

ASX ANNOUNCEMENT

8 April 2024

Patient Enrolment Completed in CYP-006TK Diabetic Foot Ulcer Clinical Trial

Melbourne, Australia; 8 April 2024: Cynata Therapeutics Limited (ASX: “CYP”, “Cynata”, or the “Company”), a clinical-stage biotechnology company specialising in cell therapeutics, is pleased to announce the completion of patient enrolment in its Phase 1 clinical trial of CYP-006TK in diabetic foot ulcers (DFU).

CYP-006TK is Cynata’s Cymerus™ iPSC¹-derived MSC² topical wound dressing product candidate, which comprises MSCs seeded onto a novel silicon dressing. Due to reduced blood flow, patients with diabetes are at risk of developing non-healing wounds on the feet/lower limbs, which are also known as DFU. In addition to causing severe pain and discomfort, DFU pose a significant risk of infection, and if therapy is unsuccessful, amputation may be necessary. In this trial, CYP-006TK is being investigated as a potential treatment to promote wound healing in patients with DFU.

The pre-specified sample size has now been reached, with a total of 30 patients with DFU randomised on a 1:1 basis 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. In accordance with the study protocol, patients will be followed for 24 weeks following treatment initiation, which means that the last patient visit in this trial is expected to occur around September 2024.

Dr Jolanta Airey MD, Cynata’s Chief Medical Officer, said:

“We are delighted to have completed enrolment, and we extend our thanks to all of the investigators, study staff and patients for helping us to achieve this milestone. We recently announced very encouraging initial data from the first 16 patients enrolled in this trial after 10 weeks’ follow-up, with a median percentage reduction in wound surface area of 87.6% in the active CYP-006TK group, compared to 51.1% in the control group. We now look forward to completing the follow-up period and releasing the full results from this study shortly thereafter.”

-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 the near future. 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 current 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