

## Cynata Adds New Sites for DFU Clinical Trial

**Melbourne, Australia; 16 March 2023:** Cynata Therapeutics Limited (ASX: “CYP”, “Cynata”, or the “Company”), a clinical-stage biotechnology company specialising in cell therapeutics, has today announced that three additional clinical sites have opened for recruitment in the ongoing clinical trial of CYP-006TK in patients with diabetic foot ulcers (DFU). 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.

The additional clinical sites are all based in Perth, Western Australia, namely the Royal Perth Hospital, Fiona Stanley Hospital and Sir Charles Gairdner Hospital. The Company has also established its unique CYP-006TK manufacturing process locally at The Ray and Bill Dobney Cell and Tissue Therapies WA (CTTWA) facility at Royal Perth Hospital (RPH), to manufacture CYP-006TK for the new sites. It is expected that the inclusion of these additional hospitals will accelerate enrolment in the trial. The Company aims to complete recruitment mid-way through 2023 with trial results and top-line data to be released by the end of the year.

Cynata’s current clinical sites will continue to enrol and treat patients without change, and the Company looks forward to continuing its relationships with these prestigious hospitals. Similarly, product manufacture at TekCyte for clinical sites in Adelaide will also continue without change.

**Dr Ross Macdonald, Cynata’s Chief Executive Officer, said:**

*“We are excited with the addition of three new clinical sites to our ongoing DFU trial. Increasing the number of sites will help us drive recruitment activity and achieve our goal of releasing top-line data by the end of 2023. We remain confident that our cell therapy products offer a unique solution to those affected by DFUs, which is a large portion of the 400 million diabetics globally, and look forward to updating the market with trial progress.”*

**Dr Kilian Kelly, Cynata’s Chief Operating Officer, said:**

*“We are very pleased with this important progress towards increasing patient numbers for our ongoing DFU clinical trial and to ensuring we are on track to complete the trial on schedule. Notably, Perth has a rich history of innovation and successful clinical translation in regenerative medicine technologies, with the ground-breaking research on “spray on skin” having been conducted in Perth. We look forward to working with CTTWA and the new clinical sites in this important and challenging target.”*

-ENDS-

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

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### **About Diabetic Foot Ulcers**

DFU are sores/wounds on the feet of patients with diabetes (also known as diabetic wounds), representing a very significant unmet medical need. Diabetes is the fastest growing chronic disease worldwide<sup>1</sup> affecting an estimated 425 million, or 1 in 11, adults globally in 2017 and forecast to affect 629 million adults by 2045<sup>2</sup>. Up to 34% of those with diabetes will develop a foot ulcer<sup>3</sup>, providing a portal for infection that can lead to life-threatening sepsis and/or amputation<sup>4</sup>. With one diabetes-related extremity amputation now performed every 20 seconds<sup>5</sup>, the burden associated with this condition is extremely high for both the individuals affected and for society as a whole. In the USA alone the estimated annual burden of diabetic foot ulcers is at least US\$15b<sup>6</sup> with the global DFU treatment market estimated to be ~US\$10 billion<sup>7</sup>.

### **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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<sup>1</sup> Zimmet P, Alberti KG, Shaw J. Global and societal implications of the diabetes epidemic. *Nature*. 2001;414(6865): 782-7.

<sup>2</sup> International Diabetes Federation. *IDF Diabetes Atlas*, 8th edn. Brussels, Belgium: International Diabetes Federation, 2017

<sup>3</sup> Armstrong DG, Boulton AJM, Bus SA. Diabetic foot ulcers and their recurrence. *N Engl J Med*. 2017;376: 2367-75

<sup>4</sup> Brem H, Tomic-Canic M. Cellular and molecular basis of wound healing in diabetes. *J Clin Invest*. 2007;117(5): 1219-22.

<sup>5</sup> Armstrong DG, Kanda VA, Lavery LA, Marston W, Mills Sr JL, Boulton JM. Mind the gap: disparity between research funding and costs of care for diabetic foot ulcers. *Diabetes Care*. 2013;36(7): 1815-1817

<sup>6</sup> American Podiatric Medical Association: [https://www.apma.org/files/APMA\\_TodaysPodiatrist\\_Infographic\\_8.5x11\\_NOCROPS-2.pdf](https://www.apma.org/files/APMA_TodaysPodiatrist_Infographic_8.5x11_NOCROPS-2.pdf)

<sup>7</sup> Estimated DFU market (Source: Transparency Market Research, 2020 (Reflects global DFU treatment market by 2027)).

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