ASX ANNOUNCEMENT

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# Cynata provides guidance on planned osteoarthritis and CLI clinical trials

**Melbourne, Australia; 1 April 2020:** Cynata Therapeutics Limited (ASX: CYP), a clinical-stage biotechnology company specialising in cell therapeutics provides the following guidance on the planned Phase 2 clinical trials of Cynata's Cymerus™ mesenchymal stem cell (MSC) products for osteoarthritis and critical limb ischemia (CLI), and its ongoing pre-clinical studies.

Cynata continues to liaise closely with partners, regulatory authorities and relevant collaborators to track the impact of the current COVID-19 pandemic on upcoming and ongoing studies.

## Osteoarthritis Phase 2 clinical trial update

Together with the trial sponsor, the University of Sydney, good progress continues to be made toward obtaining approval by the University of Sydney Human Research Ethics Committee (HREC). This is a key milestone in the procedural aspects toward commencing the trial.

In parallel, Cynata is working closely with trial co-ordinators to ascertain the impact of the current COVID-19 pandemic on the possible schedule for trial commencement. The Clinical Trial Support Office of the University of Sydney has advised that newly approved trials should not commence trial participant involvement (first visits) until further notice. This advice is expected to remain in place until the COVID-19 situation resolves. In the meantime, Cynata will continue to work with the trial Chief Investigator, Professor David Hunter, to continue to prepare for the trial to be ready for enrolment when the current restrictions are removed.

## CLI Phase 2 clinical trial update

Cynata is currently in discussions with study partners and collaborators regarding its CLI Phase 2 clinical trial and continues to progress study start-up activities. Given the current situation and widespread restrictions now in place globally, it is expected that the commencement of patient recruitment in the CLI trial will also face timing uncertainty until the current COVID-19 situation resolves.

## Ongoing preclinical program progress on schedule

The key active pre-clinical study is in Acute Respiratory Distress Syndrome (ARDS), which continues to progress with initial results expected by mid CY20.

Cynata remains well funded with A$5.92m in cash as at 31 December 2019 and received R&D tax rebates of A$1.89m in January 2020 and A$0.62m in March 2020, and will continue to invest in accretive R&D opportunities and responsibly manage cash flow. The Company will vigilantly monitor the evolving global situation and provide further updates in due course.

Dr Ross Macdonald, Cynata's MD and CEO, commented:
*"Despite the dynamic and unprecedented environment we now face during the coronavirus pandemic we continue to make good progress toward completing start-up activities for the planned Phase 2 trials in osteoarthritis and CLI. We expect to be in a good position to commence recruitment once current measures are relaxed, but prudence dictates that we accommodate these uncertainties into our scheduling. We will continue to progress activities towards the final stage before clinical trial commencement and will actively monitor the evolving developments, providing further guidance as the situation progresses."*

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**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.