ASX ANNOUNCEMENT **24 May 2018**

Enrolment Completed in Cynata's Phase 1 Clinical Trial of CYP-001 in GvHD

Melbourne, Australia, 24 May 2018: Australian stem cell and regenerative medicine company Cynata Therapeutics Limited (ASX: CYP) is pleased to announce that the final patient has been treated in Cohort B of its Phase 1 clinical trial of CYP-001, its Cymerus™ mesenchymal stem cell (MSC) product candidate, in steroid-resistant acute graft-versus-host disease (GvHD).

Key highlights:

- Patient enrolment and dosing in the Phase 1 trial has completed, with data analysis to commence at 28 and 100 days post treatment
- Follows positive safety and efficacy data from the primary evaluation period of patients in Cohort A, in which overall survival at day 100 was 87.5 percent, overall response rate by day 100 was 100 percent and complete response rate by day 100 was 50 percent

Dr Kilian Kelly, Cynata's Vice President of Product Development, said, "Treating the final patient in the Phase 1 trial of our novel CYP-001 stem cell therapy in GvHD represents a significant milestone and great achievement for Cynata. In an analysis of patients in Cohort A, CYP-001 demonstrated strong efficacy and compelling patient response, as well as a lack of treatment-related serious adverse events, which is very encouraging in this devastating and often fatal disease. A positive trial outcome would bring us one step closer to providing the first-ever allogenic induced pluripotent stem cell-derived mesenchymal stem cell therapy to patients in need."

Eight patients with steroid-resistant acute GvHD disease were enrolled in Cohort B, as originally planned. Seven out of eight patients were dosed with two infusions of CYP-001 administered one week apart. Each dose was two million cells per kilogram of body weight (cells/kg), up to a maximum dose of 200 million cells, which was twice (2x) the dose level received by patients in Cohort A.

The clinical investigator determined that one patient in Cohort B was no longer a suitable candidate for treatment, due to a medical complication that occurred shortly after enrolment but prior to treatment with CYP-001. This decision was consistent with pre-specified criteria outlined in the trial protocol. The patient will be excluded from safety and efficacy analyses, as they did not receive CYP-001 treatment.

Now that the final patient has been treated, analysis of the safety and efficacy data will commence at the day 28 and day 100 post-treatment time points.

Ends

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About Graft-versus-host-disease

Graft-versus-host-disease (GvHD) is a complication that can occur after a bone marrow transplant or similar procedure, when the donor's immune cells (from the "graft") attack the recipient of the transplant (the "host"). The only approved treatment for GvHD is corticosteroid therapy, which is typically only effective in about 50 percent of patients. When GvHD fails to improve or worsens despite steroid treatment, patients are described as having steroid-resistant GvHD. The prognosis for these patients is poor, with mortality rates in excess of 90 percent.[1]

About the Phase 1 Clinical Trial (Protocol Number: CYP-GvHD-P1-01)

The trial is entitled "An Open-Label Phase 1 Study to Investigate the Safety and Efficacy of CYP-001 for the Treatment of Adults With Steroid-Resistant Acute Graft Versus Host Disease." Participants were required to be adults who received an allogeneic haematopoietic stem cell transplant (HSCT) to treat a haematological (blood) disorder, and were subsequently diagnosed with steroid-resistant Grade II-IV GvHD.

The first eight participants were enrolled in Cohort A and received two infusions of CYP-001 at a dose of one million cells per kilogram of body weight (cells/kg), up to a maximum dose of 100 million cells. There was one week between the two CYP-001 infusions in each participant. The next eight participants were enrolled into Cohort B and received two infusions of CYP-001 at a dose of two million cells/kg, up to a maximum dose of 200 million cells.

The trial's primary objective is to assess the safety and tolerability of CYP-001, while the secondary objective is to evaluate the efficacy of two infusions of CYP-001 in adults with steroid-resistant GvHD. The primary evaluation period concludes 100 days after the first dose in each participant. Efficacy is assessed on the basis of response to treatment (as determined by change in GvHD grade) and overall survival at 28 and 100 days after the administration of the first dose. After the completion of the primary evaluation period, participants enter a longer-term, non-interventional follow-up period, which will continue for up to two years after the initial dose.

About Cynata Therapeutics (ASX: CYP)

Cynata Therapeutics Limited (ASX: CYP) is an Australian clinical-stage 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™ utilises induced pluripotent stem cells (iPSCs) to produce a particular type of MSC precursor, called a mesenchymoangioblast (MCA). Cymerus™ provides a source of MSCs that is independent of donor limitations and an "off-the-shelf" stem cell platform for therapeutic product use, with a pharmaceutical product 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.

[1] *Westin JR, Saliba RM, De Lima M, et al. Steroid-Refractory Acute GVHD: Predictors and Outcomes. Adv Hematol. 2011; 2011:601953.*

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