

ASX ANNOUNCEMENT

27 June 2024

Investor Presentation

Melbourne, Australia; 27 June 2024: Cynata Therapeutics Limited (ASX: “CYP”, “Cynata”, or the “Company”), a clinical-stage biotechnology company specialising in cell therapeutics, is pleased to invite shareholders to attend an investor webinar hosted by *Sharewise*, to be held today, Thursday 27 June at 2pm AEST.

The webinar will commence with a presentation, followed by a live questions and answers session with Cynata’s CEO and MD, Dr Kilian Kelly.

Attendees are required to register in advance for the webinar – using the following link: https://zoom.us/webinar/register/3517188549370/WN_1vt2vITETWYLKotFC0-IEg#/registration

An updated version of the Company’s Investor Presentation, which will be delivered during the webinar, is attached to this announcement.

-ENDS-

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

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Lauren Nowak, Media Contact, +61 (0)400 434 299, littlebigdealconsulting@gmail.com

About Cynata Therapeutics (ASX: CYP)

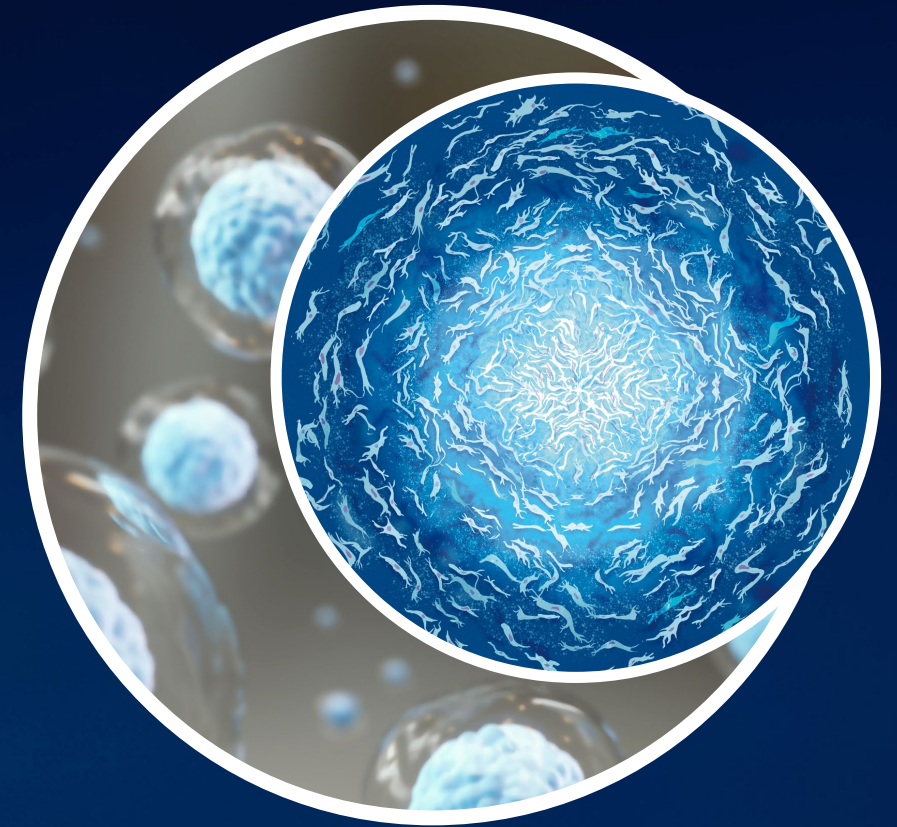
Cynata Therapeutics Limited (ASX: CYP) is an Australian clinical-stage stem cell and regenerative medicine company focused on the development of therapies based on Cymerus™, a proprietary therapeutic stem cell platform technology. Cymerus™ overcomes the challenges of other production methods by using 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. A Phase 2 clinical trial in GvHD under a cleared US FDA IND, as well as trials of Cymerus products in osteoarthritis (Phase 3 – patient enrolment completed) and diabetic foot ulcers (DFU – patient enrolment completed) are currently ongoing, while a trial in renal transplant is expected to commence in the near future. In addition, Cynata has also demonstrated utility of its Cymerus technology in preclinical models of numerous diseases, including 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 Clinical Stage Next Generation Stem Cell Therapeutics Company



Investor Presentation
June 2024

Important information

Summary information

This Presentation contains summary information about Cynata Therapeutics Limited and its subsidiaries (CYP) which is current as at 26 June 2024. 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.

Not an offer

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Financial data

All financial information in this Presentation is in Australian currency (A\$) unless otherwise stated. This Presentation contains historical financial information based on the Company's results for the quarter to 31 March 2024. This information is disclosed in the Appendix 4C report lodged with the ASX on 30 April 2024. Any discrepancies between totals and sums of components in tables and figures in this Presentation are due to rounding.

Forward-looking statements

This Presentation contains certain 'forward looking statements', which can generally be identified by the use of forward looking words such as 'expect', 'anticipate', 'likely', 'intend', 'should', 'could', 'may', 'predict', 'plan', 'propose', 'will', 'believe', 'forecast', 'estimate', 'target', 'outlook', 'guidance', 'potential' and other similar expressions. The forward looking statements contained in this Presentation are not guarantees or predictions of future performance and involve known and unknown risks and uncertainties and other factors, many of which are beyond the control of CYP, its directors and management, and may involve significant elements of subjective judgment and assumptions as to future events which may or may not be correct. There can be no assurance that actual outcomes will not differ materially from these forward looking statements. A number of important factors could cause actual results or performance to differ materially from the forward looking statements. No representation or warranty, express or implied, is made as to the accuracy, likelihood of achievement or reasonableness of any forecasts, prospects, returns or statements in relation to future matters contained in this Presentation. The forward looking statements are based on information available to CYP as at the date of this Presentation. Except as required by law or regulation (including the ASX Listing Rules), CYP and its directors, officers, employees, advisers, agents and intermediaries undertake no obligation to provide any additional or updated information whether as a result of new information, future events or results or otherwise. You are strongly cautioned not to place undue reliance on forward-looking statements, particularly in light of the current economic climate and the significant volatility, uncertainty and disruption caused by the outbreak of COVID-19.

Industry and Market data

Certain market and industry data used in connection with this Presentation may have been obtained from research, surveys or studies conducted by third parties, including industry or general publications. Neither CYP nor its representatives have independently verified any such market or industry data provided by third parties or industry or general publications.

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Company highlights

Revolutionary Cymerus™ manufacturing platform

- **Mesenchymal stem cells (MSCs)**¹ have shown potential to treat a wide range of illnesses,² but standard manufacture requires ongoing supply of new donors → challenges with consistency, potency and scale
- The patented **Cymerus™** platform is based on **induced pluripotent stem cell (iPSC)** technology
- Overcomes major obstacle to commercialisation in this highly promising field, by enabling production of an **effectively limitless** quantity of **consistent, high-quality** MSC doses from a **single blood donation**

Compelling clinical data

- **Acute graft versus host disease (aGvHD) Phase 1:** 53% complete response; 87% overall response
- **Diabetic foot ulcer (DFU) Phase 1:** 88% median wound surface area reduction vs 51% in controls³

Rich clinical pipeline

- Three major randomised controlled clinical trial readouts upcoming:
DFU (Ph 1) – late 2024/early 2025; **aGvHD** (Ph 2) – 2H 2025; and **osteoarthritis** (Ph 3) – early 2026
- New trial in kidney transplantation to commence in mid 2024

1. Also known as mesenchymal stromal cells

2. Zhou, J., Shi, Y. Cell Mol Immunol 20, 555–557 (2023).

3. Initial data in first 16 patients (n=8 per group) after 10 weeks; final results in all 30 patients expected in late 2024/early 2025

FY 2024 – a year of progress

Completion of patient enrolment in two randomised controlled trials

- Phase 3 osteoarthritis – enrolment completed November 2023
- Phase 1 DFU – enrolment completed April 2024

Further encouraging clinical efficacy data

- Promising initial data from ongoing DFU trial released in February 2024

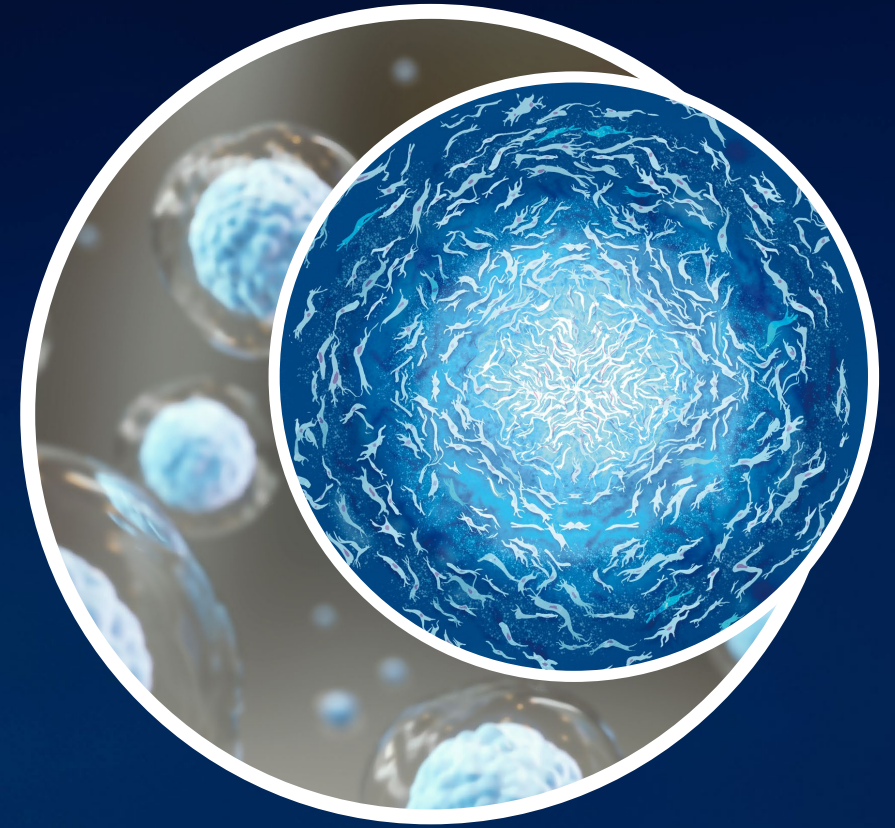
New trials adding to rich pipeline

- Global Phase 2 aGvHD trial – first patient enrolled in March 2024
- New kidney transplant trial approved and ready to commence

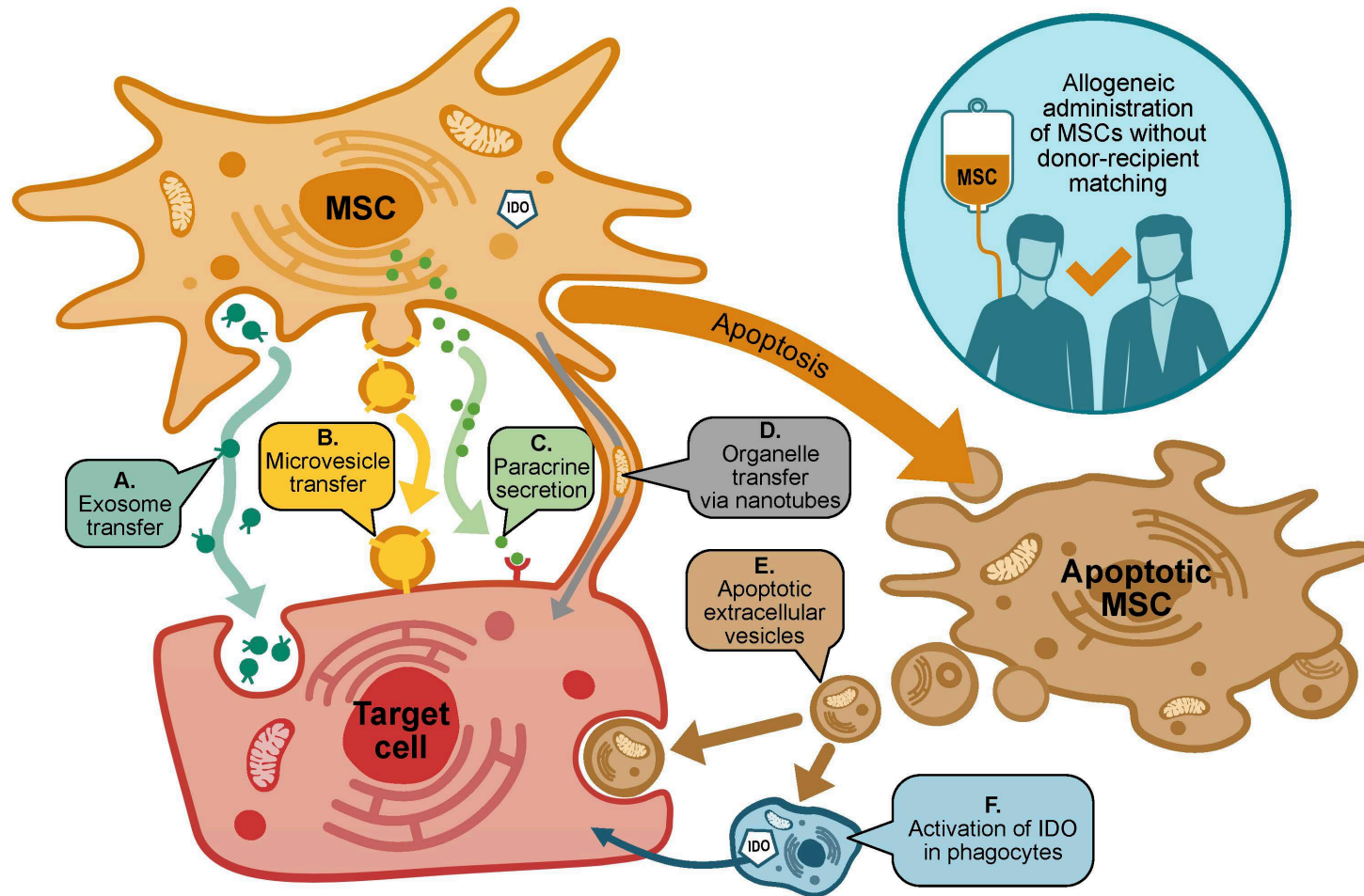
Senior management team strengthened

- New Chief Business Officer position created to drive next stage of commercial growth (Dr Mathias Kroll – commenced Apr 2024)

Revolutionary iPSC-based Cymerus™ Manufacturing Platform



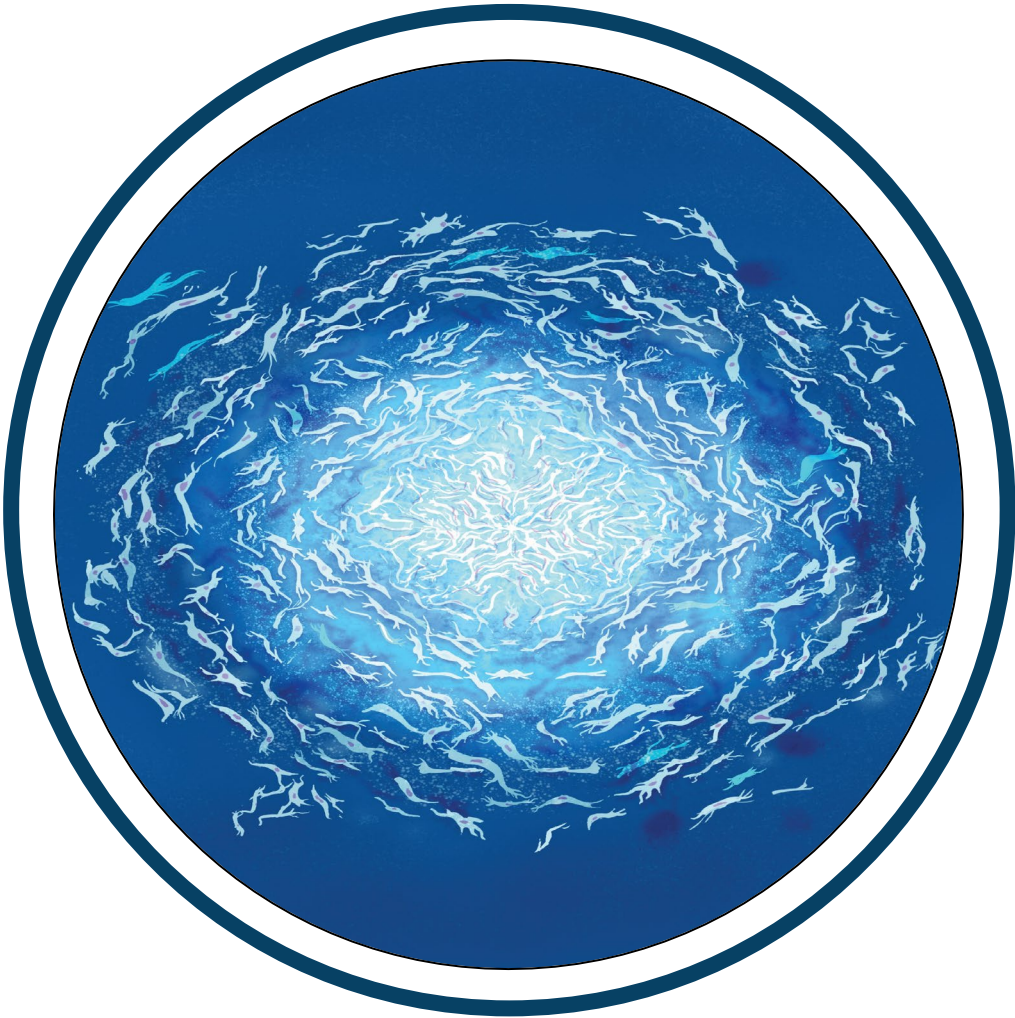
Therapeutic potential of MSCs



Mesenchymal stem cells¹ (MSCs):

- Promote an **immunomodulatory** environment²
- The “sensor and switcher of the immune system”³
- Promote **tissue repair** and **regeneration**
- Can be used **without** matching donors to recipients
- Can be **engineered** to express other functional/therapeutic molecules
- However, with conventional manufacturing methods, there are consistency, potency and scalability challenges

Advantages of iPSC-based platform



Induced pluripotent stem cells (iPSCs):

- Mature **adult** cells **reprogrammed** to become **pluripotent**, which means:
 - Effectively **limitless** proliferation capacity
 - Potential to differentiate into any adult cell type (including MSCs)
 - Similar properties to embryonic stem cells ... but iPSCs are derived from **adult donors**, so they **avoid** ethical controversy associated with embryonic stem cells
- iPSCs are **ideal** starting material for commercial production of cellular products

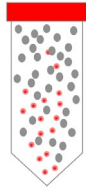
Conventional MSC process

Ongoing need for new donors



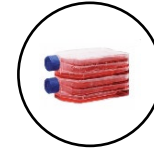
Substantial inter-donor **variability**

MSC isolation



Small number of MSCs per donation

Culture expansion



Extensive MSC culture expansion required

Major challenges:

- Logistically challenging
- Inter-donor **variability** – **inconsistent** activity in MSCs from different donors
- MSCs undergo **functional changes** and **loss of potency** during extensive culture expansion

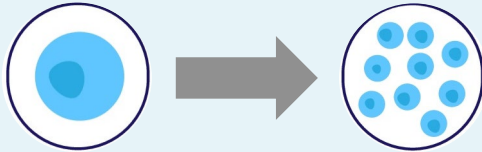
Cymerus™ iPSC-based process

One donor, one time



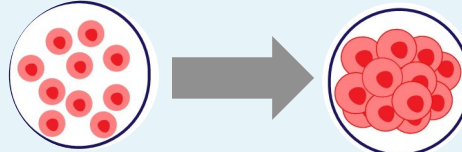
Avoids inter-donor variability

Reprogramming & iPSC expansion



Effectively limitless expansion potential

Differentiation into MSCs & culture expansion



Minimal MSC culture expansion

Robust patent protection

Advantages of **Cymerus™** platform:

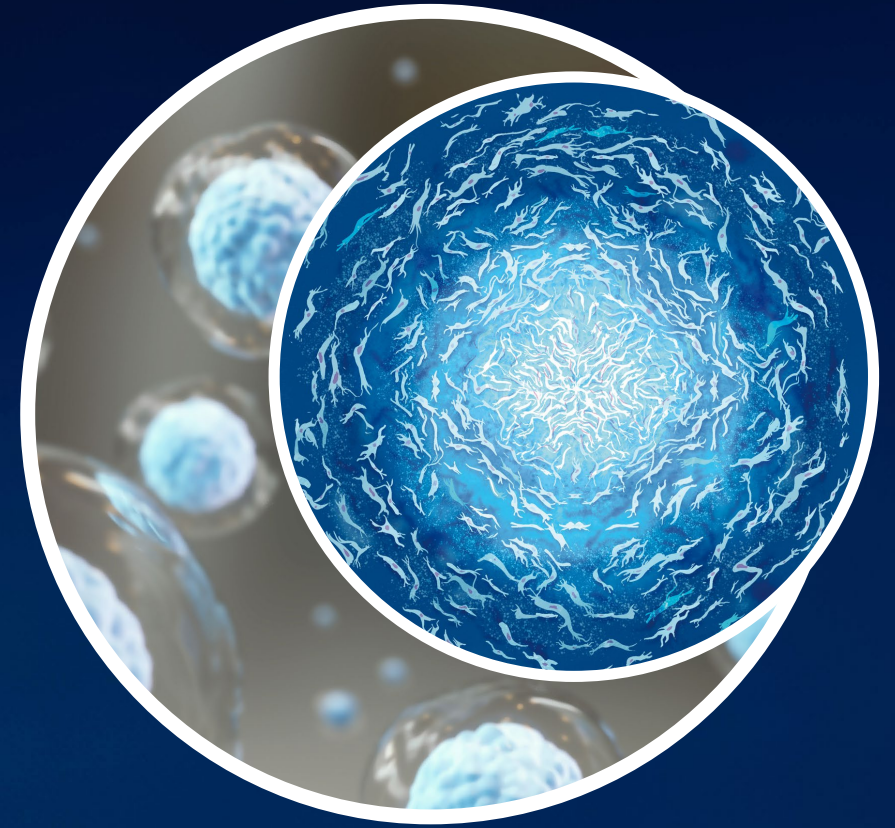
- **Effectively limitless** iPSC expansion potential
- **Avoids** need for new donors
- **Avoids** inter-donor variability
- **Avoids** extensive MSC expansion
- High level **potency, consistency** and **scalability**

Strategic partnership with Fujifilm

- Fujifilm: one of largest healthcare conglomerates globally, with significant assets in biotechnology sector, bolstered by recent multi-billion dollar investments
- Fujifilm Cellular Dynamics Inc (FCDI: subsidiary of Fujifilm) developed the original iPSC line used in Cynata's Cymerus™ manufacturing process
- Cymerus™ manufacturing process being established at FCDI, with Cynata's progress showcasing Fujifilm's iPSC platform
- Fujifilm holds a 4.5% shareholding in Cynata



Compelling Clinical Data: CYP-001 for aGvHD



CYP-001: Two *Nature Medicine* publications

Phase 1 trial of CYP-001 was the first completed clinical trial worldwide with **any iPSC-derived product**



nature
medicine

LETTERS

<https://doi.org/10.1038/s41591-020-1050-x>

Nature Medicine 26, 1720–1725 (2020)

Production, safety and efficacy of iPSC-derived mesenchymal stromal cells in acute steroid-resistant graft versus host disease: a phase I, multicenter, open-label, dose-escalation study

Adrian J. C. Bloor^{1,2}, Amit Patel¹, James E. Griffin³, Maria H. Gilleece⁴, Rohini Radia⁵, David T. Yeung^{6,7}, Diana Drier⁸, Laurie S. Larson⁸, Gene I. Uenishi⁹, Derek Hei¹⁰, Kilian Kelly¹¹, Igor Slukvin⁹ and John E. J. Rasko^{12,13,14}

nature medicine

Nature Medicine 30, 1556–1558 (2024)

<https://doi.org/10.1038/s41591-024-02990-z>

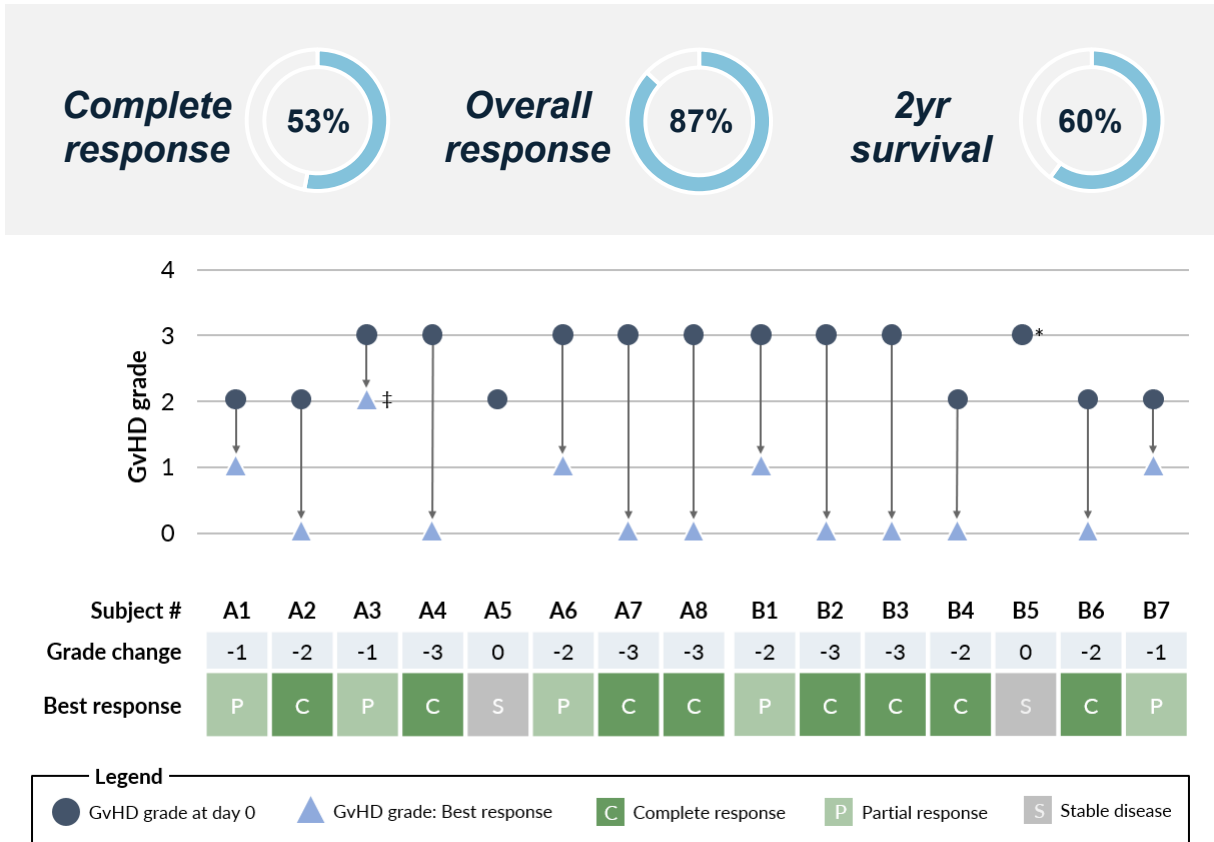
Two-year safety outcomes of iPSC cell-derived mesenchymal stromal cells in acute steroid-resistant graft-versus-host disease

Kilian Kelly¹, Adrian J. C. Bloor², James E. Griffin³, Rohini Radia⁴, David T. Yeung^{5,6} & John E. J. Rasko^{7,8,9}

aGvHD | Phase 1 clinical trial - results

Product: CYP-001 (Cymerus™ MSCs for intravenous infusion)

Trial conducted in 15 patients with **steroid-resistant aGvHD**



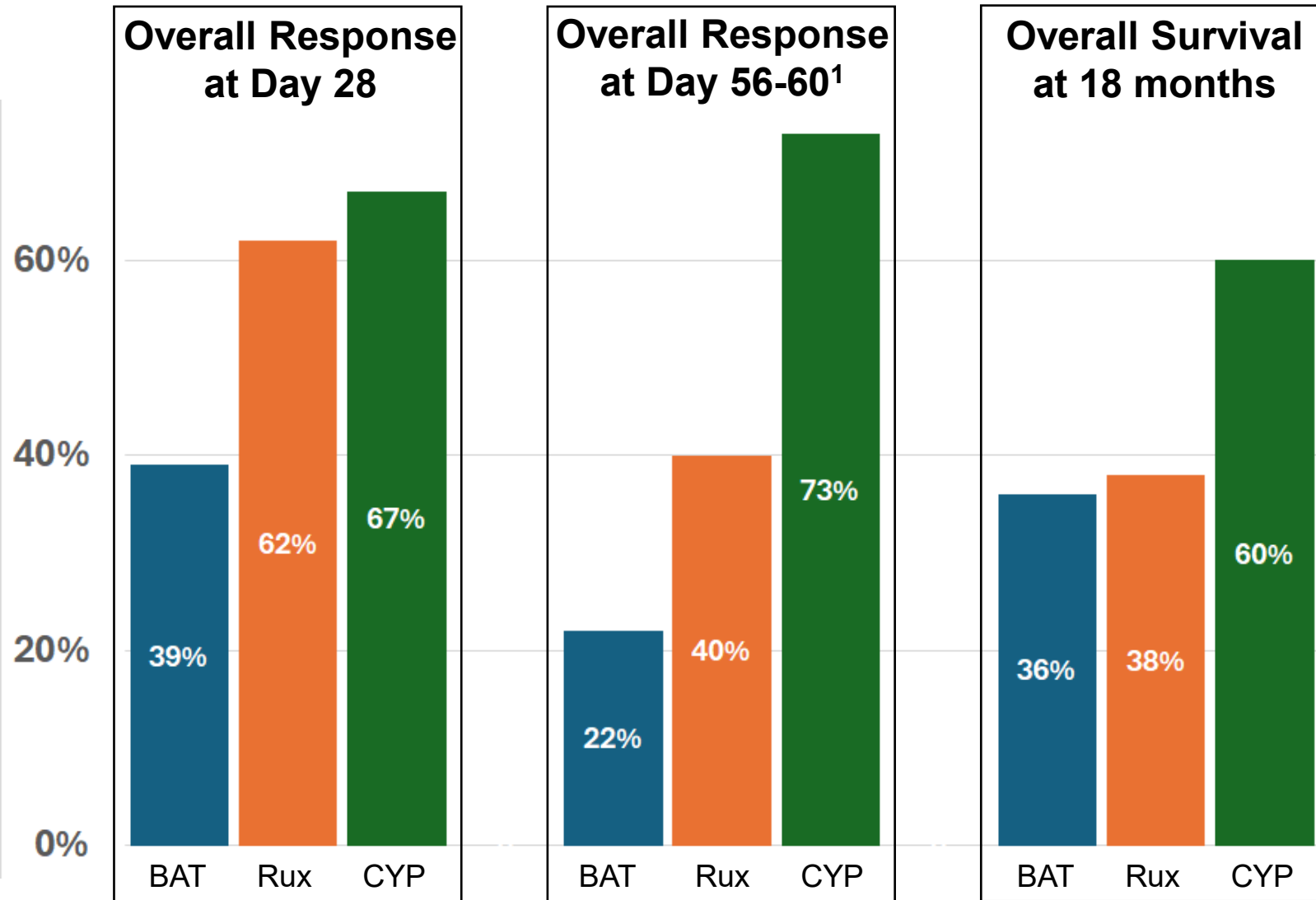
- CYP-001 was shown to be **safe and well tolerated**, with **sustained outcomes up to 2 years** after the first infusion
- **No serious adverse events or other safety concerns related to CYP-001**
- **Very encouraging response rates and overall survival**

aGvHD treatment landscape

- First line treatment for aGvHD is corticosteroids – but up to 50% fail to respond – known as steroid-resistant aGvHD (SR-aGvHD)
- Numerous other therapies (e.g. immunosuppressants) have been investigated for SR-aGvHD, but most have limited efficacy and/or problematic safety profiles
- Ruxolitinib (a JAK kinase inhibitor):
 - Approved for treatment of SR-aGvHD in 2019 by the US FDA
 - Forecast sales of US\$4.5b in 2024¹
 - Led to relatively good response rates in SR-aGvHD, but **no apparent improvement in overall survival**
 - Associated with a **high rate of potentially serious adverse reactions**

→ There remains a **significant unmet need** for **safer and more effective** aGvHD treatments

Efficacy of CYP-001 vs other treatments in SR-aGvHD



- Overall response rates for BAT and Rux **declined** between D28 and D56
- Overall response rate for CYP-001 **increased** between D28 and D60
- Overall survival rate for CYP-001 was **60% at both 18 and 24 months**
- Overall survival rates for BAT and Rux were **36% and 38% at 18 months**, and **not evaluable at 24 months**

BAT = “best available therapy” in study NCT02913261 - other therapies commonly used in patients with steroid-resistant acute graft versus host disease (SR-aGvHD)

Rux = ruxolitinib (now approved for SR-aGvHD) in study NCT02913261

CYP = CYP-001 in study NCT02923375

Safety of CYP-001 vs other treatments in SR-aGvHD

- **No safety concerns related to CYP-001** have been identified
- Conversely, **adverse reactions to ruxolitinib are common**
- Grade 3-4 (**serious/life-threatening**) adverse reactions to ruxolitinib in aGvHD patients include:¹

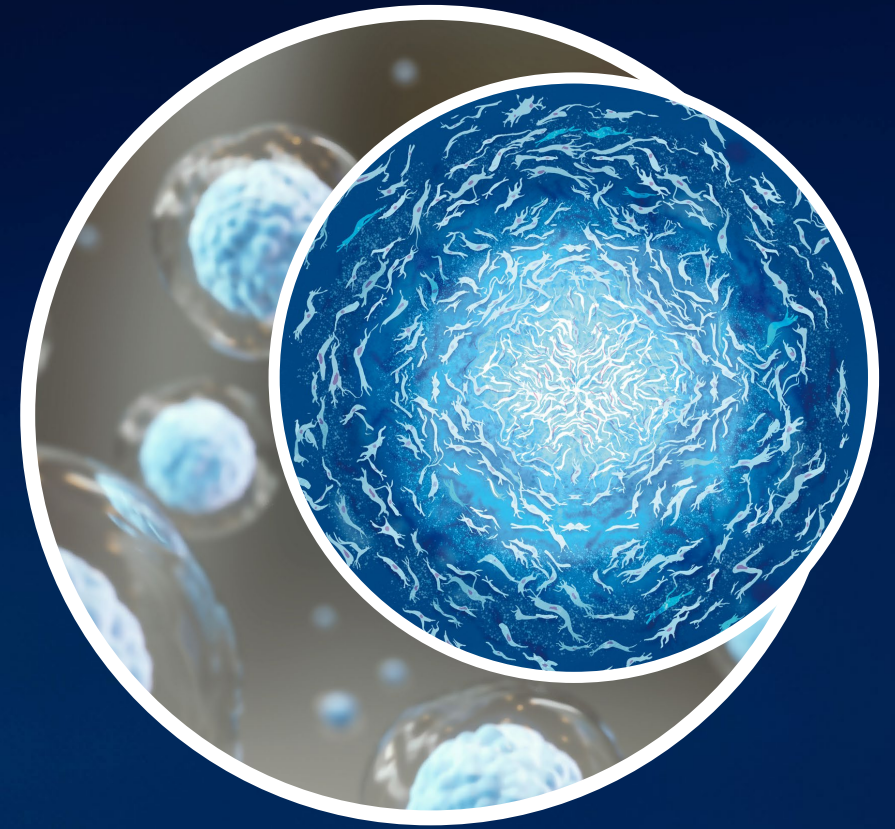
Adverse Reaction	Grade 3-4 Incidence
Infections (type of infection not specified)	41%
Bacterial infections	28%
Haemorrhage (bleeding)	20%
Fatigue	14%
Viral infections	14%
Hypertension (high blood pressure)	13%
Oedema (fluid retention)	13%
Thrombosis (blood clots)	11%
Blood disorders (thrombocytopenia, anaemia, neutropenia)	61%, 45%, 40%

1. JAKAFI® (ruxolitinib) tablets, for oral use, US FDA approved Prescribing Information, September 2021.

Grade 3 = Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care

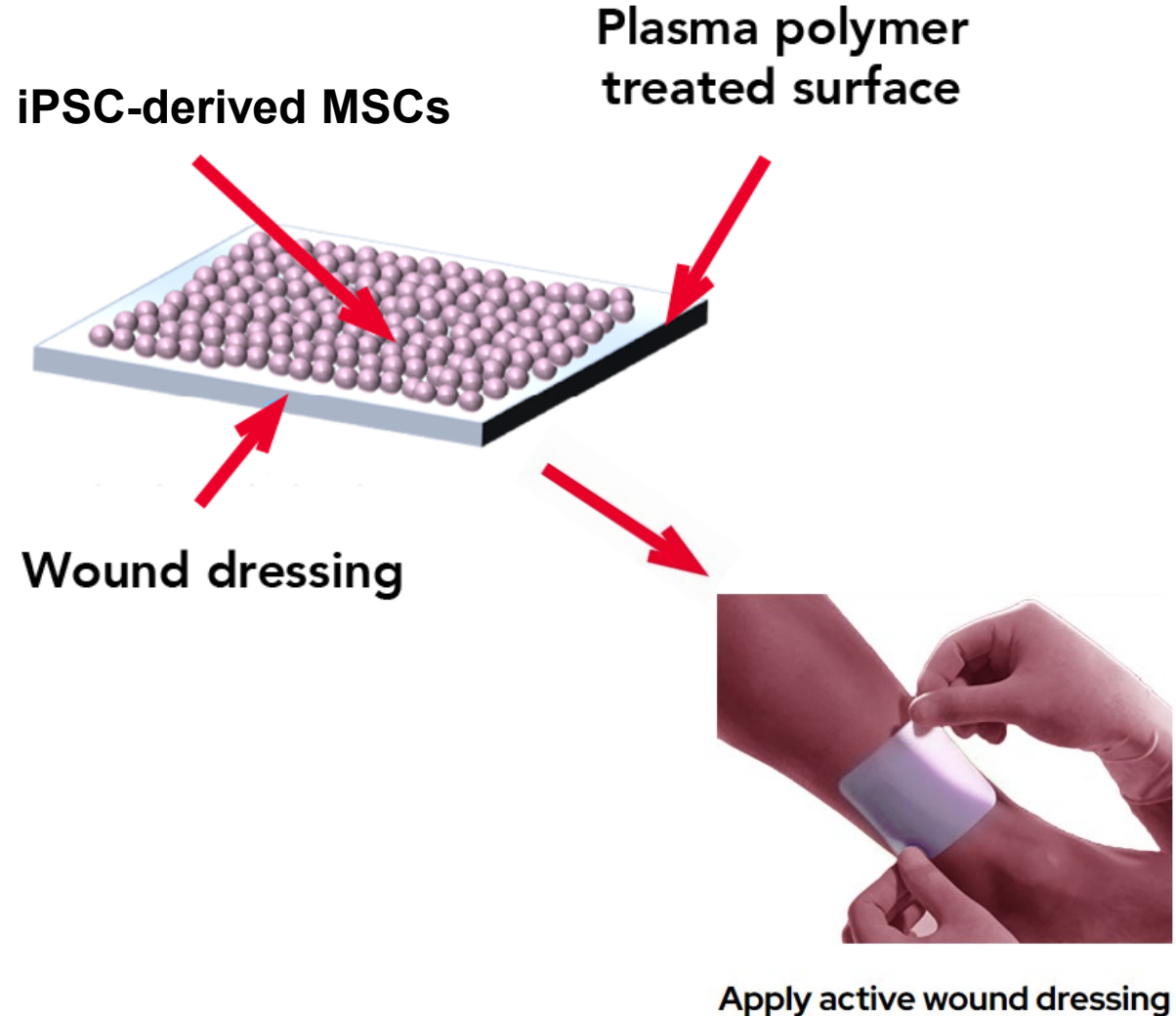
Grade 4 = Life-threatening consequences; urgent intervention indicated.

CYP-006TK for DFU



CYP-006TK – a novel topical MSC product

- CYP-006TK utilises a proprietary surface-coating, optimised for the delivery of MSCs directly to the wound bed
- Technology exclusively licenced to Cynata by Tekcyte Limited



DFU | Phase 1 clinical trial – initial data

Product: CYP-006TK (topical Cymerus™ MSC wound dressing)

- Ongoing trial in non-healing diabetic foot ulcer (DFU)
- Patients randomised to receive standard of care (SoC) or CYP-006TK for 4 weeks, followed by SoC
- In the first 16 patients enrolled in the trial (8 per group), after 10 weeks' follow-up, the median reduction in wound surface area was:
 - **87.6%** in the active CYP-006TK group
 - compared to **51.1%** in SoC group

Example of ulcer healing in patient treated with CYP-006TK:

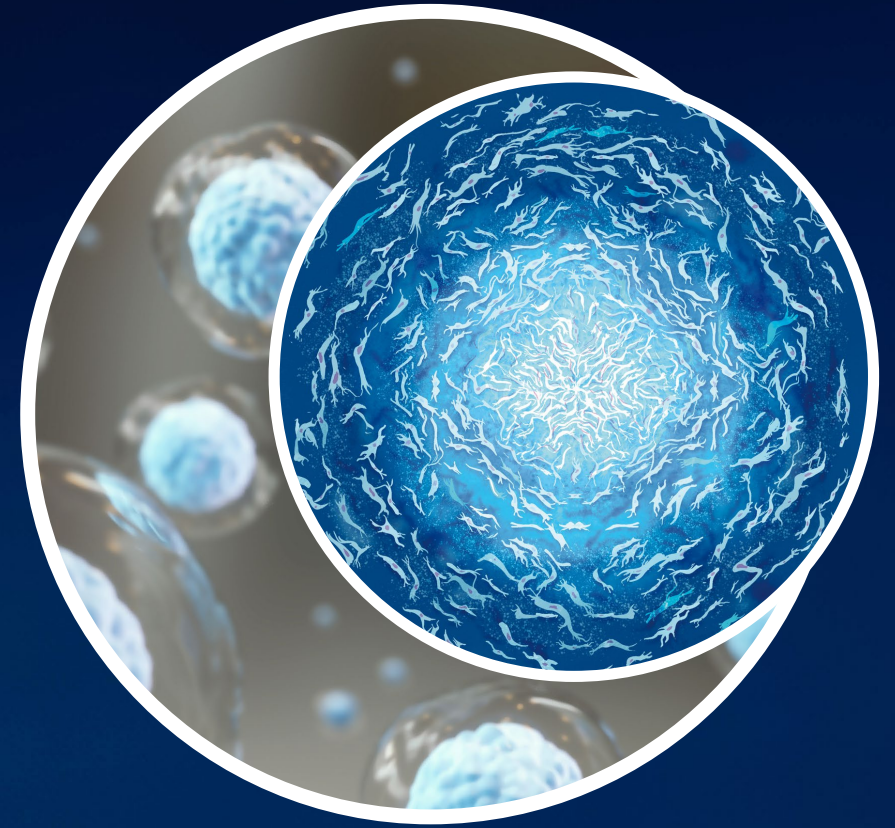
Day 0







Day 28



Rich Clinical Pipeline
– Multiple Upcoming Data
Readouts



Advanced and diverse clinical pipeline

	Indication	Trial phase	Market opportunity
Cynata Sponsored	 Acute Graft vs Host Disease (aGvHD) CYP-001 <i>(FDA Orphan Designation)</i>	Phase 2 underway	US\$600m ¹
	 Diabetic Foot Ulcers (DFU) CYP-006TK	Phase 1 underway (patient enrolment complete)	US\$9.6bn ²
Partnered	 Osteoarthritis (OA) CYP-004 <i>(managed by USYD, funded by NHMRC)</i>	Phase 3 underway (patient enrolment complete)	US\$11.6bn ³
	 Renal Transplantation (Renal) CYP-001 <i>(managed and funded by LUMC)</i>	Phase 1 approved	US\$5.9bn ⁴

1. Global Graft versus Host Disease Market 2019-2029 (Reflects forecast market in 2026); 2. Zion Market Research, 2019 (represents global treatment market in 2025); 3. Persistence Market Research 2018 research report: "Osteoarthritis Treatment Market: Global Industry Analysis (2012-2016) and Forecast (2017-2025) (Reflect OA market by 2025); 4. Organ Transplant Immunosuppressant Drugs Market in 2026, Grand View Research, Inc., 2019

USYD = University of Sydney; NHMRC = National Health and Medical Research Council; LUMC = Leiden University Medical Center

aGvHD | Phase 2 clinical trial

Product

CYP-001 (Cymerus™ iPSC-derived MSCs for intravenous infusion)

Indication

High risk acute graft versus host disease (aGvHD)¹

Study Design

- Randomised controlled trial in ~60 adults (steroids + CYP-001 vs steroids + placebo)
- Primary objective is to assess efficacy of CYP-001 based on Overall Response Rate at Day 28

Study Conduct

- Clinical sites in USA, Europe and Australia
- Regulatory/ethics clearance secured in all participating jurisdictions – including IND from US FDA
- First patient enrolled – March 2024
- Aiming to complete patient enrolment by end of calendar year 2024

Results

Primary evaluation results anticipated in 2H CY 2025

DFU | Phase 1 clinical trial

Product

CYP-006TK (Novel silicone dressing seeded with Cymerus™ iPSC-derived MSCs)

Indication

Non-healing diabetic foot ulcers (DFU)

Study Design

- Randomised controlled trial in ~30 adults
- Patients randomised to receive either standard of care or CYP-006TK for 4 weeks, followed by standard of care
- Primary objective is safety; efficacy measures include wound healing, pain and quality of life

Study Conduct

- Clinical sites in Australia (Adelaide and Perth)
- Patient enrolment complete (April 2024)
- Last patient visit expected ~September 2024

Results

- Positive initial results from first 16 patients – median reduction in wound surface area after 10 weeks was **87.6%** in CYP-006TK group compared to **51.1%** in controls (n=8 per group)
- Final results anticipated in Q4 2024 or Q1 2025

OA | Phase 3 clinical trial¹

Product

CYP-004 (Cymerus™ iPSC-derived MSCs for intra-articular injection)

Indication

Osteoarthritis (OA) of the knee (Kellgren-Lawrence Grade 2-3)

Study Design

- Randomised, double-blind placebo-controlled trial in ~320 adults
- Each participant receives 3 injections over 12 months; follow-up of 24 months from first dose
- Co-primary endpoints are reduction of knee symptoms and measure of cartilage loss

Study Conduct

- Trial conducted by University of Sydney, funded by Australian Government NHMRC grant
- Clinical centres in Australia (Sydney and Hobart)
- Patient enrolment complete (November 2023)
- Last patient last visit expected ~November 2025

Results

- Results anticipated in H1 CY 2026

Renal transplant | Phase 1 clinical trial

Product

CYP-001 (Cymerus™ iPSC-derived MSCs for intravenous infusion)

Indication

Prevention of kidney transplant rejection

Study Design

- ~16 patients to receive CYP-001 after kidney transplantation: cohort 1 (n=3); cohort 2 (n=3); cohort 3 (n=10)
- Trial will evaluate safety (all cohorts) and efficacy of MSCs in facilitating reduction of calcineurin inhibitors (anti-rejection medication; Cohort 3)

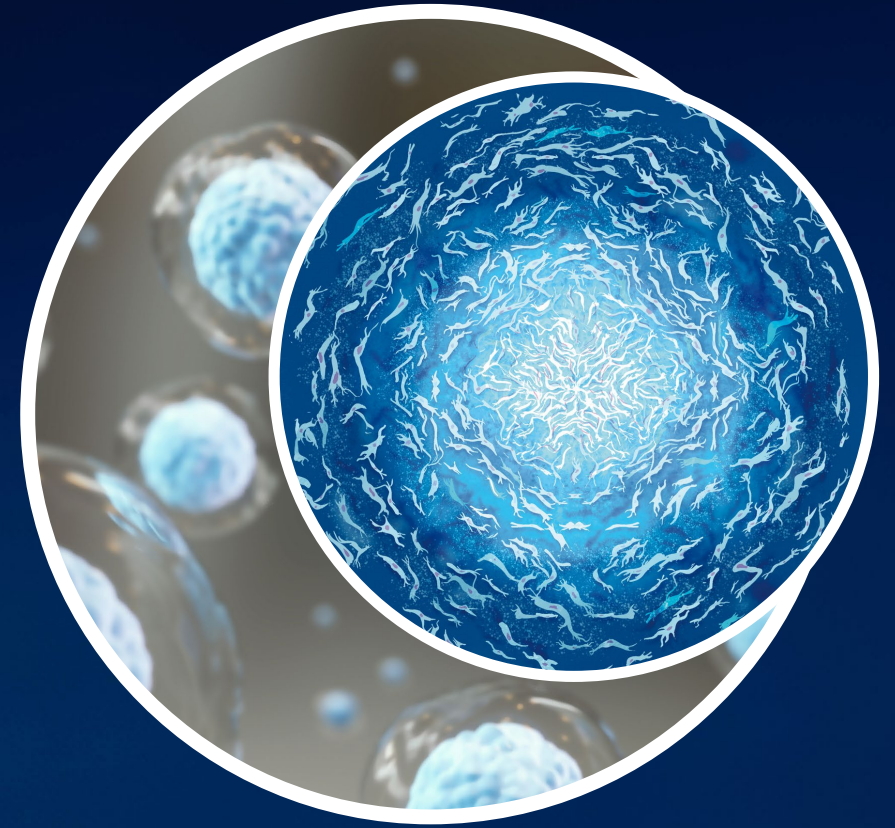
Study Conduct

- Trial to be conducted and funded by Leiden University Medical Center (LUMC), Netherlands
- Regulatory and ethics approvals in place; final trial start-up activities ongoing
- Aiming to commence patient enrolment in mid 2024

Results

Results of Cohort 1 anticipated in late 2024

Strategy, Outlook and Corporate Overview



Research partnerships

Large body of positive preclinical data generated via R&D partnerships:

- GvHD
- Diabetic wounds
- Critical limb ischaemia
- Organ transplant rejection
- Osteoarthritis
- Respiratory disorders (including asthma, pulmonary fibrosis, acute respiratory distress syndrome)
- Sepsis
- Cardiovascular disorders (including coronary artery disease, myocardial infarction)
- Cytokine release syndrome
- Glioblastoma

Several of these studies have been published in peer-reviewed journals – see [cynata.com/science_publications](https://www.cynata.com/science_publications)

Studies conducted in partnership with leading research groups worldwide



MONASH University



THE UNIVERSITY
of
WISCONSIN
MADISON



THE UNIVERSITY OF
SYDNEY



UNSW
SYDNEY



RCSI



University of
Massachusetts
Amherst



**Cell Therapy
Manufacturing**
Cooperative Research Centre

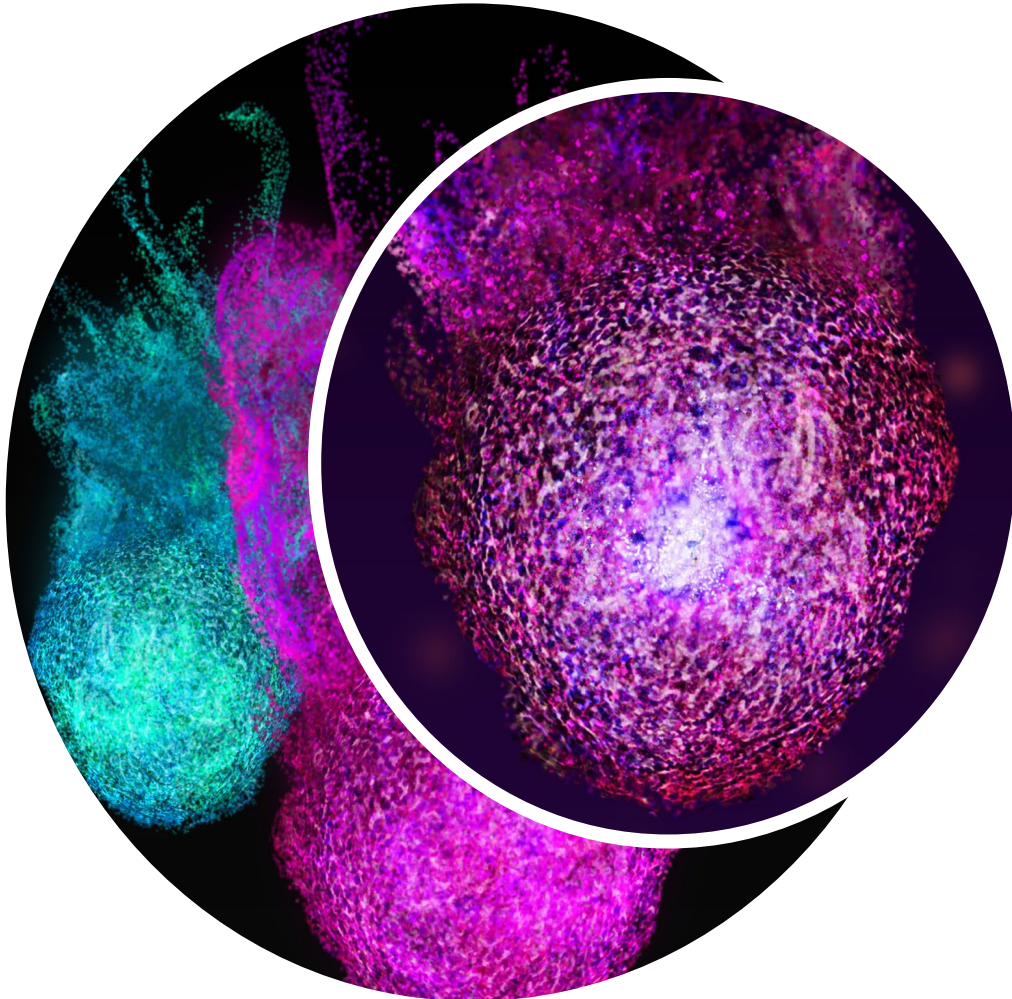


HSCI
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criticalcare
RESEARCH GROUP

SVI
St Vincent's Institute
MEDICAL RESEARCH

Commercial partnering



Several distinct products in development → potential for multiple partnerships



Reinvestment of proceeds to maximise potential of the platform

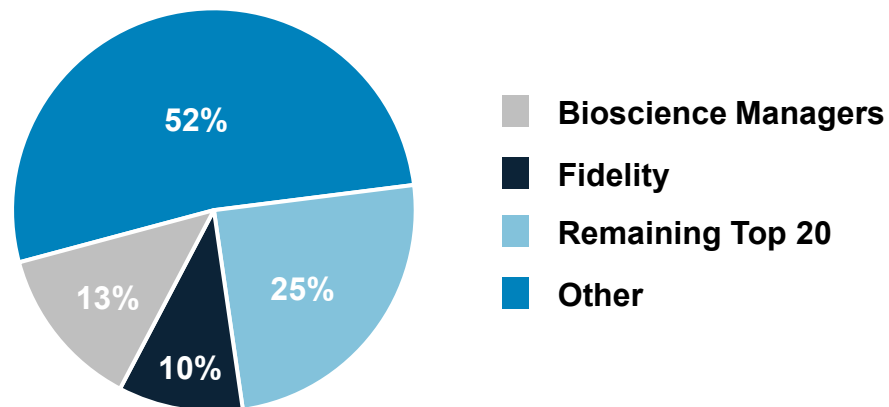


Platform also available to partners pursuing other indications and/or engineered MSC applications

Corporate overview

Cynata has been listed on the Australian Securities Exchange (ASX) since 2013 (Ticker: CYP)

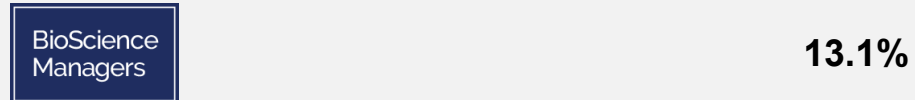
Shareholder distribution



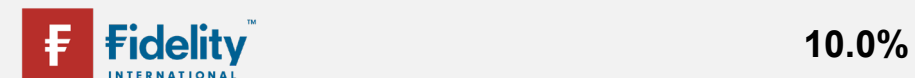
Financial information

Share price (26 June 2024)	A\$0.28
Shares on issue	179m
Market capitalisation	~A\$50m
Cash ¹	~A\$9.0m

Substantial shareholders (>5%)



BioScience Managers is an international healthcare investment firm headquarter in Melbourne that finances and enables innovative science and technology with the potential to transform healthcare.



Fidelity International is a world leading investment and asset management firm, responsible for total client assets of >US\$750 billion, from clients across Asia Pacific, Europe, the Middle East, South America and Canada.

Board & senior management

Highly skilled and experienced senior leadership team with decades of experience




Dr Kilian Kelly
Chief Executive Officer &
Managing Director

- 20+ years' experience in biopharma R&D
- Previous roles at Biota Pharmaceuticals, Mesoblast, Amgen & AstraZeneca



Dr Geoff Brooke
Independent Non-Executive Chair

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




Dr Paul Wotton
Independent Non-Executive Director

- 30+ years' experience
- Previously CEO of Ocata Therapeutics (acquired by Astellas) and Obsidian Therapeutics
- EY Entrepreneur of the Year (NJ, 2014)



Ms Janine Rolfe
Independent Non-Executive Director

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




Dr Darryl Maher
Independent Non-Executive Director

- Former Vice President, R&D and Medical Affairs at CSL Behring
- Former President of Australian Pharmaceutical Physicians Association and Director of Vaccine Solutions



Mr Peter Webse
Company Secretary

- 25+ years company secretarial experience
- Director of Governance Corporate Pty Ltd



Dr Jolanta Airey
Chief Medical Officer

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



Dr Mathias Kroll
Chief Business Officer

- 25+ years' experience in biopharmaceutical industry
- Previously held leadership positions at various institutions, including Bayer, Sanofi-Aventis and GlaxoSmithKline

Upcoming catalysts*

Results of three randomised controlled clinical trials expected between early 2025 and early 2026

Mid 2024

- Renal trial – start of enrolment

2H 2024

- Renal trial – results (Cohort A)
- aGvHD trial – completion of enrolment

1H 2025

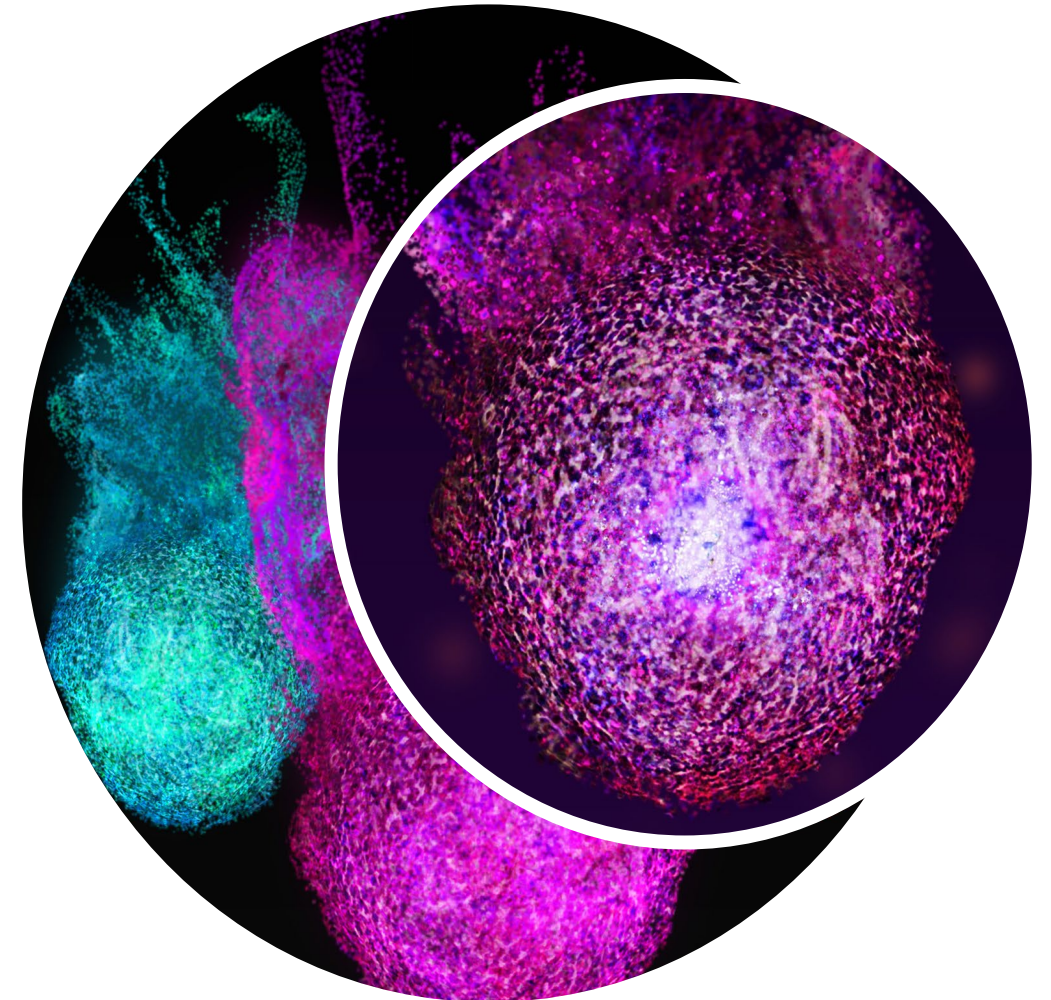
- DFU trial – results (potentially late 2024)

2H 2025

- aGvHD trial – results

1H 2026

- OA trial - results



Summary



Next generation stem cell company

- Leading platform technology in burgeoning stem cell sector
- Diverse and highly credentialed leadership team with proven experience



Scalable manufacturing

- Cymerus™ manufacturing technology protected by robust patent portfolio
- Enables scalable production of consistent MSCs from a single donation from a single donor, overcoming major challenges with conventional approaches



Compelling clinical data

- Very encouraging safety and efficacy results from aGvHD clinical trial (CYP-001)
- Promising initial data from ongoing DFU clinical trial (CYP-006TK)



Rich clinical pipeline

- Broad pipeline with four active clinical programs
- FDA cleared IND for Phase 2 aGvHD clinical trial; study underway
- Patient enrolment complete in DFU & OA clinical trials
- Commencement of renal transplantation clinical trial imminent



Significant growth potential

- Global estimated market opportunity across targeted indications of ~US\$28bn¹
- Focus on indications with significant unmet need
- Proactive B-2-B outreach to drive partnering strategy



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