ASX ANNOUNCEMENT 12 October 2022

Successful Completion of Planned DSMB Review of Cynata's DFU Clinical Trial

Key highlights

- **A planned Data Safety Monitoring Board (DSMB) review of Cynata's diabetic foot ulcer (DFU) clinical trial has been successfully completed**
- **The DSMB recommends the DFU clinical trial continue unchanged**
- **The DFU clinical trial is investigating the safety and early efficacy of Cynata's unique topical Cymerus™ mesenchymal stem cell (MSC) product, CYP-006TK, in patients with DFUs**
- **DFUs are chronic wounds on the feet of patients with diabetes (also known as diabetic wounds), potentially leading to serious infection and amputation. They represent a very significant unmet medical need affecting up to 34% of diabetes patients**

Melbourne, Australia; 12 October 2022: Cynata Therapeutics Limited (ASX: **"CYP"** or **"Cynata"**), a clinical-stage biotechnology company specialising in cell therapeutics, has today announced that an independent DSMB has successful concluded a review of Cynata's DFU clinical trial. Following the routine review, the DSMB has recommended that the clinical trial continue as planned.

Undertaking a review by an independent DSMB is consistent with good clinical practice. The primary responsibilities of the DSMB are to review and evaluate the available study data for participant safety, study conduct and progress, and to make recommendations concerning the continuation, modification, or termination of the trial. The study protocol for the DFU clinical trial includes oversight by a DSMB as well as provision for an interim review, which has now been successfully completed.

Dr Jolanta Airey, Cynata's Chief Medical Officer, said:

"We thank the members of the independent DSMB for completing this important review. The DSMB's positive recommendation is a key milestone, which enables us to continue patient enrolment as planned and to complete the trial as soon as possible."

-ENDS-

Authorised for release by Dr Ross Macdonald, Managing Director & CEO

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About the DFU Clinical Trial

The trial, entitled "A Randomised, Controlled, Phase 1 Study to Investigate Safety, Tolerability and Efficacy of CYP-006TK in Adults with Diabetic Foot Ulcers", aims to recruit 30 participants, who will be randomly assigned to receive either CYP-006TK or standard care treatment. This will be the first clinical trial to utilise CYP-006TK, a polymer-coated silicon dressing (seeded with Cymerus MSCs) that Cynata has licensed from TekCyte Pty Ltd (TekCyte). The investigational treatment period is 4 weeks, and each patient will be evaluated for a total of 24 weeks. The primary endpoint of the trial is safety, while secondary efficacy endpoints include the following outcome measures after 12 and 24 weeks:

- Percentage ulcer area change
- Days to complete ulcer healing
- Days to 50% ulcer healing
- Percentage change in ulcer volume
- Ulcer pain

The trial is taking place at Royal Adelaide Hospital and The Queen Elizabeth Hospital in Adelaide, under the leadership of Professor Robert Fitridge, who is Professor of Vascular Surgery at the University of Adelaide, Head of Vascular Surgery at The Queen Elizabeth Hospital, and Consultant Vascular Surgeon with the Central Adelaide Local Health Network.

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) and a precursor cell known as mesenchymoangioblast (MCA) to achieve economic manufacture of cell therapy products, including mesenchymal stem cells (MSCs), at commercial scale without the limitation of multiple donors.

Cynata's lead product candidate CYP-001 met all clinical endpoints and demonstrated positive safety and efficacy data for the treatment of steroid-resistant acute graft-versus-host disease (GvHD) in a Phase 1 trial. Planning for a Phase 2 clinical trial in GvHD under a cleared US FDA IND is presently underway. Clinical trials of Cymerus products in osteoarthritis (Phase 3) and diabetic foot ulcers (DFU) are currently ongoing. In addition, Cynata has demonstrated utility of its Cymerus technology in preclinical models of numerous diseases, including the clinical targets mentioned above, as well as 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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