

## Encouraging Initial Data from CYP-006TK Diabetic Foot Ulcer Clinical Trial

**Melbourne, Australia; 26 February 2024:** Cynata Therapeutics Limited (ASX: “CYP”, “Cynata”, or the “Company”), a clinical-stage biotechnology company specialising in cell therapeutics, has completed initial analysis of wound surface area in the first 16 patients in its Phase 1 clinical trial of CYP-006TK in diabetic foot ulcers (DFU), up to the 10-week follow-up time point.

### Key Highlights

- The median percentage reduction in wound surface area in the active CYP-006TK group after 10 weeks was 87.6%, compared to 51.1% in the control group (n=8 per group)
- Recruitment in the trial is progressing well, with 25 out of a planned 30 participants now enrolled

CYP-006TK is Cynata’s Cymerus™ iPSC<sup>1</sup>-derived MSC<sup>2</sup> 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 treatment 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. Enrolled participants 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.

Follow-up visits in this trial continue until 24 weeks after the initiation of study treatment. At each follow-up visit, 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.

The analysis of the first 16 patients (n=8 per group) found that the median percentage reduction in wound surface area in the active CYP-006TK group after 10 weeks’ follow-up was 87.6%, compared to 51.1% in the control group.<sup>3</sup> For clarity, a 100% reduction in wound surface area represents complete wound healing.

These findings are consistent with the trend observed in the results from the first six patients enrolled in this trial (n=3 per group) up to Day 28, which were released in April 2023.

In view of these very encouraging initial results, the Company confirms that the trial will continue as planned, with the aim of enrolling a total of 30 participants. Recruitment has progressed well in recent months, with 25 participants now enrolled.

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

*“These initial results are very promising, and consistent with the previous data readout. We look forward to completing enrolment in the near future, which will take us a step closer to our objective of demonstrating safety and efficacy of CYP-006TK in DFU.”*

**-ENDS-**

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

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

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

<sup>3</sup> No formal statistical analysis has been performed, due to the preliminary stage of this readout and the small sample size



**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.**