ASX ANNOUNCEMENT **12 June 2018**

Cynata Reports Positive Six-Month Data from Cohort A in Phase 1 Trial of CYP-001 in GvHD

Melbourne, Australia, 12 June 2018: Australian stem cell and regenerative medicine company Cynata Therapeutics Limited (ASX: CYP) is pleased to announce positive safety and sustained overall survival rates from a six month follow-up assessment of patients enrolled in Cohort A of its Phase 1 clinical trial of CYP-001, the company's lead Cymerus™ mesenchymal stem cell (MSC) product candidate, in steroid-resistant acute graft-versus-host disease (GvHD).

Key highlights:

A follow up safety analysis was undertaken in all eligible patients enrolled in Cohort A, six months following their initial dose of CYP-001. The assessment found:

- Overall survival in Cohort A remains at seven out of eight patients (87.5 percent)
- No treatment-related serious adverse events (SAEs) or safety concerns have been identified

Dr Kilian Kelly, Cynata's Vice President of Product Development, said, "There is a clear unmet need for improved treatment options in steroid-resistant GvHD, where the prognosis for patients remains poor and there are very high mortality rates. We are delighted to report that all patients evaluated in Cohort A continue to do well six months after treatment with CYP-001, and that no safety concerns have arisen. We look forward to reporting further follow-up data from these patients late this year, and to the first data readout from our higher-dose Cohort B in the coming weeks."

In the Phase 1 trial, eight patients with steroid-resistant acute GvHD were enrolled in Cohort A, and received two infusions of CYP-001 administered one week apart. Each dose was 1 million cells per kilogram of body weight (cells/kg), up to a maximum dose of 100 million cells.

The primary evaluation period involved assessment of safety and efficacy (response to treatment) up to day 100. In accordance with the trial protocol, patients then entered the long term follow-up phase of the trial, primarily to monitor safety, with assessments at approximately six, 12, 18 and 24 months after the first dose of CYP-001.

As reported in February 2018, overall survival in Cohort A at day 100 was 87.5 percent, while the Overall and Complete Response rates by day 100 were 100 percent and 50 percent, respectively.[1] As previously reported, one patient in Cohort A died after developing pneumonia, which is common in recipients of bone marrow transplants and similar procedures. This death was not considered to be treatment related.

Ends

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[1] A Partial Response is an improvement in the severity of GvHD by at least one grade compared to baseline. A Complete Response is the absence of any GvHD signs and symptoms. The Overall Response Rate is the proportion of patients showing either a Partial or a Complete Response.

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.[2]

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 1 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 2 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.

[2] 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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