ASX ANNOUNCEMENT **3 June 2026**

EMA PDCO Positive Opinion on CYP-001 Paediatric Investigation Plan

Melbourne, Australia; 3 June 2026: Cynata Therapeutics Limited (ASX: "CYP", "Cynata", or the "Company"), a clinical-stage biotechnology company specialising in cell therapeutics, has received a Positive Opinion from the Paediatric Committee (PDCO) of the European Medicines Agency (EMA), on the Paediatric Investigation Plan (PIP) for CYP-001 in acute graft versus host disease (aGvHD).

Key Highlights:

- An agreed PIP[1] is required before commencement of a Phase 3 clinical trial in the European Union (EU), regardless of whether the Phase 3 trial will include adults, children or both.
- The PDCO has agreed to the Company's proposed PIP, which will involve a single randomised controlled Phase 2/3 clinical trial of CYP-001 in ~72 aGvHD patients aged from 28 days to 18 years.
- The Company plans to commence a Phase 3 clinical trial in adults initially. After completion of the primary analysis of the adult Phase 3 trial, the Company plans to commence the paediatric clinical trial.

CYP-001 is Cynata's Cymerus™ iPSC[2]-derived MSC[3] product for intravenous use, which is designed to modulate the immune system and improve both response rates and survival outcomes in aGvHD.

aGvHD is a serious and often life-threatening complication of bone marrow transplantation and similar procedures,[4] where the donor's immune cells (the graft) attack the recipient's tissues (the host). aGvHD affects up to 50% of patients who receive transplants from other donors. Standard first-line treatment with steroids fails in around one-half of all aGvHD cases, which are known as "steroid-resistant" or steroid-resistant aGvHD (SR-aGvHD) cases. Historical two-year survival rates in patients with SR-aGvHD are less than 20%.[5]

A Phase 1 trial in adults with SR-aGvHD delivered an 87% Overall Response Rate, a 53% Complete Response Rate, and 60% two-year overall survival, with no serious adverse events or safety concerns related to CYP-001 treatment. This ground-breaking trial led to two publications in the prestigious journal *Nature Medicine*.[6,7]

In March this year, the primary evaluation period was completed in the Company's Phase 2 trial of CYP-001 in adults with high risk aGvHD. A total of 65 participants were enrolled across clinical centres in Australia, the USA and Europe, randomised to receive either steroids plus CYP-001 or steroids plus placebo. The primary endpoint is Overall Response Rate at Day 28, with results anticipated in late June or early July 2026.

Subject to positive data from the Phase 2 trial in adults, the Company's development plan for CYP-001 for aGvHD currently envisages a single Phase 3 trial in adults, followed by a separate Phase 2/3 trial in children. In both trials, it is anticipated that patients will be randomised to receive either steroids plus CYP-001 or steroids plus placebo. The PDCO has now agreed with this plan, including with the proposed timing of the paediatric trial, which means that the Marketing Authorisation Application for adults could be submitted while the paediatric trial is still ongoing. The PDCO's Positive Opinion will now be sent to the European Commission for formal adoption.

Nuket Desem, Cynata's Director of Regulatory and Scientific Affairs, said:

"Gaining EMA approval of our PIP is a key step towards late-phase clinical development and commercialisation of CYP-001 in the EU, for both adults and children. Europe is a very important market for us in general, and for aGvHD in particular. aGvHD is more common in Europe than in any other region, with approximately twice as many cases as in the USA,[8] and there are currently no EMA-approved cell-based therapies for the treatment of aGvHD in any age group."

-ENDS-

Cynata Therapeutics Limited
ABN – 98 104 037 372

Level 3, 100 Cubitt Street
Cremorne
VIC 3121
Australia

T: +613 7067 6940
E: info@cynata.com
www.cynata.com

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

CONTACTS: Dr Kilian Kelly, CEO & MD, Cynata Therapeutics, +61 (03) 7067 6940, kilian.kelly@cynata.com
Lauren Nowak, Media Contact, +61 (0)400 434 299, investors@cynata.com

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 and limitations of conventional MSC production by using induced pluripotent stem cells (iPSCs) to achieve economic manufacture of cell therapy products, including mesenchymal stem cells (MSCs), at commercial scale without the necessity to obtain tissue from multiple donors on an ongoing basis, and without the complexity and product inconsistency resulting from conventional methods.

Cynata has demonstrated positive safety and efficacy data for its Cymerus™ product candidates CYP-001 and CYP-006TK in Phase 1 clinical trials in steroid-resistant acute graft versus host disease (GvHD) and diabetic foot ulcers (DFU), respectively. Further clinical trials are now ongoing: a Phase 2 trial of CYP-001 in GvHD under a cleared US FDA IND; a Phase 1/2 trial of CYP-001 in patients undergoing kidney transplantation; and a Phase 3 trial of CYP-004 in osteoarthritis. In addition, Cynata has demonstrated utility of its Cymerus™ technology in preclinical models of numerous other diseases, including critical limb ischaemia, idiopathic pulmonary fibrosis, asthma, heart attack, sepsis, acute respiratory distress syndrome (ARDS) and cytokine release syndrome.

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[1] In accordance with the EU Paediatric Regulation (Regulation (EC) No 1901/2006)
[2] iPSC = induced pluripotent stem cell.
[3] MSC = mesenchymal stem (or stromal) cell.
[4] Technically referred to as allogeneic haematopoietic stem cell transplantation (HSCT).
[5] Westin JR, et al. Adv Hematol. 2011;2011:601953
[6] Bloor AJC, et al. Nat Med. 2020;26:1720–1725
[7] Kelly K, et al. Nat Med. 2024;30:1556–1558
[8] aGvHD is a consequence of allogeneic haematopoietic stem cell transplantation (HSCT). >20,000 allogeneic HSCTs are performed per annum in Europe (Passweg JR et al, Bone Marrow Transplant. 2025;60:519–528) compared to <10,000 in the USA (Spellman SR et al, Transplant Cell Ther. 2025;31(8):505-532).