

Cynata Receives Favourable Advice from UK MHRA on CLI Clinical Trial

Melbourne, Australia; 12 March 2019: Cynata Therapeutics Limited (ASX: CYP), a clinical-stage biotechnology company specialising in cell therapeutics, is pleased to announce that it has received favourable advice from the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom, regarding its planned Phase 2 clinical trial of CYP-002 (Cymerus™ MSCs) in patients with critical limb ischemia (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.

Following a recent scientific advice meeting, the MHRA has confirmed the following:

- The CYP-002 manufacturing process and quality control testing is acceptable.
- The completed preclinical proof of concept study in a model of CLI is acceptable.
- Cynata's proposed preclinical biodistribution study is acceptable, and no other preclinical safety studies are required to support the clinical trial.
- The proposed 90-patient Phase 2 clinical trial design is generally acceptable.

Cynata anticipates conducting the clinical trial at a number of centres in the UK and Australia, and expects it to commence during the second half of 2019.

Dr Kilian Kelly, Cynata's Vice President, Product Development said "This highly successful meeting builds on the strong relationship that we have established with the MHRA, one of the most respected regulatory authorities worldwide. We are very pleased with this outcome. Perhaps most notably, this confirms Cynata's understanding that the safety data from the completed Phase 1 trial of Cymerus MSCs in graft versus host disease support direct progression to Phase 2 trials in other indications. Furthermore, this strengthens our confidence that the manufacturing and preclinical data packages are expected to support progression of CYP-002 into a clinical trial in patients with CLI."

Ends

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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 and critical limb ischemia. In addition, Cynata has demonstrated utility of its Cymerus MSC technology in preclinical models of asthma, critical limb ischemia, diabetic wounds, heart attack and cytokine release syndrome, a life-threatening condition stemming from cancer immunotherapy.

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