

Cynata Participating in Euroz Hartleys Institutional Investor Conference

Melbourne, Australia; 12 March 2025: Cynata Therapeutics Limited (ASX: “CYP”, “Cynata”, or the “Company”), a clinical-stage biotechnology company specialising in cell therapeutics, is participating at the 2025 Euroz Hartleys Institutional Investor Conference in Rottnest Island, Western Australia.

Dr Kilian Kelly (Cynata’s Chief Executive Officer & Managing Director) will present on the Company and participate in a Healthcare Panel at 12 noon AWST today. Additionally, Dr Kelly will hold meetings with institutional investors during the conference. A copy of the Company’s investor presentation, which will be used during the conference, is attached.

-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 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 transplant; 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.

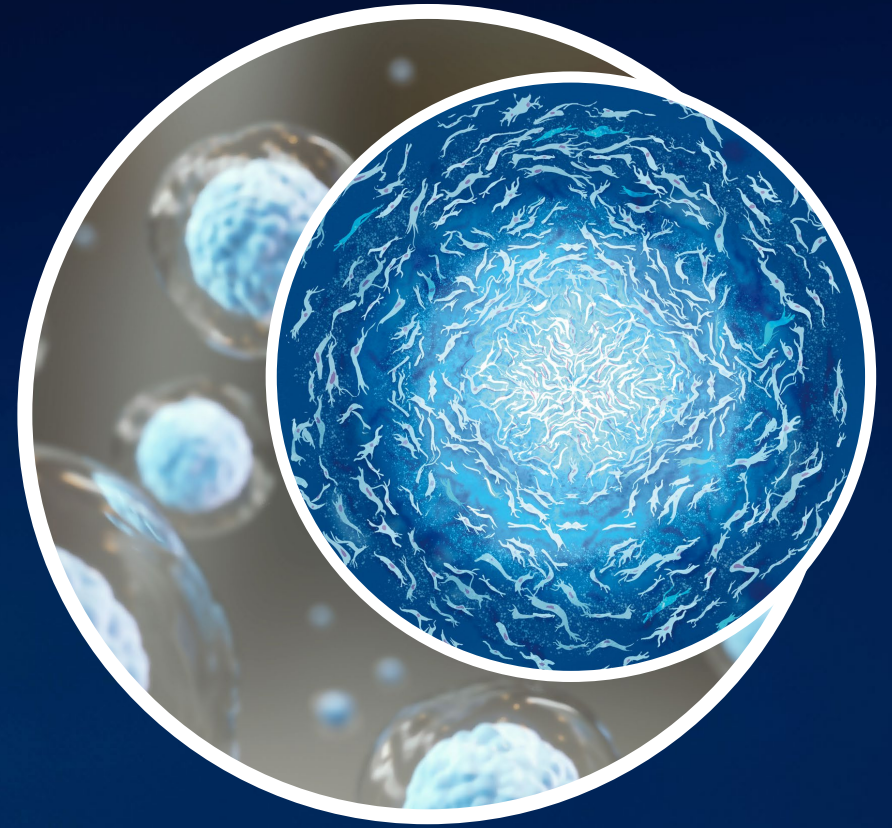
Cynata Therapeutics encourages all current investors to go paperless by registering their details with the designated registry service provider, Automic Group.



A Clinical Stage Company Pioneering the
Next Generation of Cellular Therapies

Investor Presentation

March 2025



Important information

Summary information

This Presentation contains summary information about Cynata Therapeutics Limited and its subsidiaries (**CYP**, or **Cynata**) which is current as at 11 March 2025. 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.

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Corporate overview

Cynata is an ASX-listed company (ticker **CYP**), founded to commercialise the novel iPSC-based Cymerus™ platform, for the scalable and consistent production of mesenchymal stem cell (MSC)-based therapies

Financial information

Share price (11 March 2025)	A\$0.21
Shares on issue	~225m
Market capitalisation	~A\$47m

Share price performance¹



AUD | Australian | End of Date as of 11 Mar 2025

Largest shareholders

BioScience
Managers

10.5%

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

10%

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.





FUJIFILM

3.6%

Fujifilm is a Japanese multinational conglomerate. Cynata has a strategic manufacturing partnership with Fujifilm.

Top 20 shareholders hold ~47% of shares on issue

Target indications

Indication		Trial phase	Upcoming catalysts*	Market opportunity
 Acute Graft vs Host Disease (aGvHD) FDA Orphan Designation	Cynata Funded & Managed	Phase 2 ongoing	Enrolment completion – H1 2025 Results – H2 2025	US\$600m ¹
 Diabetic Foot Ulcers (DFU)		Phase 1 complete	Results released Dec 2024	US\$9.6bn ²
 Osteoarthritis (OA) <i>(managed by USYD, funded by NHMRC)</i>	Partner Funded & Managed	Phase 3 ongoing (enrolment complete)	Results – H1 2026	US\$11.6bn ³
 Kidney Transplantation <i>(managed and funded by LUMC)</i>		Phase 1/2 ongoing	Results (Cohort 1) – H1 2025	US\$5.9bn ⁴

Note: Cynata retains commercial rights for both of the partner funded & managed programs

Introduction to MSCs

What are MSCs?

- **Mesenchymal stem cells**
(also known as **mesenchymal stromal cells** or **medicinal signalling cells**)
- These cells occur naturally in **small numbers** in the human body
- Key MSC properties¹:
 - **Immunomodulatory** effects – they help balance the immune system
 - **Anti-inflammatory** effects
 - Promote **tissue repair** and **regeneration**

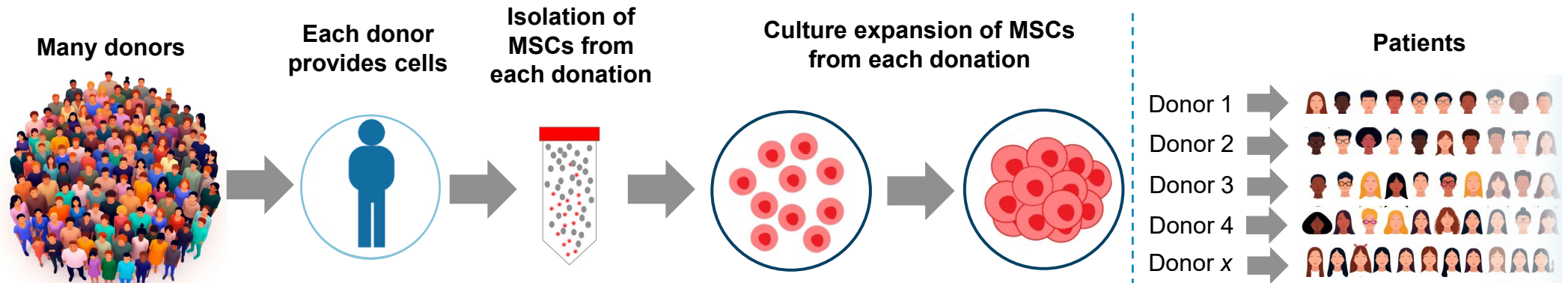
MSC-based therapy:

- Involves administration of much **larger numbers** of MSCs than exist within the body naturally, to treat/prevent disease
- First investigated in 2004, in a 9-year old boy with graft versus host disease²
- Since then, more than 1,700 clinical trials have been initiated, to investigate MSC therapy for many different diseases³



Conventional MSC manufacturing process

Standard Process¹



New donors must be identified on regular basis; donors must consent to **surgical extraction**

MSCs must be **isolated** from **mixture of cells** from **each** donation – producing only **small number** of MSCs per donation

Extensive culture expansion required (growing cells) – **large number** of MSCs required

Different batches of MSCs come from **different donors**

Major Challenges

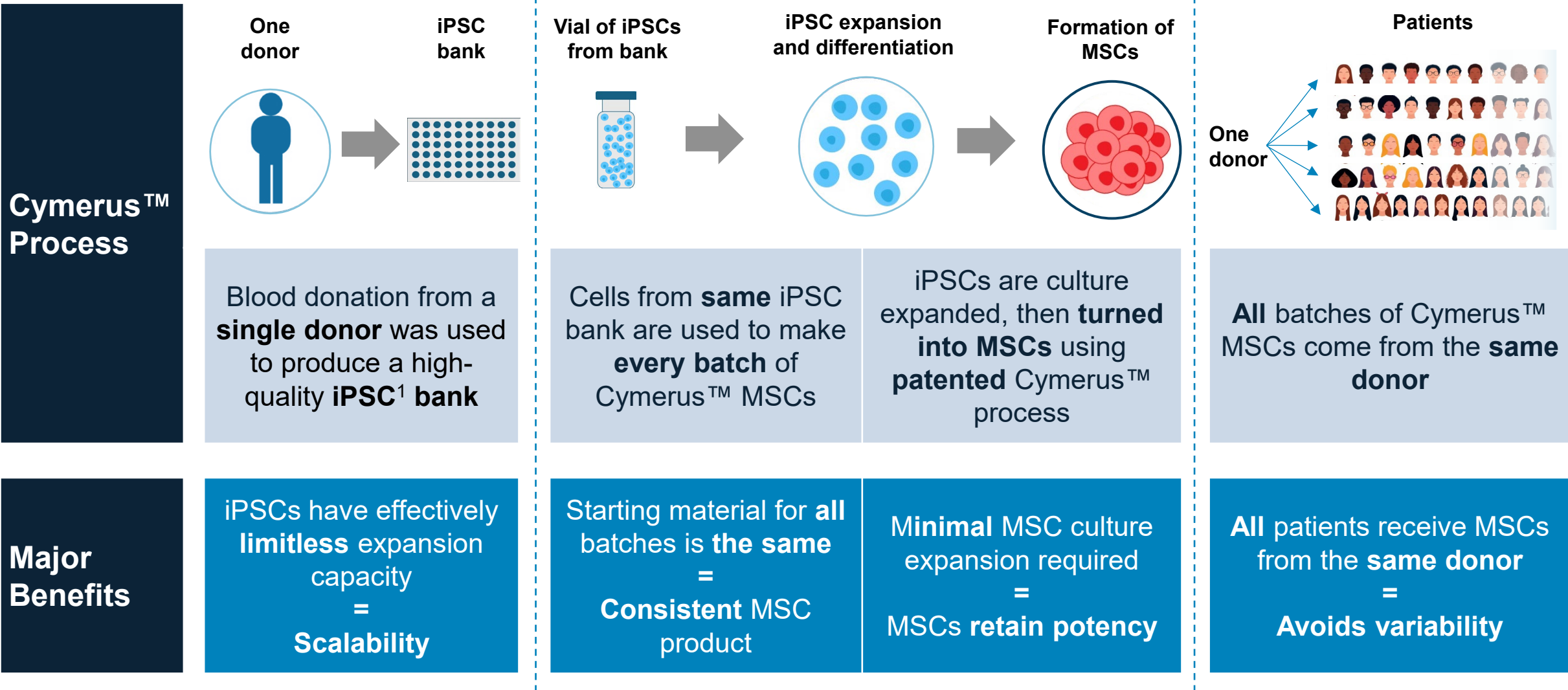
Different donors
=
Variable starting material
=
Inconsistent product

Small number of MSCs retrieved per donation
=
Extensive MSC culture expansion required

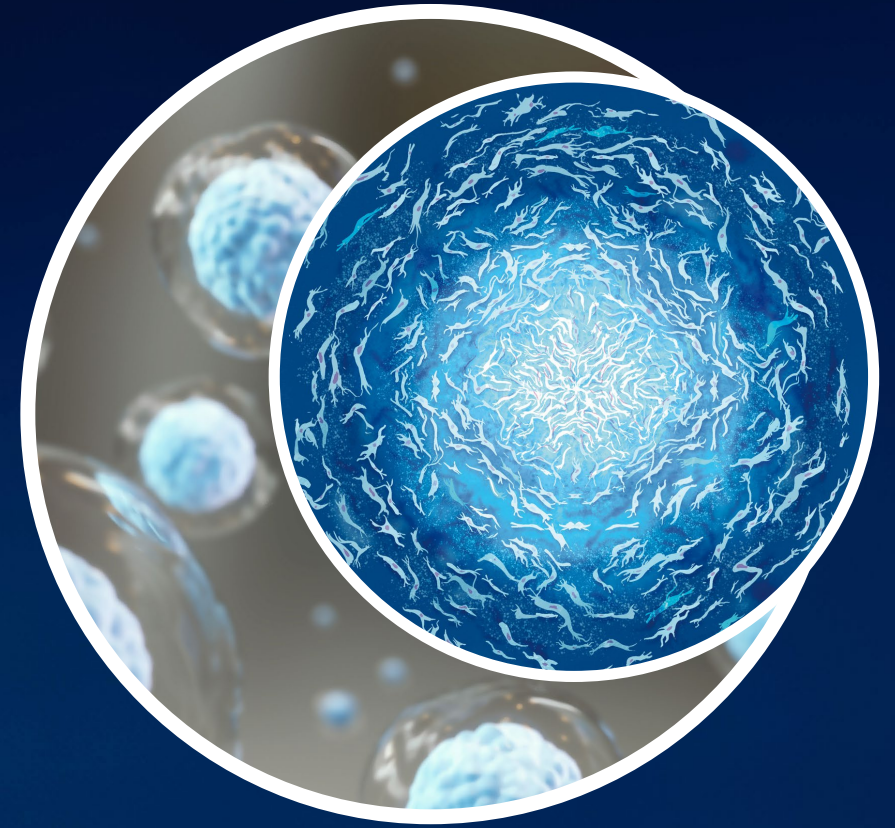
Extensive MSC culture expansion
=
Functional changes
=
Loss of potency

MSCs from **different donors** are administered to **different patients**
=
Inconsistent results

The solution: the Cymerus™ process



Acute Graft versus Host Disease (aGvHD)



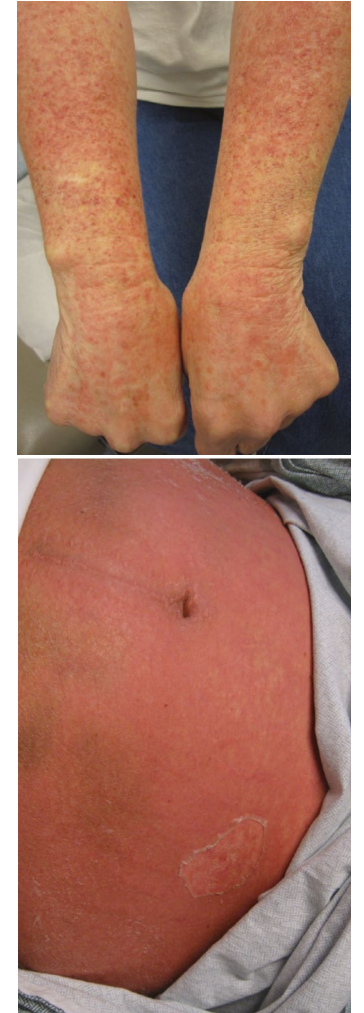
Bone marrow transplants & GvHD

Bone marrow transplant (also known as blood stem cell transplant)

- The procedure replaces blood stem cells in people whose bone marrow has been destroyed by large doses of chemotherapy or radiotherapy
- Bone marrow transplants can be curative for blood cancers (e.g. lymphoma & leukaemia)
- However, these procedures, if they use third party donors (“allogeneic”), can result in graft versus host disease (GvHD)

Graft versus host disease

- GvHD is where the transplanted cells recognise the recipient’s cells as “foreign”
- This results in the transplant (the “graft”) attacking the recipient’s (the “host’s”) tissues and organs
- First-line treatment for acute GvHD (aGvHD) is corticosteroids, but ~50% of patients develop what’s known as steroid-resistant acute GvHD (SR-aGvHD)
- In steroid-resistant patients, 2-year survival rate is less than 20%¹



Acute graft versus host disease (aGvHD)

>38,000
allogeneic
transplants*
per year¹

~35-50%
develop
aGvHD^{2,3}

Almost all
receive
steroids

<50% respond
to steroids⁴

Up to 9,500
steroid-
resistant cases
per year

2-year survival
rate in SR-
aGvHD: **<20%**⁵

* "Allogeneic" means cells come from someone else (a donor) rather than the recipient; "transplant" refers to blood stem cell transplants

Current treatments for steroid-resistant aGvHD (SR-aGvHD):

- **Ruxolitinib**

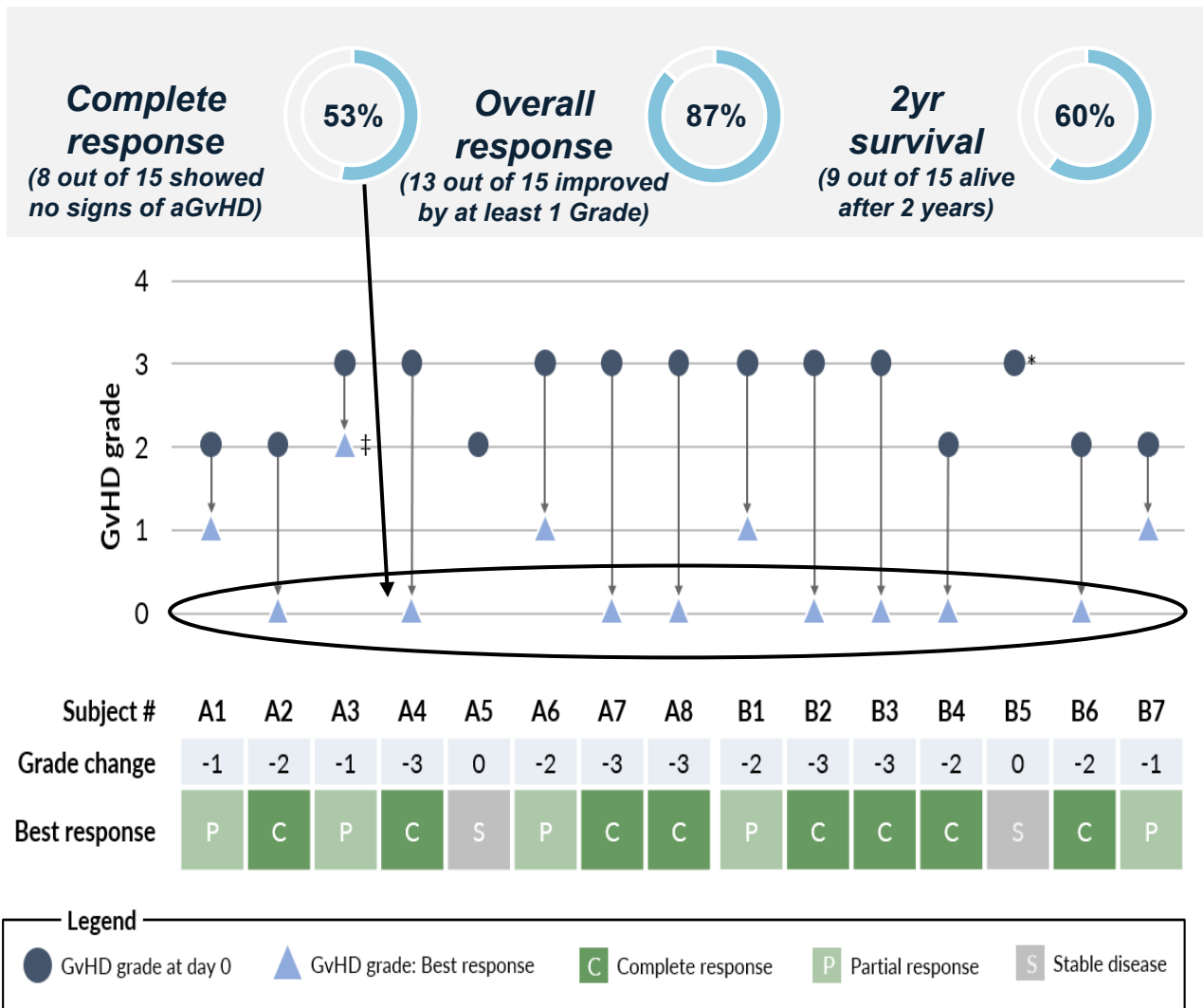
- Good initial response rates but no apparent increase in longer-term survival rates (18 months +) compared to controls⁶
- Serious/life threatening adverse reactions are common in patients who receive Ruxolitinib (e.g. infections, blood disorders)⁷
- Ruxolitinib is priced at ~US\$18k per month, and typically requires at least 6 months treatment for GvHD (i.e. >US\$100k per patient), and has forecast sales of US\$4.5b in 2024 across all indications⁸


- **Other investigational agents**


- Sometimes referred to as "Best Available Therapy (BAT)" in clinical trials
- Most have shown limited efficacy and/or poor safety profiles


Safer and more effective treatments are desperately needed for aGvHD

SR-aGvHD | Phase 1 clinical trial – results



 Outstanding **response rates** and **overall survival**

 **Sustained outcomes achieved up to 2 years** after the first infusion

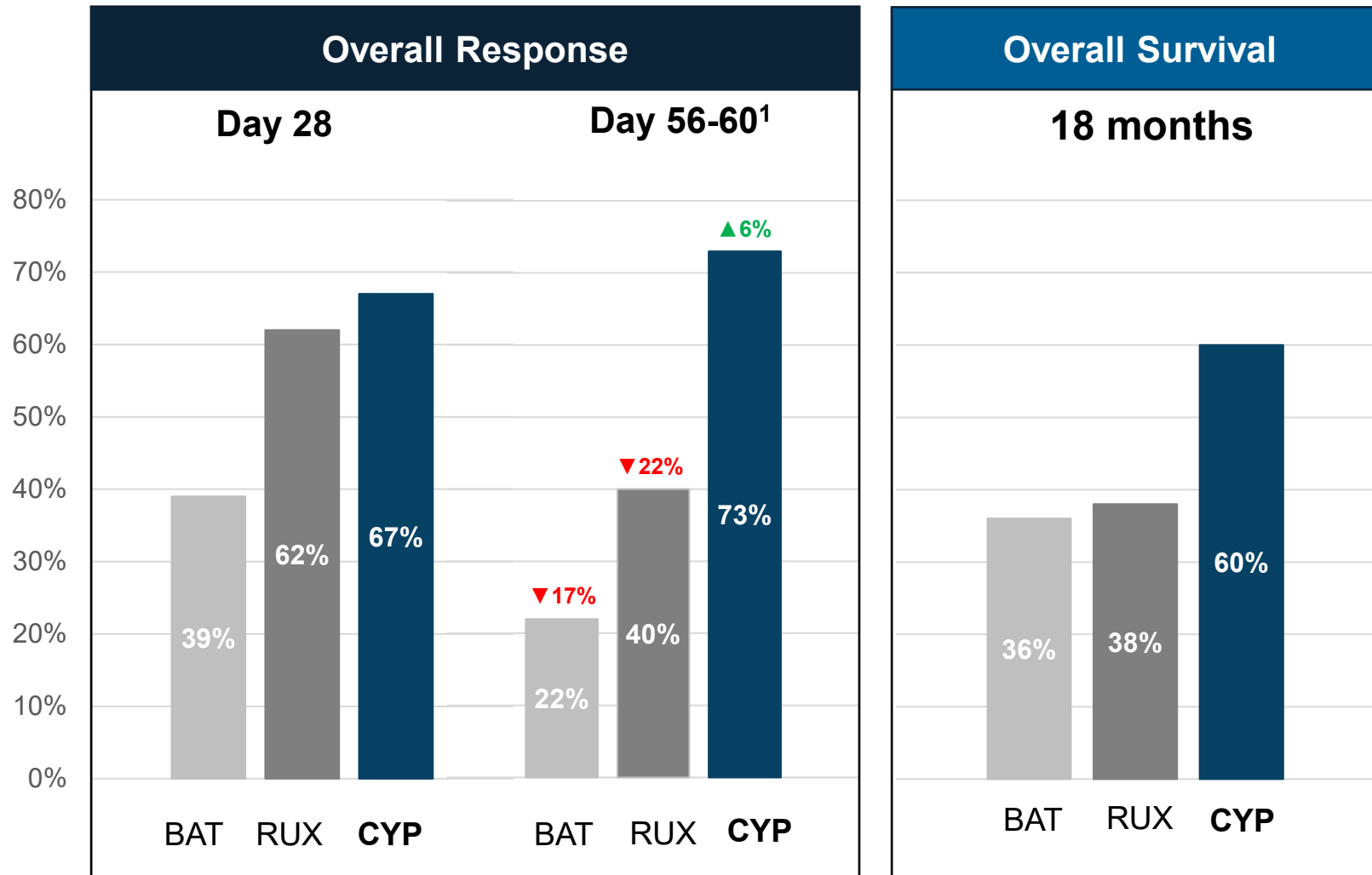
 **Importantly:** CYP-001 was shown to be **safe and well tolerated**



No serious adverse events or other safety concerns related to CYP-001

Trial conducted in 15 patients with steroid-resistant aGvHD (SR-aGvHD)
Product: CYP-001 (Cymerus™ MSCs for intravenous infusion)

CYP-001 vs other treatments in SR-aGvHD



Overall Response

- Between Day 28 and Day 56-60, the Overall Response Rate (ORR) for both RUX and BAT **decreased** markedly, while the ORR for CYP-001 marginally **increased**

Overall Survival

- CYP also reported **60% survival at 24 months** (not shown on graph, as 18 months was the latest timepoint reported in RUX/BAT trial)

Safety

- No serious adverse events or safety concerns for CYP-001

CYP = CYP-001 in Phase 1 trial (NCT02923375). Rux = ruxolitinib in Phase 3 trial (NCT02913261) (ruxolitinib is now approved for SR-aGvHD). BAT = "best available therapy" control arm in ruxolitinib Phase 3 trial (NCT02913261)

Scientific and regulatory recognition

Scientific: Publications

- Cynata was published in two editions of the highly prestigious *Nature Medicine* journal following its Phase I trial results



Cynata featured on front-page of Nature Medicine

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}

Regulatory: Orphan Drug Designation

- CYP-001 has been granted Orphan Drug Designation by the US FDA for the treatment of GvHD



Benefits include:

- Tax credits for qualified clinical trials
- Exemption from user fees
- Potential seven years of market exclusivity after approval

aGvHD | Phase 2 clinical trial

Indication

High risk acute graft versus host disease (aGvHD)¹

Product

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

Study Design

- Randomised, double-blind, placebo-controlled trial
- ~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

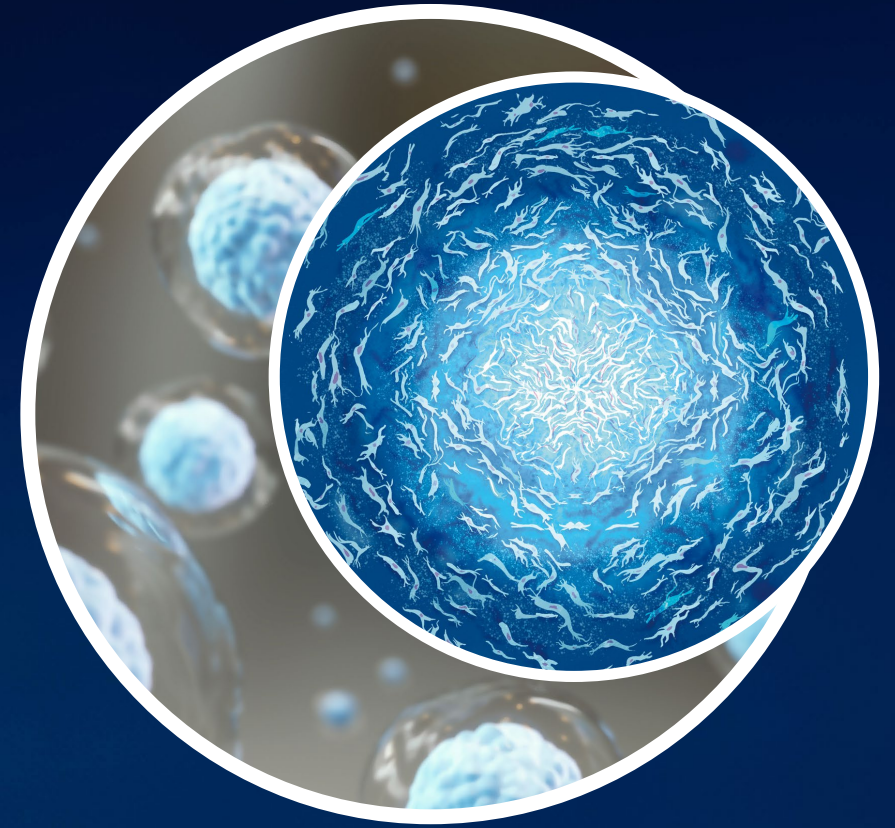
Study Conduct

- Conducted under IND from US FDA
- Clinical sites in USA, Europe and Australia
- First patient enrolled in March 2024; enrolment >40% complete²
- Aiming to complete patient enrolment in H1 2025

Results

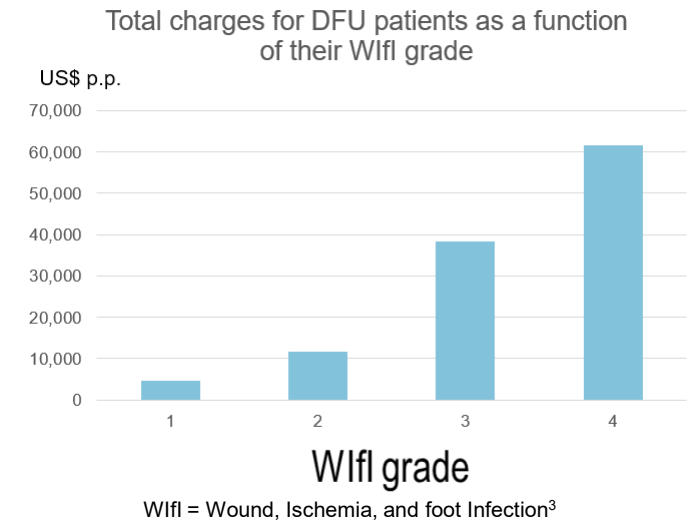
Results anticipated in H2 2025 (primary evaluation)

CYP-006TK for Diabetic Foot Ulcers



Diabetic foot ulcers (DFU)

- Open sore or wound that develops in patients with diabetes
- Very difficult to heal, which can lead to serious complications such as serious infection
- 20% of patients who develop DFU will require an amputation¹
- Multi-disciplinary team can be required to treat: GP, endocrinologist, podiatrist, wound care nurse, vascular surgeon and infectious disease specialist
- Cost to treat DFU in the US can exceed US\$60,000 per patient (depending on severity)²
- Annual costs to US public and private payers estimated to be US\$9 – 13 billion per year²



Diabetes is the **fastest growing** public health concern worldwide⁴

~38 million Americans have diabetes⁵

Up to 34% of those with diabetes will develop a foot ulcer¹

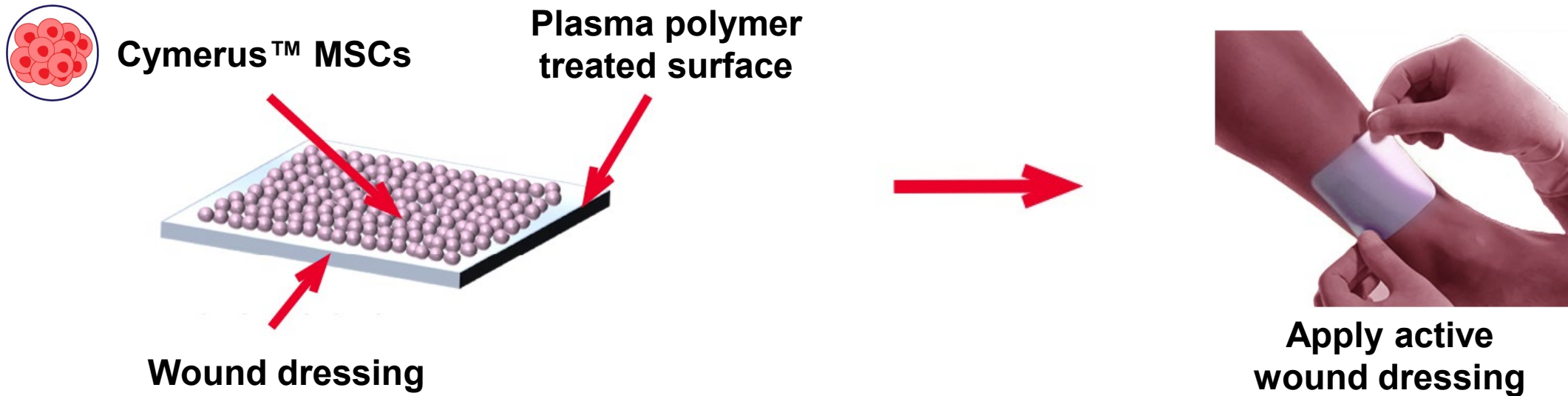
20% of patients with DFU will require **amputation** of the foot or limb¹

150,000+ amputations **per year** in the US due to **DFU**⁶

Estimated costs to US public and private payers **US\$9–13 billion** per year²

Cynata's MSC product for DFU

- Cynata has developed a proprietary wound dressing using MSCs ("CYP-006TK")
- CYP-006TK utilises a proprietary surface-coating, optimised for the delivery of MSCs directly to the wound



DFU | Phase 1 clinical trial

Indication

Non-healing diabetic foot ulcers (DFU)

Product

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

Study Design

- Randomised controlled trial in ~30 adults
- Patients randomised to receive either standard of care (SOC) or CYP-006TK for 4 weeks, followed by SOC
- SOC treatment = current best practice as determined by investigator (e.g. conventional wound dressings etc)
- Primary objective was safety; efficacy measures included wound healing, pain and quality of life
- Clinical sites in Australia (Adelaide and Perth)

Study Conduct

- Patient enrolment complete (April 2024)
- All patient visits complete (September 2024)

Results

Final results released in December 2024

Safety and tolerability

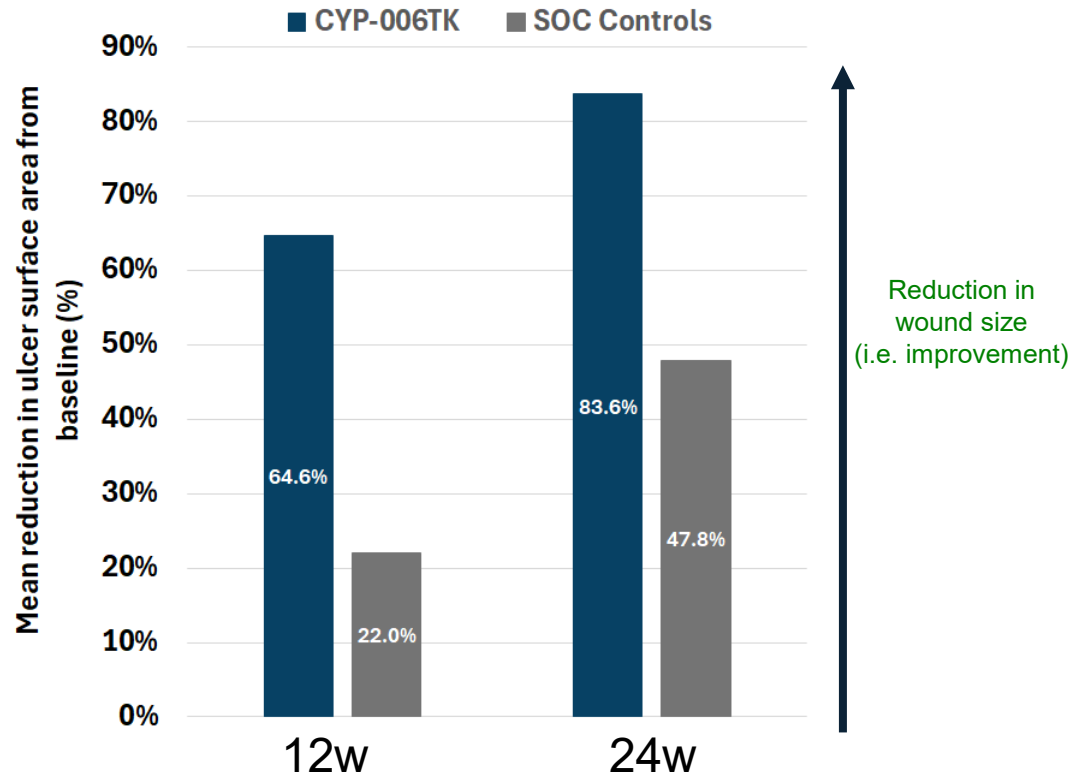
Primary Objective

Phase 1 clinical trial of CYP-006TK in DFU **successfully achieved** its primary objective:

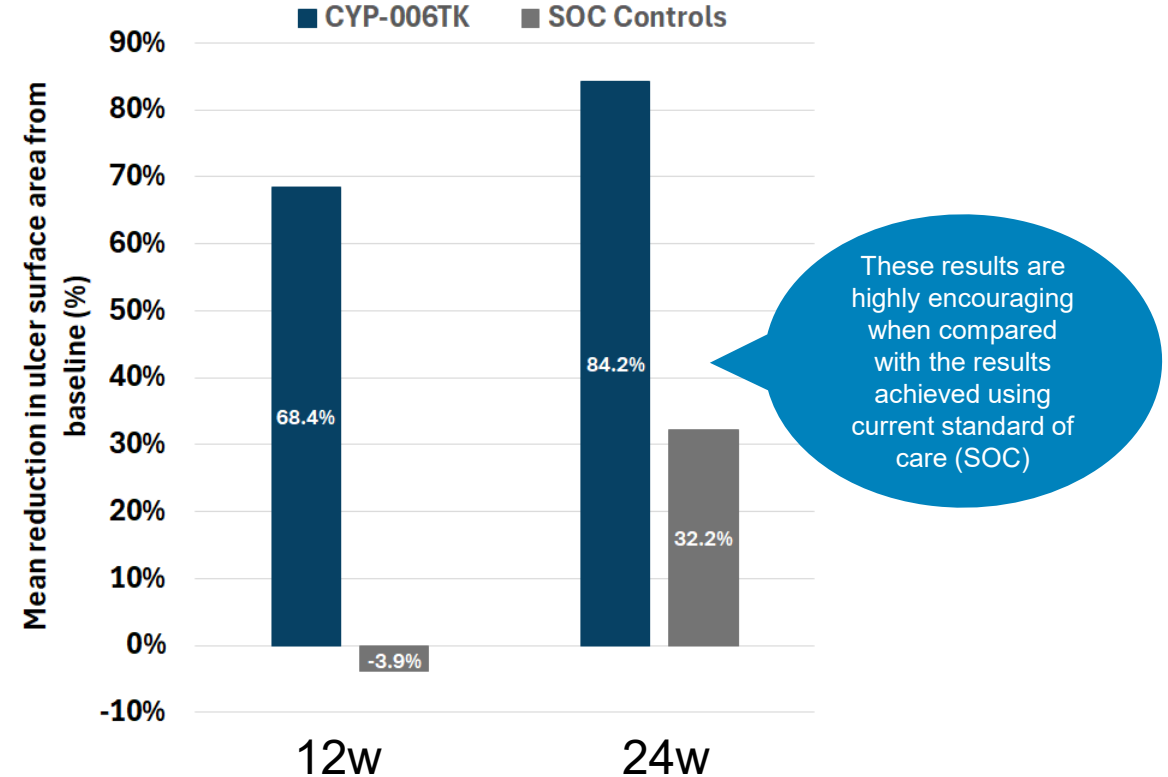
- safe and well-tolerated
- no participants withdrew from the trial due to adverse events
- no suspected serious adverse reactions were reported

Efficacy

Mean change in wound surface area (all wounds)



Larger wounds measuring >200 mm²



Diabetes **fastest** growing disease worldwide¹

Est. 38 million Americans have diabetes²

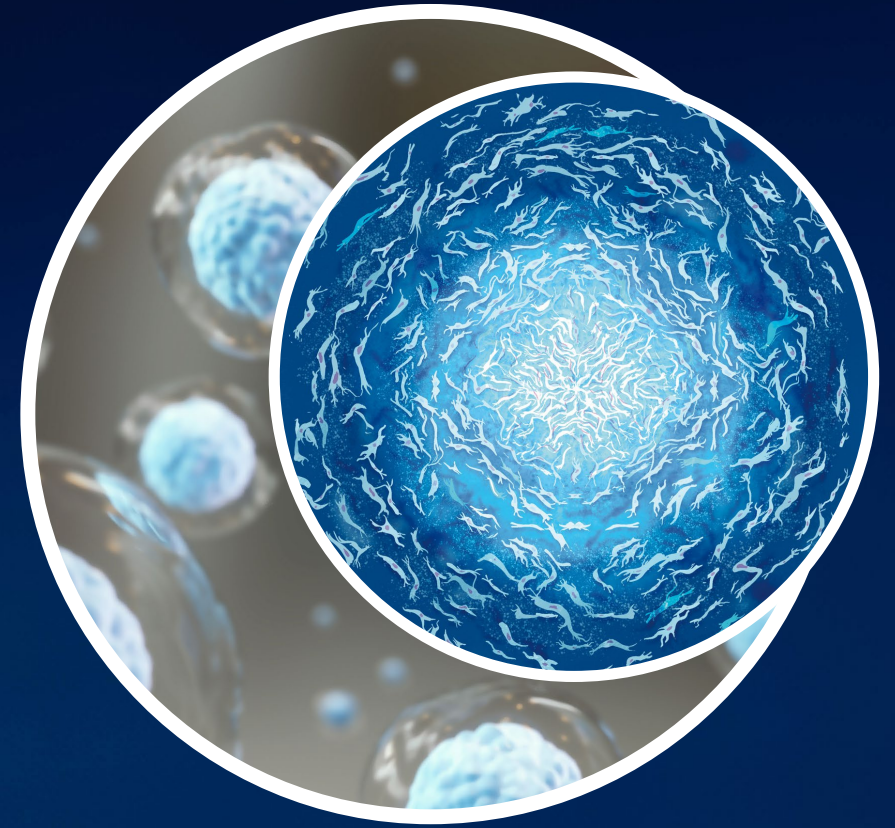
Up to 34% of those with diabetes will develop a foot ulcer³

More than 15% of foot ulcers result in amputation of the foot or limb³

150,000+ lower extremity amputations **per year** in the US following **chronic DFU**⁴

Estimated annual costs to US public and private payers: **US\$9–13 billion**⁵

Leveraging the unique
potential of Cymerus MSCs



OA | Phase 3 clinical trial

Indication

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

Product

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

Study Design

- Randomised, double-blind placebo-controlled trial in ~320 adults¹
- 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, while Cynata retains commercial rights
- Clinical centres in Australia (Sydney and Hobart)
- Patient enrolment complete (November 2023)
- Last patient last visit expected ~November 2025

Results

- Results anticipated in H1 2026

Kidney transplant | Phase 1/2 clinical trial

Indication

Prevention of kidney transplant rejection

Product

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

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 conducted and funded by Leiden University Medical Center (LUMC), Netherlands, while Cynata retains commercial rights
- Patient enrolment commenced in Q4 2024, with first patient treatment completed in Dec 2024

Results

Outcome of Cohort 1 anticipated in H1 2025

Research partnerships

PLATFORM POTENTIAL OF CYNATA

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

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



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criticalcare
RESEARCH GROUP

SVI
St Vincent's Institute
MEDICAL RESEARCH

Comparison of MSCs from different sources

npj | regenerative medicine

Published in partnership with the Australian Regenerative Medicine Institute

Article



<https://doi.org/10.1038/s41536-024-00382-y>

Proteomic profiling of iPSC and tissue-derived MSC secretomes reveal a global signature of inflammatory licensing

Margeaux Hodgson-Garms^{1,2}✉, Matthew J. Moore¹, Mikael M. Martino^{3,4}, Kilian Kelly² & Jessica E. Frith^{1,3}✉

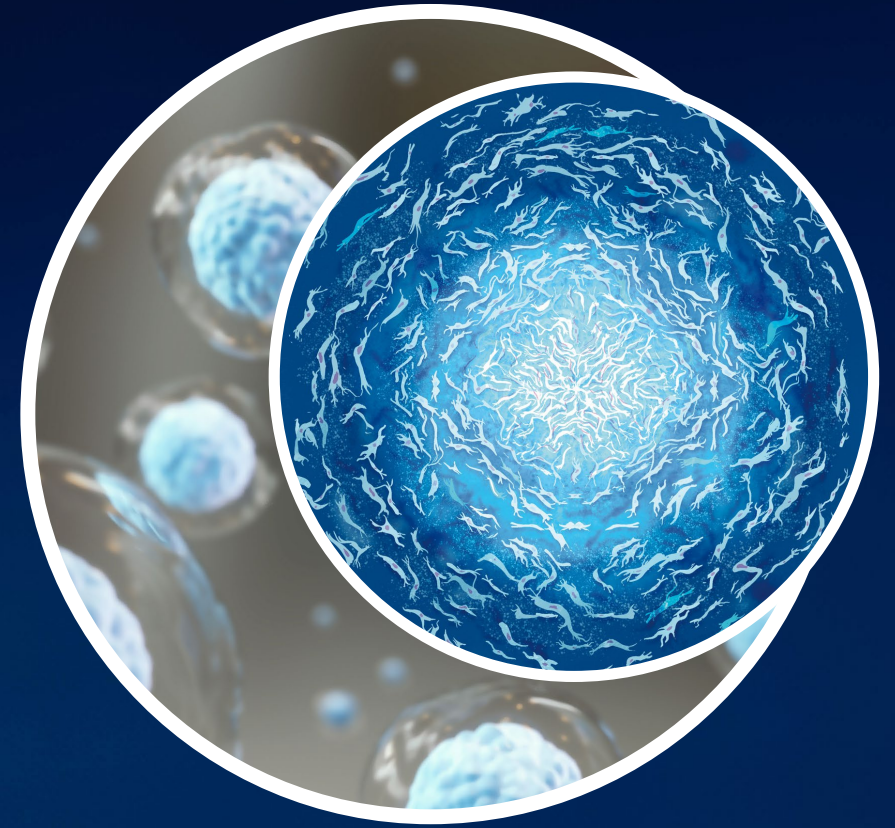
Background

- Effects of MSCs depend largely on “secretome” – proteins and other molecules released by cells
- This study assessed similarities/differences between secretomes of MSCs derived from either iPSCs or a donor tissue source (bone marrow, adipose tissue or umbilical cord), under different conditions
- Important to assess MSCs under different conditions because MSCs respond to their environment, which changes their effects
- Notably, MSCs are often exposed to inflammatory conditions after administration to patients

Key Highlights






- Substantial differences between MSCs from different sources
- Substantially less variability between batches of iPSC-derived MSCs than between batches of MSCs derived from donor tissue, especially bone marrow
- iPSC-derived MSCs released many more unique proteins than donor tissue-derived MSCs: indicates iPSC-derived MSCs could have additional effects compared to donor tissue-derived MSCs
- iPSC-derived and umbilical cord-derived MSCs displayed features consistent with “younger” cells, suggesting sustained ability to avoid ageing (“senescence”)
- Strong regenerative potential of iPSC-derived and umbilical cord-derived MSCs (but not bone marrow or adipose tissue-derived MSCs) maintained under both resting and inflammatory conditions
- *In vitro* studies of MSC secretomes found:
 - iPSC-derived and umbilical cord-derived MSCs resulted in significantly faster wound closure than bone marrow or adipose tissue-derived MSCs
 - iPSC-derived MSCs showed greater immunomodulatory effects than MSCs derived from any donor tissue source

Outlook and commercial potential



Commercial Attractiveness



 Proprietary Platform Technology	<ul style="list-style-type: none">• Ability to produce MSCs consistently and at scale allows for MSCs to be used in multiple indications = Platform Technology appeal
 Platform Technology	<ul style="list-style-type: none">• Platform Technology allows CYP to target multiple multi-billion dollar indications
 Multiple Multi-Billion Dollar Indications	<ul style="list-style-type: none">• Four clinical indications currently targeted have total combined market opportunities of ~US\$27.7 billion• All indications capable of being out-licensed / partnered
 Commercial interest	<ul style="list-style-type: none">• In 2019 (post Phase I results in GvHD), the Company received a non-binding indicative offer to acquire all shares in Cynata for \$2 per share (The parties subsequently withdrew from discussions as a result of being unable to reach agreement on satisfactory terms)• Cynata anticipates significant commercial interest following any positive read-outs• Three further read-outs expected by H1 CY2026
 Seeking Partnership Opportunities	<ul style="list-style-type: none">• Following the successful DFU results, Cynata will now continue discussions with potential commercial partners and engage with regulatory agencies (including FDA) as part of its strategy for further clinical development

Industry connections

- Upcoming catalysts will accelerate and broaden partnering discussions
- We attend leading conferences in our sector, to tell our story and open new discussions
- Following on from multiple events in past year, selected key events going forward include:



Advanced Therapies Congress
London, March 2025

Company presentation,
partnering meetings



International Society of Cell and Gene Therapy
New Orleans, May 2025

Invited speaker,
partnering meetings



BIO International
Boston, June 2025

Partnering meetings



BIO Japan, RM Japan
Yokohama, October 2025

Partnering meetings

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
- Joined Cynata in 2014
- 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*

DFU results announced Dec 2024; results from THREE further trials expected by 1H 2026

Phase 1
DFU

Results
announced
– Dec 2024



Phase 2
aGvHD

Enrolment
complete

Results

Phase 3
osteo-
arthritis

Results

Phase 1/2
kidney
transplant

Results
(Cohort 1)

Q1
2025

Q2
2025

Q3
2025

Q4
2025

Q1
2026

Q2
2026



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