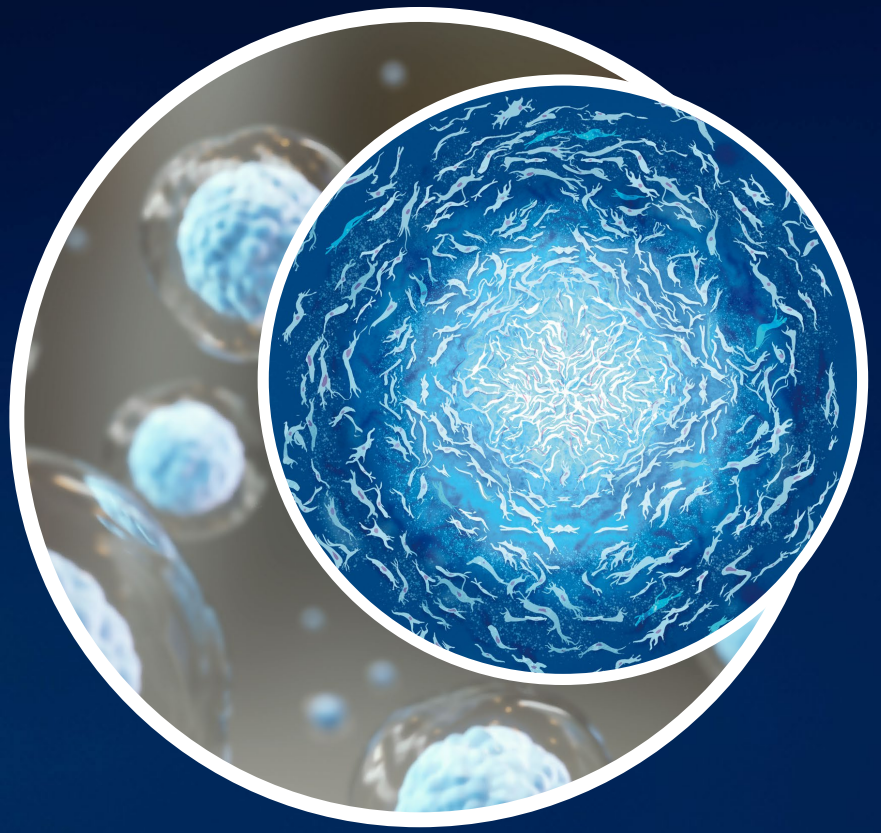
cynata therapeutics



A Clinical Stage Company Pioneering the Next Generation of Cellular Therapies

Bell Potter Healthcare Conference

20 November 2024

Important information

Summary information

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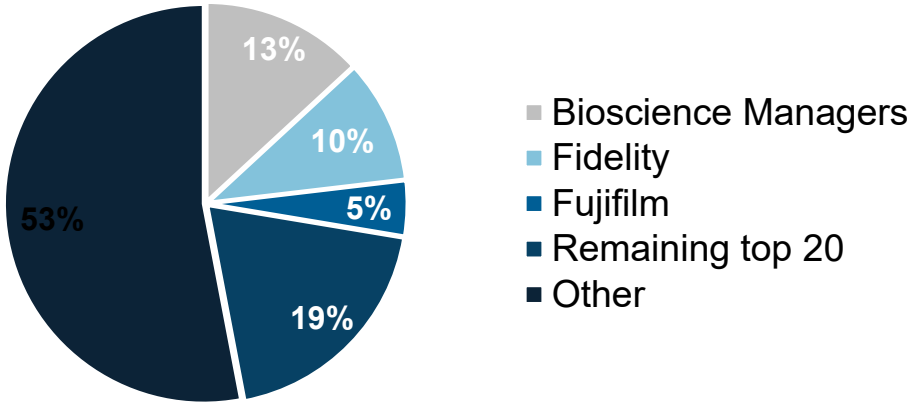
Corporate overview

Shareholder distribution



Financial information

Share price (15 November 2024)	A$0.245
Shares on issue	~181m
Market capitalisation	**~A$44m**
Cash[1]	~A$4.3m

Largest shareholders

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.

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 register[2]

Source: IRESS
1. As at 30 September 2024

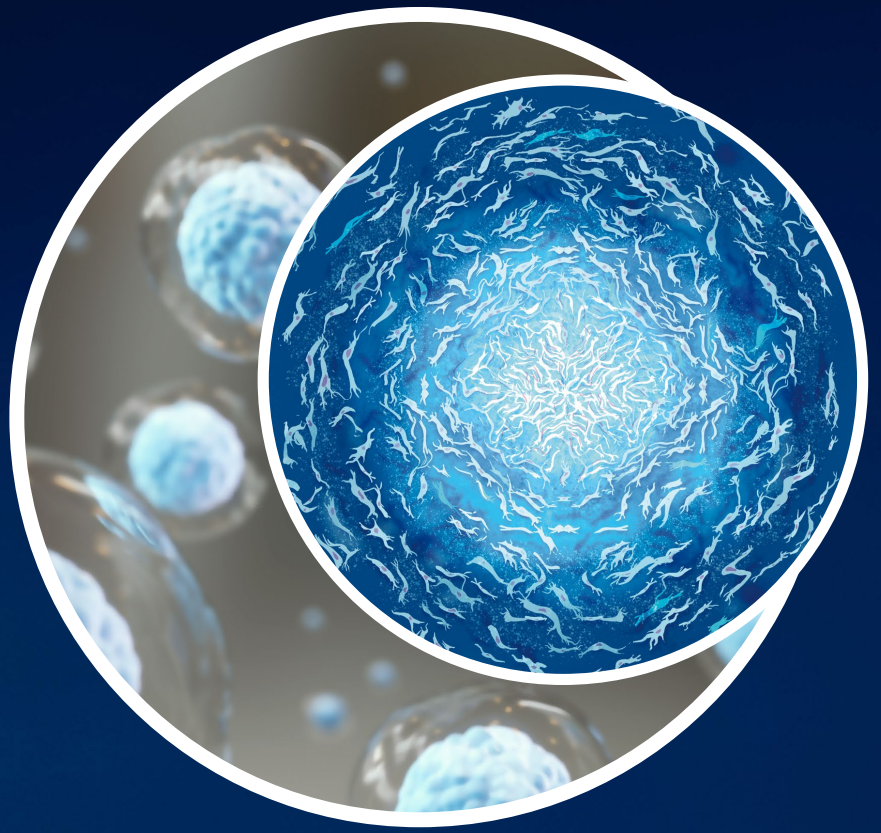
Target indications

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)	Cynata Funded & Managed	**Phase 1 ongoing** (enrolment complete)	**Results – Q4 2024/Q1 2025**	US$9.6bn[2]
Osteoarthritis (OA) *(managed by USYD, **funded by NHMRC**)*	Partner Funded & Managed	**Phase 3 ongoing** (enrolment complete)	**Results – H1 2026**	US$11.6bn[3]
Kidney Transplantation *(managed and **funded by LUMC**)*	Partner Funded & Managed	**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

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
* Timing of events is approximate, based on the Company's information as at the date of this presentation, and subject to change. Timing refers to calendar years.

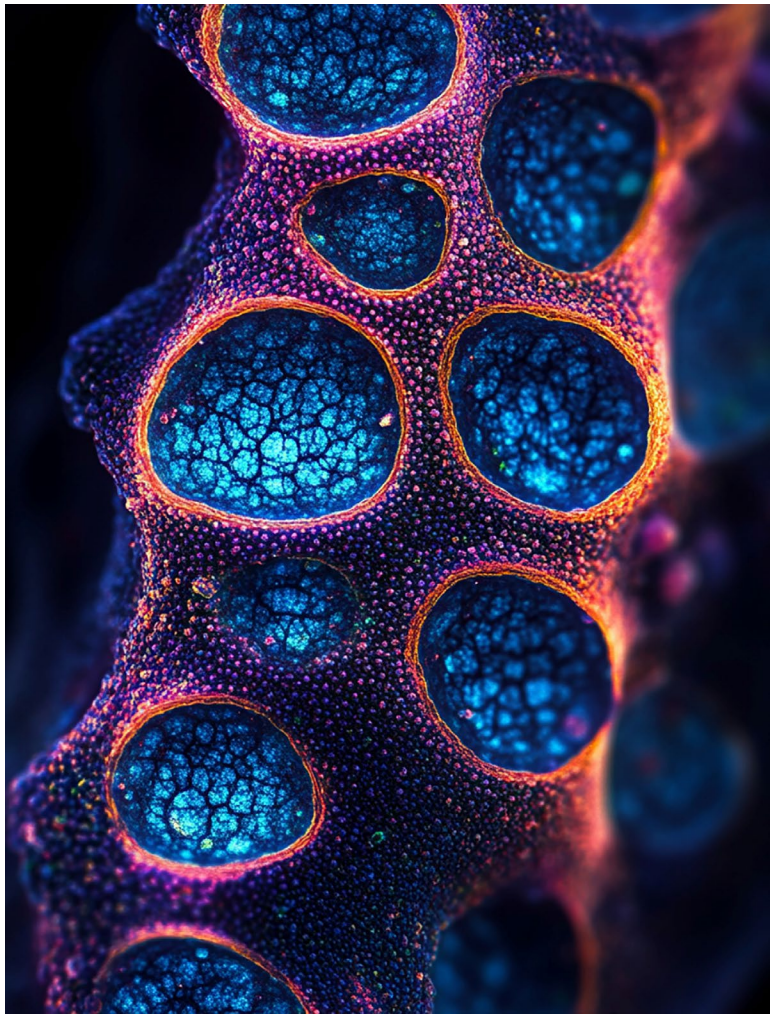
Cynata’s revolutionary Cymerus™ platform technology



Introduction to MSCs

What are Mesenchymal Stem Cells (MSCs)?[1]

- MSCs are cells that naturally occur in the human body, which have key unique properties which make them ideal for potentially treating various diseases:
  - **Anti-inflammatory properties** – important as many diseases are the result of excess inflammation
  - **Immunomodulatory properties**[2] – either promote the body's own immune system to fight off infection/disease or suppress the immune system when it may be overreacting and causing disease
  - **Tissue repair** and **regeneration**[3] – MSCs provide support to other cells, promoting tissue repair and regeneration
- MSCs have immense therapeutic potential, but these cells only occur naturally in the human body in **small numbers**



MSC-based therapy (using MSCs to treat diseases):

- 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 disease[4]
- Since then, more than 1,700 clinical trials have been initiated, to investigate MSC therapy for many different diseases[5]

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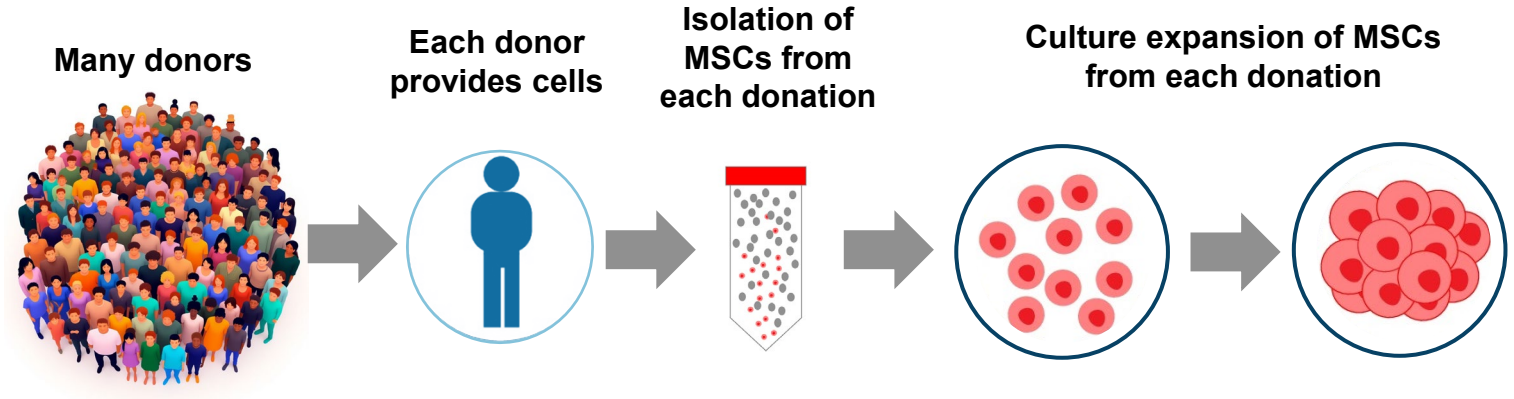
1. Also known as **mesenchymal stromal cells** or **medicinal signalling cells**
2. Kelly and Rasko, Front. Immunol. 12:761616 (2021)
3. Spees et al, Stem Cell Res Ther 7:125 (2016)
4. Le Blanc et al, Lancet. 363: 1439–41 (2004)
5. Clinicaltrials.gov

Conventional MSC manufacturing process

Standard Process[1]



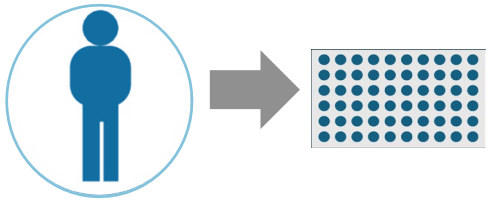
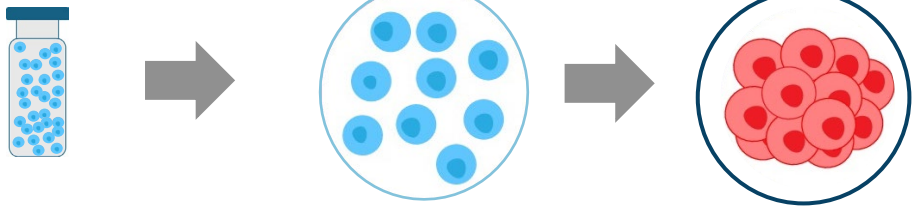
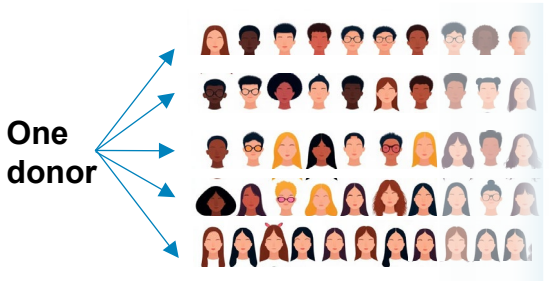
New donors must be identified on regular basis; donors must consent to **surgical extraction**	MSCs must be **isolated** from **mixture of cells** from **each** donation – producing only **small number** of MSCs per donation	**Extensive** culture expansion required (growing cells) – **large number** 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**

This is a representative, high-level summary of a typical process to produce donor-derived MSCs. Some manufacturing processes may differ.

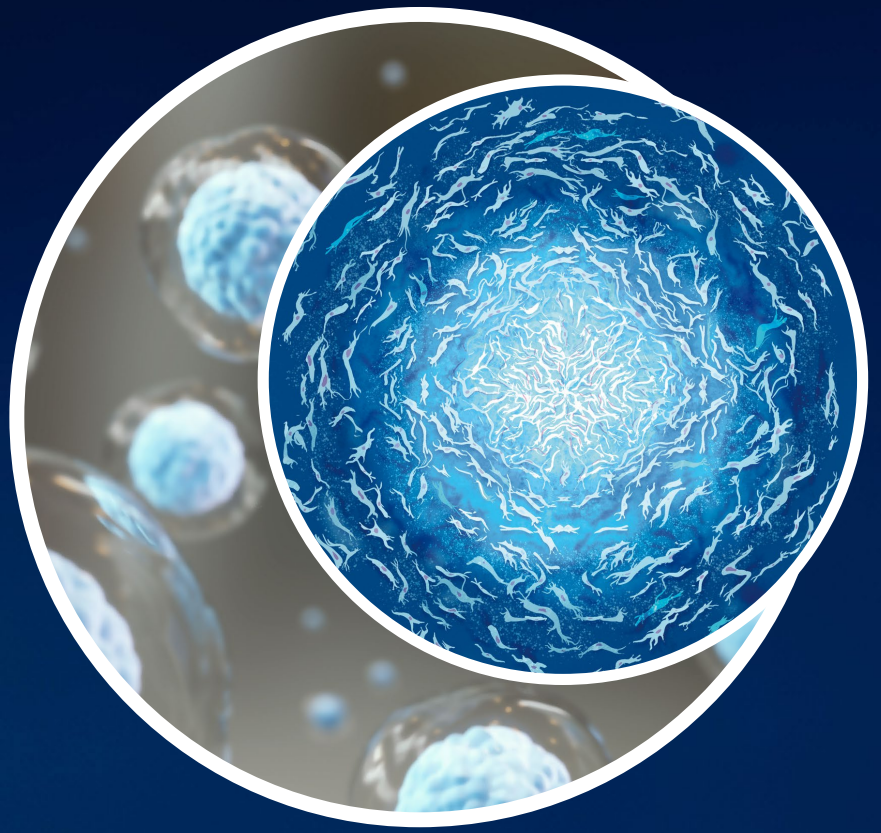
Cymerus™ process

Cymerus™ Process	**One donor** → **iPSC bank**	**Vial of iPSCs from bank**	**iPSC expansion and differentiation**	**Formation of MSCs** → **Patients**
				
	Blood donation from a **single donor** was used to produce a high-quality **iPSC**[1] **bank**	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**

1. iPSCs are induced pluripotent stem cells (iPSCs). Mature adult cells reprogrammed to become pluripotent, which means they have effectively limitless proliferation capacity and potential to differentiate into any adult cell type (including MSCs). iPSCs are the ideal starting material for commercial production of cellular products.

Acute Graft versus Host Disease (aGvHD)

An opportunity based on compelling clinical data



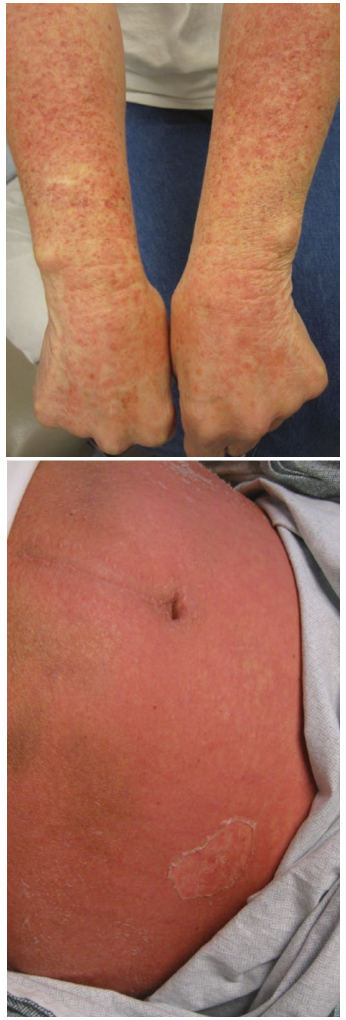
Bone marrow transplants & GvHD

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
- Recipients are then typically provided corticosteroids (first-line treatment), however 50% of develop what’s known as steroid-resistant acute GvHD (aGvHD)
- In steroid-resistant patients, 2-year survival rate is less than 20%[1]



1. Westin JR et al. Adv Hematol. 2011:601953 (2011)

Images from: A Cotliar, Atlas of Graft-versus-Host Disease, 2016

Acute graft versus host disease (aGvHD)

>38,000 allogeneic transplants* **per year**[1]

~35-50% develop aGvHD[2,3]

Almost all receive steroids

<50% respond to steroids[4]

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 controls[6]
  - 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 indications[8]
- **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

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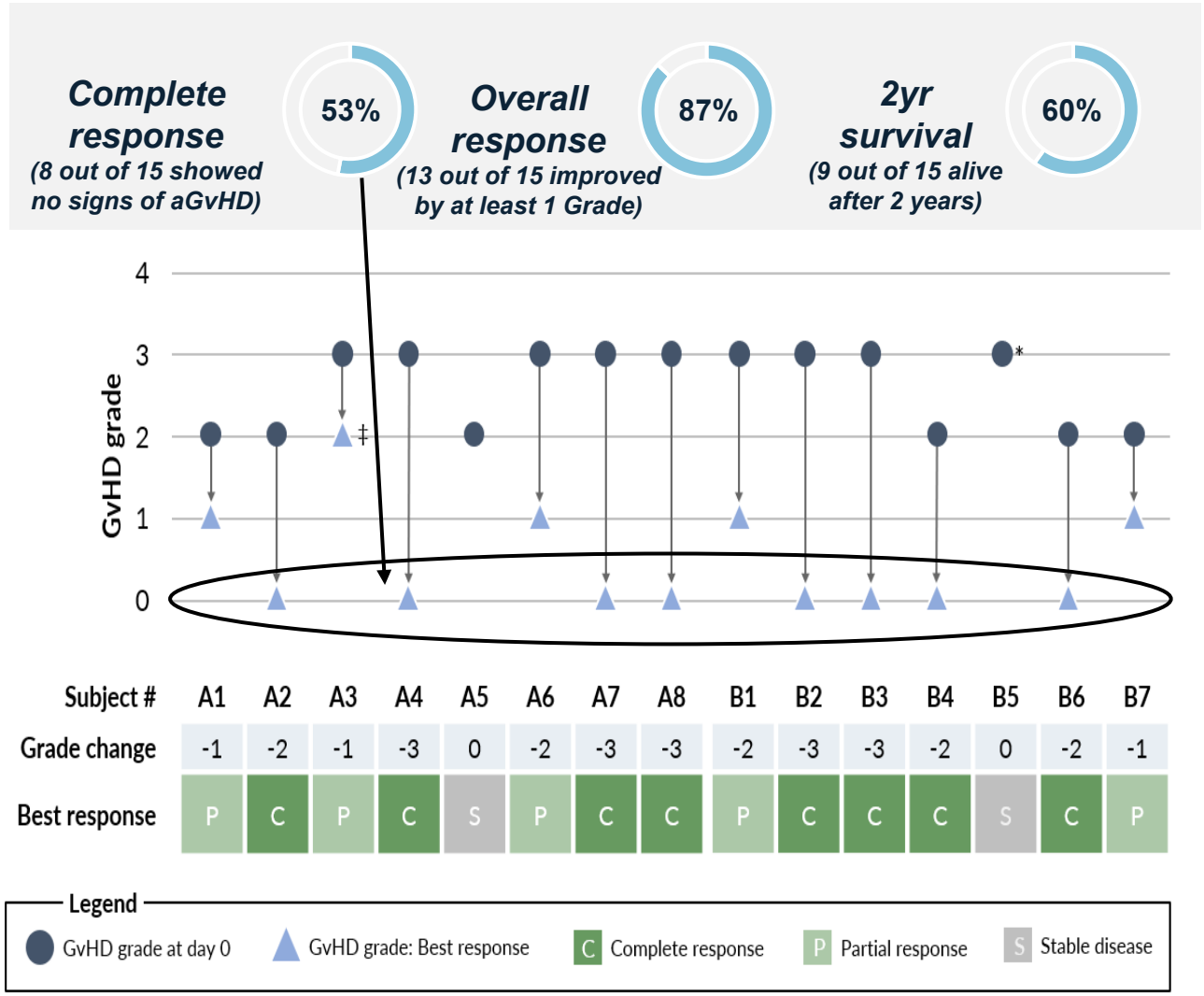
1. Malard et al, Nature Reviews Disease Primers 9: 27 (2023).
2. Reshef et al, J Clin Oncol. 39(17):1878-1887 (2021).
3. Akahoshi et al, Blood Adv. 7(16):4479-4491 (2023).
4. Major-Monfried et al, Blood.131(25):2846-2855 (2018).
5. Westin JR et al, Adv Hematol. 2011:601953 (2011).
6. Zeiser et al, N Engl J Med 2020;382:1800-1810 (2020).
7. JAKAFI® (ruxolitinib) tablets, for oral use, US FDA approved Prescribing Information, September 2021.
8. Sales figures relate to all approved indications, including myelofibrosis, polycythemia vera, and GvHD.

Phase 1 clinical trial – results (SR-aGvHD)



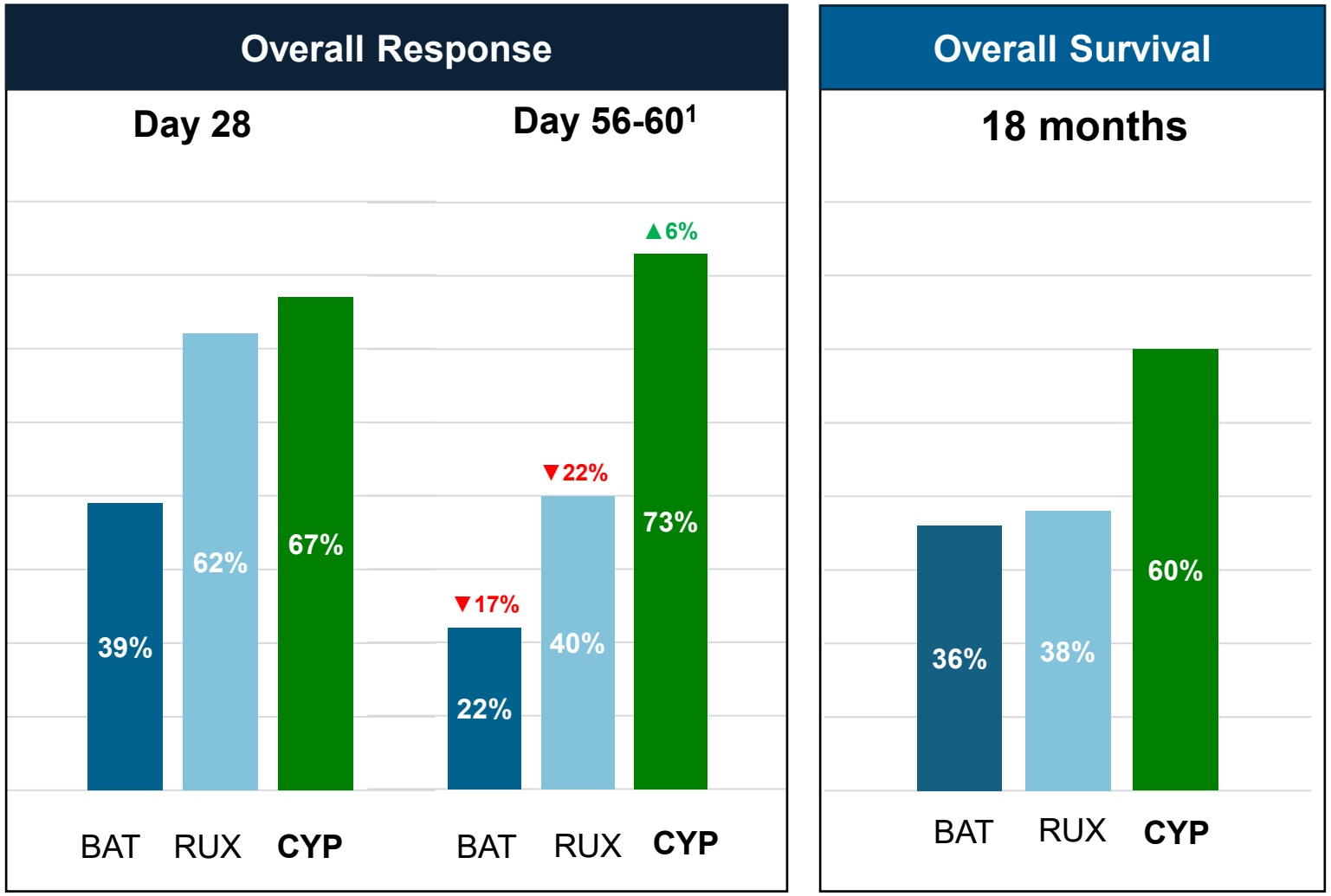
- Outstanding **response rates** and **overall survival**
- **Sustained outcomes achieved up to 2 years** after the first infusion
- **Importantly:** CYP-001 was shown to be **safe and well tolerated**
- **No serious adverse events or other safety concerns related to CYP-001**

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

- Subjects received $1x10^6$ cells/kg (max $1x10^8$ cells) or $2x10^6$ cells/kg (max $2x10^8$ cells) by IV infusion on D0 and D7
- Eight subjects were enrolled in each cohort, but one subject in Cohort B withdrew prior to infusion of CYP-001

‡ Subject A3 showed a PR at Days 14 and 21 but died due to pneumonia on Day 28; * Subject B5 withdrew from the trial on Day 22 to commence palliative care
For further information: https://clinicaltrials.gov/study/NCT02923375

CYP-001 vs other treatments in SR-aGvHD



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)

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

Note: comparisons are for illustrative purposes only; data taken from different clinical trials with different sample sizes (BAT: n=155; Rux: n=154; CYP-001: n=15).
D28/D56 time points used for response rate comparison as D28/D56 were the only response rate time points reported in the BAT/Rux clinical trial (NCT02913261; Zeiser et al. N Engl J Med 382:1800-1810 [2020]).
1. Overall Response at Day 56-60 refers to Day 56 response for BAT & Rux, and Day 60 response for CYP-001

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 Patel[1], James E. Griffin[3], Maria H. Gilleece[4], Rohini Radia[5], David T. Yeung[6,7], Diana Drier[8], Laurie S. Larson[8], Gene I. Uenishi[9], Derek Hei[10], Kilian Kelly[11], Igor Slukvin[9] 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 iPS cell-derived mesenchymal stromal cells in acute steroid-resistant graft-versus-host disease

Kilian Kelly[1], Adrian J. C. Bloor[2], James E. Griffin[3], Rohini Radia[4], 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

FDA U.S. FOOD & DRUG ADMINISTRATION

Benefits include:

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

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1. CYP-001 is Cynata's Cymerus iPSC-derived MSC product candidate for intravenous infusion

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% complete[2] • Aiming to complete patient enrolment in 1H 2025
Results	Results anticipated in 2H 2025 (primary evaluation)

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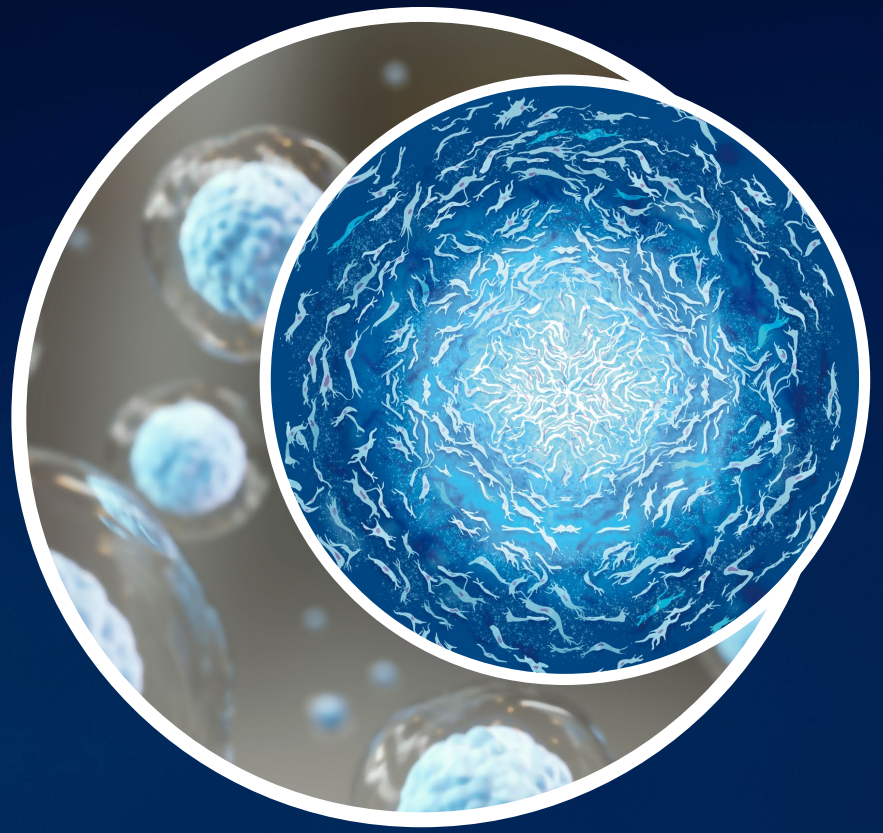
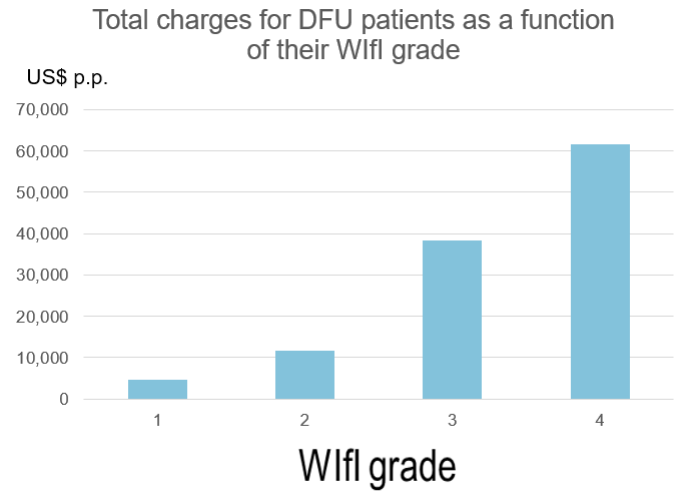
1. Trial is recruiting patients with High Risk newly diagnosed aGvHD (risk assessed based on refined Minnesota criteria), which means patients are not yet eligible to receive ruxolitinib. This is earlier in treatment pathway than completed Phase 1 trial, which was conducted in patients with steroid-resistant aGvHD. For further information see: https://clinicaltrials.gov/study/NCT05643638
2. As of September 2024 Quarterly Activity Report, released to ASX on 25 October 2024

CYP-006TK for Diabetic Foot Ulcers (DFU)



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 amputation[1]
- 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 year[2]



WIfI = Wound, Ischemia, and foot Infection[3]

Diabetes is the **fastest growing** public health concern worldwide[4]

~38 million Americans have diabetes[5]

Up to 34% of those with diabetes will develop a foot ulcer[1]

20% of patients with DFU will require **amputation** of the foot or limb[1]

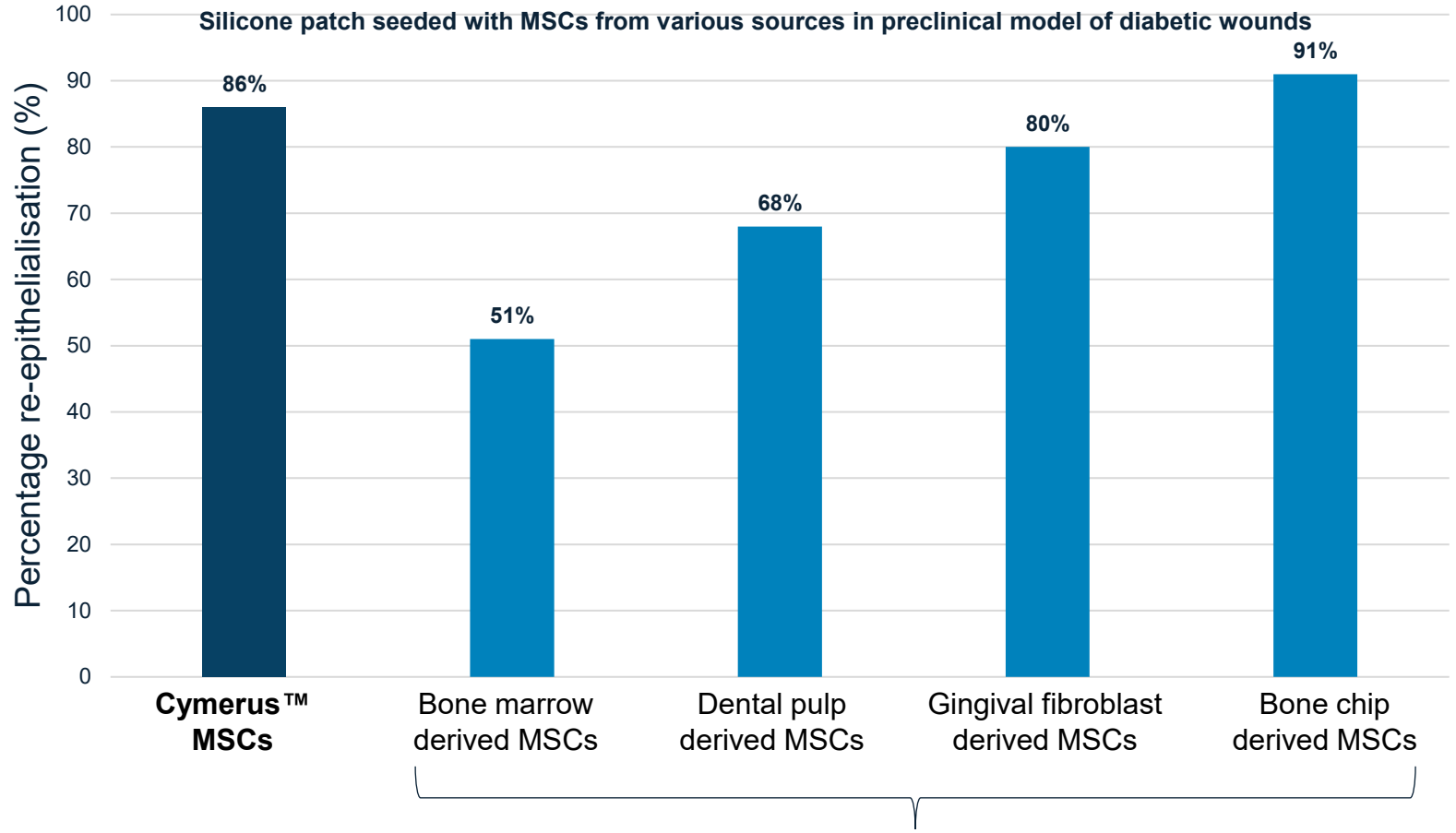
150,000+ amputations **per year** in the US due to **DFU**[6]

Estimated costs to US public and private payers **US$9–13 billion** per year[2]

1. McDermott et al. Diabetes Care. 46:209–221 (2023).
2. Raghav et al. Ther Adv Endocrinol Metab. 9(1) 29-31 (2018).
3. Hicks et al. J Vasc Surg. 67:1455-62 (2018).
4. Hossain et al. Health Sci Rep. 7(3):e2004 (2024).
5. American Diabetes Association: https://diabetes.org/about-diabetes/statistics/about-diabetes
6. American Diabetes Association: https://diabetes.org/advocacy/amputation-prevention-alliance

MSCs in DFU

MSCs have demonstrated strong success in pre-clinical DFU models



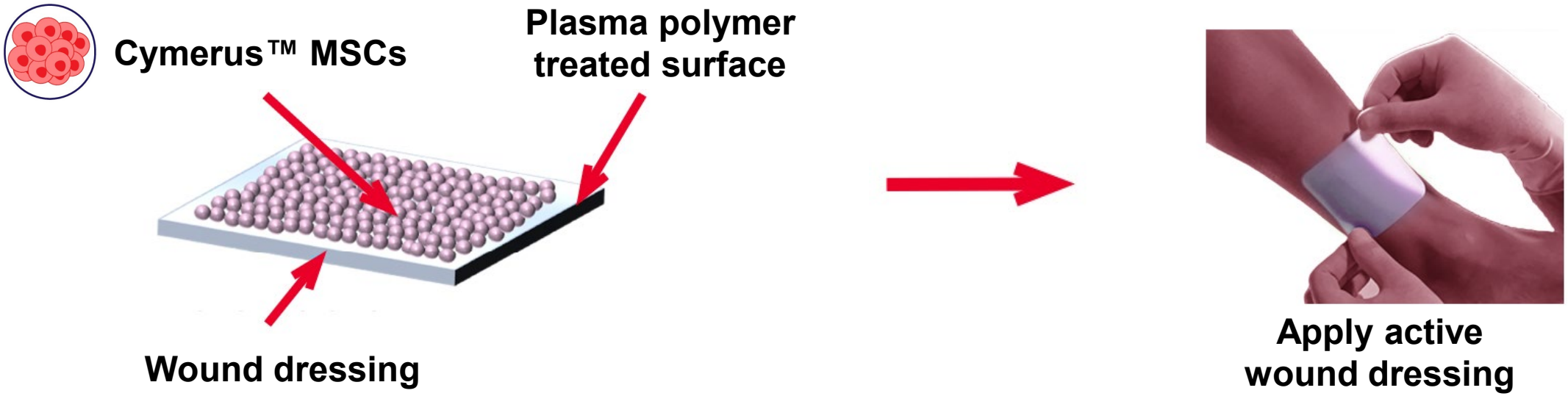
Major Challenges with manufacturing these MSCs consistently at scale

Key findings

- Primary outcome measured was extent of wound surface re-epithelialisation (healing) after 3 days
- Cynata's Cymerus™ MSCs resulted in significantly greater re-epithelialisation (86%) compared to bone marrow MSCs (51%)
- Cynata's Cymerus™ MSCs are the only MSCs capable of being produced consistently at scale

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 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)**

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For further information: https://clinicaltrials.gov/study/NCT05165628

DFU | timeline

Product: CYP-006TK

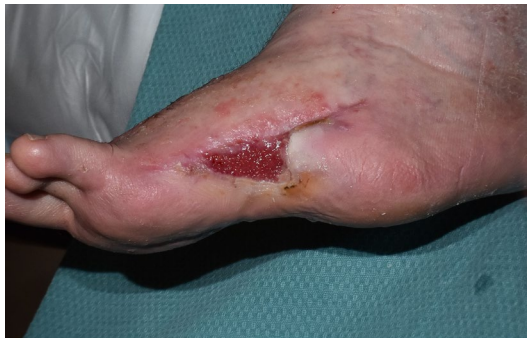
Phase I Study Timeline

Mar 22	Feb 24	Apr 24	Q4 24 / Q1 25
Enrolment Commences	Interim Results[1]	Recruitment Completes	Final Results

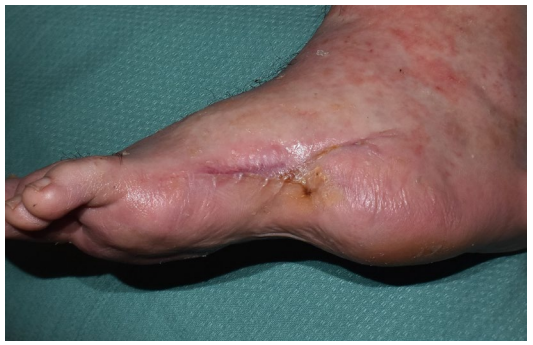
Interim Results

- 16 patients reviewed after 10 weeks':
  - 8 Standard of Care (SoC)
  - 8 CYP-006TK
- Median reduction in wound surface area was:
  - **87.6%** in the active **CYP-006TK** group
  - compared to **51.1%** in **SoC** group

Day 0



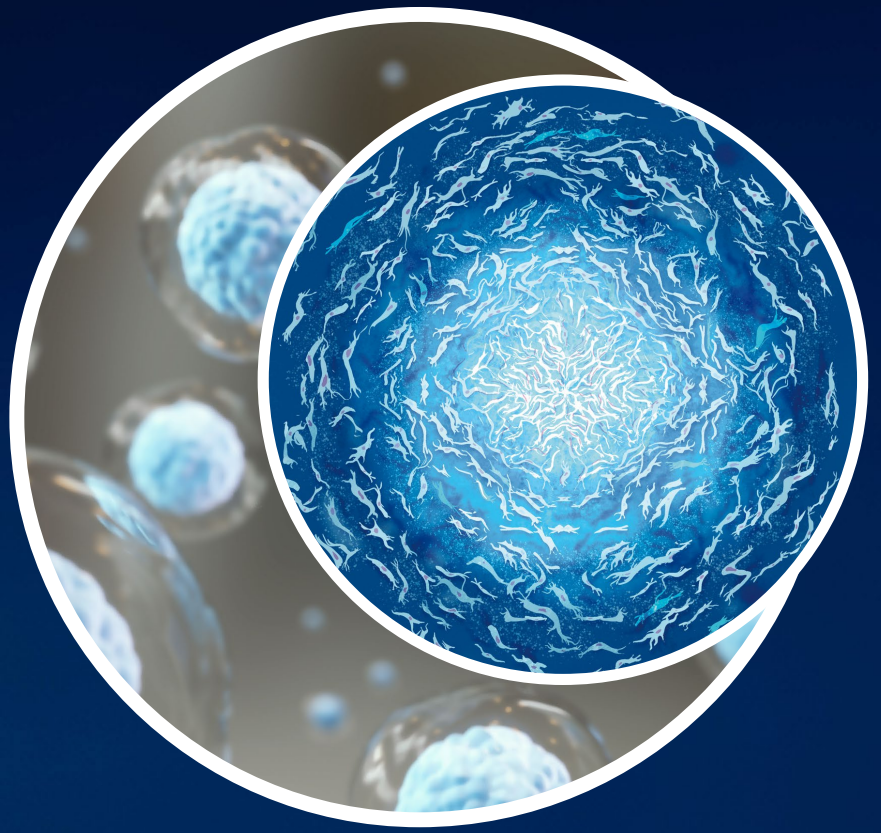
Day 28



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

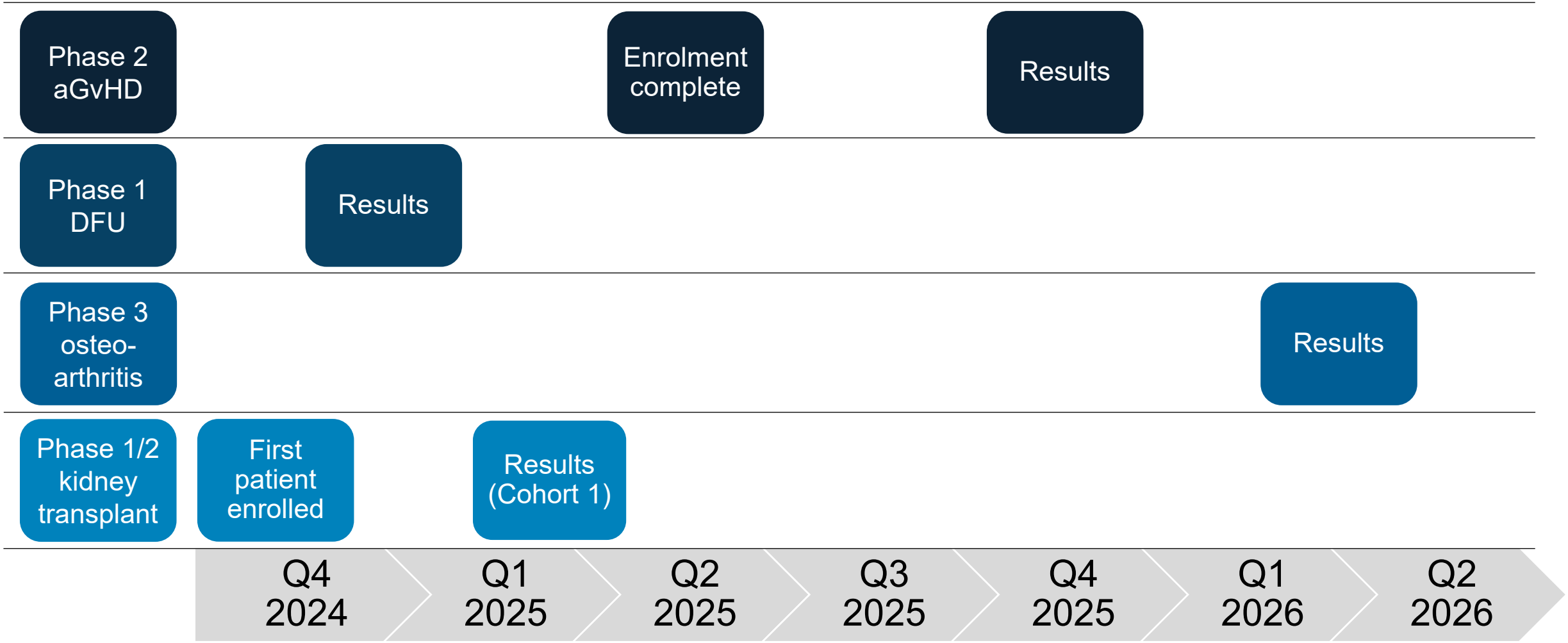
For further information: https://clinicaltrials.gov/study/NCT05165628

Outlook and commercial potential



Upcoming catalysts*

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



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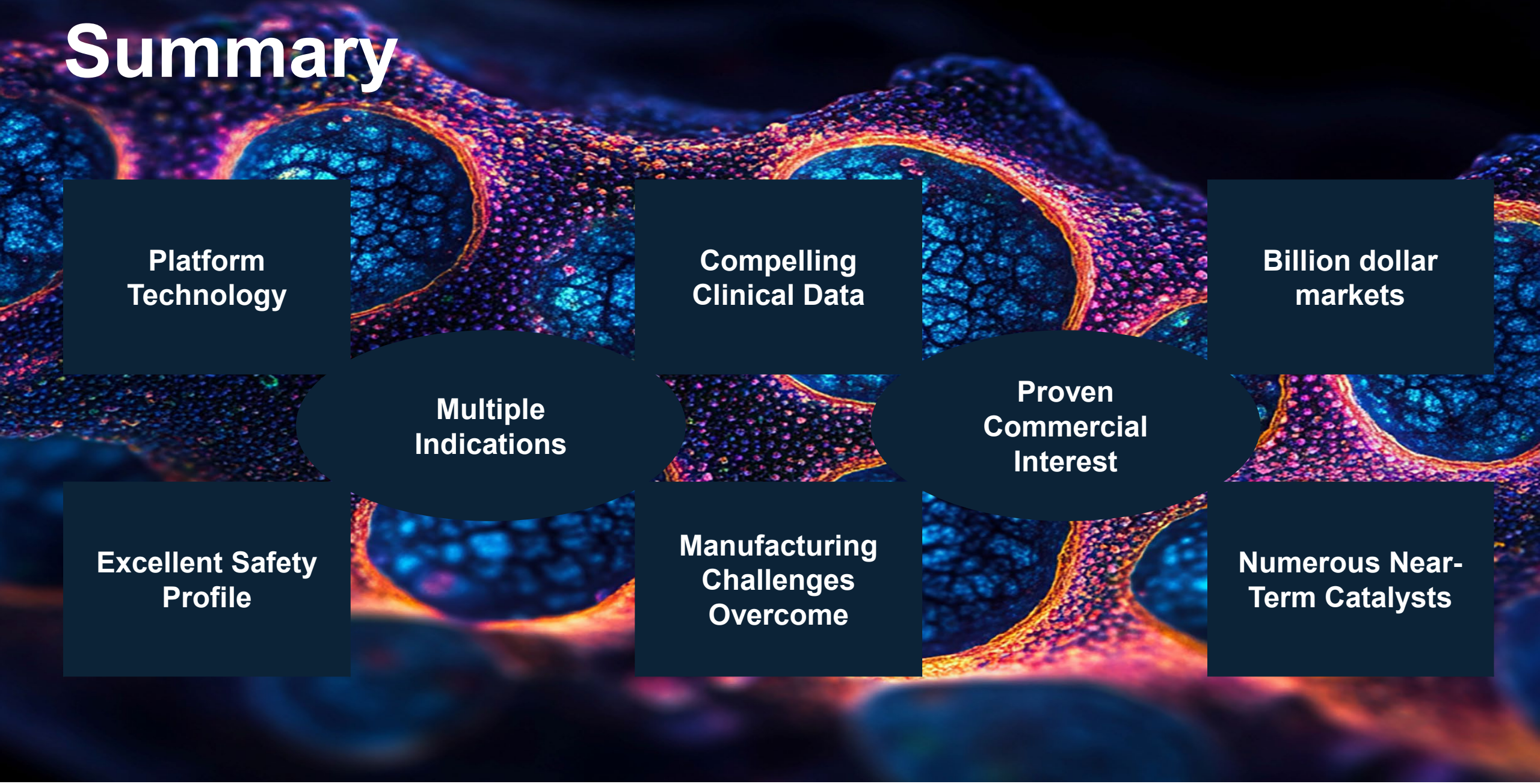
* Timing of events is approximate, based on the Company's information as at the date of this presentation, and subject to change. Timing refers to calendar years.

Summary


Platform Technology
Compelling Clinical Data
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Contact Us

Cynata Therapeutics Limited
Level 3, 100 Cubitt Street
Cremorne
Victoria 3121
Australia

info@cynata.com

www.cynata.com

cynatatherapeutics

@cynatastemcells

cynata-therapeutics