ASX ANNOUNCEMENT 22 May 2023

Two-Year Follow-Up Results of Phase 1 SR-aGvHD Trial Presented at ISCT

Key highlights

- **Two-year patient follow-up data from Cynata's Phase 1 clinical trial of CYP-001 in SR-aGvHD selected for oral presentation at major international conference**
- **Patients treated with CYP-001 had a two-year overall survival rate of 60% (9/15 patients)**
- **The two-year overall survival rate in patients treated with CYP-001 compares highly favourably to previously published outcomes, including for a drug currently approved to treat SR-aGvHD**
- **No treatment-related serious adverse events or safety concerns were identified**

Melbourne, Australia; 22 May 2023: Cynata Therapeutics Limited (ASX: "**CYP", "Cynata",** or the **"Company"**), a clinical-stage biotechnology company specialising in cell therapeutics, is pleased to announce that further data on CYP-001, Cynata's Cymerus™ mesenchymal stem cell (MSC) product candidate for aGvHD, will be presented at the upcoming Annual Meeting of the International Society for Cell and Gene Therapy (ISCT) in Paris, France.

An abstract summarising Cynata's data was selected for oral presentation, which will be delivered by Professor John Rasko, AO (Head of Department, Cell & Molecular Therapies, Royal Prince Alfred Hospital, Sydney; Professor, Faculty of Medicine & Health, The University of Sydney; and Head, Gene and Stem Cell Therapy Program, Centenary Institute, Sydney). The abstract has also been published in a special supplement of *Cytotherapy*,[1] which is the official journal of ISCT.

The presentation summarises the two-year patient follow-up data from the Phase 1 clinical trial of CYP-001 in 15 adults with steroid-resistant acute GvHD (SR-aGvHD). As previously announced, and published in the prestigious journal *Nature Medicine*,[2] the primary evaluation at Day 100 revealed highly promising results with Complete Response and Overall Response rates of 53% and 87%, observed respectively. Today's presentation showed a sustained outcome with the two-year overall survival at 60% (9/15 patients), with no treatment-related serious adverse events or safety concerns identified. This survival rate compares very favourably to previously reported outcomes in SR-aGvHD. For example, in the Phase 3 study that supported approval of the drug ruxolitinib, the 18-month overall survival rates were only 38% in the ruxolitinib group and 36% in the "best available treatment" control group (survival at two years was not evaluable).[3]

Professor Rasko said:

"As this was the first completed clinical trial worldwide of iPSC-derived cells in any disease, the long-term follow-up data are of substantial importance. In addition to the encouraging overall survival rate, the absence of any safety signals is very reassuring, and strongly supports further investigation of CYP-001 in patients with aGvHD."

Dr Kilian Kelly, Cynata's Chief Operating Officer, said:

"The selection of our clinical study data for oral presentation at the ISCT Annual Meeting is further recognition of the ground-breaking nature of this trial, and its relevance to the wider cell and gene therapy research community. We look forward to building on these very positive results, both through our Phase 2 clinical trial in aGvHD, as well as our ongoing clinical trials in osteoarthritis and diabetic foot ulcers."

Founded in 1992, the ISCT is a global society comprised of clinicians, regulators, researchers, technologists, and industry partners, focused on the development of cell and gene therapy products. This year's ISCT Annual Meeting, which will take place from 31 May to 3 June, will be attended by delegates from more than 50 countries worldwide.

Cynata is now in the advanced stages of starting a Phase 2 clinical trial of Cymerus MSCs in high risk aGvHD, which aims to recruit approximately 60 patients at clinical centres in the US, Europe, and Australia.

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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. Planning for a Phase 2 clinical trial in GvHD under a cleared US FDA IND is presently underway. Clinical trials of Cymerus products in osteoarthritis (Phase 3) and diabetic foot ulcers (DFU) are currently ongoing. In addition, Cynata has demonstrated utility of its Cymerus technology in preclinical models of numerous diseases, including the clinical targets mentioned above, as well as critical limb ischaemia, idiopathic pulmonary fibrosis, asthma, heart attack, sepsis, acute respiratory distress syndrome (ARDS) and cytokine release syndrome.

Cynata Therapeutics encourages all current investors to go paperless by registering their details with the designated registry service provider, Automic Group.

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[1] Kelly K, et al. A phase I clinical trial of iPSC-derived MSCs (CYP-001) in steroid-resistant acute GvHD: two year follow-up results. Cytotherapy. 2023:25S7–S283.

[2] Bloor AJC, et al. Production, safety and efficacy of iPSC-derived mesenchymal stromal cells in acute steroid-resistant graft versus host disease: a phase I, multicenter, open-label, dose-escalation study. Nat Med. 2020;26:1720–1725.

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