

## Promising Efficacy Data in Preclinical Studies of Cymerus MSCs in Heart Disease

**Melbourne, Australia; 7 April 2025:** [Cynata Therapeutics Limited](#) (ASX: “CYP”, “Cynata”, or the “Company”), a clinical-stage biotechnology company specialising in cell therapeutics, today announced positive efficacy data observed in preclinical studies conducted with Cynata’s Cymerus™ iPSC<sup>1</sup>-derived MSCs<sup>2</sup> in models of ischaemic heart disease.

MSCs have the potential to treat ischaemic heart disease, the leading cause of death worldwide,<sup>3</sup> by releasing proteins and other bioactive molecules. This project evaluated a new, minimally invasive method to deliver beneficial molecules from MSCs over an extended period, using a retrievable encapsulation device.<sup>4</sup> The device, which can be implanted under the skin, protects the cells while still permitting the release of molecules into the circulation.

### Key Highlights

- In a rat model of heart attack (known as an “*ischaemia-reperfusion model*”), treatment with encapsulated Cymerus™ MSCs resulted in the following:
  - Significantly improved heart function and a reduction in harmful structural changes in the heart, compared to controls treated with encapsulated placebo.
  - Less heart muscle thickening, smaller scar tissue, and fewer fibrous tissue buildups.
- Encapsulated Cymerus™ MSCs were still alive and functional twelve weeks after implantation.
- Cymerus™ MSCs produce proteins that support tissue health, aid in healing, help to protect cells from damage, play a role in regulating the immune system and reduce inflammation.
- In an *in vitro* model of human heart tissues created and grown in a laboratory (known as “*cardiac spheroids*”), tissues treated with proteins from Cymerus™ MSCs showed improved survival and function compared to controls treated with placebo.

**Chief Investigator of the study, Associate Professor Shiang (Max) Lim (Head, Cardiac Regeneration Laboratory, St Vincent’s Institute of Medical Research, Melbourne) said:**

*“This study demonstrates the utility of a clinically viable, minimally invasive method for sustained delivery of active molecules released by Cymerus™ MSCs, which has the potential to address a major gap in the treatment of ischaemic heart disease. Despite substantial advances in cardiovascular medicine, ischaemic heart disease remains the leading global cause of death, with patients who survive heart attacks often developing heart failure due to heart muscle damage. Current treatments for post-heart attack care fail to adequately repair damaged heart tissue. Stem cell therapy presents a promising opportunity to address this critical unmet need.”*

**Dr Kilian Kelly, Cynata’s Chief Executive Officer and Managing Director, said:**

*“These results build on previous preclinical studies conducted with Cymerus™ MSCs, which also showed beneficial effects of the cells in models of heart disease. The novel delivery method utilised in this study may have important advantages with respect to clinical translation and longer-term effects. We look forward to continuing to work with Associate Professor Lim and the wider team on the next steps for this exciting program.”*

This project was undertaken using a ~\$1m Australian Government Medical Research Future Fund (MRFF) grant, as announced on [26 September 2022](#). It was led by Associate Professor Lim, in collaboration with researchers from multiple other institutions in Australia and overseas.<sup>5</sup>



The study team has now submitted a manuscript describing this study to a leading peer-reviewed journal. The manuscript has also been deposited on a pre-print server known as bioRxiv, where it may be accessed using the Digital Object Identifier 10.1101/2025.04.01.646502.<sup>6</sup>

**-ENDS-**

**Authorised for release by Dr Kilian Kelly, CEO & Managing Director**

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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 focused on the development of therapies based on Cymerus™, a proprietary therapeutic stem cell platform technology. Cymerus™ overcomes the challenges of other production methods by using induced pluripotent stem cells (iPSCs) to achieve economic manufacture of cell therapy products, including mesenchymal stem cells (MSCs), at commercial scale without the limitation of multiple donors.

Cynata has demonstrated positive safety and efficacy data for its Cymerus™ product candidates CYP-001 and CYP-006TK, in Phase 1 clinical trials in steroid-resistant acute graft versus host disease (GvHD), and diabetic foot ulcers (DFU), respectively. Further clinical trials are now ongoing: a Phase 2 trial of CYP-001 in GvHD under a cleared US FDA IND; a Phase 1/2 trial of CYP-001 in patients undergoing kidney transplant; and a Phase 3 trial of CYP-004 in osteoarthritis. In addition, Cynata has demonstrated utility of its Cymerus™ technology in preclinical models of numerous other diseases, including critical limb ischaemia, idiopathic pulmonary fibrosis, asthma, heart attack, sepsis, acute respiratory distress syndrome (ARDS) and cytokine release syndrome.

**Cynata Therapeutics encourages all current investors to go paperless by registering their details with the designated registry service provider, [Automic Group](#).**

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<sup>1</sup> iPSC = induced pluripotent stem cell

<sup>2</sup> MSC = mesenchymal stem (or stromal) cell

<sup>3</sup> Source: World Health Organization Global Health Estimates: Life expectancy and leading causes of death and disability

<sup>4</sup> Cells were encapsulated in a clinical grade device, supplied by Procyon Technologies LLC (Tucson, Arizona, USA)

<sup>5</sup> Including: University of Melbourne; Baker Heart and Diabetes Institute; La Trobe University; Monash University; University of South Australia; Hearts4heart; Westmead Hospital; Westmead; St Vincent's Hospital, Melbourne; The Westmead Institute for Medical Research; University of Toronto and The Hospital for Sick Children; University of Arizona; Procyon Technologies, LLC; University College London; Duke-NUS Medical School; National University Singapore; National Heart Research Institute Singapore.

<sup>6</sup> Please note that this article is a preprint and has not been yet peer reviewed.