ASX ANNOUNCEMENT **24 July 2023**

Strategic Review of Cynata's Clinical Development Portfolio

Key highlights:

- **Strategic review of Cynata's clinical development portfolio completed, led by recently appointed CEO and Managing Director, Dr Kilian Kelly**
- **Patient recruitment for Phase 2 aGvHD trial expected to commence this quarter**
- **Approximately 300 patients enrolled into the Phase 3 osteoarthritis trial to date, with recruitment expected to conclude late 2023/early 2024 - underpinned by accelerated enrolment rates this year**
- **Assessment of Phase 1 trial in diabetic foot ulcers has resulted in key initiatives implemented to increase enrolment rates, with recruitment now expected to conclude by end of 2023**
- **Regulatory approval process for the Phase 1 trial in renal transplantation well progressed, with outcome expected this quarter**
- **Investor webcast scheduled for 9:15am (AEST) on Thursday, 27 July 2023**

Melbourne, Australia; 24 July 2023: Cynata Therapeutics Limited (ASX: "**CYP", "Cynata",** or the **"Company"**), a clinical-stage biotechnology company specialising in cell therapeutics, today announced that a strategic review of its clinical development portfolio has been completed, led by the recently appointed CEO and Managing Director, Dr Kilian Kelly.

The review incorporated a detailed assessment of all ongoing and planned clinical development programs with extensive input from existing strategic partners, contract research organisations and clinical centres to ensure the timely progression and completion of the Company's comprehensive Cymerus™ mesenchymal stem cell (MSC) clinical trial programs.

Dr Kilian Kelly, Cynata's CEO & Managing Director, said:
"Successful execution of our clinical trials is our number one priority, and we intend to focus all available resources on achieving recruitment targets in the new financial year. Importantly, our existing cash balance is sufficient to fund the GvHD and DFU trials, while the osteoarthritis and renal transplant trials are funded by our external partners. We expect to have the majority of clinical centres in the GvHD trial open for recruitment this year, and we look forward to building on the highly encouraging Phase 1 clinical trial of CYP-001 in Steroid-Resistant aGvHD. We have also made significant progress on our other indications and look forward to achieving key milestones in the coming months."

Graft Versus Host Disease
Cynata is currently finalising trial startup activities, including securing regulatory and ethics approvals, for the planned Phase 2 clinical trial of CYP-001, in patients with High-Risk acute Graft versus Host Disease (HR-aGvHD). It is anticipated that centres in the US and Australia will be initiated and opened for recruitment this quarter.

The Company is also seeking approval to commence the trial within a number of European countries Cynata is in the process of providing additional information requested by the EU regulatory authorities to conclude the application. The additional information relates primarily to understanding the raw materials used in the manufacture of CYP-001, and assays used to test the product.

Based on an updated analysis of the expected commencement date and recruitment rate at each participating centre, the Company now anticipates completion of enrolment in this trial by the end of 2024. Following patient treatment, follow-up and data analysis, the release of primary evaluation results is expected in the second half of 2025.

Osteoarthritis
The University of Sydney, in collaboration with Cynata, has made significant progress with the Phase 3 SCUlpTOR trial of CYP-004 in patients with osteoarthritis (OA) of the knee.

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While the recruitment rate for the trial was initially slower than expected, primarily due to the impact of pandemic-related restrictions on centres, the enrolment rate this year has accelerated dramatically, and approximately 300 patients have now been enrolled in the trial.

The Phase 3 SCUlpTOR trial is taking place at two clinical centres in Australia, and based on consultation with The University of Sydney, Cynata expects patient recruitment to conclude late 2023 or early 2024. Following patient treatment, follow-up and data analysis, the Company expects primary evaluation results to be released in the first half of 2026.

Diabetic Foot Ulcer

Recruitment of patients continues in the Phase 1 clinical trial of CYP-006TK in patients with diabetic foot ulcer (DFU), across four clinical centres in Australia. Due to an unexpectedly high screening failure rate, which means many potential patients failed to meet the eligibility criteria, the trial has experienced lower than expected enrolment rates.

The Company has actively taken steps to address this, including updating the clinical trial protocol and opening additional clinical centres (as previously announced on 16 March 2023) while still optimising the likelihood of trial success. It is now anticipated that recruitment will conclude by the end of 2023, with results available in mid-2024.

Renal Transplant

The Company is working with Leiden University Medical Center (LUMC) in the Netherlands to commence the proposed Phase 1 clinical trial of CYP-001 in patients who have undergone renal transplantation. This trial will be funded and managed by LUMC, while Cynata will supply CYP-001 for use in the trial. The regulatory approval process for this trial is currently underway, with all information submitted and being reviewed by the regulators. An outcome is expected this quarter.

Investor Webinar

Investors are invited to join a webcast hosted by CEO and Managing Director, Dr Kilian Kelly at 9:15am (AEST) on Thursday, 27 July 2023. To pre-register for the event, please follow this link:

https://ccmediaframe.com/?id=nwqmPZoz

Upon registration, participants will receive a calendar invitation, details and a link to access the webcast.

-ENDS-

Authorised for release by Dr Kilian Kelly, CEO & Managing Director

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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.