31 August 2017



ASX ANNOUNCEMENT

Health Canada Meeting Advances Cynata's Global Development Plans

- Successful meeting between Cynata and Health Canada to discuss development of Cymerus™ MSCs as a therapeutic product
- Health Canada agreed that the Cymerus manufacturing dossier meets expectations
- Preclinical expectations consistent with recent advice from US FDA
- Cynata expects to be able to include Canadian sites in future clinical trials

Melbourne, Australia; 31 August 2017: Australian stem cell and regenerative medicine company, Cynata Therapeutics Limited (ASX: CYP), has completed a successful and informative meeting with the Canadian regulatory authority, Health Canada, regarding the clinical development of Cynata's proprietary Cymerus mesenchymal stem cell (MSC) products in Canada.

Health Canada agreed in principle that the unique Cymerus process, including donor screening and testing, the induced pluripotent stem cell (iPSC) derivation process and the manufacture and testing of the final product, meets its expectations for a product entering clinical trials.

Cynata also received clarification from Health Canada on the design of preclinical studies required to support a Clinical Trial Application in Canada. This advice was consistent with that recently obtained from the US FDA (announced on 5 July 2017).

"Although we have already gained approval for our Phase 1 trial of CYP-001 in patients with acute GvHD in the UK and Australia, we feel it is important to continue consultations with regulatory authorities in other key jurisdictions. Our objective is to ensure that there is a clear path for global clinical development of Cymerus products, for both Cynata and our partners," said Dr Kilian Kelly, Cynata's Vice President, Product Development. "The input from Health Canada was extremely helpful, and we are confident that we will be in a position to include Canadian sites in future clinical trials of Cymerus MSCs".

Ends

CONTACTS: Dr Ross Macdonald, CEO, 0412 119343, <u>ross.macdonald@cynata.com</u> Daniel Paproth, Australia Media Contact, 0421 858 982 , <u>daniel.paproth@mcpartners.com.au</u> Laura Bagby, U.S. Media Contact, 312-448-8098, <u>lbagby@6degreespr.com</u>

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.

Cynata Therapeutics Limited Level 3, 62 Lygon Street, Carlton, Victoria 3053, Australia PO Box 7165, Hawthorn North, Victoria 3122 T: + 613 9824 5254 F: + 613 9822 7735 E: admin@cynata.com ABN - 98 104 037 372