

Diabetic Foot Ulcer: Initial Results in First 16 Patients Expected in Q1 2024

Melbourne, Australia; 28 December 2023: Cynata Therapeutics Limited (ASX: “CYP”, “Cynata”, or the “Company”), a clinical-stage biotechnology company specialising in cell therapeutics, has initiated analysis of wound surface area in the first 16 patients in its Phase 1 clinical trial of CYP-006TK in diabetic foot ulcer (DFU), up to the 10-week follow-up time point. The Company anticipates receiving these initial results in Q1 2024.

CYP-006TK is Cynata’s Cymerus™ off-the-shelf iPSC¹-derived MSC² topical wound dressing product candidate, which comprises MSCs seeded onto a novel silicon dressing. This trial aims to enrol a total of 30 patients with DFU, who are randomised to receive either: (i) CYP-006TK treatment for four weeks, followed by standard of care treatment for the rest of the study; or (ii) standard of care treatment throughout the study.

At each visit in this trial, three-dimensional images of the study ulcer are taken using specialised camera equipment. Images are then analysed by a technician who is independent of the clinical site and blind to treatment allocation. This facilitates calculation of the wound surface area, and consequently the change in the size of the wound over time.

Encouraging initial results from the first six patients enrolled in this trial up to Day 28 have previously been released, which showed an increased level of wound healing in patients treated with CYP-006TK compared to those who received standard of care treatment.

After optimising the trial protocol and opening additional clinical sites earlier this year, the recruitment rate in the trial accelerated markedly, but the Company now expects recruitment to continue into 2024. A further update on expected timelines for full study results will be provided when the initial results are released.

Dr Kilian Kelly, Cynata’s CEO and MD, said:

“This analysis will provide a valuable initial indication of the effects of CYP-006TK in this subgroup of patients. We have partnered with a specialist imaging contract research organisation, and we are working with them to deliver this analysis as soon as possible. We look forward to releasing these initial results in the near future.”

-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) 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. A Phase 2 clinical trial in GvHD under a cleared US FDA IND, as well as trials of Cymerus products in osteoarthritis (Phase 3) and diabetic foot ulcers (DFU) are currently ongoing, while a trial in renal transplant is expected to commence in 2024. In addition, Cynata has also demonstrated utility of its Cymerus technology in preclinical models of numerous 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 investors to go paperless by registering their details with the designated registry service provider, Automic Group.

¹ iPSC = induced pluripotent stem cell

² MSC = mesenchymal stem (or stromal) cell