



ASX ANNOUNCEMENT

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Cynata Therapeutics Progresses Start-Up Activities for Clinical Trial in Critical Limb Ischaemia

Melbourne, Australia; 6 May 2019: Cynata Therapeutics Limited (ASX: CYP), a clinical-stage biotechnology company specialising in cell therapeutics, announced today a progress update on the preparation and start-up activities for its planned Phase 2 clinical trial of its 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), a narrowing of arteries in the limbs. CLI often results in amputation of the affected limb and is also a major risk factor for cardiovascular events. Cynata anticipates conducting the clinical trial at a number of centres in the UK and Australia. The Company recently received favourable advice regarding this trial from the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom (announced 12 March 2019).

The clinical trial protocol is now at final draft stage, and has been reviewed and commented on by clinical key opinion leaders with expertise in CLI. The Company has also engaged a leading contract research organisation (CRO), which is currently focussed on the following activities:

- Finalisation of the clinical trial protocol
- Preparation of other documents required for the trial, including patient information and consent forms, study reference manuals, case report forms and project plans
- Clinical site selection and qualification
- Establishing data management and pharmacovigilance (safety monitoring) systems
- Project team training
- Preparation and submission of regulatory and ethics applications

The Company expects to be in a position to commence recruitment in this trial by the fourth quarter of this calendar year.

Dr Kilian Kelly, Cynata's Vice President, Product Development:

"There is a very high level of enthusiasm among the clinical community about this trial, which we hope will help to address what is currently an extremely serious and difficult to treat condition. We look forward to working with our CRO and clinical investigators over the coming months to get the trial underway."

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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 and 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 of asthma, diabetic wounds, heart attack and cytokine release syndrome, a life-threatening condition stemming from cancer immunotherapy.