



ASX ANNOUNCEMENT

19 November 2024

Melbourne, Australia; 19 November 2024: Cynata Therapeutics Limited (ASX: “**CYP**”, “**Cynata**”, or the “**Company**”), a clinical-stage biotechnology company specialising in cell therapeutics, is pleased to release a copy of the Chair’s address and Managing Director’s presentation, which will be delivered at the Company’s Annual General Meeting today.

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’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), diabetic foot ulcers (DFU) and renal transplant are currently ongoing. 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.

Chair's Address to Shareholders

2024 Annual General Meeting

It is my pleasure to address you all today and provide an overview of Cynata's progress over the last year.

Following my address, I will invite Kilian and his senior management team to provide an update on the Company's activities and outlook, with a particular focus on the multiple approaching clinical development inflexion points. I ask that any questions relating to the Company's operations be held until the team has completed the presentation.

During the last financial year, the Company made very substantial progress. The year commenced with the promotion of Kilian to the position of Chief Executive Officer and Managing Director, and we then further strengthened the management team with the appointment of Mathias to the new position of Chief Business Officer. Together with Jolanta as Chief Medical Officer, and a highly credentialed and experienced board, I believe we have the right leadership in place to drive the Company's success in the years ahead.

Highlights for the financial year include:

- We enrolled the first patient in our Phase 2 graft versus host disease clinical trial, and have continued to make progress since with further enrolments.
- We completed patient enrolment in our Phase 1 diabetic foot ulcer clinical trial.
- Our partners at the University of Sydney completed patient enrolment in the Phase 3 osteoarthritis clinical trial.
- Our partners at Leiden University Medical Center secured regulatory and ethics approval for the Phase 1/2 kidney transplant clinical trial, and have subsequently enrolled the first patient.
- In addition, we released more encouraging clinical data, including initial data from our ongoing diabetic foot ulcer trial, as well as further data from our Phase 1 GvHD trial, which was published in *Nature Medicine*.

I was particularly pleased to see each of the Company's four clinical development programs progressing well over the year. We are now in a position where there are multiple upcoming clinical readouts, over the next 18 months or so. Consequentially, this is as extremely exciting time for the Company.

Furthermore, it is reassuring that the share price has started to recover, increasing by more than 130% over the financial year, and I am optimistic that with further progress we should see better recognition of the Company's true value.

On behalf of the Board, I would like to thank my fellow directors and extend my gratitude to our staff for their commitment to our Company. I would also like to sincerely thank all of our shareholders for their ongoing support, which I am confident will be rewarded.

I would now like to pass on to Kilian and team to provide a comprehensive update on the Company's clinical development and outlook.



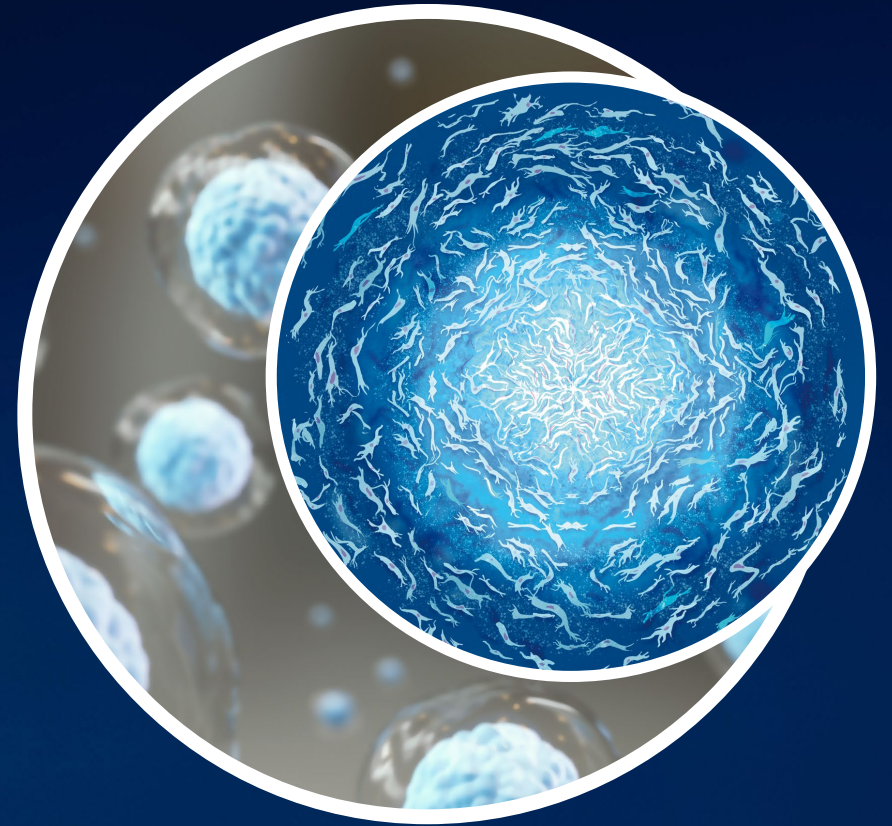
A Clinical Stage Company Pioneering the Next Generation of Cellular Therapies

Managing Director's Presentation

Dr Kilian Kelly

Annual General Meeting

19 November 2024



Important information

Summary information

This Presentation contains summary information about Cynata Therapeutics Limited and its subsidiaries (**CYP**, or **Cynata**) which is current as at 15 November 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.

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Corporate overview

Share price¹



Financial information

Share price (15 November 2024) A\$0.245

Shares on issue ~181m

Market capitalisation ~A\$44m

Cash² ~A\$4.3m

Largest shareholders

BioScience
Managers

13.1%

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.



10.0%

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

4.5%

Fujifilm is a Japanese multinational conglomerate operating in the realms of photography, optics, medical electronics, biotechnology and chemicals. Cynata has a strategic manufacturing partnership with Fujifilm.

Top 20 hold ~47% of the Company's share register²

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 ongoing (enrolment complete)	Results – Q4 2024/Q1 2025	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

FY 2024 | A year of progress

Multiple clinical trials advanced

- Phase 3 osteoarthritis trial – patient enrolment completed
- Phase 2 aGvHD trial – first patient enrolled
- Phase 1 DFU trial – patient enrolment completed
- Phase 1/2 kidney transplant trial approved

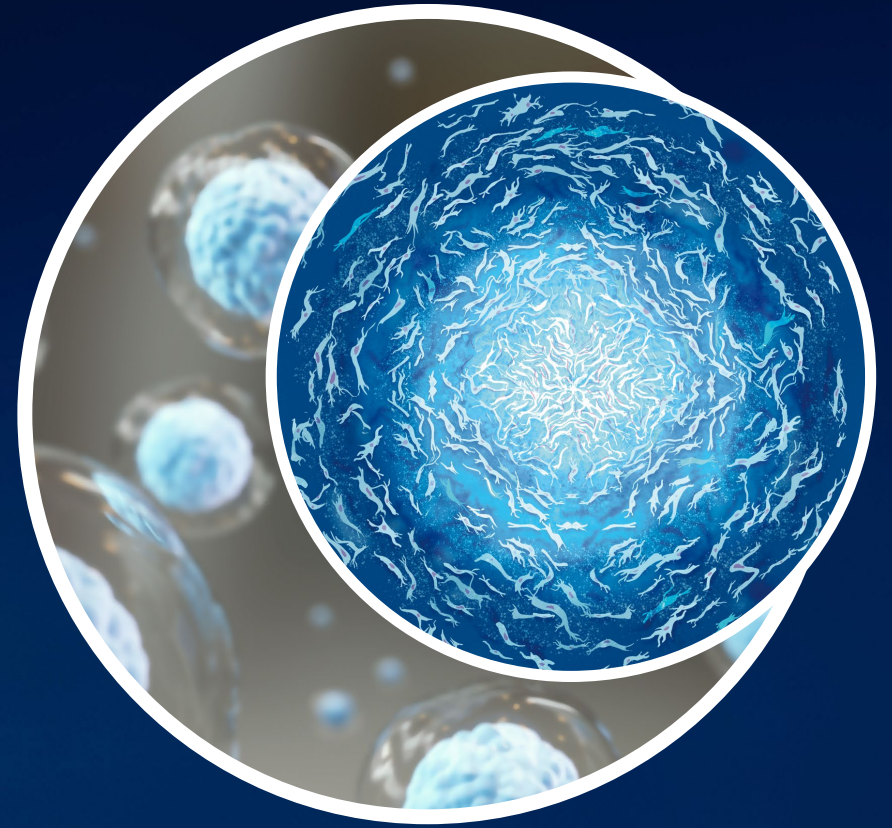
Further encouraging clinical efficacy data

- Promising initial data from ongoing DFU trial, in first 16 patients after 10 weeks:
 - 87.6% median reduction in wound surface area in active group compared to 51.1% in controls
- Additional data from Phase 1 GvHD trial published in *Nature Medicine*:
 - Two-year overall survival rate in patients with steroid-resistant aGvHD was 60%

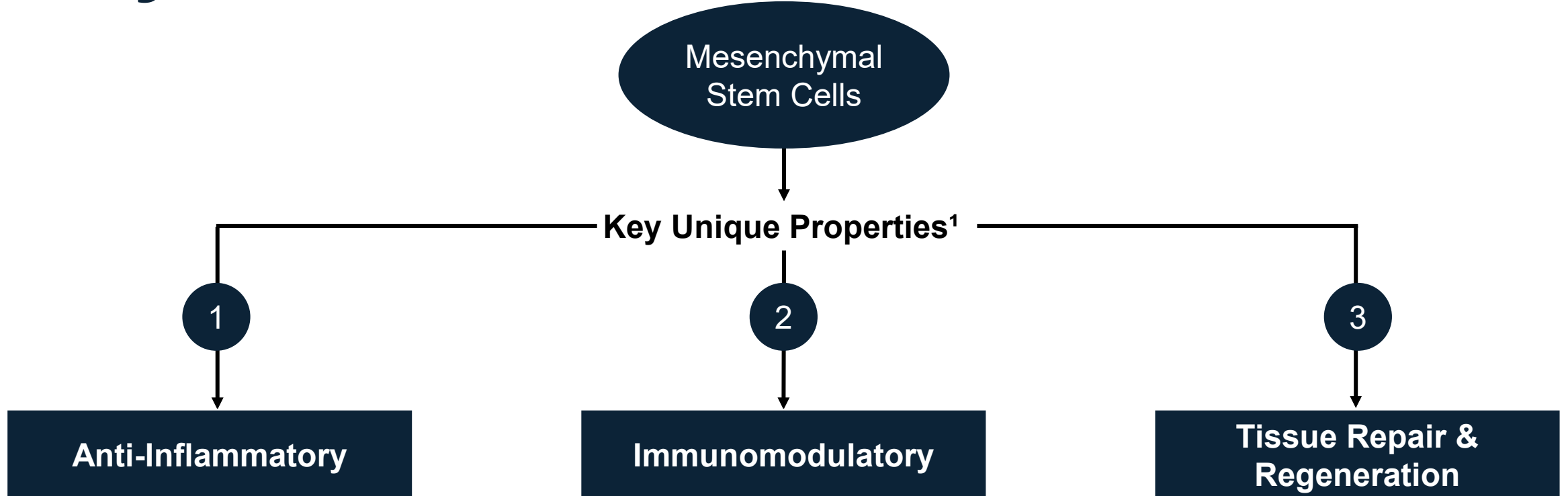
Senior management team strengthened

- Dr Mathias Kroll commenced in new position of Chief Business Officer

Cynata's revolutionary
Cymerus™ platform
technology



Why MSCs?



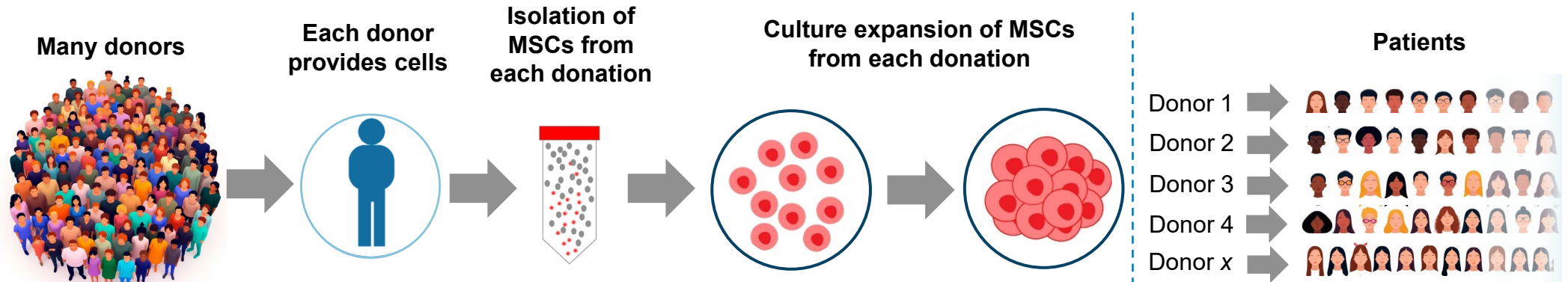
Importance:

Inflammation and inappropriate immune responses contribute to many diseases/medical disorders, and often lead to tissue damage. Consequently, the anti-inflammatory and immunomodulatory properties of MSCs, as well their ability to promote tissue repair and regeneration, can play an important role in treating many diseases.

Unlike many other cell therapies where patients have to be matched to donors, MSCs can be used without matching donors to recipients

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 problem

Traditional manufacturing methods used to produce MSCs can encounter the following challenges:

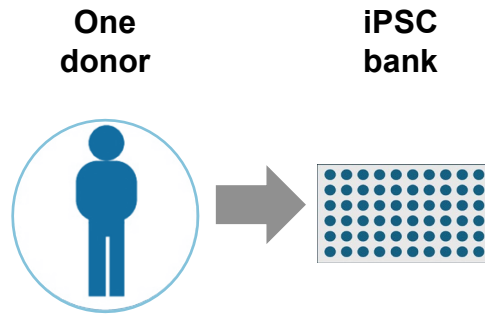
- Consistency issues** → Inconsistent MSCs produce inconsistent & unreliable results
- Potency issues** → Different potency levels in MSCs produce inconsistent & unreliable results
- Scalability issues** → Logistically and technically challenging to scale-up



Unless these issues are resolved, MSCs will differ from batch to batch
Standardised MSCs are required for effective and consistent treatment of diseases

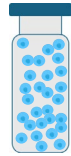
The solution: the Cymerus™ process

Cymerus™ Process

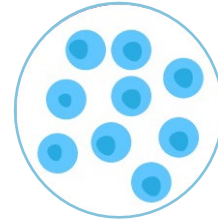


Blood donation from a **single donor** was used to produce a high-quality **iPSC¹ bank**

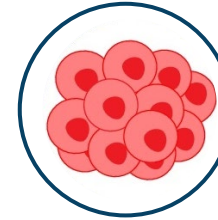
Vial of iPSCs from bank



iPSC expansion and differentiation

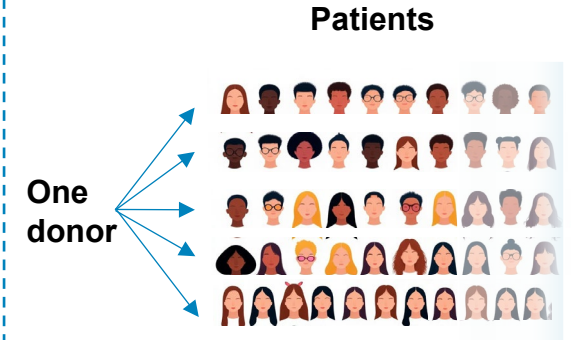


Formation of MSCs



Cells from **same** iPSC bank are used to make **every batch** of Cymerus™ MSCs

iPSCs are culture expanded, then **turned into MSCs** using **patented** Cymerus™ process



All batches of Cymerus™ MSCs come from the **same donor**

Major Benefits

iPSCs have effectively **limitless** expansion capacity
=
Scalability

Starting material for **all** batches is **the same**
=
Consistent MSC product

Minimal MSC culture expansion required
=
MSCs **retain potency**

All patients receive MSCs from the **same donor**
=
Avoids variability

Summary: advantages of Cymerus™ platform

	Traditional MSCs	Cymerus™ Platform
Effectively limitless expansion capacity	✗	✓
Retain MSC potency	✗	✓
Highest-level of batch-batch consistency	✗	✓
Single donor to avoid donor variability issues	✗	✓
Strong safety profile	✓	✓

Traditional MSC Manufacturing Process

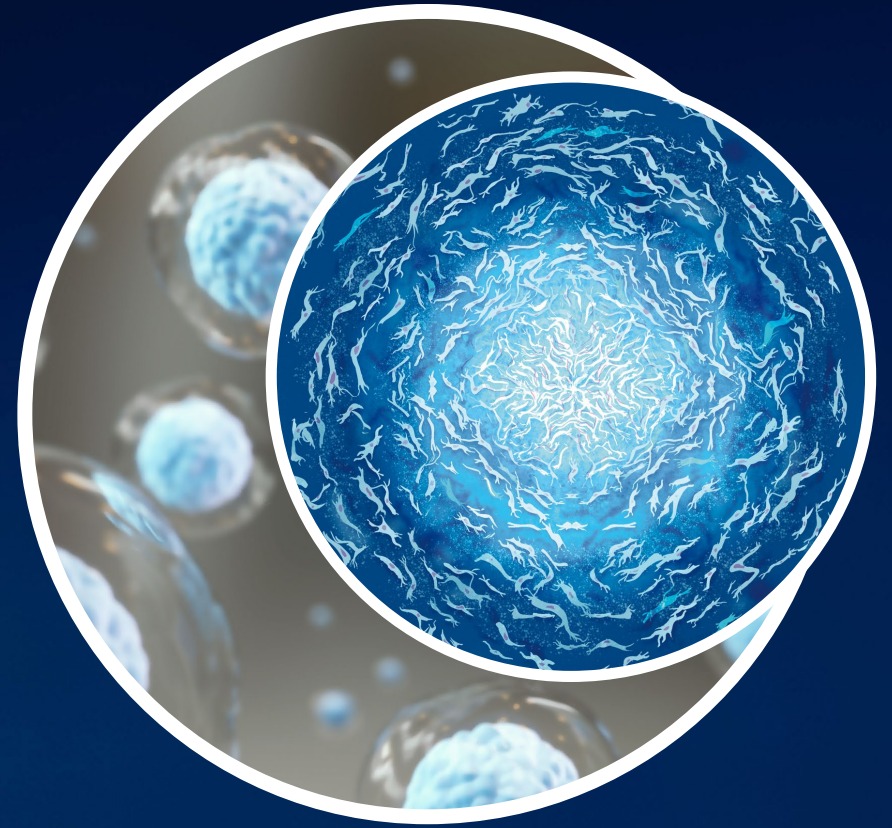
Conventional donor-derived MSCs are difficult to produce at scale, and since they are derived from different donors, issues with potential inconsistency and reduced potency can arise. These potential inconsistencies can reasonably be expected to lead to inconsistent results in clinical trials.

Cymerus™ Platform

The Cymerus™ platform enables manufacture of an **effectively limitless** quantity of **consistent** MSCs from **one donor**, without negatively impacting MSC **potency**. Cymerus™ MSCs can potentially be used to **treat multiple different diseases**.

Cymerus™ is a true “platform technology”

Ongoing clinical trials



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 ~20% complete²
- Aiming to complete patient enrolment in H1 2025

Results

Results anticipated in H2 2025 (primary evaluation)

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 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)
- All patient visits complete (September 2024)

Results

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

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)

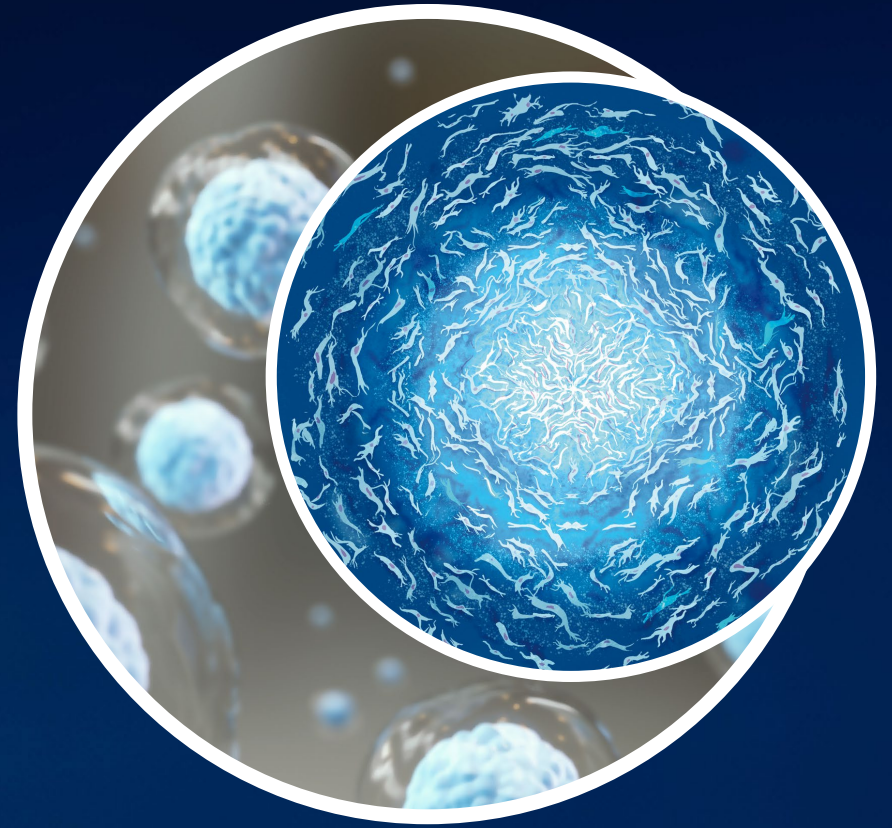
Study Conduct

- Trial conducted and funded by Leiden University Medical Center (LUMC), Netherlands, while Cynata retains commercial rights
- Patient enrolment commenced in Q4 2024

Results

Outcome of Cohort 1 anticipated in H1 2025

Outlook and commercial potential



Drivers of commercial partnering

Lining up the ingredients for success

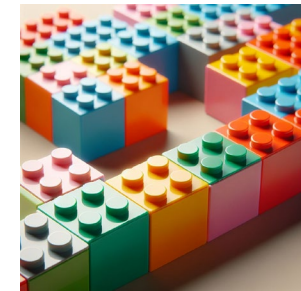
- Compelling clinical efficacy and safety
- Ethical source
- Simple administration
- Scalable to large output



- Broad portfolio of clinical and preclinical programs
- Potential demonstrated in multiple distinct therapeutic areas



- iPSC source is ideal basis for adding additional functionalities developed by partners (Lego principle)



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:

**BIOTECH
SHOWCASE™**

JP Morgan BioWeek/Biotech Showcase
San Francisco, January 2025

Company presentation and
partnering meetings

**advanced
THERAPIES**

Advanced Therapies Congress
London, March 2025

Company presentation and
partnering meetings

**Bio International
Convention**

BIO International
Boston, June 2025

Partnering meetings

BioJapan **RI-MJ**
Regenerative
Medicine
Japan

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

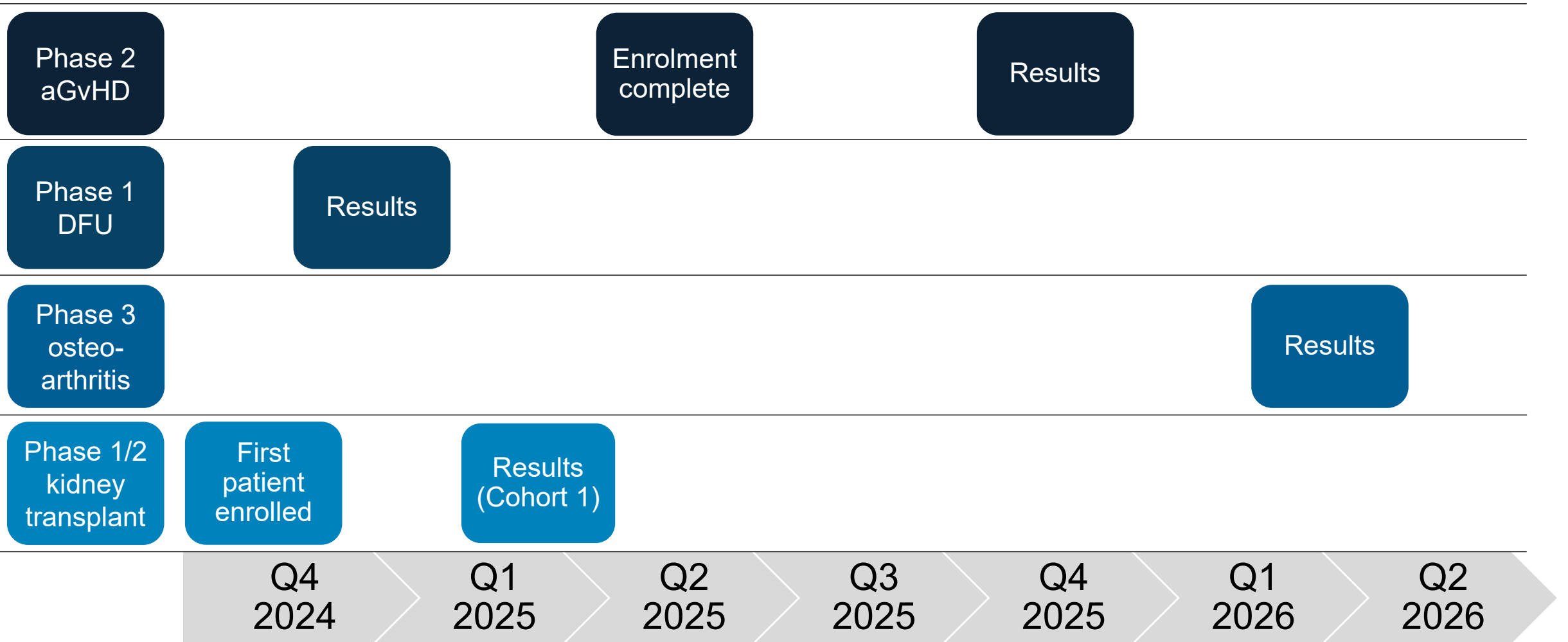
JP Morgan BioWeek – key for partnering

- JP Morgan BioWeek*, held in San Francisco in the first half of January every year, is the world's most significant biotech and pharma partnering and investment event.
- Usually more than 10,000 pharma and biotech representatives and investors come to the city for partnering and investment.
- Several high-profile partnering events are running in parallel and Biotech Showcase is a leading one. Cynata will present at Biotech Showcase and connect with key Industry players, promoting its progress and upcoming catalysts.
- BioWeek uniquely attracts a high proportion of senior decision makers and investors, starting or advancing business discussions not only on strategic alliances but also on investment, mergers and acquisitions.
- Many meetings are individually arranged and outside of any conference or platform.

**BIOTECH
SHOWCASE™**

Upcoming catalysts*

Results of FOUR clinical trials expected between late 2024 and early 2026



Summary

**Platform
Technology**

**Compelling
Clinical Data**

**Billion dollar
markets**

**Multiple
Indications**

**Proven
Commercial
Interest**

**Excellent Safety
Profile**

**Manufacturing
Challenges
Overcome**

**Numerous Near-
Term Catalysts**



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