A Next Generation Stem Cell Therapeutics Company

AGM Presentation

22 November 2022

Authorised for release by Dr Ross Macdonald, Managing Director and CEO

Key Highlights: FY22

Clinical & Pre-clinical

Actively recruiting and treating patients in the phase 3 Osteoarthritis (OA) trial

Actively recruiting and treating patients in the Diabetic Foot Ulcers (DFU) trial

Received clearance from the FDA for IND application for phase 2 trial in aGvHD[1]

New phase 1 clinical trial focused on kidney transplantation to be funded by LUMC[2]

Progress toward partnering clinical pipeline opportunities

Reported compelling data from preclinical studies in IPF[3] and heart attack

Published papers in leading peer-reviewed journals

Planning underway for phase 2 GvHD trial in the US

1. aGvHD: Acute Graft vs Host Disease
2. Post FY22 event, LUMC: Leiden University Medical Centre
3. IPF: idiopathic pulmonary fibrosis

Key Highlights: FY22

Commercial & Corporate

Signed a Strategic Partnership Agreement (SPA) and Manufacturing Services Agreement with Fujifilm: tech transfer advancing well

Regained development and commercialisation rights to CYP-001 for GvHD

Received payment of US$5m as part of the SPA

Strengthened IP portfolio, with patents granted in the US, Canada, Russia, China and Japan

Dr Jolanta Airey appointed as Chief Medical Officer to drive Cynata's advanced clinical product pipeline

Conventional vs. Cynata's Cymerus MSC manufacturing process

Conventional Processes

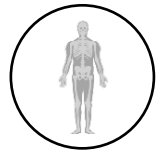
Cells donated → **Conventional process** → **MSCs**

1. Cells from **multiple** donors

2. **Limited** quantity of MSCs isolated

3. **Significant MSC expansion** required

4. Cell therapy product



Cynata's Process

Cells donated → **Cynata's patented process: Cymerus** → **MSCs**

1. Cells from **one** donation from **one** donor

2. iPSCs: effectively **limitless** expansion

3. **Minimal** MSC culture expansion via MCAs

4. Cell therapy product

CONSISTENCY	QUANTITY	QUALITY	EFFICIENCY

iPSC: Induced Pluripotent Stem Cells. iPSC's derived directly from adult cells and can propagate indefinitely.
MCA: Mesenchymoangioblasts. These are produced from iPSCs.

Competitive strengths of the Cymerus platform

Cymerus technology elegantly addresses each of the major challenges faced by existing approaches to manufacturing MSCs, facilitating scalable and reproducible production at low cost

	Conventional manufacture	Cymerus platform
Potency	Mandatory requirement to expand MSCs isolated from donors causes a **dramatic reduction in potency** while compromising scalability	Expansion at the iPSC stage ensures **fresh, highly potent MSCs** following final differentiation step
Consistency	Reliance on multiple donors and donations **compromises product consistency** while posing logistical, practical and regulatory challenges	**Same starting material** for every batch
Cost of treatment	Need for multiple/higher doses of product results in **high COGS**	CYP-001 required **substantially lower number of doses** in aGvHD

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Cynata's technology addresses FDA concerns

Cynata's Cymerus process actively addresses current inefficiencies of MSC manufacturing, de-risking clinical development in the US

Traditional MSC manufacturing is sub-optimal

Other MSC therapy (also targeting GvHD) was not approved by the FDA due to substantial functional variability between lots.

*"Substantial **functional heterogeneity** has been observed between MSC batches **derived from different donors** and **expanded using different tissue culture conditions or duration**, even though all of these batches meet the ISCT criteria for MSCs."*

- Excerpt from **FDA ODAC Briefing** document for 13 August 2020

Cynata's technology is optimal

- ✓ Consistency: No inter-donor variability as only one donor is required (single blood donation)
- ✓ Scalability: Cynata can produce essentially limitless quantities of MSCs from initial donation
- ✓ Potency: iPSC-derived manufacturing process does not require excessive culture expansion of MSCs
- ✓ FDA advisory meeting observations to be leveraged to maximise chance of FDA approval

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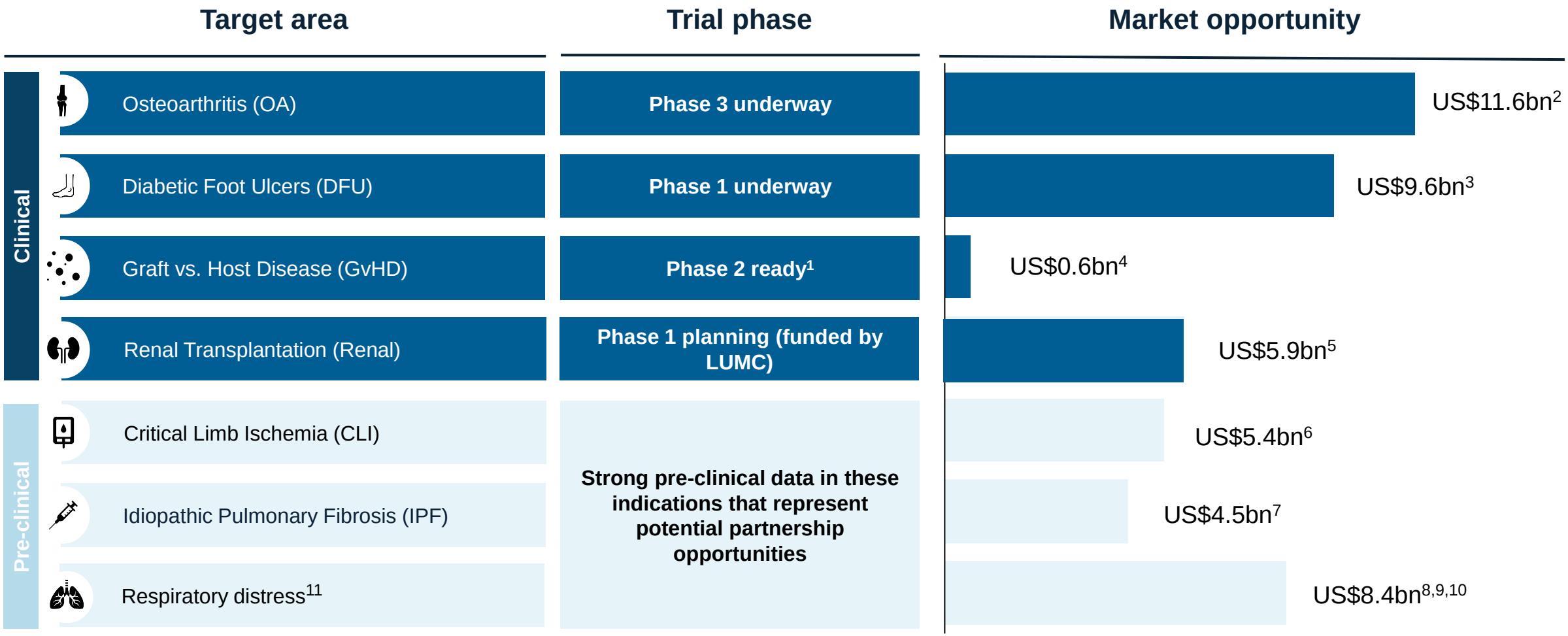
Source: FDA Briefing Document, Oncologic Drugs Advisory Committee (ODAC) Meeting. Session on Product Characterization (AM Session) 13 August, 2020.

Cynata has an advanced and diverse product pipeline

Cynata is 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. Persistence Market Research 2018 research report: "Osteoarthritis Treatment Market: Global Industry Analysis (2012-2016) and Forecast (2017-2025) (Reflect OA market by 2025); 3. Zion Market Research, 2019 (represents global treatment market in 2025); 4. Global Graft versus Host Disease Market 2019-2029 (Reflects forecast market in 2026); 5. Organ Transplant Immunosuppressant Drugs Market in 2026, Grand View Research, Inc.,2019; 6. Transparency Market Research, 2020 (Reflect global DFU treatment market by 2027). 7. iHealthcareAnalyst Inc, 2019 (represents global market by 2025); 8. Vasomune Therapeutics company announcement, 2018 (Reflects ARDS global market opportunity of US$2.5bn) 9. GlobeNewswire, 2020 (Represents CRS global market opportunity of US$0.16m in 2017) 10. GlobalData 2017 (Reflects Sepsis global market opportunity of US$5.9bn in 2026)
11. MEND clinical trial concluded following strategic review of clinical pipeline as announced 12 August 2022

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GvHD | Ground-breaking Phase 1 clinical trial results

Cynata's phase 1 GvHD trial met all safety and efficacy endpoints and broke ground by being the world's first completed clinical trial of an allogeneic iPSC-derived product

Key results[1] demonstrate safety and efficacy of Cymerus MSCs

All endpoints achieved

(Day 100)

Complete response 53%

Overall response 87%

Survival rate ≥87%

Efficacy endpoints were the **same required in a phase 3 trial**

Response rates were **higher than what we expect would be required in phase 3** (to support marketing approval)

Outstanding follow-up results

(Two year)

Overall survival rate: Cynata MSCs 60%

Compares favourably with other results

17% *Standard of care*

17 - 40% *Other MSC products*

Published in prestigious journal[2]

Nature medicine is the preeminent peer-reviewed medical journal worldwide

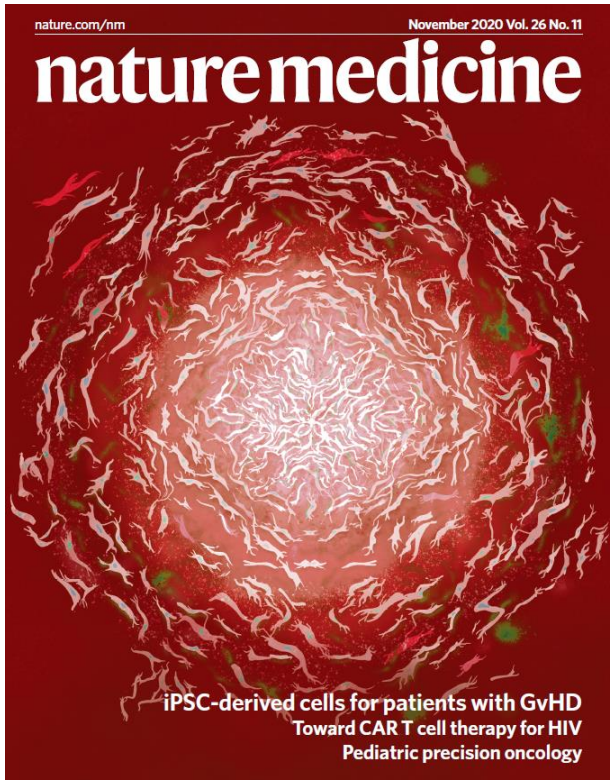


Image Source: https://www.nature.com/nm/; illustration by Patton'd Studios, Melbourne

1. Primary evaluation at Day 100. 2.Cynata featured on cover of prestigious journal, *Nature Medicine*, with the November 2020 issue including a paper describing Cynata's Phase 1 clinical trial of CYP-001 in patients with GvHD: Bloor AJC, et al;. Production, safety and efficacy of iPSC-derived mesenchymal stromal cells in acute steroid-resistant graft versus host disease: a Phase I, multi-centre, open label, dose-escalation study. Nat Med 26, 1720-1725 (2020).

aGvHD | Phase 2 clinical trial in aGvHD

With a cleared IND from the FDA Cynata expects to commence a clinical trial in acute GvHD by early 2023

aGvHD

- **Acute Graft vs Host Disease (aGvHD)** remains a common complication of allogeneic hematopoietic stem cell transplants (e.g., bone marrow transplants) when the donor's immune cells (from the "graft") attack the recipient of the transplant (the "host").

Unmet medical need

- The only first line treatment is corticosteroids, **which is only effective in ~50% of patients**
- Patients who fail current treatments face **mortality rates in excess of 90%**

Validated by Phase 1 results

- Cynata's **phase 1 GvHD trial met all safety and efficacy endpoints** and broke ground by being the world's first completed clinical trial of an allogeneic iPSC-derived product

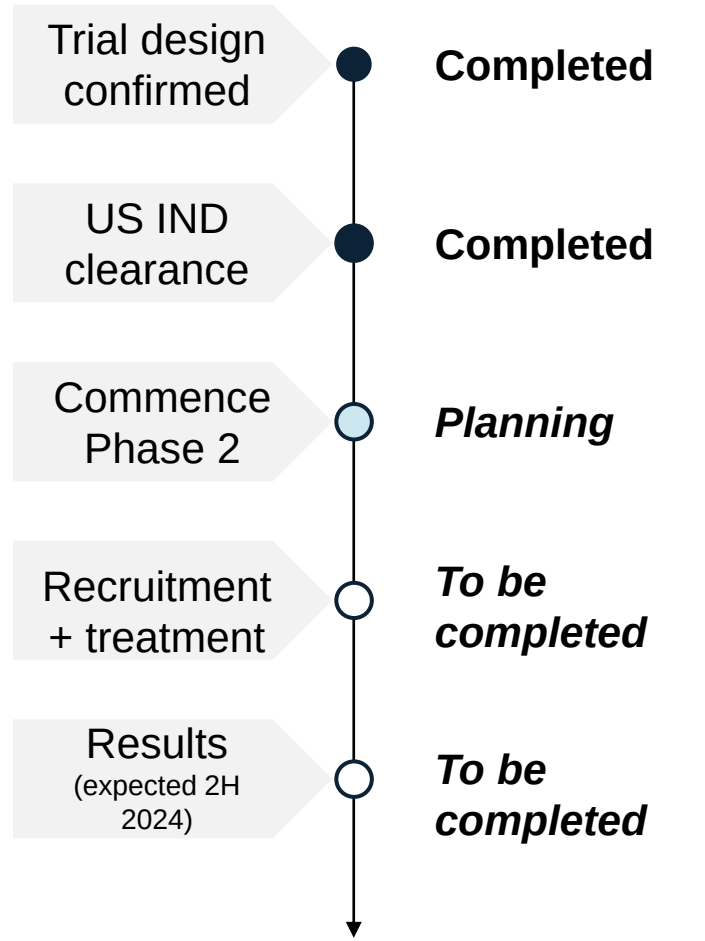
US FDA approval

- **US Food and Drug Administration (FDA)** has **cleared** Cynata's **Investigational New Drug (IND) application** for a phase 2 clinical trial of CYP-001 in aGvHD

Trial design

- Proposed trial will seek to recruit **~60 patients** with high risk aGvHD at clinical centres in a number of countries, including US and Australia
- Final start-up activities underway in concert with CRO IQVIA

Key Milestones



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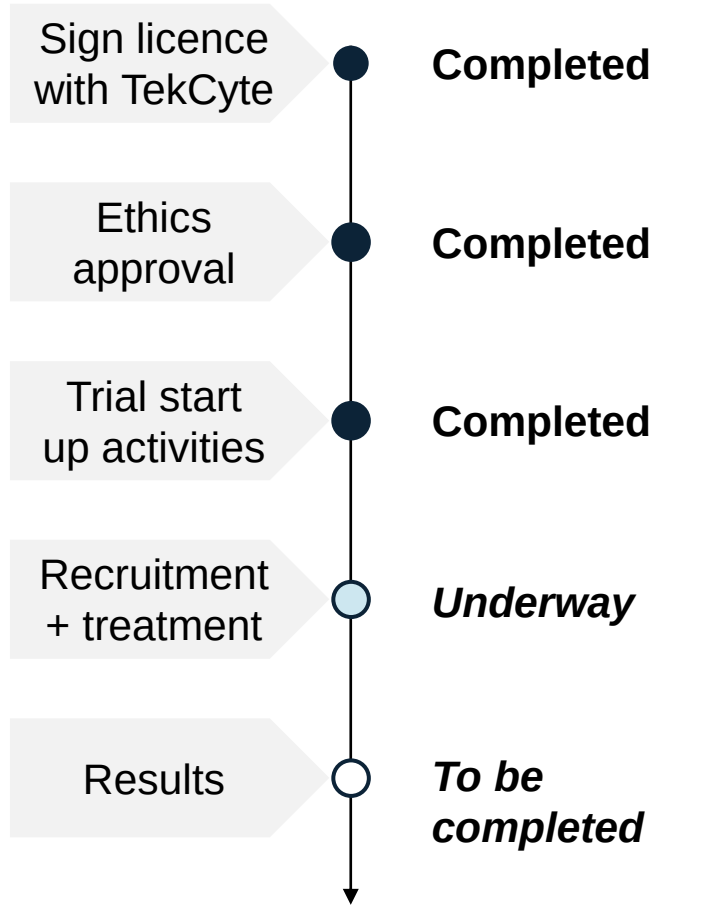
DFU | Phase 1 clinical trial update

Enrolment opened in December 2021 with completion expected in 1H23

Diabetic Foot Ulcers (DFU)	• DFU are sores on the feet of patients with diabetes (also known as diabetic wounds)
Huge Market Opportunity	• **>400m diabetics globally,** with DFU estimated to **occur in ~15-25% of patients** during their lifetime[1] • Global market is estimated to be **~US$10bn**[2]
Strong preclinical data	• Positive efficacy data of MSCs in a preclinical model • **Cymerus MSCs achieved 86% skin restoration** after three days
Unique competitive positioning	• **Secured a worldwide exclusive licence agreement with TekCyte** to a novel polymer-coated dressing technology to deliver MSCs topically • CYP-006TK: polymer-coated silicon dressing seeded with Cymerus MSCs
Trial design	• **30 patients** with DFU will be randomly assigned to receive CYP-006TK or standard care of treatment, over 4 weeks
Timing update	• Recruitment expected to finish by mid way through 2023 with results released by the end of 2023

Key Milestones



1. Diabetics Australia (estimated ~415m adults with diabetes in 2015) ; Mutluoglu M, Uzun G, Turhan V, Gorenek L, Ay H, Lipsky BA. How reliable are cultures of specimens from superficial swabs compared with those of deep tissue in patients with diabetic foot ulcers? J Diabetes Complications. 2012 May-Jun;26(3):225-9
2. Estimated DFU market (Source: Transparency Market Research, 2020 (Reflects global DFU treatment market by 2027)).

Osteoarthritis-SCUlpTOR[1] | Phase 3 clinical trial update

Clinical trial underway, sponsored by the University of Sydney and funded by an NHMRC project grant

Osteoarthritis	• **Osteoarthritis (OA)** occurs when the cartilage in a joint wears away • Causes pain, inflammation, swelling and difficulty with movement
Huge Market Opportunity	• **There is currently no complete cure** • OA estimated to affect >30m Americans, global market of ~**US$11.6bn**[2]
Strong preclinical data	• **Preclinical research** supports efficacy of MSCs • Potential to **improve the underlying disease** as well as alleviating pain
Non-dilutive funding	• **Funded** by the Australian Government NHMRC[3] project grant • **Led by Professor David Hunter**, who is the Florance and Cope Chair of Rheumatology and Professor of Medicine at the University of Sydney
Trial design	• University of Sydney to **enrol 440 patients** to participate in the randomised, double-blind placebo-controlled trial
Timing update	• Results readout expected in 2025, revised from late-2024 by the University of Sydney based on the current recruitment rate

Key Milestones

Initial safety follow-up	**Completed**
Recruitment + treatment	***Underway***
Follow up (24 months from baseline)	***To be completed***
Results (expected 2025[4])	***To be completed***

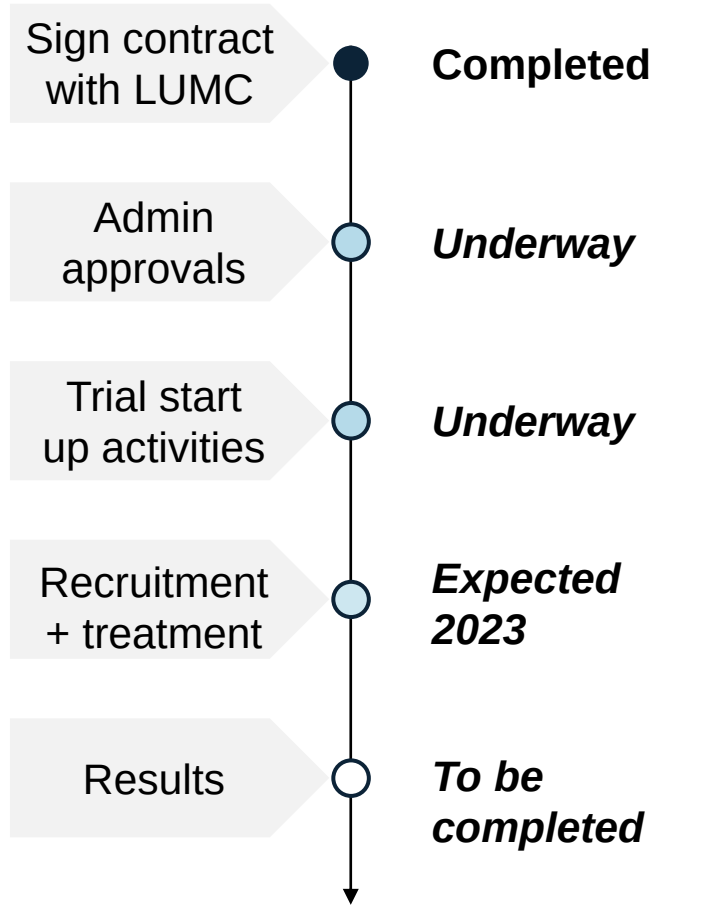
1. Clinical trial entitled Stem Cells as a symptom – and strUcture-modifying Treatment for medial tibiofemoral OsteoaRthritis: a randomised placebo-controlled trial (SCUlpTOR).
2. Reflects OA market by 2025; Persistence Market Research 2018 research report: "Osteoarthritis Treatment Market: Global Industry Analysis (2012-2016) and Forecast (2017-2025).
3. NHMRC: National Health and Medical Research Council
4. Note: Timing is dependent on a number of external factors (including COVID-19 restrictions)

Renal | Phase 1 clinical trial update

Funding to conduct trial secured from Leiden University Medical Center (LUMC)

Renal Transplants	• MSCs may reduce or eliminate the requirement for aggressive and toxic anti-rejection drugs, leading to a substantial breakthrough in transplantation medicine
Huge Market Opportunity	• **There are approximately 130,000 kidney transplants** around the world each year[1] • Global market is estimated to be **~US$5.9bn**[2]
Strong early data	• Positive efficacy data of MSCs in a preclinical model and in clinical trials
Unique competitive positioning	• **Funded by LUMC;** Cynata providing cells • Cynata has full commercial rights
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.

Key Milestones



1. https://www.statista.com/statistics/398645/global-estimation-of-organ-transplantations/
2. Organ Transplant Immunosuppressant Drugs Market in 2026, Grand View Research, Inc.,2019.

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Near term catalysts

Cynata is in a strong position to advance its proprietary Cymerus platform technology

End 2022 + 1H 2023

- ✓ **DSMB review** in DFU trial
- ❑ **Commence phase 2** trial in aGvHD
- ❑ **Complete recruitment** of 30 patients in DFU clinical trial

During 2H 2023

- ❑ **Complete recruitment** of 440 patients in U Syd phase 3 osteoarthritis trial
- ❑ **Announce** DFU clinical trial results
- ❑ **Commence** renal transplant clinical trial with LUMC

Ongoing

- ❑ **Further clinical trial results:** expecting ongoing newsflow as our clinical pipeline matures and our broad pre-clinical pipeline enters clinical trials
- ❑ **Progress commercial discussions** and execute further corporate partnership(s)

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Board & management

Highly skilled and experienced senior leadership team with decades of experience

Dr Geoff Brooke
Chairman

- **30+ years experience** in the healthcare investment industry
- Founder and MD of Medvest Inc and GBS Venture Partners

Dr Ross Macdonald
Managing Director / CEO

- **30+ years experience and a track record of success** in pharmaceutical and biotechnology businesses
- Previously CEO of Hatchtech

Dr Kilian Kelly
Chief Operating Officer

- **15+ years experience** in biopharma research & development
- Previously Senior Director, Drug Development at Biota Pharmaceuticals, VP, Regulatory and Clinical at Mesoblast

Dr Jolanta Airey
Chief Medical Officer

- **25+ years experience** in respiratory, rheumatology, dermatology, biologicals and listed companies
- Previously Director, Translational Development at CSL

Ms Janine Rolfe, GAICD
Non-Exec Director

- **20+ years legal, governance and management** experience across multiple sectors
- Founder of Company Matters

Dr Paul Wotton
Non-Exec Director

- **30+ years experience** in senior positions of life sciences companies
- Previously **President and CEO** of Ocata Therapeutics, Inc

Dr Stewart Washer
Non-Exec Director

- **20+ years of CEO and Board experience**
- Chairman of Orthocell (ASX:OCC) and Emyria (ASX:EMD), Director of Botanix Pharmaceuticals (ASX:BOT).

Dr Darryl Maher
Non-Exec Director

- **Vice President** of R&D and Medical Affairs at **CSL Behring**
- He was a **former President** of the Australian Pharmaceutical Physicians Association and a director of Vaccine Solutions

Mr Peter Webse
Company Secretary

- **23+ years company secretarial experience**
- MD of Platinum Corporate Secretariat Pty Ltd, providing company secretarial and other services

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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 overcomes suboptimalities in conventional MSC manufacturing

Strong safety and efficacy

Positive pre-clinical and clinical data supporting versatility and efficacy of Cynata's MSCs

Validation through strategic partnership with FUJIFILM

Multiple clinical trials underway

Rich clinical pipeline:

- **Diabetic Foot Ulcers**
- **Osteoarthritis** (phase 3)
- **Renal transplantation** to commence in 2023[1]
- **Phase 2 aGvHD** trial to commence in 2023[1] under cleared **IND**

Large addressable market

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

Significant value upside

Multiple pathways to commercialisation, including strategic partnering

DFU: Diabetic Foot Ulcers
1. Current expectation

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