ASX ANNOUNCEMENT 18 November 2021

Site Initiation Visit Completed for Cynata's DFU Clinical Trial

Melbourne, Australia; 18 November 2021: Cynata Therapeutics Limited (ASX: **"CYP"** or **"Cynata"**), a clinical-stage biotechnology company specialising in cell therapeutics, is pleased to announce the successful completion of the Site Initiation Visit (SIV) for its clinical trial of CYP-006TK in patients with diabetic foot ulcers (DFU).

The trial has now received human research ethics committee and research governance approvals from the Central Adelaide Local Health Network (CALHN). Cynata has also received confirmation from the Therapeutic Goods Administration (TGA) that the trial can proceed under the Clinical Trial Notification (CTN) scheme. In addition to these regulatory and administrative approvals, it is a requirement for an SIV to be completed by the study sponsor (i.e. Cynata) before patient enrolment can commence. Patient enrolment is expected to open in the coming weeks.

CYP-006TK is a polymer-coated silicon wound dressing seeded with Cymerus™ 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 Phase I DFU 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. The treatment period will be 4 weeks, and each patient will be evaluated for a total of 24 weeks.

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.

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

"We are pleased to have initiated the clinical site in this important study, and now look forward to enrolling patients in the near future. This is the first clinical trial of CYP-006TK, which represents a novel way of administering MSCs directly to non-healing ulcers. DFU can lead to hospitalisations, amputations and fatalities, and existing treatment options are limited. Based on the encouraging pre-clinical data with this product in a model of DFU, we are optimistic about the potential difference that this product can make to the lives of patients battling this debilitating disease."

-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[1] affecting an estimated 425 million, or 1 in 11, adults globally in 2017 and forecast to affect 629 million adults by 2045[2]. Up to 34% of those with diabetes will develop a foot ulcer[3], providing a portal for infection that can lead to life-threatening sepsis and/or amputation[4]. With one diabetes-related extremity amputation now performed every 20 seconds[5], 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 billion[6].

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.

[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
[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)).

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