

Cynata Reports Compelling Results from Pre-clinical Stem Cell Study in Graft-versus-Host Disease (GvHD)

- Strong survival benefit demonstrated by Cymerus™ MSC product, CYP-001
- Clear confirmation of biological activity of Cymerus MSCs as seen in previous study in critical limb ischemia (CLI) model
- Supports forthcoming clinical study of CYP-001 in GvHD

Melbourne, Australia; 7 April 2016: Australian stem cell and regenerative medicine company, Cynata Therapeutics Limited (ASX: CYP), has received extremely positive interim data from a proof of concept study of its lead Cymerus mesenchymal stem cell (MSC) product, CYP-001.

In this study, a humanised mouse model of severe acute graft versus host disease (GvHD) was induced by infusing human peripheral blood mononuclear cells (PBMCs) into mice.

The interim data demonstrate that CYP-001 treatment substantially prolonged survival in this model. Animals in the control group had a median survival time of just 25.5 days, compared to a median survival time of at least 54 days -more than double that of the controls- in the CYP-001 treated groups ($p=0.0011$). All control animals succumbed to the disease between 24 and 31 days after induction, whilst as at the date of the interim review, survival among the CYP-001 treated animals has been 31-68 days with three animals still alive. Further analysis will be performed once these last three animals have completed the study.

The study is being conducted under the supervision of Associate Professor Lisa Minter at the University of Massachusetts Amherst (UMass), USA. Animals were randomly assigned to control or treatment groups. Treated animals received either one or two doses of CYP-001, while control animals received only saline.

“We are delighted with these initial results, which are consistent with the substantial body of evidence we have generated from *in vitro* laboratory testing of our product,” said Cynata Vice President of Product Development, Dr Kilian Kelly. “Collectively, these data show that Cynata’s proprietary Cymerus MSCs exert pronounced immunomodulatory effects. The results are also consistent with the successful study of Cymerus MSCs in a model of critical limb ischemia (CLI), which was recently published in *Cytotherapy*. This augurs well for our initial planned clinical trial in patients with GvHD, and indeed for the potential use of these cells to treat a wide range of other conditions”, said Dr Kelly.

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“Cynata’s unique MSCs appear to have a pronounced beneficial effect in our model of this devastating disease”, said Associate Professor Minter. “We are very pleased to be involved in this study of CYP-001, which has the potential to become a very important therapeutic product” she added.

An additional study is also underway at a different centre, in which GvHD was induced using a lower dose of human PBMCs, so that the symptoms are less severe and progress less rapidly. This study is also investigating alternative CYP-001 dose levels and additional outcome measures. The majority of animals in this study have yet to reach the study endpoint, so the extent of the treatment effect in this model is not yet known. Additional results from this study are expected soon.

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About Cynata Therapeutics (ASX: CYP)

Cynata Therapeutics Limited (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.

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