

Cynata Commences DFU Clinical Trial

Melbourne, Australia; 22 December 2021: Cynata Therapeutics Limited (ASX: “CYP” or “Cynata”), a clinical-stage biotechnology company specialising in cell therapeutics, is pleased to announce its clinical trial of CYP-006TK in patients with diabetic foot ulcers (DFU) has commenced and is now open for patient enrolment.

The Phase I trial (protocol number CYP-DFU-P1-01) aims to recruit 30 adult patients with DFU who will be randomly assigned to receive CYP-006TK or standard care of treatment. CYP-006TK is a novel polymer-coated silicon wound dressing seeded with Cymerus™ mesenchymal stem cells (MSCs) to facilitate topical application to the wound. Cynata has exclusively licensed the dressing technology from leading manufacturer of innovative biomedical coatings, TekCyte Limited.

The trial will take place at Royal Adelaide Hospital and The Queen Elizabeth Hospital, Adelaide, under the leadership of Professor Robert Fitridge, who is Professor of Vascular Surgery at the University of Adelaide, and Consultant Vascular Surgeon with the Central Adelaide Local Health Network. Patients will receive study treatment for a period of 4 weeks, evaluation will continue for a total of 24 weeks. The primary outcome measure in the trial will be safety, while secondary outcome measures will include wound healing, pain and quality of life at 12 and 24 weeks after treatment initiation. Cynata currently expects to complete the trial during the 2022 calendar year.

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

“Commencing the first human trial is a major milestone in the development of any new product, and we are pleased to have achieved this for our DFU program prior to the end of the year as projected. We look forward to evaluating the effects of this novel treatment on DFU, which are a debilitating and potentially limb or even life-threatening chronic complication of diabetes.”

-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 worldwide¹ affecting an estimated 425 million, or 1 in 11, adults globally in 2017 and forecast to affect 629 million adults by 2045². Up to 34% of those with diabetes will develop a foot ulcer³, providing a portal for infection that can lead to life-threatening sepsis and/or

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

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

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



amputation⁴. With one diabetes-related extremity amputation now performed every 20 seconds⁵, the burden associated with this condition is extremely high for both the individuals affected and for society as a whole. The global DFU treatment market is estimated to be ~US\$10 billion⁶.

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 is presently underway. Clinical trials of Cymerus products in osteoarthritis (Phase 3) and in patients with respiratory failure 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 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.

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

⁵ Armstong 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

⁶ Estimated DFU market (Source: Transparency Market Research, 2020 (Reflects global DFU treatment market by 2027)).