

Cynata Therapeutics GvHD Clinical Trial and Corporate Progress

- Patient dosing commenced in world-first Phase I trial of stem cell therapy CYP-001 in graft-versus-host disease; recruiting at six centres in the UK and Australia
- Secured \$60-million-plus FUJIFILM partnership and license option for CYP-001 in GvHD
- Raised additional \$10 million: \$4 million equity investment from FUJIFILM and \$6 million placement
- Reported positive pre-clinical data in heart attack and asthma; expanded pre-clinical pipeline to acute respiratory distress syndrome
- Filed two new patent applications with IP Australia to expand opportunities in cancer immunotherapy
- Completed pre-Investigational New Drug meeting with U.S. Food and Drug Administration Office of Cellular, Tissue and Gene Therapy; written recommendation expected by July 2017

Melbourne, Australia; 27 June 2017: Australian stem cell and regenerative medicine company, Cynata Therapeutics Limited (ASX: CYP), is pleased to provide a review of the Company's clinical and corporate progress for the second half of fiscal year 2017.

"It has been an exciting few months at Cynata, and we are delivering on key milestones that will enable us to continue to advance our clinical and corporate objectives," said Dr Ross Macdonald, Cynata's Managing Director and Chief Executive Officer. "The successful initiation of our Phase I trial in graft-versus-host disease (GvHD) marks our progression to clinical-stage and the first-ever clinical trial of an allogenic, induced pluripotent stem cell-derived mesenchymal stem cell (MSC) therapy. This trial is a major achievement in our evolution and we have been pleased with its progress to date. Moreover, we have picked up the pace in other key indications, including reporting positive data from pre-clinical trials in heart attack and asthma, which will pave the way for future clinical programs and for our ongoing partnering activities. We look forward to continuing to explore our Cymerus™ technology in many disease areas, with the goal of generating "off-the-shelf" stem cell therapies that benefit patients in need."

Phase I Trial of CYP-001 in GvHD

In May 2017, Cynata announced the dosing of the first patient in the Phase I trial of its MSC product, CYP-001, for the treatment of GvHD. The commencement marks the first time that a MSC therapy produced by Cynata's proprietary Cymerus technology platform has been evaluated in a clinical trial, and the first time that a patient has been treated with an allogenic, induced pluripotent stem cell (iPSC)-derived therapeutic MSC product.

Cynata is pleased to report that the trial is advancing as planned and is recruiting at six major centres in the UK and Australia. Cynata plans to expand to additional locations in the coming months to accelerate patient recruitment, and expects to provide an update on trial progress following the Data and Safety Monitoring Board review to be conducted after the treatment of the eighth patient.

FUJIFILM Corporation has optioned license rights to CYP-001 in GvHD, and can exercise the option any time during or up to 90 days after the completion of the Phase I trial. Upon signing the license agreement, Cynata will receive an upfront US\$3 million cash payment, along with future milestone payments that potentially total \$60 million, plus future royalties.



Pre-clinical Product Pipeline

In April 2017, Cynata reported a collaboration with the Critical Care Research Group to investigate Cymerus MSCs as a treatment for acute respiratory distress syndrome (ARDS). The pre-clinical trial, which will be conducted in association with the Prince Charles Hospital in Brisbane, will evaluate the effectiveness of Cymerus MSCs in sheep with ARDS which are currently supported by extracorporeal membrane oxygenation (ECMO). If successful, Cynata anticipates the data will support progression into a clinical trial in humans with ARDS undergoing ECMO support.

In March 2017, Cynata announced the final report from a pre-clinical trial in asthma being conducted at Monash University. The report confirmed that Cymerus MSCs have a significant and beneficial impact on all three components of asthma: hyper-responsiveness, inflammation and airway remodelling. These data were published in June 2017 in the FASEB Journal, a peer-reviewed scientific publication. A further pre-clinical trial is being conducted at Monash for the treatment of asthma in combination with or in comparison to corticosteroids.

Cynata released positive preliminary data in February 2017 from a pre-clinical trial of Cymerus MSCs for the treatment of heart attack, which is being conducted at the Westmead Institute for Medical Research, Sydney. The data indicated the potential to restore cardiac function and reduce scar size after a heart attack. The trial is expected to conclude within the next few months.

Regulatory and Intellectual Property

In April and June 2017, Cynata filed further patent applications with IP Australia covering certain novel and innovative uses of Cymerus MSCs in cancer-related treatments, specifically immunotherapy.

In May 2017, the Company was granted a pre-Investigational New Drug (IND) meeting with the U.S. Food and Drug Administration (FDA) Office of Cellular, Tissue and Gene Therapy, to discuss the regulatory approval path for Cymerus MSC products in the U.S. Cynata expects to receive the FDA's written recommendations by July 2017.

In June 2017, Cynata received Notice of Allowance from the U.S. Patent and Trademark Office for a key Cymerus manufacturing patent application.

Funding Position

As part of its strategic partnership with Cynata, FUJIFILM took a \$3.97 million equity stake in the Company, making it Cynata's largest shareholder with an approximately nine percent holding. Cynata also secured \$6 million in an equity placement bringing the total raised to \$10 million. The funding is being used to continue to develop Cymerus products in the key therapeutic areas of GvHD, cardiovascular disease, oncology, and respiratory and pulmonary diseases.

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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.