



**ASX ANNOUNCEMENT**

**05 November 2015**

## **Cynata Engages CRO to Conduct GvHD Clinical Trial**

- Cynata engages The Clinical Trial Company Ltd as CRO for upcoming Phase 1 clinical study
- First clinical study with Cymerus™ MSCs will be conducted in patients with steroid-refractory GvHD

**Melbourne, Australia; 5 November 2015:** Australian stem cell and regenerative medicine company, Cynata Therapeutics Ltd (ASX: CYP), announced today that it has engaged The Clinical Trial Company Ltd. (TCTC) as the Contract Research Organisation (CRO) for Cynata's upcoming Phase I clinical study, which will investigate CYP-001 as a treatment for steroid-refractory graft versus host disease (GvHD). This engagement follows planning and logistics development undertaken during the earlier part of this year for the clinical trial.

GvHD is a complication of bone marrow transplantation and related procedures. It is an extremely debilitating condition, in which transplanted cells attack the recipient. Steroids are the first-line treatment for GvHD, but when that proves to be ineffective (steroid-refractory GvHD), the prognosis is extremely poor, with mortality rates of up to 80%.

CYP-001 is the lead mesenchymal stem cell (MSC) product manufactured using Cynata's unique Cymerus™ technology, which enables large scale production MSCs from a single donation from a sole donor. MSCs have shown significant promise in the treatment of GvHD, due to MSCs ability to modulate a recipient's immune response and reduce inflammation.

Formed in 2002, TCTC is a privately owned full-service clinical research provider, which specialises in studies involving advanced therapies, including stem cells. TCTC has offices in the UK, USA, Canada, Australia and Singapore, and field-based staff in a range of additional locations. TCTC will manage the conduct of this important Phase I clinical trial for Cynata.

Cynata Vice President of Product Development, Dr Kilian Kelly, said "This clinical trial is a critically important milestone in the development of the Cymerus™ platform technology, so it is of paramount importance that we select the right CRO. Clinical trials with stem cells present a number of unique challenges, and we believe TCTC is ideally suited to manage this trial, given its specialisation and extensive experience in the field of advanced therapies and regenerative medicine. We look forward to working with TCTC on this initial clinical study of CYP-001. Cynata has further meetings scheduled with regulatory bodies and subject to the outcome of those meetings we expect to commence the trial in the first half of 2016."

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### **About Cynata Therapeutics (ASX: CYP)**

Cynata Therapeutics Limited (ASX: CYP) is an Australian stem cell and regenerative medicine company that is developing a therapeutic stem cell platform technology, Cymerus™, originating from the University of Wisconsin-Madison, a world leader in stem cell research. The proprietary Cymerus™ technology addresses a critical shortcoming in existing methods of production of mesenchymal stem cells (MSCs) for therapeutic use, which is the ability to achieve economic manufacture at commercial scale. Cymerus™ does so through the production of a particular type of MSC precursor, called a mesenchymoangioblast (MCA). The Cymerus™ MCA platform provides a source of MSCs that is independent of donor limitations and provides a potential “off-the-shelf” stem cell platform for therapeutic product use, with a pharmaceutical business model and economies of scale. This has the potential to create a new standard in the emergent arena of stem cell therapeutics and provides both a unique differentiator and an important competitive position.