

Investor Webinar

Melbourne, Australia; 6 February 2025: Cynata Therapeutics Limited (ASX: “CYP”, “Cynata”, or the “Company”), a clinical-stage biotechnology company specialising in cell therapeutics, reminds shareholders that CEO and Managing Director, Dr Kilian Kelly, will host an investor webinar today, Thursday 6 February 2025 at 10:30am AEDT.

Attendees are required to register in advance for the webinar – using the following link:

https://us02web.zoom.us/webinar/register/WN_X-L7ioGETN6cOcf-D0fQ1Q

Upon registration, attendees will receive a link to access the webinar.

A copy of the presentation to 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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About Cynata Therapeutics (ASX: CYP)

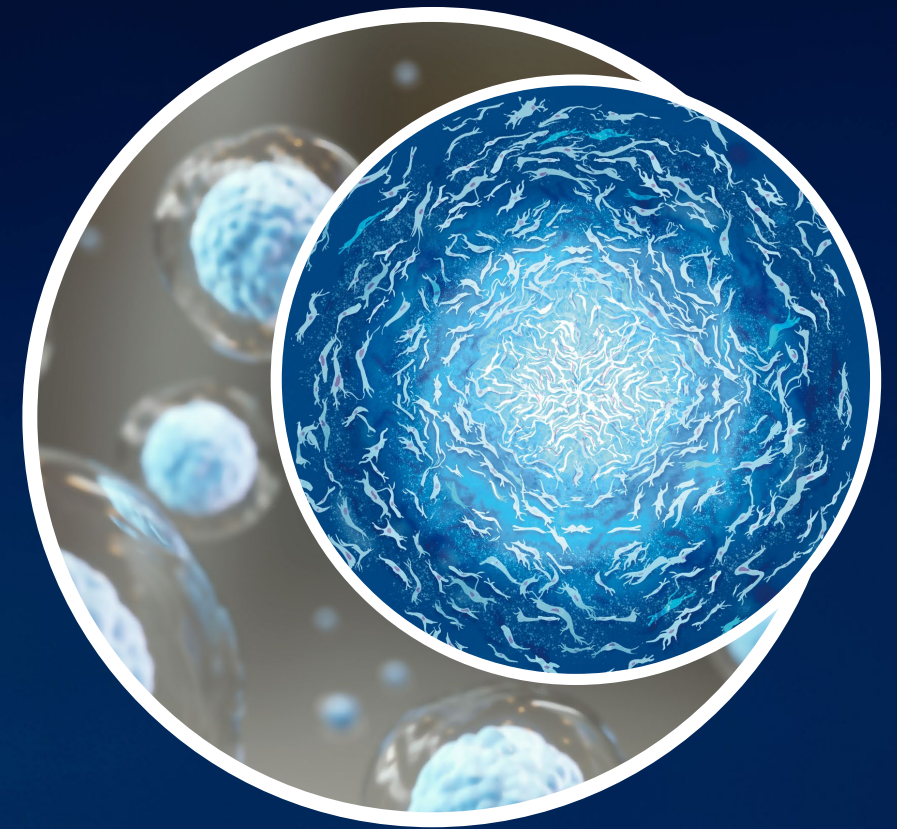
Cynata Therapeutics Limited (ASX: CYP) is an Australian clinical-stage stem cell and regenerative medicine company focused on the development of therapies based on Cymerus™, a proprietary therapeutic stem cell platform technology. Cymerus™ overcomes the challenges of other production methods by using 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 Webinar

6 February 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 5 February 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 (5 February 2025)	A\$0.245
Shares on issue	~225m
Market capitalisation	~A\$55m

Share price – calendar year 2024



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

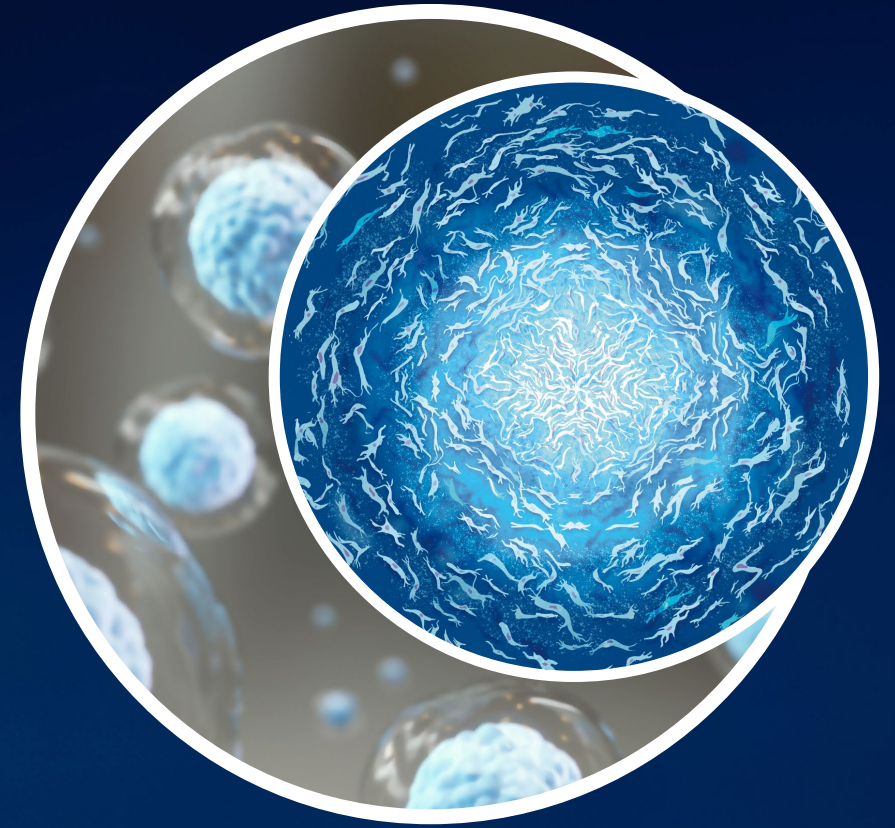
Indication		Trial phase	Upcoming catalysts*	Market opportunity
 Acute Graft vs Host Disease (aGvHD) FDA Orphan Designation	Cynata Funded & Managed	Phase 2 ongoing	Enrolment completion – H1 2025 Results – H2 2025	US\$600m ¹
 Diabetic Foot Ulcers (DFU)		Phase 1 complete	Results released Dec 2024	US\$9.6bn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

December 2024 Quarter – Key Highlights

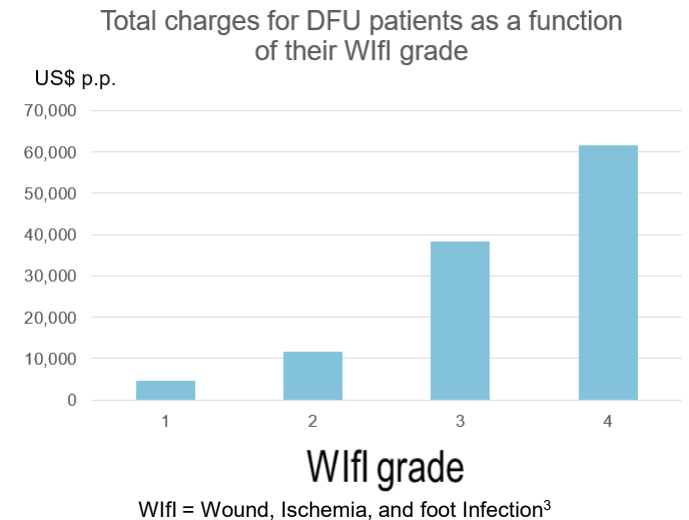
- **Phase 1 clinical trial in diabetic foot ulcer (DFU) completed**
 - CYP-006TK demonstrated to be safe and well tolerated, with positive efficacy data indicating substantially improved wound healing for CYP-006TK compared to the standard of care control group
- **Phase 2 clinical trial in acute graft-versus-host disease (aGvHD)**
 - recruitment now >40% complete, with the rate of recruitment substantially accelerating in recent months; primary results still anticipated late 2025
- **Phase 1 clinical trial in kidney transplantation**
 - first patient treated; completion of first cohort anticipated in Q1 2025
- **Phase 3 clinical trial in osteoarthritis**
 - all patients have completed study treatment; results expected in 1H 2026
- **Balance sheet strengthened**
 - \$1.88m R&D Tax Incentive rebate
 - \$8.10m institutional placement
- **Strong cash balance**
 - \$10.51m at end of quarter with forecast cash runway into mid 2026

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

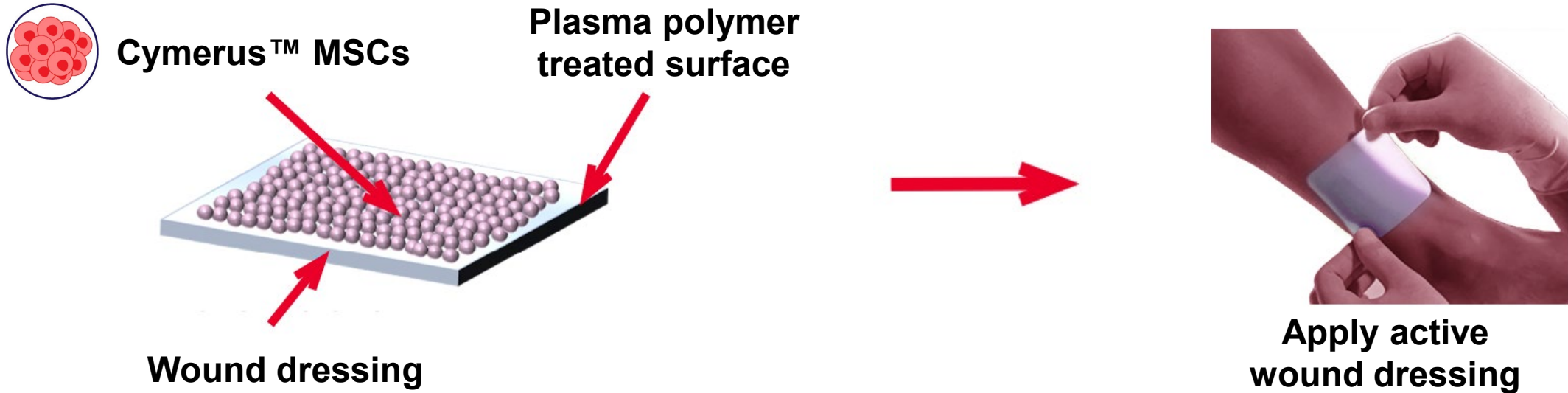
20% of patients with DFU will require **amputation** of the foot or limb¹

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

Study Conduct

Results

Final results released in December 2024

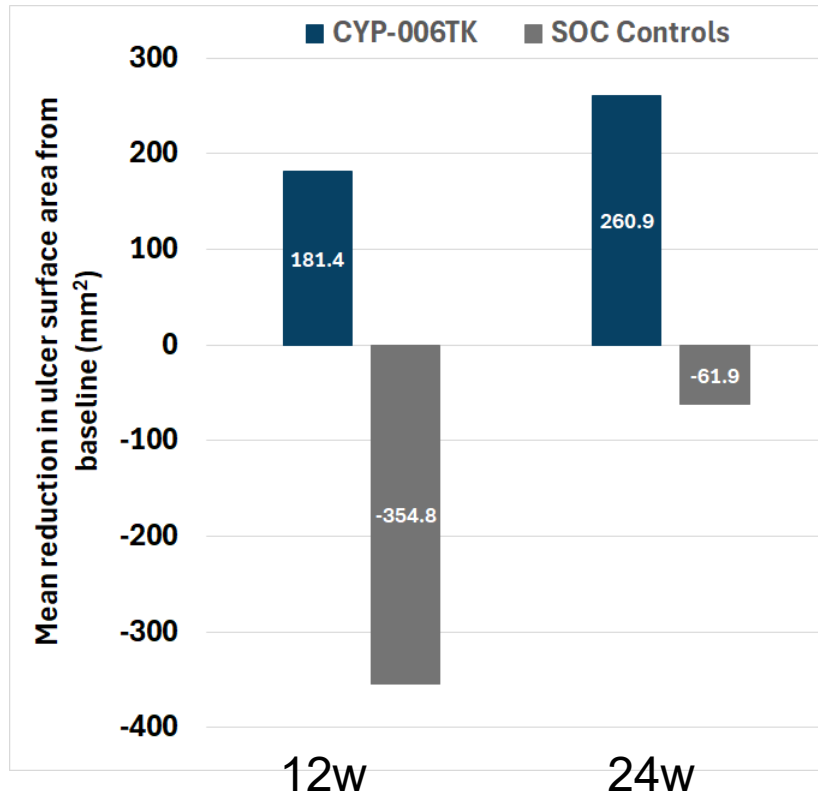
Safety and tolerability

Primary Objective

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

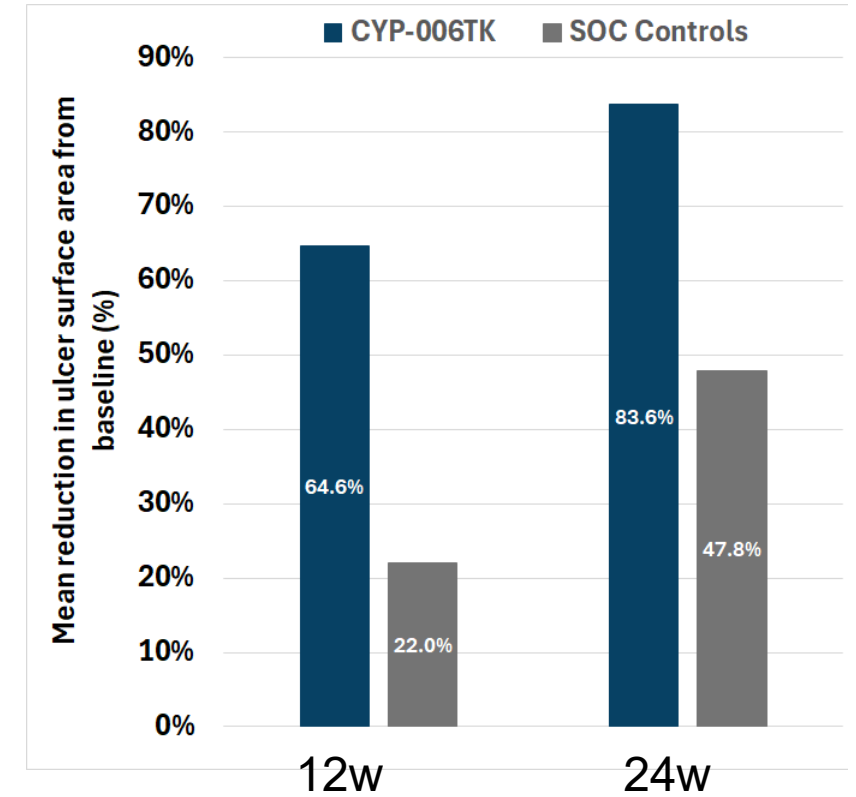
- safe and well-tolerated
- no participants withdrew from the trial due to adverse events
- no suspected serious adverse reactions were reported

Change in wound surface area



Reduction in wound size
(Improvement)

Increase in wound size
(Deterioration)



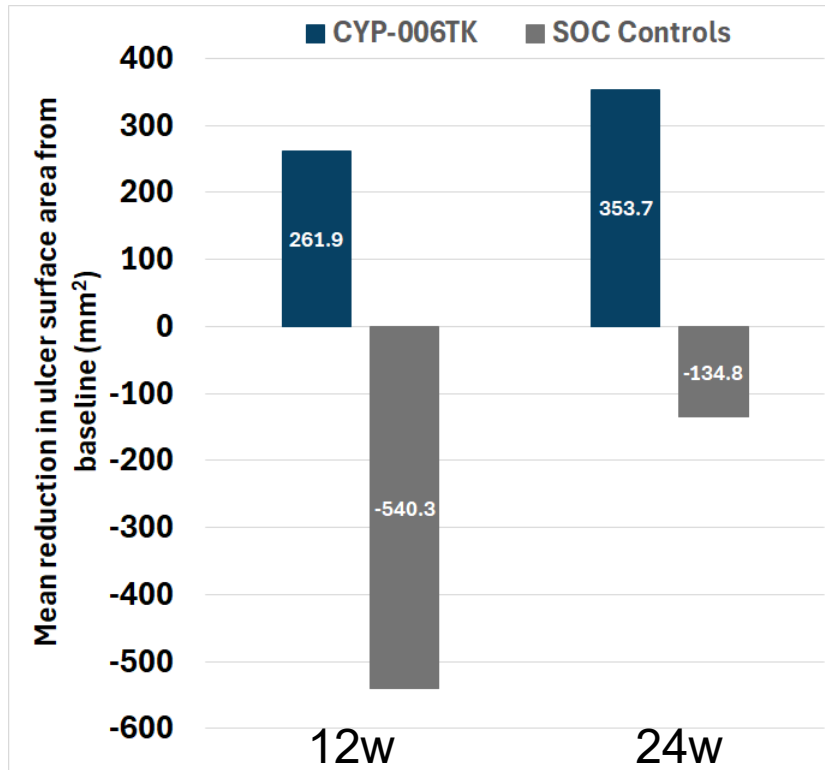
CYP-006TK

- Substantial mean reduction (improvement) in wound surface area at both 12 & 24 weeks, in both mm² and percentage terms

Standard of Care

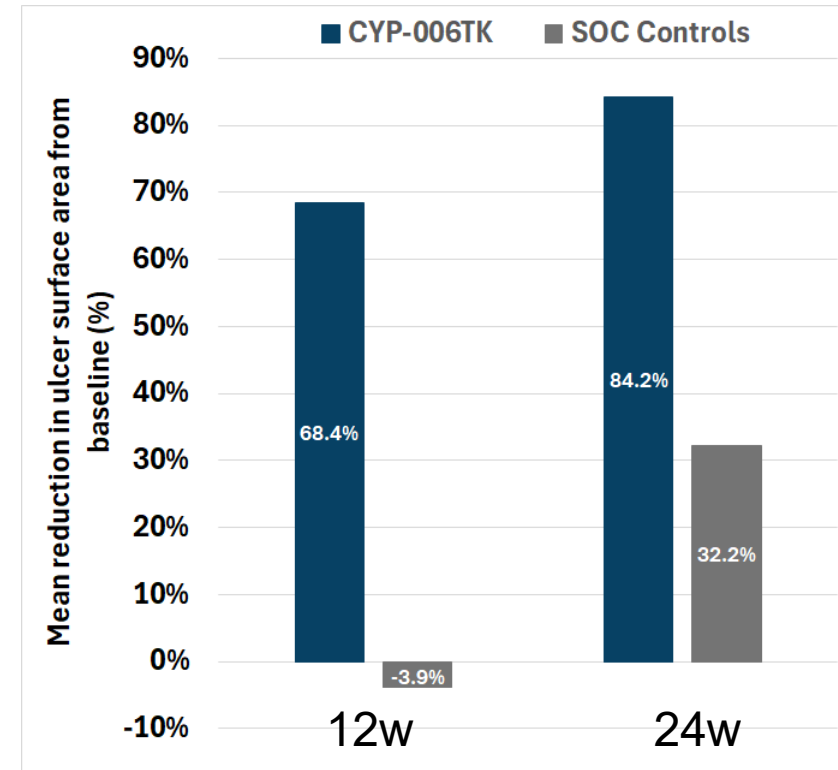
- Mean increase (deterioration) in wound surface area at both 12 & 24 weeks, in mm² terms
- Increase in mm² terms combined with moderate reduction in percentage terms indicates that **larger wounds were less likely to heal**

Larger wounds* (measuring $>200 \text{ mm}^2$)



Reduction in wound size
(Improvement)

Increase in wound size
(Deterioration)



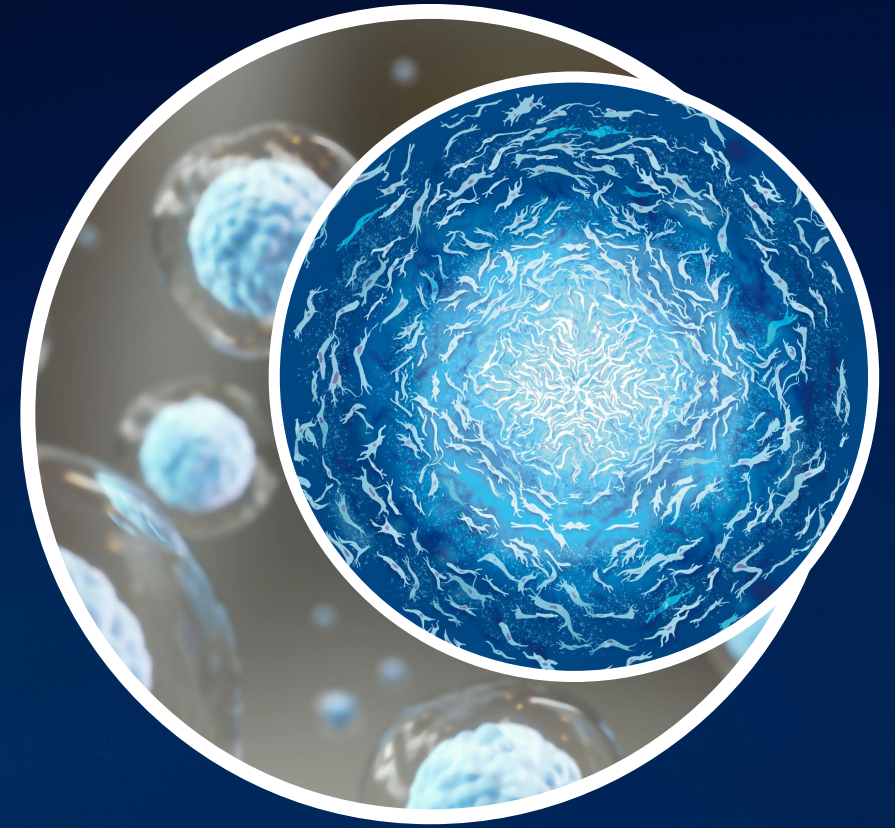
CYP-006TK

- Mean reduction in wound surface area was similar in larger wounds to when all wounds were included
- Substantial improvement in large wounds is especially encouraging as larger DFU are more likely to lead to an amputation¹

Standard of Care

- Extent of mean increase (deterioration) was greater in larger wounds than when all wounds were included
- Mean change by percentage was markedly worse in larger wounds than in all wounds

Ongoing clinical trials -
leveraging the unique
potential of Cymerus MSCs



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)

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, with clinical centres in Sydney and Hobart
- Patient enrolment complete (November 2023)
- Patient treatment complete (November 2024)
- 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)

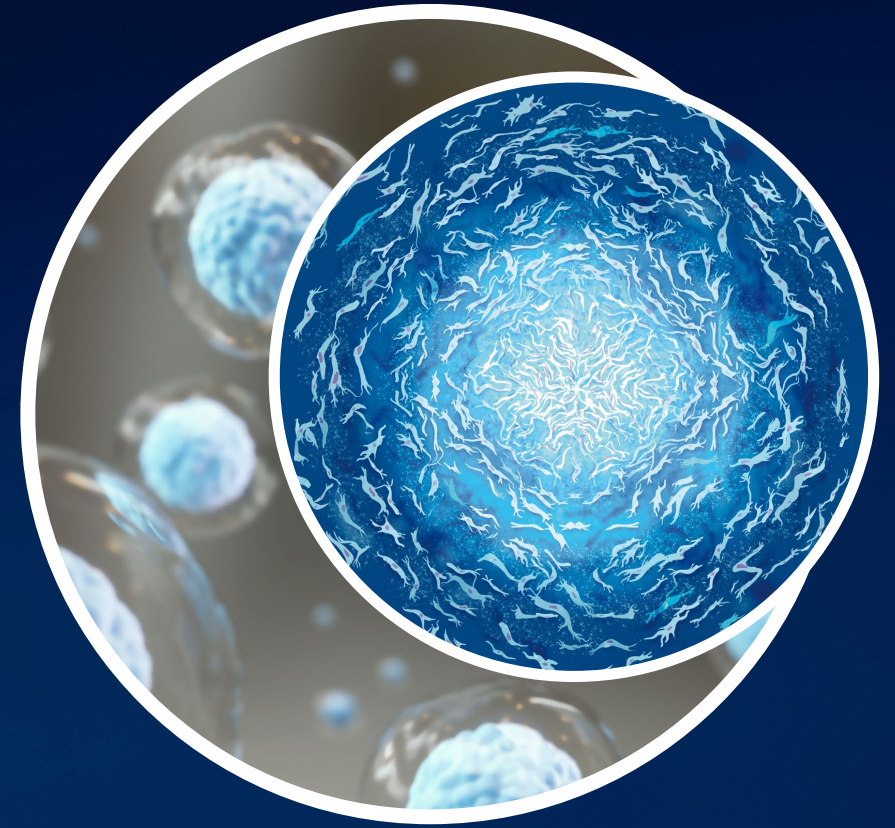
Study Conduct

- 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

Outlook and commercial potential



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 earlier this year, selected key events going forward include:

	JP Morgan BioWeek/Biotech Showcase San Francisco, January 2025	Company presentation and partnering meetings
	Advanced Therapies Congress London, March 2025	Company presentation and partnering meetings
	BIO International Boston, June 2025	Partnering meetings
	BIO Japan, RM Japan Yokohama, October 2025	Partnering meetings

- We will also attend further key events in the sector (ARM, ISCT, ISSCR) and in the regions

Important new publication

npj | regenerative medicine

Article

Published in partnership with the Australian Regenerative Medicine Institute



<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

Check for updates

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

Much of the therapeutic potential of mesenchymal stromal cells (MSCs) is underpinned by their secretome which varies significantly with source, donor and microenvironmental cues. Understanding these differences is essential to define the mechanisms of MSC-based tissue repair and optimise cell therapies. This study analysed the secretomes of bone-marrow (BM.MSCs), umbilical-cord (UC.MSCs), adipose-tissue (AT.MSCs) and clinical/commercial-grade induced pluripotent stem cell-derived MSCs (iMSCs), under resting and inflammatory licenced conditions. iMSCs recapitulated the inflammatory licensing process, validating their comparability to tissue-derived MSCs. Overall, resting secretomes were defined by extracellular matrix (ECM) and pro-regenerative proteins, while licensed secretomes were enriched in chemotactic and immunomodulatory proteins. iMSC and UC.MSC secretomes contained proteins indicating proliferative potential and telomere maintenance, whereas adult tissue-derived secretomes contained fibrotic and ECM-related proteins. The data and findings from this study will inform the optimum MSC source for particular applications and underpin further development of MSC therapies.

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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