

Cynata signs Licence Agreement with TekCyte to advance Clinical Trial in Diabetic Foot Ulcers

Melbourne, Australia; 3 June 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 worldwide exclusive licence agreement with TekCyte Pty Ltd (TekCyte) in respect of TekCyte’s wound dressing technology. Cynata has also secured an option to purchase the relevant technology outright.

Key highlights

- Secured worldwide exclusive licence agreement to TekCyte’s wound dressing technology which will be utilised in Cynata’s planned clinical trial in diabetic foot ulcers
- Preclinical studies utilising TekCyte’s dressing to apply Cymerus MSCs to the wound have demonstrated promising efficacy and support further clinical development
- Final planning to undertake a clinical trial in diabetic foot ulcers in Australia is underway, with the trial to be fully funded by Cynata from available cash reserves

TekCyte has developed proprietary surface modification technologies to produce polymer-coated dressings for the delivery of mesenchymal stem cells (MSCs) to wounds. The licence agreement enables the use of TekCyte’s technologies including in the commercial development of Cynata’s MSC product for diabetic foot ulcers (DFU). Under the license agreement, TekCyte will work with Cynata to manufacture and supply the active dressing for the planned trial. The licence is for the life of the relevant TekCyte patents and involves a signing fee and capped, success-based milestone payments.

Cynata’s Cymerus™ MSCs have demonstrated promising efficacy in a preclinical model of diabetic wounds (also known as diabetic ulcers). Those studies, conducted independently by the Cooperative Research Centre for Cell Therapy Manufacturing (CTM-CRC), were designed to compare cells from various sources and utilised TekCyte’s dressing seeded with MSCs or similar cells. Cynata now plans to undertake a clinical trial of its Cymerus MSC product in patients with DFU based on this solid pre-clinical foundation and utilising the TekCyte technology.

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

“DFU represents a significant unmet medical need, with the disease often resulting in hospitalisations, amputations and fatalities – with an estimated market value of nearly US\$10b¹. Unfortunately, there is also evidence that the burden of this disease is growing, and existing treatment options have limited success.

The encouraging data from the pre-clinical studies provides a strong basis for us to proceed with our Cymerus MSC product utilising TekCyte’s patch technology as a potential treatment. We look forward to finalising trial design and start-up activities and to getting the clinical trial underway.”

-ENDS-

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

CONTACTS: Dr Ross Macdonald, CEO, Cynata Therapeutics, +61 (0)412 119343, ross.macdonald@cynata.com
Claire LaCagnina, U.S. Media Contact, +1 315.765.1462, clacagnina@6degreespr.com

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



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.

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Cynata Therapeutics Limited

Level 3, 62 Lygon Street, Carlton, Victoria 3053, Australia
PO Box 7165, Hawthorn North, Victoria 3122

T: + 613 9824 5254 F: + 613 9822 7735 E: info@cynata.com

ABN - 98 104 037 372