

ASX ANNOUNCEMENT

27 July 2023

## Investor Webinar Presentation

**Melbourne, Australia; 27 July 2023:** Cynata Therapeutics Limited (ASX: “CYP”, “Cynata”, or the “Company”), a clinical-stage biotechnology company specialising in cell therapeutics, is pleased to release the presentation that will be delivered during today’s investor webinar.

The presentation provides an overview of the recently completed strategic review, as announced earlier this week (on 24 July 2023). As foreshadowed in that announcement, investors are invited to join a webcast hosted by CEO and Managing Director, Dr Kilian Kelly at 9:15am (AEST) today (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.

The presentation is attached to this announcement.

**-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.**



# A Next Generation Stem Cell Therapeutics Company

## **Strategic Review Presentation**

July 2023

# Introduction to new CEO

“

*It is a great honour and privilege to be appointed as CEO and Managing Director of Cynata at such an exciting time in the company's journey of developing its therapeutic stem cell platform technology, Cymerus™.*

*I look forward to working with the Cynata team to drive the successful execution of our clinical trial programs as a number one priority. Our clinical success is underpinned by our unique manufacturing process and highly encouraging data across a range of clinical and pre-clinical studies.*

*Cynata is poised for an exciting future, with a unique opportunity to make a significant impact on patient lives and create long term value for shareholders. We are well funded to advance our clinical trial program and look forward to achieving key milestones in the coming months.*

”







**Dr Kilian Kelly**  
CEO & MD

- Appointed as CEO / MD from 1 July 2023 onwards – joined Cynata in 2014 as VP of Product Development and served as COO from May 2019 to June 2023
- Oversaw the development of CYP-001, Cynata's lead Cymerus product for aGvHD, navigating its regulatory, manufacturing and clinical pathway leading to a successful clinical trial
- Has over two decades of biopharmaceutical R&D experience, and previously held roles at Biota Pharmaceuticals, Mesoblast, Kendle International, Amgen, and AstraZeneca
- Member of the Royal Pharmaceutical Society, International Society for Cell and Gene Therapy and the Australian Institute of Company Directors





# Strategic review of product pipeline completed

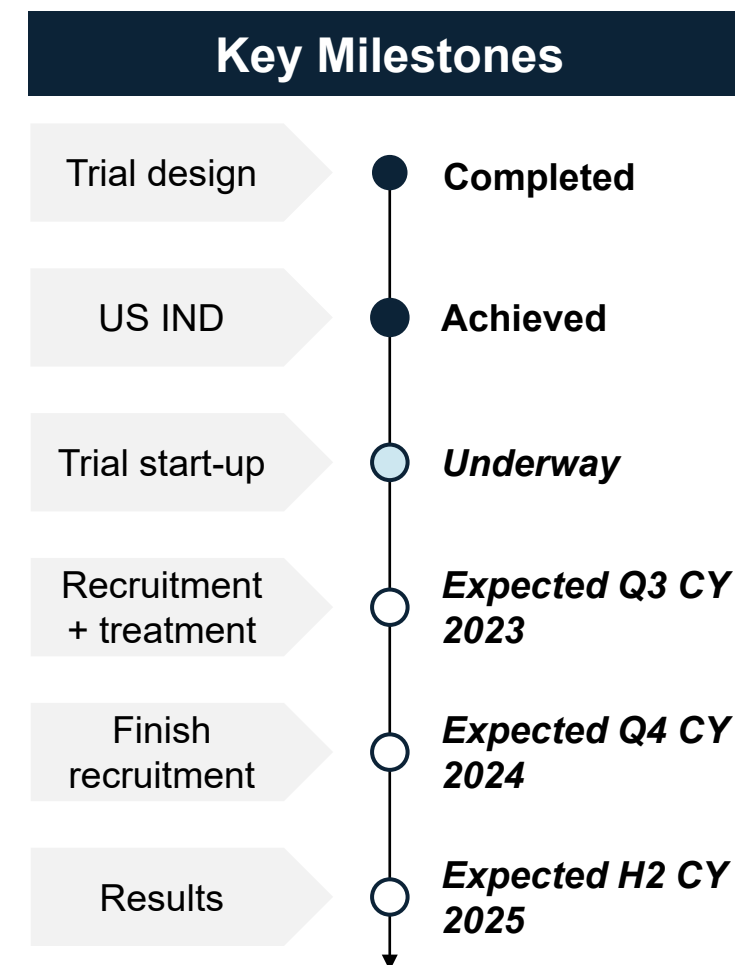
Cynata has an advanced product pipeline targeting attractive market opportunities across a range of indications

	Target area	Trial phase	Market opportunity
Cynata Sponsored	 Acute Graft vs Host Disease (aGvHD)	Phase 2 ready <sup>1</sup>	US\$0.6bn <sup>2</sup>
	 Diabetic Foot Ulcers (DFU)	Phase 1 underway	US\$9.6bn <sup>3</sup>
Partnered	 Osteoarthritis (OA) <i>(conducted by USYD, funded by NHMRC)</i>	Phase 3 underway	US\$11.6bn <sup>4</sup>
	 Renal Transplantation (Renal) <i>(funded by LUMC)</i>	Phase 1 planning	US\$5.9bn <sup>5</sup>

# aGvHD | Phase 2 clinical trial

Cynata plans to commence recruitment during the current quarter, with results expected H2 CY 2025





 <b>aGvHD</b>	<ul style="list-style-type: none"><li>Acute Graft vs Host Disease (aGvHD) is a complication that can occur after a bone marrow transplant when the donor's immune cells (from the "graft") attack the recipient of the transplant (the "host").</li></ul>
 <b>Trial design</b>	<ul style="list-style-type: none"><li>Randomised controlled trial in ~60 patients with high risk aGvHD</li><li>Clinical sites across in USA, Europe and Australia</li><li>Primary objective to assess efficacy of CYP-001 in subjects by Overall Response Rate (ORR) at Day 28</li></ul>
 <b>Strategic review</b>	<ul style="list-style-type: none"><li>Currently finalising trial startup activities including securing regulatory and ethics approval – relevant approvals in Australia and the US are secured</li><li>European regulatory approval process ongoing</li></ul>
 <b>Timing</b>	<ul style="list-style-type: none"><li>US and Australian centres expected to commence recruitment this quarter</li><li>Patient recruitment expected to conclude by the end of CY 2024</li><li>Primary evaluation results expected in H2 CY 2025</li></ul>

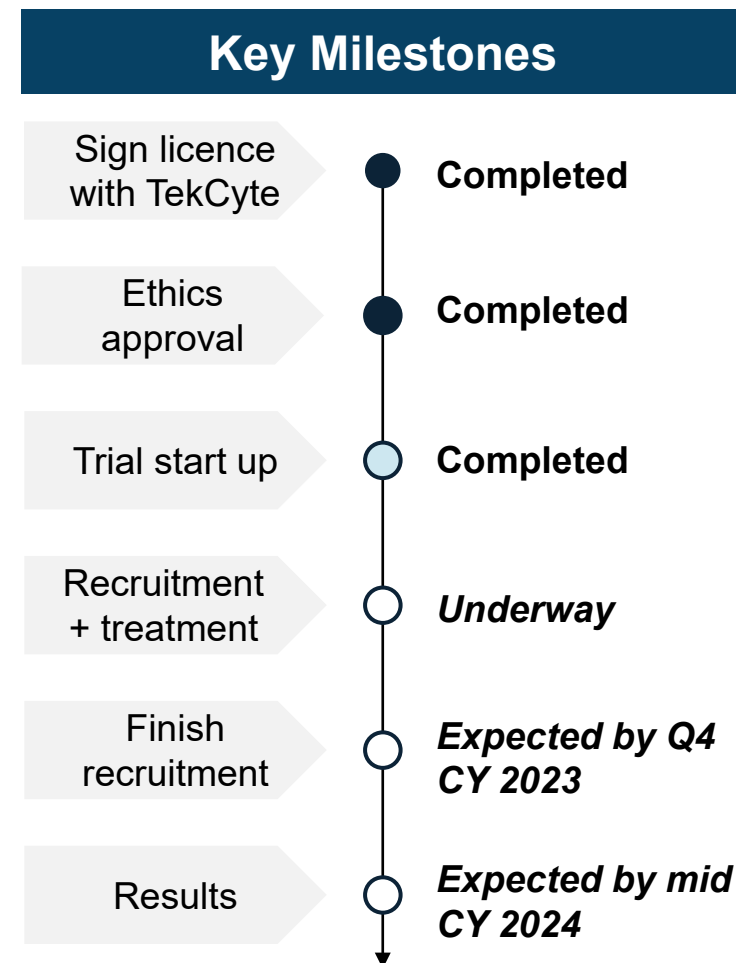




# DFU | Phase 1 clinical trial

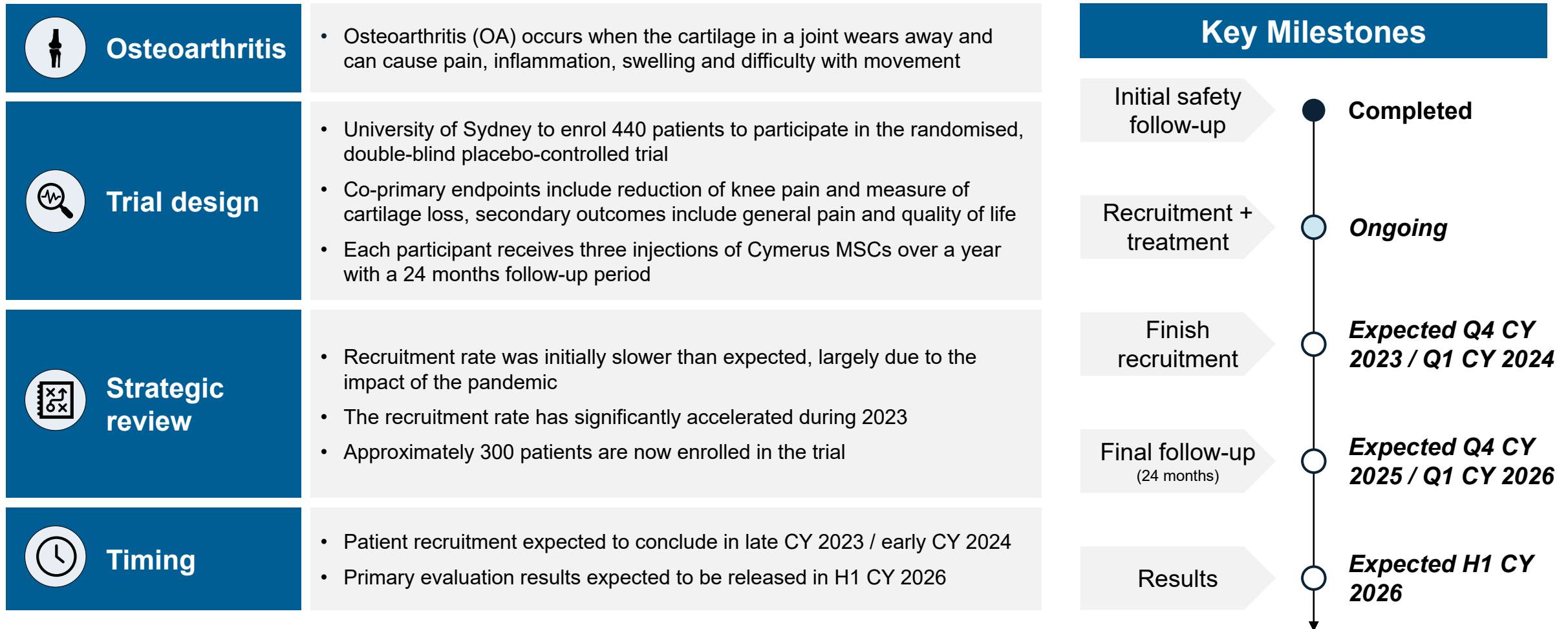
High screening failure rate has resulted in slower than expected recruitment, Cynata has undertaken steps to accelerate recruitment rate with enrolment expected to be completed by the end of CY 2023

 <b>Diabetic Foot Ulcers</b>	<ul style="list-style-type: none"><li>Diabetic Foot Ulcers (DFU) are sores on the feet of patients with diabetes (also known as diabetic wounds)</li></ul>
 <b>Trial design</b>	<ul style="list-style-type: none"><li>30 patients with DFU will be randomly assigned to receive CYP-006TK or standard care of treatment, over 4 weeks</li><li>The primary outcome measure of the trial is safety, while outcome measures include wound healing, pain and quality of life</li><li>Secondary outcome measures are measured at 12 and 24 weeks</li></ul>
 <b>Strategic review</b>	<ul style="list-style-type: none"><li>Slower than expected recruitment driven by unexpectedly high screening failure rate as potential patients failed to meet trial eligibility criteria</li><li>Trial protocol has been updated to address this issue, making it easier for patients to enrol while optimising for likelihood of a positive trial outcome</li><li>Additional centres opened taking the total number of clinical centres to four</li></ul>
 <b>Timing</b>	<ul style="list-style-type: none"><li>Patient recruitment expected to conclude in by the end of CY 2023</li><li>Primary evaluation results expected to be released by mid CY 2024</li></ul>







# OA | Phase 3 clinical trial<sup>1</sup>

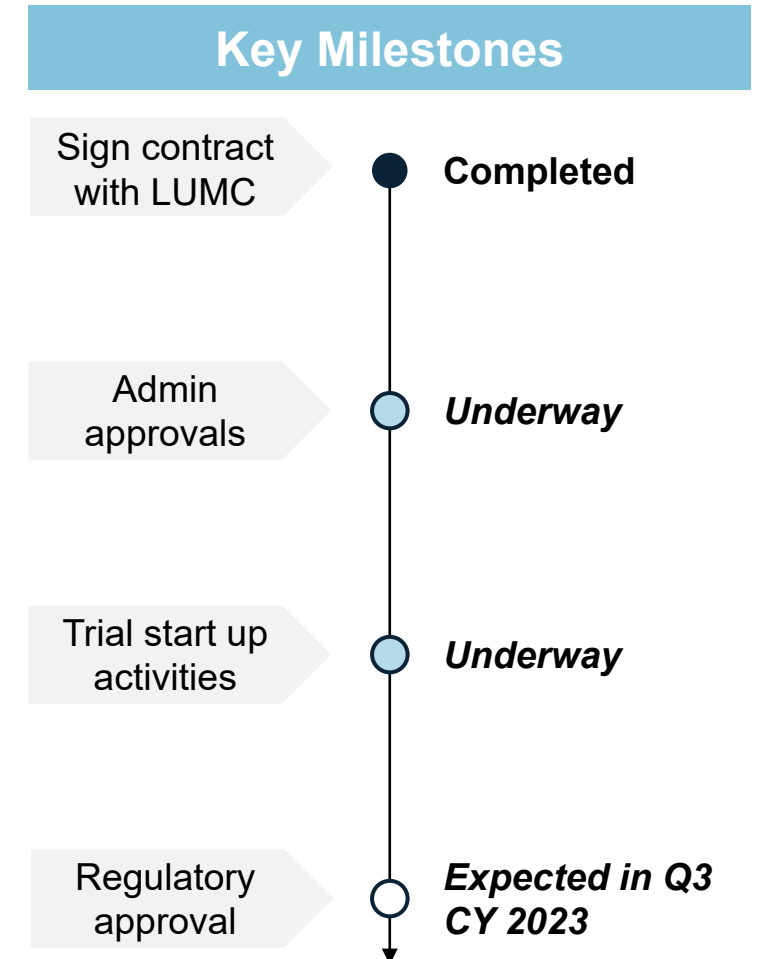
Recruitment accelerating and expected to be completed by the end of CY 2023, with evaluation results expected to be released in CY 2026



# Renal | Phase 1 clinical trial

Clinical trial start up activities with partner Leiden University Medical Center (LUMC) underway, with outcome from regulatory approval process expected during the current quarter

 <b>Renal Transplants</b>	<ul style="list-style-type: none"><li>MSCs may reduce or eliminate the requirement for aggressive and toxic anti-rejection drugs, leading to a substantial breakthrough in transplantation medicine</li></ul>
 <b>Trial design</b>	<ul style="list-style-type: none"><li>10 renal transplant patients will receive Cymerus MSCs after transplantation followed by withdrawal of anti-rejection medication</li><li>Primary endpoint is absence of graft loss after 6 months after withdrawal of anti-rejection medication</li></ul>
 <b>Strategic review</b>	<ul style="list-style-type: none"><li>Proposed trial design agreed between LUMC and Cynata</li><li>LUMC has submitted the required information package to the regulators, and it is currently undergoing review</li></ul>
 <b>Timing</b>	<ul style="list-style-type: none"><li>Regulatory approval process underway with outcome from regulators expected during the current quarter</li></ul>





# Investment Highlights

Cynata is a clinical stage biotech developing its proprietary Cymerus platform technology for the scalable manufacture of mesenchymal stem cell (MSC) therapeutic products to treat serious disorders



## Unique Manufacturing

**Single donation from a single donor**  
iPSC strategy overcomes suboptimalities in conventional MSC manufacturing



## Strong safety and efficacy

**Positive pre-clinical and clinical data**  
supporting versatility and efficacy of Cynata's MSCs; all endpoints met in aGvHD phase 1 with ORR of 87%



## Multiple clinical trials

### Rich clinical pipeline:

- **aGvHD** (phase 2)
- **DFU** (phase 1)
- **Osteoarthritis** (phase 3)
- **Renal** (phase 1)



## Large addressable market

**Combined market opportunity** of clinical trials underway and in planning is **~A\$38bn**



## Fully funded

Fully funded to complete planned clinical trials with **~A\$16m<sup>2</sup> in cash**  
  
OA and renal trials **fully funded by external partners**

# Important information

## Summary information

This Presentation contains summary information about Cynata Therapeutics Limited and its subsidiaries (CYP) which is current as at 26 July 2023. This Presentation should be read in conjunction with CYP's other periodic and continuous disclosure information lodged with the Australian Securities Exchange (ASX), which are available at [www.asx.com.au](http://www.asx.com.au).

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This Presentation contains historical financial information based on the Company's results for the quarter year to June 2023. This information is disclosed in the 4C report lodged with ASX on 26 July 2022. Any discrepancies between totals and sums of components in tables and figures in this Presentation are due to rounding.

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