

Cynata Progress Toward Clinical Trial in Diabetic Foot Ulcers

Melbourne, Australia; 28 June 2021: Cynata Therapeutics Limited (ASX: “CYP”, “Cynata”, or the “Company”), a clinical-stage biotechnology company specialising in cell therapeutics, has today announced the appointment of leading clinical research organisation (CRO) Datapharm Australia to assist in the conduct and management of the proposed clinical trial of Cynata’s Cymerus™ mesenchymal stem cell (MSC) product in diabetic foot ulcers.

Having now made substantial progress on clinical trial design and endpoint selection as presaged in the Company’s 3 June 2021 announcement, the engagement of Datapharm represents an important milestone toward commencing the trial. Commencement of the trial is subject to regulatory and ethics clearance and completion of trial start up activities, all of which are presently underway.

Patient enrolment for the trial is expected to be initiated in the second half of this year.

Datapharm is an Australian full-service CRO providing clinical trial management, design, site set-up, clinical monitoring, statistical services, data management, medical writing, pharmacovigilance, GCP auditing and patient recruitment services. The value of the contract with Datapharm is not considered material from a quantitative perspective.

Diabetic foot ulcers represent a significant unmet medical need, with the disease often resulting in hospitalisations, amputations and fatalities; the estimated market value is approaching US\$10b¹. The burden of this disease is growing, and existing treatment options have limited success.

-ENDS-

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

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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. Clinical trials of Cymerus MSC products in osteoarthritis (Phase 3) and in patients with respiratory failure are currently ongoing. Planning is also underway for further clinical trials of Cymerus MSC products in GvHD (through licensee Fujifilm), critical limb ischemia, idiopathic pulmonary fibrosis, renal transplantation, and diabetic foot ulcers. In addition, Cynata has demonstrated utility of its Cymerus MSC 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.

¹ Transparency Market Research, 2020 (Reflects global DFU treatment market by 2027).