

Cynata Advances to Official Meeting with Japanese Regulatory Agency, PMDA

- Initiates regulatory engagement in Japan
- Important advance toward eventual commercialisation in the Japan market
- Meeting led by Cynata partner FUJIFILM Group

Melbourne, Australia; 3 September 2018: Australian stem cell and regenerative medicine company, Cynata Therapeutics Limited (ASX: CYP), is pleased to announce that it has participated in a Pre-Development Meeting with the Japan Pharmaceuticals and Medical Devices Agency (PMDA), to discuss the regulatory approval path for Cynata's proprietary Cymerus™ mesenchymal stem cell (MSC) products in Japan. The meeting was led by FUJIFILM group.

Cynata's Cymerus MSCs are derived using a proprietary process from induced pluripotent stem cells (iPSCs). The original iPSC line was derived from FUJIFILM Cellular Dynamics, Inc.

"The meeting with the PMDA provided Cynata with valuable information about the Japanese regulatory framework for our unique Cymerus™ therapeutic mesenchymal stem cell (MSC) product for graft-versus-host disease, CYP-001, as well as for our broader product portfolio. This will build on the numerous constructive discussions we have had with key regulatory agencies worldwide before now, including a successful pre-IND meeting with the US FDA. This meeting and further engagement with the PMDA will facilitate planning for a clinical development program in Japan. The very promising safety and efficacy results so far from our current Phase 1 clinical trial in GvHD were an important data point in this official meeting," 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). Cymerus provides a source of MSCs that is independent of donor limitations and 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.