

ASX ANNOUNCEMENT

1 March 2021

Cynata Advances Planned Clinical Trial in Diabetic Foot Ulcers in MoU With TekCyte

Melbourne, Australia; 1 March 2021: Cynata Therapeutics Limited (ASX: “CYP”, “Cynata”, or the “Company”), a clinical-stage biotechnology company specialising in cell therapeutics, has today announced the execution of a Memorandum of Understanding with TekCyte Pty Ltd (TekCyte) in respect of TekCyte’s wound dressing technology. TekCyte has developed proprietary surface modification technologies to produce polymer-coated dressings for the delivery of mesenchymal stem cells (MSCs) to wounds. The MoU anticipates the parties negotiating and entering into a licence agreement for the use of TekCyte’s technologies in the commercial development of Cynata’s MSC product for diabetic foot ulcers (DFU).

Cynata’s Cymerus™ MSCs have demonstrated very promising efficacy in a preclinical model of diabetic wounds (also known as diabetic ulcers), a significant medical problem with an estimated market value of nearly US\$10b¹. Those studies, conducted independently by the Cooperative Research Centre for Cell Therapy Manufacturing (CTM-CRC) and designed to compare cells from various sources, utilised TekCyte’s dressing seeded with MSCs or similar cells. The related patent families are assigned to TekCyte from the CTM-CRC.

Cynata now plans to undertake a clinical trial of its Cymerus MSC product in patients with diabetic foot ulcers based on this solid pre-clinical foundation and utilising the TekCyte technology. As a supplier of medical coatings, TekCyte will work with Cynata to manufacture and supply the active dressing for the planned clinical trial.

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

“In Australia alone, diabetic foot disease results in more than 27,000 hospitalisations, 4,400 amputations and 1,700 deaths annually². Unfortunately, there is also evidence that the burden of this disease is growing year-on-year, and existing treatment options have limited success. The very encouraging data from the pre-clinical studies at the CTM-CRC with our Cymerus MSC product, especially when compared with other cell products, provides a rational and sound basis for us to proceed with TekCyte’s patch technology. We look forward to completing the planned licence agreement and to commencing a clinical trial in DFU.”

-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.

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

² Van Netten JJ, Lazzarini PA, Fitridge R, Kinnear E, Griffiths I, Malone M, Perrin BM, Prentice J, Sethi S, Wraight PR. Australian diabetes-related foot disease strategy 2018-2022: The first step towards ending avoidable amputations within a generation. Brisbane: Diabetic Foot Australia, Wound Management CRC; 2017



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 severe complications arising from COVID-19 (Phase 2) 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.

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