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A Next Generation Stem Cell Therapeutics Company

Strategic Review Presentation

July 2023

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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

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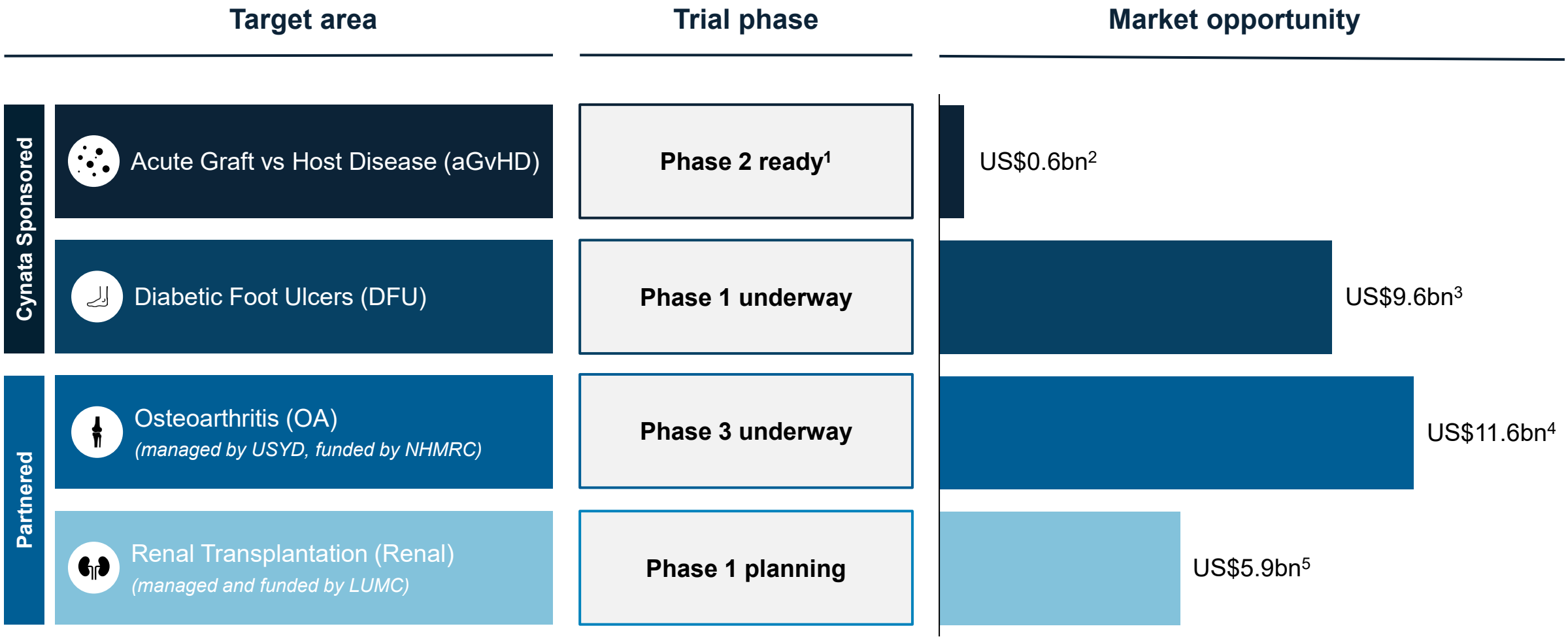
Strategic review of product pipeline completed

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



1.Investigational New Drug approval received from the US Food and Drug Administration to commence a Phase 2 GvHD trial; 2. Global Graft versus Host Disease Market 2019-2029 (Reflects forecast market in 2026); 3. Zion Market Research, 2019 (represents global treatment market in 2025); 4. Persistence Market Research 2018 research report: "Osteoarthritis Treatment Market: Global Industry Analysis (2012-2016) and Forecast (2017-2025) (Reflect OA market by 2025); 5. Organ Transplant Immunosuppressant Drugs Market in 2026, Grand View Research, Inc.,2019

aGvHD | Phase 2 clinical trial

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

aGvHD

- 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").

Trial design

- Randomised controlled trial in ~60 patients with high risk aGvHD
- Clinical sites across in USA, Europe and Australia
- Primary objective to assess efficacy of CYP-001 in subjects by Overall Response Rate (ORR) at Day 28

Strategic review

- Currently finalising trial startup activities including securing regulatory and ethics approval – relevant approvals in Australia and the US are secured
- European regulatory approval process ongoing

Timing

- US and Australian centres expected to commence recruitment this quarter
- Patient recruitment expected to conclude by the end of CY 2024
- Primary evaluation results expected in H2 CY 2025

Key Milestones

Trial design	**Completed**
US IND	**Achieved**
Trial start-up	***Underway***
Recruitment + treatment	***Expected Q3 CY 2023***
Finish recruitment	***Expected Q4 CY 2024***
Results	***Expected H2 CY 2025***

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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

Diabetic Foot Ulcers

- Diabetic Foot Ulcers (DFU) are sores on the feet of patients with diabetes (also known as diabetic wounds)

Trial design

- 30 patients with DFU will be randomly assigned to receive CYP-006TK or standard care of treatment, over 4 weeks
- The primary outcome measure of the trial is safety, while outcome measures include wound healing, pain and quality of life
- Secondary outcome measures are measured at 12 and 24 weeks

Strategic review

- Slower than expected recruitment driven by unexpectedly high screening failure rate as potential patients failed to meet trial eligibility criteria
- 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
- Additional centres opened taking the total number of clinical centres to four

Timing

- Patient recruitment expected to conclude in by the end of CY 2023
- Primary evaluation results expected to be released by mid CY 2024

Key Milestones

Sign licence with TekCyte	**Completed**
Ethics approval	**Completed**
Trial start up	**Completed**
Recruitment + treatment	***Underway***
Finish recruitment	***Expected by Q4 CY 2023***
Results	***Expected by mid CY 2024***

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OA | Phase 3 clinical trial[1]

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

Osteoarthritis

- Osteoarthritis (OA) occurs when the cartilage in a joint wears away and can cause pain, inflammation, swelling and difficulty with movement

Trial design

- University of Sydney to enrol 440 patients to participate in the randomised, double-blind placebo-controlled trial
- Co-primary endpoints include reduction of knee pain and measure of cartilage loss, secondary outcomes include general pain and quality of life
- Each participant receives three injections of Cymerus MSCs over a year with a 24 months follow-up period

Strategic review

- Recruitment rate was initially slower than expected, largely due to the impact of the pandemic
- The recruitment rate has significantly accelerated during 2023
- Approximately 300 patients are now enrolled in the trial

Timing

- Patient recruitment expected to conclude in late CY 2023 / early CY 2024
- Primary evaluation results expected to be released in H1 CY 2026

Key Milestones

Initial safety follow-up	**Completed**
Recruitment + treatment	***Ongoing***
Finish recruitment	***Expected Q4 CY 2023 / Q1 CY 2024***
Final follow-up (24 months)	***Expected Q4 CY 2025 / Q1 CY 2026***
Results	***Expected H1 CY 2026***

1. Clinical trial entitled Stem Cells as a symptom – and strUcture-modifying Treatment for medial tibiofemoral OsteoaRthritis: a randomised placebo-controlled trial (SCUlpTOR).

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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

Renal Transplants	• MSCs may reduce or eliminate the requirement for aggressive and toxic anti-rejection drugs, leading to a substantial breakthrough in transplantation medicine
Trial design	• 10 renal transplant patients will receive Cymerus MSCs after transplantation followed by withdrawal of anti-rejection medication • Primary endpoint is absence of graft loss after 6 months after withdrawal of anti-rejection medication
Strategic review	• Proposed trial design agreed between LUMC and Cynata • LUMC has submitted the required information package to the regulators, and it is currently undergoing review
Timing	• Regulatory approval process underway with outcome from regulators expected during the current quarter

Key Milestones

- Sign contract with LUMC — **Completed**
- Admin approvals — ***Underway***
- Trial start up activities — ***Underway***
- Regulatory approval — ***Expected in Q3 CY 2023***

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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[2] in cash**

OA and renal trials **fully funded by external partners**

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1. Current expectation
2. Cash as at 30 June 2023

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