

**ASX ANNOUNCEMENT**

***Cynata Announces Progress on Cymerus™ Mesenchymal Stem Cell Product Development Activities***

**Melbourne, Australia; 21 May 2015:** Stem cell and regenerative medicine company, Cynata Therapeutics Ltd (ASX: CYP), is pleased to provide a progress report on the development of its lead Cymerus™ mesenchymal stem cell (MSC) product, CYP-001. The product development program is occurring in parallel with the Company's business development and partnering activities.

Product Manufacture:

Following successful completion of process validation and technology transfer to a good manufacturing practice (GMP) environment at Waisman Biomanufacturing, the Company recently announced the commencement, at Waisman, of a further stage of manufacture-related activities. These activities are focused on manufacturing quantities of cells and on ensuring that the Cymerus MSC manufacturing process is robust and ready for due diligence activities by potential partners. Cymerus MSCs produced at Waisman have been subjected to a series of testing procedures to ensure that they consistently meet expectations and attain standards appropriate for their intended clinical use. These procedures include phenotypic characterisations, genetic studies and functional analyses, including an immunopotency assay, in which the Cymerus MSCs have been shown to have similar or better immunomodulatory activity to reference-standard bone marrow-derived MSCs. Further details will be provided after the Company completes certain intellectual property matters relating to the findings.

The manufacture, testing and release of the Company's clinical-grade induced pluripotent stem cell (iPSC) Master Cell Bank (MCB) has also been completed. The MCB was manufactured by Waisman on Cynata's behalf, using the iPSC line supplied to the Company by Cellular Dynamics International (CDI). This iPSC MCB has the capacity to serve as an effectively limitless starting material for CYP-001.

Consistent with a plan to maximally investigate all potential applications of the Cymerus platform, exploratory work has commenced on the potential to manufacture additional, novel iPSC-derived therapeutic products. The Company will provide further information to the market at the appropriate time.

Preclinical Studies

The results from the study of Cymerus™ MSCs in a rodent model of critical limb ischaemia have been submitted for publication in a peer-reviewed journal. This study demonstrated Cymerus™ MSCs improved blood flow, reduced necrosis and maintained muscle mass and gross muscle appearance, leading to the conclusion that the MSCs have a significant protective effect against ischemic insults.

To complement the previously announced study of Cymerus™ MSCs in a humanised rodent model of graft versus host disease (GvHD), the Company has now engaged Assistant Professor, Lisa M Minter,



University of Massachusetts, Amherst, to conduct additional *in vitro* studies that are considered to be predictive of MSC efficacy in immune-mediated diseases.

The previously announced program investigating the potential utility of Cymerus MSCs in lung fibrosis at The University of Western Australia's Centre for Cell Therapy and Regenerative Medicine (CCTRM) is also now underway, while the Company is in discussions with a number of other academic researchers with regard to the use of Cymerus™ MSCs in additional animal disease models.

The Company has also commissioned a study of the biodistribution and persistence of Cymerus™ MSCs, using state-of-the-art fluorine-19 magnetic resonance imaging (19F-MRI). This study will help to complete the regulatory package to support the Company's planned clinical trial of CYP-001 in patients with steroid-refractory GvHD.

#### Regulatory Interactions and Clinical Trial Program

Through its Clinical Research Organization (CRO) the Company has successfully identified and engaged with several leading clinical study centers for the conduct of the proposed Phase 1 clinical trial in GvHD. The Company is now continuing direct interactions with a number of key opinion leaders in this field, with a view to finalising the logistical and operational plans for the study. Meanwhile the Company continues discussions with regulatory authorities on the study design and other aspects of the clinical program. Once clarity has been obtained and the Company selects the preferred jurisdiction(s) in which to conduct the trial, it expects to announce a schedule for commencement and completion of the trial.

"Since the completion of the manufacturing validation program earlier this year, we have been able to accelerate all other aspects of the development of our lead off-the-shelf product, CYP-001. The regulatory dossiers now being compiled by the Company are comprehensive and technically first-class", said Cynata Vice President of Product Development, Dr Kilian Kelly. "We are very excited to be in the real business-end of our pre-clinical program as a prelude to commencing our proposed Phase 1 clinical study."

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#### **About Cynata Therapeutics (ASX: CYP)**

Cynata Therapeutics Ltd (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.