

## Market Update and Additional A\$618k R&D Tax Refund

**Melbourne, Australia; 11 March 2020:** Cynata Therapeutics Limited (ASX: CYP), a clinical-stage biotechnology company specialising in cell therapeutics, is pleased to announce that it has received an additional A\$618,667 R&D Tax Incentive Refund for the 2018/2019 financial year and to provide a market update on other activities.

### Key highlights

- Cynata received an additional A\$619k R&D tax incentive refund, extending cash runway
- COVID-19 outbreak has not impacted current clinical trial plans but has resulted in growing industry interest in the potential of mesenchymal stem cells (MSCs) to form part of the treatment management plan for patients with conditions caused by severe COVID-19 infection
- Strengthened IP protection of Cynata's unique stem cell technology, with Canadian patent issued, and Notices of Allowance received from both Israel and Japan
- Cynata is focused on progressing the development of its MSC platform technology to provide a treatment for a range of indications with three Phase 2 trials in planning

### R&D Tax incentive rebate

The A\$618k R&D tax incentive refund is in addition to the A\$1.892m already received in January this year. The further refund follows confirmation from AusIndustry that overseas R&D expenditure related to Cynata's planned Phase 2 clinical trial in critical limb ischemia trial (CLI) is eligible for the rebate.

This additional cash injection extends Cynata's cash balance, and enables further resources to be invested towards Cynata's robust Phase 2 clinical trial programs for CLI and osteoarthritis, alongside the anticipated Phase 2 trial for CYP-001 in graft-versus-host disease (GvHD) which is to be conducted by FUJIFILM.

### COVID-19 Update

Cynata wishes to inform investors that the current Phase 2 trial plans remain on track and confirms the Company does not currently have any logistic or supply chain issues arising from the COVID-19 outbreak (formerly known as Novel Coronavirus (2019-nCoV)).

Additionally, Cynata is responding to enquiries and is in active discussions with international pharmaceutical companies and other parties about the potential of its Cymerus MSCs to be a useful adjunct in the management of patients with serious and ongoing issues associated with COVID-19 infection. COVID-19 has been shown to cause conditions including acute respiratory distress syndrome (ARDS), sepsis and cytokine release syndrome (CRS), indications where Cynata has previously demonstrated utility of its Cymerus MSCs in preclinical studies. Of direct relevance are observations in these preclinical studies that Cynata's Cymerus MSCs significantly reduce levels of pro-inflammatory cytokines and increase both anti-inflammatory proteins and regulatory T cells<sup>1</sup>.

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<sup>1</sup> Khan M, et al. Stem Cell Res Ther. 2019 Sep 23;10(1):290. doi: 10.1186/s13287-019-1397-4. Ozay E, et al. Stem Cell Res. 2019 Mar;35:101401. doi: 10.1016/j.scr.2019.101401



The potential of MSCs for treating the consequences of COVID-19 is underpinned by very recent clinical results in China, suggesting that MSCs may protect against serious outcomes of the infection, particularly pneumonia. Critically ill COVID-19 patients in China favourably responded to treatment with MSCs in a clinical study<sup>2</sup>.

### **Strengthened IP protection**

As announced previously, Cynata continues to extend its robust intellectual property protection of its Cymerus platform. The Canadian Intellectual Property Office has granted a patent for Cynata's unique MSC technology with an expiration date of 16 March 2031. Further, Notices of Allowance have been received from both the Israel Patent Office and the Japan Patent Office, for patent applications covering the Cymerus MSC technology, with both patents having an anticipated expiration date of 12 March 2034.

### **Outlook**

Cynata remains focused on progressing the development of Cymerus MSCs in multiple planned upcoming Phase 2 trials. Further progress has been made for the Phase 2 trial in CLI, and Cynata is working with FUJIFILM to advance Phase 2 trial planning and activities in GvHD.

In addition, the osteoarthritis Phase 2 trial planning is in the final stages toward commencement, with the expectation that this major trial will begin enrolling patients in the near term. This 448-patient study is substantially funded by the Australian National Health and Medical Research Council (NHMRC) and is expected to be conducted at study centres in Sydney and Tasmania.

**-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 GvHD, critical limb ischemia and osteoarthritis. In addition, Cynata has demonstrated utility of its Cymerus MSC technology in preclinical models of asthma, diabetic wounds, sepsis, heart attack and cytokine release syndrome, a life-threatening condition stemming from cancer immunotherapy.

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<sup>2</sup> Leng Z, et al. Transplantation of ACE2- Mesenchymal Stem Cells Improves the Outcome of Patients with COVID-19 Pneumonia. Aging and Disease, 10.14336/AD.2020.0228