality for clinical trial use in the US.

Cynata received clarification on the design of preclinical studies required to support a US IND, and anticipates conducting those studies in parallel with the ongoing clinical trial of CYP-001 for the treatment of graft-versus-host disease (GvHD) being conducted in the United Kingdom and Australia. The FDA also provided advice regarding the protocol for a planned GvHD clinical trial in the US.

Additionally, the FDA clarified that Cynata may submit a request for "Regenerative Medicine Advanced Therapy" (RMAT) designation for its CYP-001 product to treat GvHD once preliminary results of the world first clinical trial are available, assuming those results support such a request. RMAT designation is an initiative that arose from the 21st Century Cures Act, which recently came into law in the US. The initiative allows companies with RMAT designated products to avail of additional and earlier interactions with the FDA and to seek priority review and accelerated approval.

"The pre-IND meeting was an enormously valuable exercise for Cynata. The outcome of the meeting was very positive, and we are optimistic that we will be able to open an IND and include clinical centres in the US in future trials," said Dr Kilian Kelly, Cynata's Vice President, Product Development." "This will be an important step in the commercial development of CYP-001 in the world's largest market for pharmaceutical products".

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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 developing therapies based on its proprietary Cymerus™ stem cell technology platform. Cymerus overcomes critical issues in the production of therapeutic mesenchymal stem cells (MSCs) by enabling the economical manufacture of commercial-scale MSCs, independent of multi-donor limitations. Cymerus' novel approach utilises induced pluripotent stem cells (iPSCs) derived from a single blood donation to generate mesenchymoangioblasts (MCAs), a precursor that is used to manufacture an unlimited number of therapeutic MSCs. Cynata's unique "off-the-shelf" Cymerus platform has the potential to create a new standard in the development and manufacture of stem cell therapeutics.