ASX ANNOUNCEMENT 30 July 2020

Cynata Completes Phase 1 GvHD Clinical Trial Follow-up with Positive Results

Melbourne, Australia; 30 July 2020: Cynata Therapeutics Limited (ASX: "**CYP", "Cynata",** or the **"Company"**), a clinical-stage biotechnology company specialising in cell therapeutics, has today announced positive results from the two-year follow-up of patients enrolled in the Phase 1 clinical trial of CYP-001, Cynata's lead induced pluripotent stem cell (iPSC)-derived Cymerus™ mesenchymal stem cell (MSC) product. The Phase 1 trial, which was the world's first clinical trial of an allogeneic iPSC-derived MSC product, evaluated the safety and efficacy of CYP-001 for the treatment of patients with steroid-resistant acute graft-versus-host disease (GvHD).

Highlights:

- **Overall survival after two years was 60%** (9/15 patients), which compares favourably to previously published outcomes in this patient population
- **No treatment-related serious adverse events** or safety concerns were identified
- Cynata working with licensee FUJIFILM towards the **planned Phase 2 GvHD clinical trial**

The Phase 1 clinical trial enrolled 15 patients with steroid-resistant acute GvHD. The primary evaluation at Day 100 revealed highly promising safety and efficacy results, as announced on 18 December 2018. By Day 100, the Complete Response and Overall Response rates were 53% and 87% respectively, and overall survival was at least 87%.

Participants who completed the Primary Evaluation Period then continued to a follow-up period for up to two years after the initial dose, which has now been completed.

The overall survival rate after two years was 60% (9/15 patients), which compares favourably with previously published outcomes. An overall survival rate of just 17% after two years has been reported in patients with steroid-resistant acute GvHD who received standard of care treatment.[1] Furthermore, a recently published review article summarised numerous studies with bone marrow and adipose tissue derived MSCs in patients with steroid-resistant acute GvHD. Six of the studies reviewed reported two year survival in MSC-treated patients, which ranged from 16.6% to 40%.[2] Similarly, in another recently published Phase 3 trial of an investigational drug (ruxolitinib) in patients with steroid-resistant acute GvHD, overall survival after 12 months was 38%, while there were insufficient surviving patients remaining on study to calculate the survival rate at later timepoints.[3] The results of Cynata's trial illustrate the significant potential of CYP-001 as a new treatment option for GvHD.

Study close-out procedures are now underway, which will include the preparation of a formal addendum to the clinical study report. Cynata's GvHD license partner, FUJIFILM, is responsible for the further development of CYP-001, with planning for a Phase 2 clinical trial advancing.

Dr. Kilian Kelly, Cynata's Chief Operating Officer, said*: "The prognosis in patients with this condition is extremely poor, not only due to GvHD itself, but also because these patients generally have an underlying cancer and a compromised immune system. These follow-up results suggest that the high initial treatment response rates observed with CYP-001 100 days after treatment may result in a longer-term benefit. Overall, our Phase 1 study results are very positive compared to published results with other methods of treatment. We continue to work with our partners at FUJIFILM toward the planned Phase 2 clinical trial in GvHD to build on these very encouraging results, and we look forward to that commencing in the near future"*.

-ENDS-

Authorised for release by Dr Ross Macdonald, Managing Director & CEO

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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 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 severe complications arising from COVID-19, GvHD and critical limb ischemia and a Phase 3 trial in osteoarthritis. In addition, Cynata has demonstrated utility of its Cymerus™ MSC technology in preclinical models of asthma, diabetic wounds, heart attack, sepsis, acute respiratory distress syndrome (ARDS) and cytokine release syndrome.

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 have undergone an allogeneic haematopoietic stem cell transplant (HSCT) to treat a haematological (blood) disorder and subsequently been 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. Seven participants in Cohort B received two infusions of CYP-001 at a dose of 2 million cells/kg, up to a maximum dose of 200 million cells. There was one week between the two CYP-001 infusions in each participant.

The trial's primary objective was to assess the safety and tolerability of CYP-001, while the secondary objective was to evaluate the efficacy of two infusions of CYP-001 in adults with steroid-resistant GvHD. The primary evaluation period concluded 100 days after the first dose in each participant. Efficacy was 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 entered a longer-term, non-interventional follow-up period, which continued for up to two years after the initial dose.

About Cynata's Partnership with Fujifilm Corporation

In 2017, Cynata entered into a Development and Commercialisation Partnership Agreement with Fujifilm Corporation of Japan, and in September 2019 Cynata granted Fujifilm an exclusive, worldwide license to develop and commercialise CYP-001 for the prevention and treatment of GvHD in humans.

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[1] Westin JR, et al. Steroid-Refractory Acute GVHD: Predictors and Outcomes. Adv Hematol. 2011; 2011:601953.

[2] Elgaz, S. et al. Clinical Use of Mesenchymal Stromal Cells in the Treatment of Acute Graft-versus-Host Disease. Transfus Med Hemother.46:27-34 (2019)..

[3] Zeiser R, et al. Ruxolitinib for Glucocorticoid-Refractory Acute Graft-versus-Host Disease. N Engl J Med. 2020;382(19):1800-1810.