

## **UK Regulatory Authority Approves Cynata's Phase 2 Clinical Trial in Critical Limb Ischaemia**

**Melbourne, Australia; 14 January 2020:** Cynata Therapeutics Limited (ASX: CYP), a clinical-stage biotechnology company specialising in cell therapeutics, is pleased to announce that it has received approval from the UK Medicines and Healthcare products Regulatory Agency (MHRA) to proceed with its Phase 2 clinical trial of the Cymerus™ mesenchymal stem cell (MSC) product CYP-002 in patients with critical limb ischaemia (CLI).

Dr Kilian Kelly, Cynata's Chief Operating Officer, said, "The approval of this Phase 2 clinical trial by the MHRA is a major advancement for the development of Cymerus MSCs. We look forward to working with our contract research organisation and clinical investigators to evaluate CYP-002 in this devastating condition, for which there remains an enormous unmet need. The approval also confirms the successful implementation of the Company's strategy to use the positive Phase 1 trial of Cymerus MSCs in graft versus host disease to support direct progression from preclinical to Phase 2 clinical studies for CLI and multiple other indications."

CLI is an advanced stage of peripheral artery disease (PAD), which is a narrowing of arteries in the limbs, particularly the legs. The risk of PAD is increased in patients with diabetes, obesity or high blood pressure and also in people who smoke. CLI often results in amputation of the affected limb and is a major risk factor for cardiovascular events such as heart attack. The value of the global CLI treatment market has been forecasted to reach US\$5.4 billion by 2025.<sup>1</sup>

As previously announced, in a preclinical study in a mouse model of CLI, treatment with Cymerus MSCs led to significantly higher blood flow in the ischaemic limb and protection against muscle damage, fibrosis, and limb loss.<sup>2</sup>

Cynata anticipates conducting the clinical trial at multiple centres in the UK and Australia.

-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.

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<sup>1</sup> Zion Market Research report titled "Critical Limb Ischemia Treatment Market By Treatment (Devices and Medications): Global Industry Perspective, Comprehensive Analysis, and Forecast, 2018–2025"

<sup>2</sup> <https://doi.org/10.1016/j.jcyt.2015.10.013>



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. Cynata plans to advance its Cymerus™ MSCs into Phase 2 trials for GvHD, critical limb ischemia and osteoarthritis. In addition, Cynata has demonstrated utility of its Cymerus MSC technology in preclinical models of asthma, diabetic wounds, heart attack and cytokine release syndrome, a life-threatening condition stemming from cancer immunotherapy.

### About Critical Limb Ischaemia (CLI)

Critical limb ischaemia (CLI) is a chronic and severe obstruction of the arteries which markedly reduces blood flow to the legs, feet and hands. The disease is caused by atherosclerosis, the hardening and narrowing of the arteries over time due to the build-up of fatty deposits called plaque. CLI results in severe pain in the feet or toes, even while resting. CLI is the most severe form of peripheral artery disease (PAD) and is associated with very serious outcomes such as sores and wounds that won't heal and eventually amputation of the affected limb. Treatment of CLI typically involves surgery such as stents, angioplasty and vascular grafts. Outcomes in CLI patients are typically poor and with CLI prevalence estimated to be approximately 2 million patients in the United States alone and likely to rise<sup>3</sup> there is a very large and growing commercial need for better treatment options.

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<sup>3</sup> <https://doi.org/10.2147/VHRM.S209241>