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Cynata Files Application to Commence Phase 2 Clinical Trial in Critical Limb Ischaemia

Melbourne, Australia; 25 November 2019: Australian stem cell and regenerative medicine company, Cynata Therapeutics Limited (ASX: CYP), announced today that it has filed a Clinical Trial Authorisation application with the UK Medicines and Healthcare products Regulatory Agency (MHRA) for the proposed Phase 2 clinical trial of Cynata's Cymerus™ mesenchymal stem cell (MSC) product CYP-002 in patients with critical limb ischaemia (CLI).

CLI is an advanced stage of peripheral artery disease (PAD), which is a narrowing of arteries in the limbs, particularly the legs. 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.[1]

Cynata anticipates conducting the clinical trial at multiple centres in the UK and Australia. The submission of the clinical trial application follows a successful scientific advice meeting that Cynata held with the MHRA earlier this year regarding this trial. The MHRA review process is expected to take up to 60 days.

Dr Kilian Kelly, Cynata's Chief Operating Officer, said, "CLI is an extremely serious condition and existing therapies have limited success. We are optimistic that CYP-002 may offer a valuable new treatment option. We look forward to the MHRA's review of this important trial, and we aim to commence the recruitment of patients early in the coming year."

A preclinical study in a mouse model of CLI demonstrated that treatment with Cymerus MSCs led to significantly higher blood flow in the ischaemic limb versus placebo where blood flow remained low and resulted in limb loss.[2]

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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. 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

[1] *Zion Market Research report titled "Critical Limb Ischemia Treatment Market By Treatment (Devices and Medications): Global Industry Perspective, Comprehensive Analysis, and Forecast, 2018–2025"*
[2] *https://doi.org/10.1016/j.jcyt.2015.10.013*

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[3] there is a very large and growing commercial need for better treatment options.

[3] *https://doi.org/10.2147/VHRM.S209241*

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