

Updated Investor Presentation

Melbourne, Australia; 12 November 2024: Cynata Therapeutics Limited (ASX: “**CYP**”, “**Cynata**”, or the “**Company**”), a clinical-stage biotechnology company specialising in cell therapeutics, is pleased to release an updated investor presentation, which will be used in upcoming non-deal investor roadshow meetings.

A copy of the presentation 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)

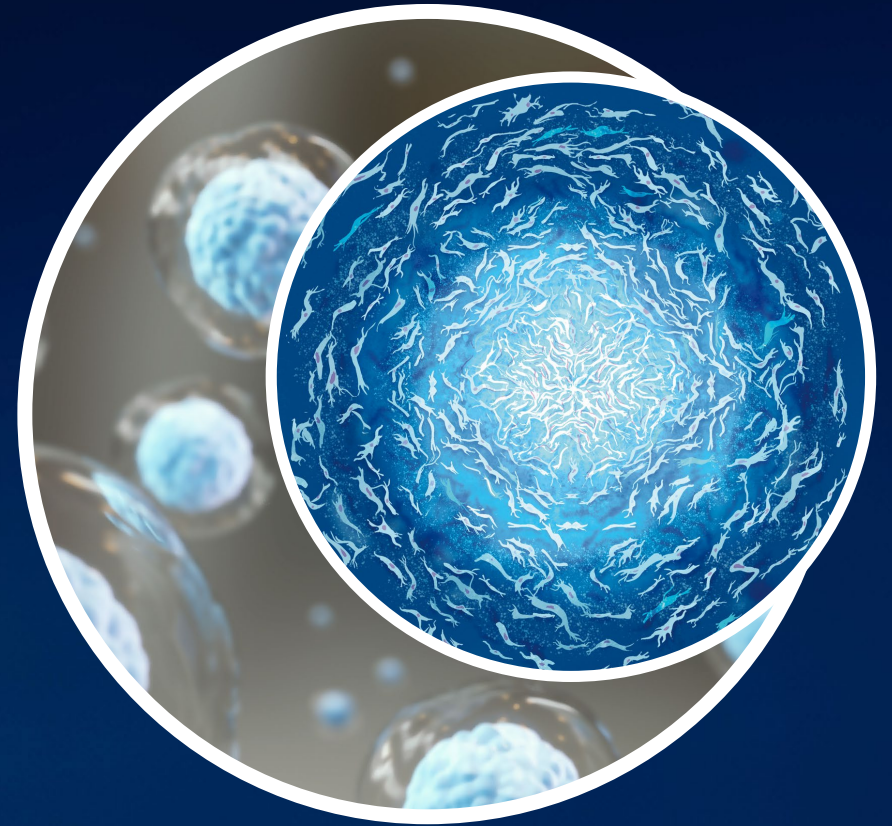
Cynata Therapeutics Limited (ASX: CYP) is an Australian clinical-stage stem cell and regenerative medicine company focused on the development of therapies based on Cymerus™, a proprietary therapeutic stem cell platform technology. Cymerus™ overcomes the challenges of other production methods by using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



A Clinical Stage Company Pioneering the Next Generation of Cellular Therapies



Investor Presentation
12 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 12 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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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.

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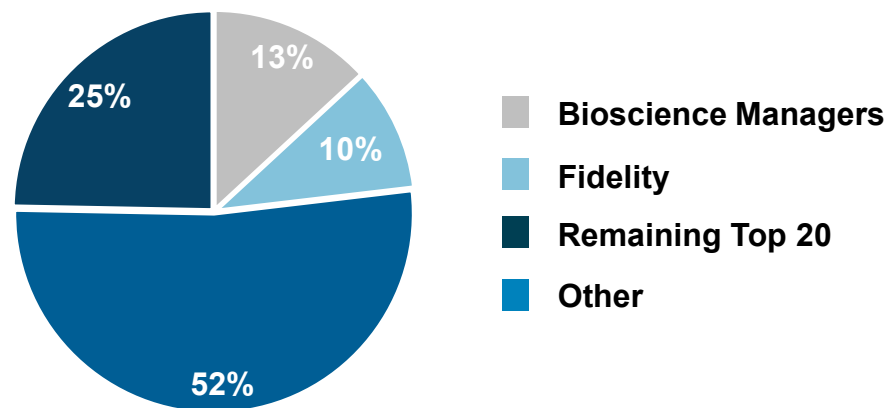
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Corporate overview

Shareholder distribution



Financial information

Share price (11 November 2024)	A\$0.22
Shares on issue	~181m
Market capitalisation	~A\$40m
Cash ¹	~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 register¹

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 – Q4 2024 Results – 2H 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 – 1H 2026	US\$11.6bn ³
 Kidney Transplantation <i>(managed and funded by LUMC)</i>		Phase 1/2 approved	Enrolment start – Q3 2024 Cohort 1 results – Q1 2025	US\$5.9bn ⁴

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

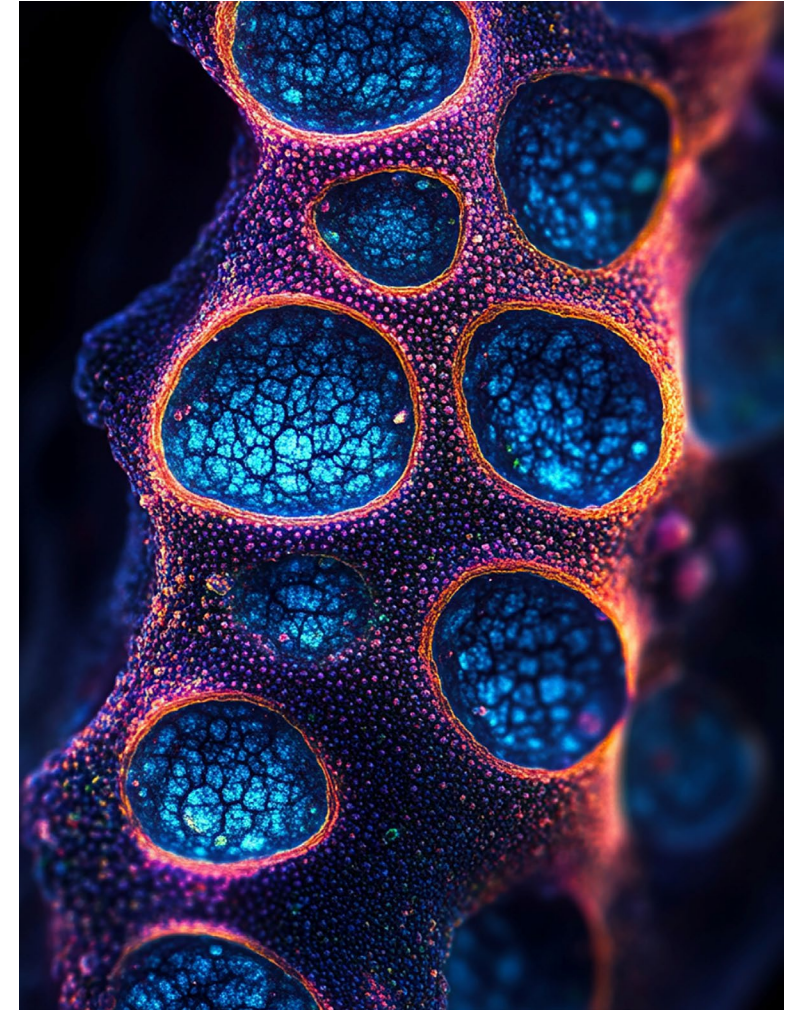
Introduction to MSCs

What are Mesenchymal Stem Cells (MSCs)?¹

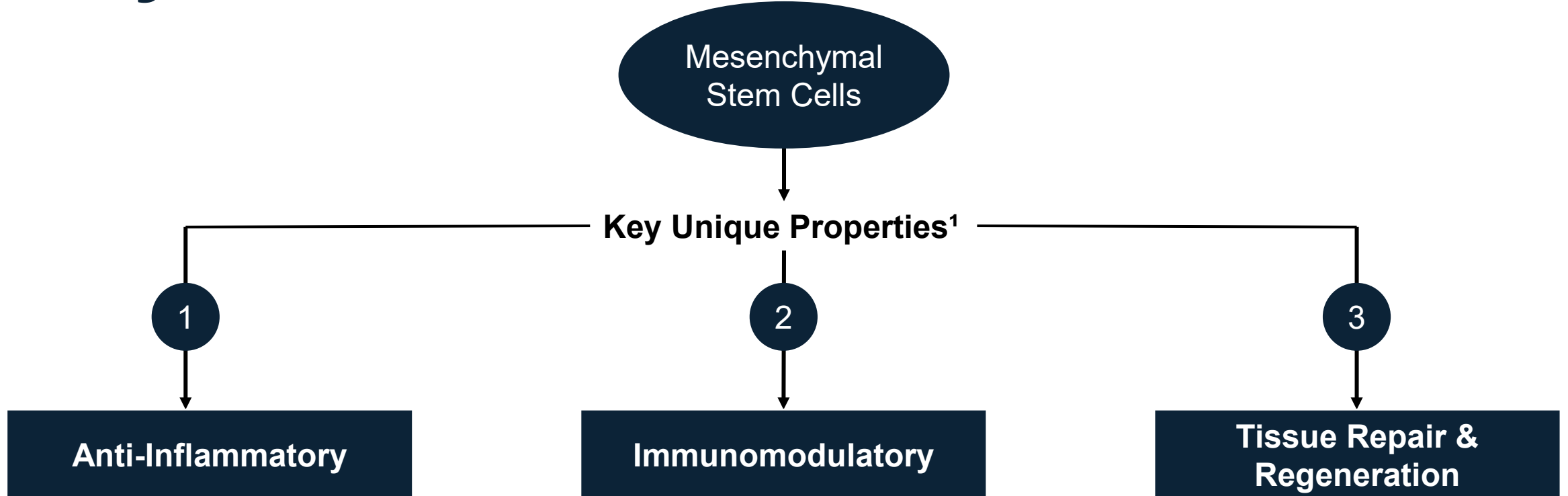
- MSCs are cells that naturally occur in the human body, which have key unique properties which make them ideal for potentially treating various diseases:
 - **Anti-inflammatory properties** – important as many diseases are the result of excess inflammation
 - **Immunomodulatory properties**² – either 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 disease⁴
- Since then, more than 1,700 clinical trials have been initiated, to investigate MSC therapy for many different diseases⁵



Why MSCs?



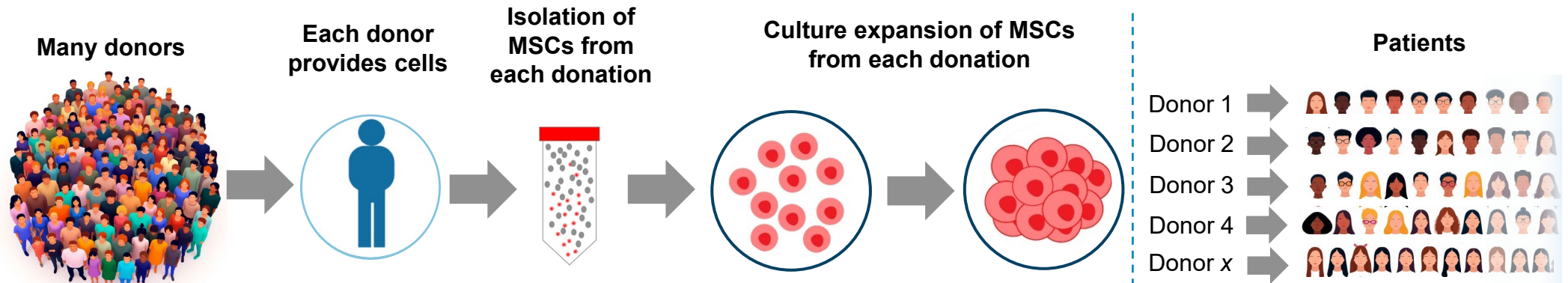
Importance:

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

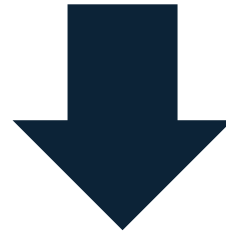
Extensive MSC culture expansion
=
Functional changes
=
Loss of potency

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

The problem

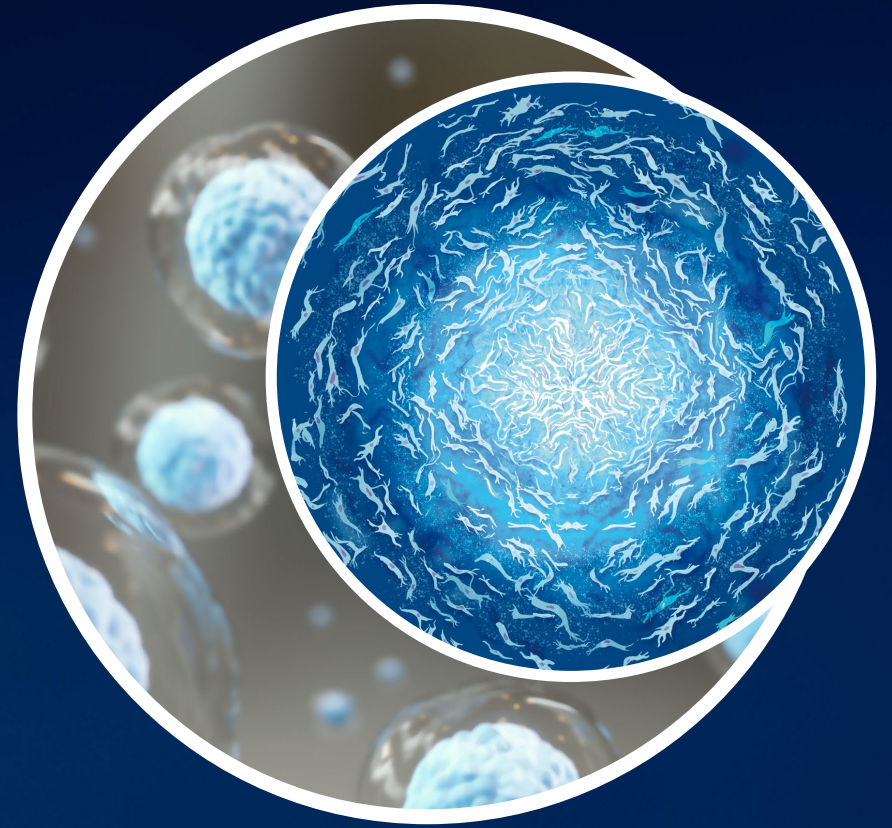
Traditional manufacturing methods used to produce MSCs can encounter the following challenges:

- 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



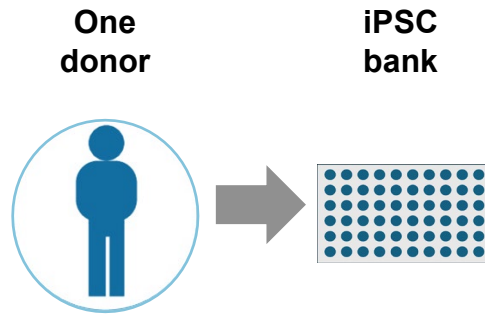
Unless these issues are resolved, MSCs will differ from batch to batch
Standardised MSCs are required for effective and consistent treatment of diseases

The solution:
Cynata's revolutionary
iPSC-based Cymerus™
manufacturing platform



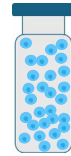
Cymerus™ process

Cymerus™ Process

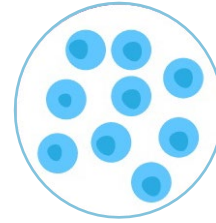


Blood donation from a **single donor** was used to produce a high-quality **iPSC¹ bank**

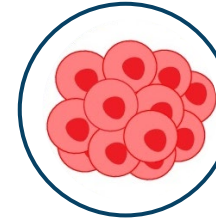
Vial of iPSCs from bank



iPSC expansion and differentiation

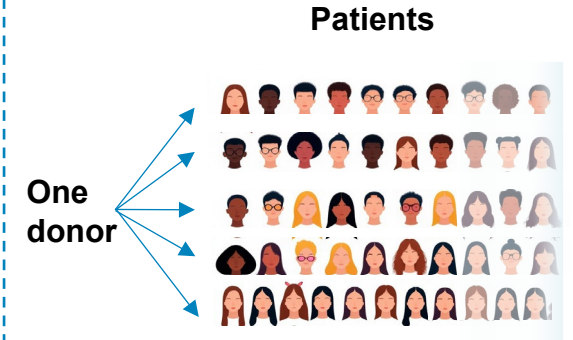


Formation of MSCs



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 of Manufacturing Challenges

High-level comparison of manufacturing challenges for producing MSCs

	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

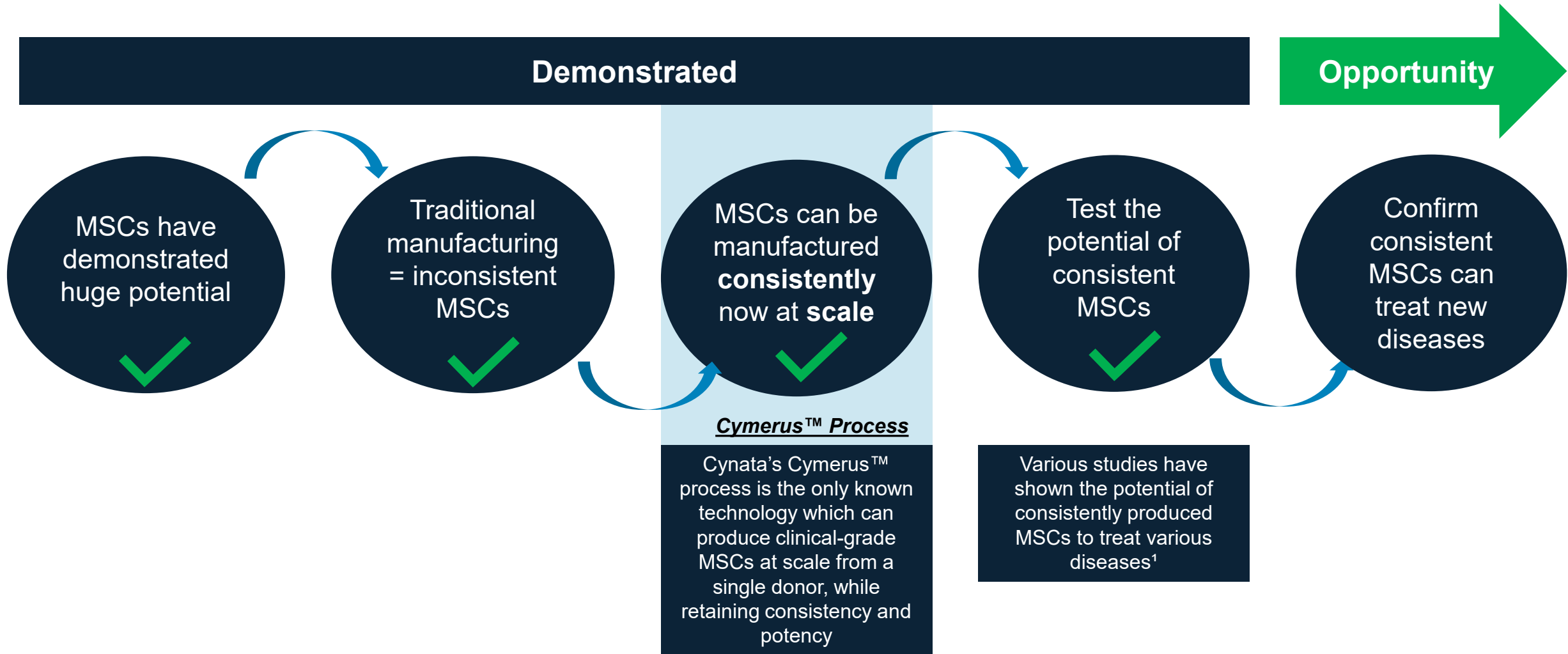
Conventional donor-derived MSCs are difficult to produce at scale, and since they are derived from different donors, issues with potential inconsistency and reduced potency can arise. These potential inconsistencies can reasonably be expected to lead to inconsistent results in clinical trials.

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**.

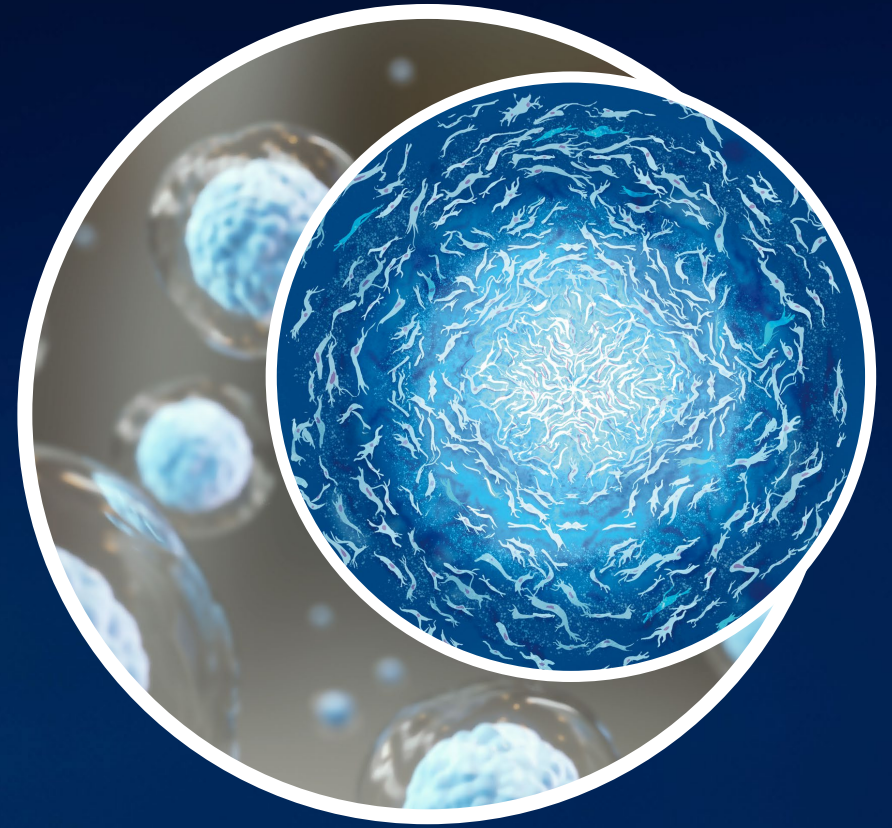
Cymerus™ is a true “platform technology”

Current State of Play



Graft Versus Host Disease (aGvHD)

An opportunity based on
Compelling clinical data



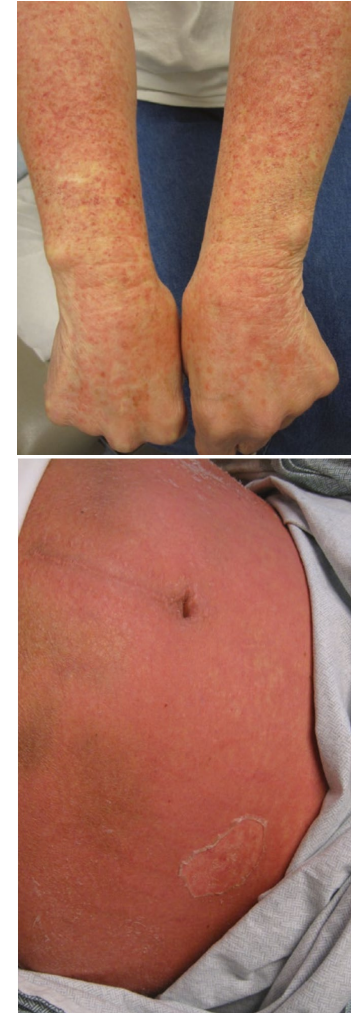
Bone marrow transplants & GvHD

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 these become resistant and develop what’s known as steroid-resistant 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**

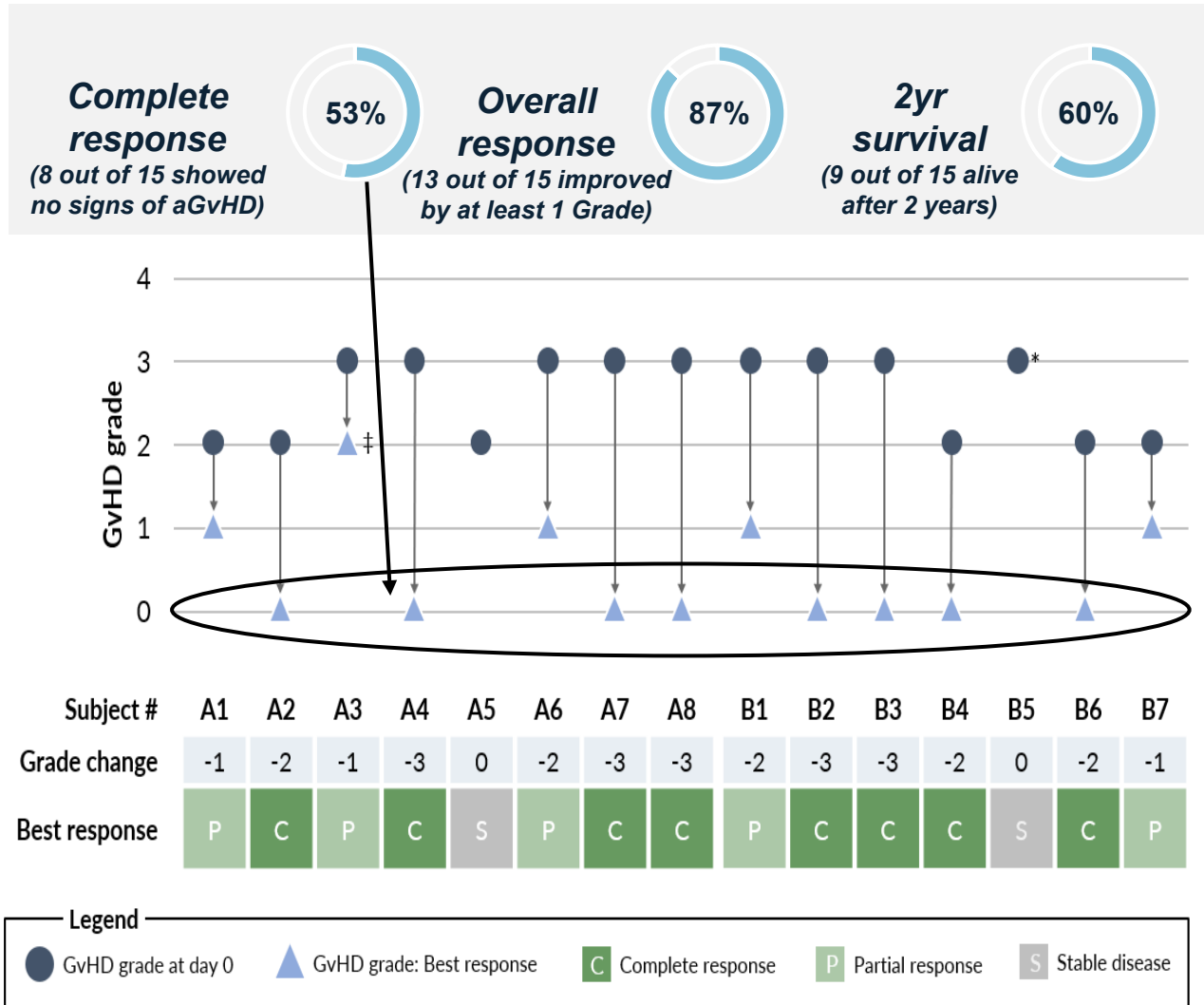
- Good initial response rates but no apparent increase in longer-term survival rates (18 months +) compared to controls⁶
- Serious/life threatening adverse reactions are common in patients who receive Ruxolitinib (e.g. infections, blood disorders)⁷
- Ruxolitinib is priced at ~US\$18k per month, and typically 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

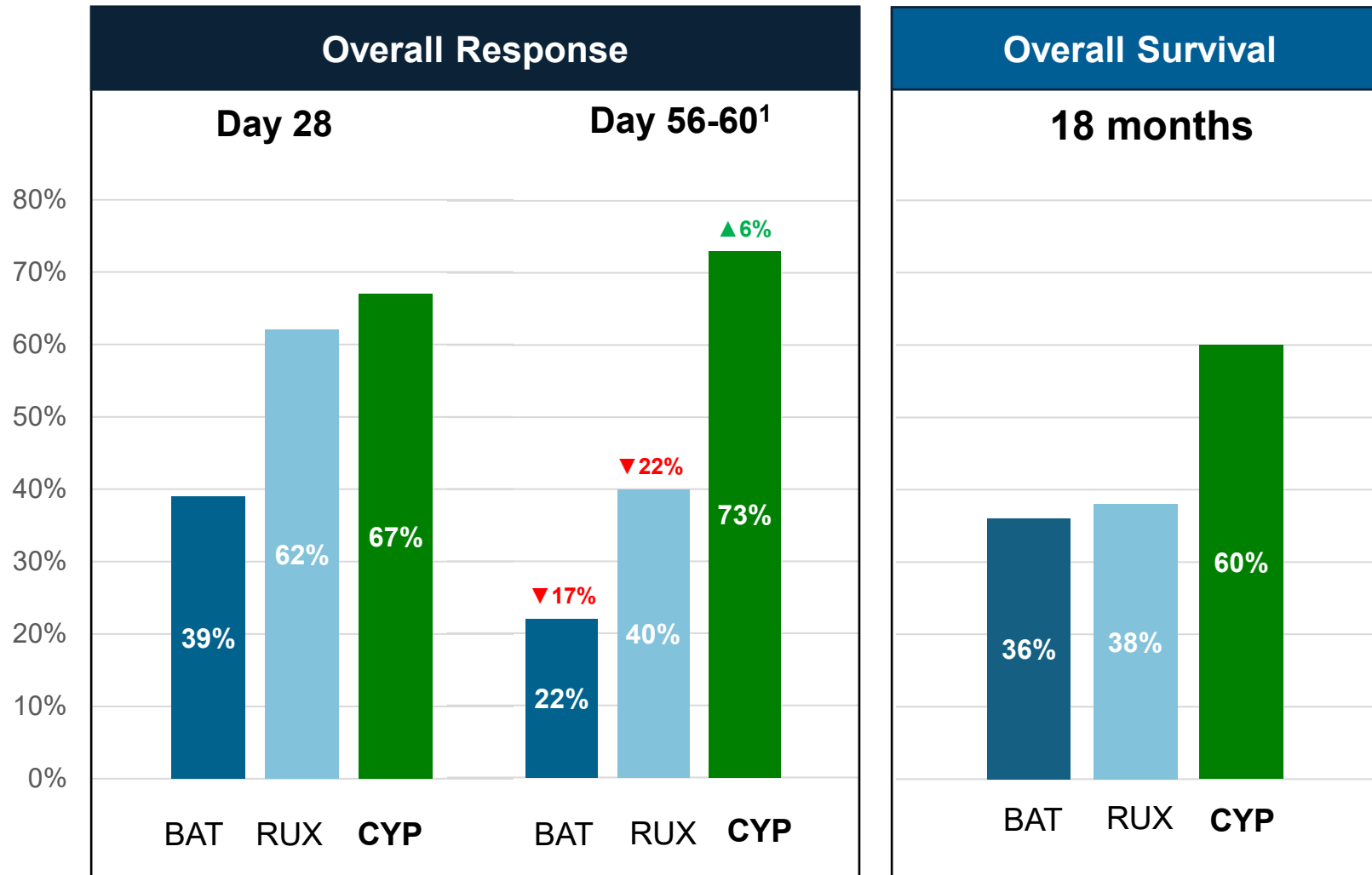
Phase 1 clinical trial – results (aGvHD)



- ✓ 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)

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

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 iPS 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

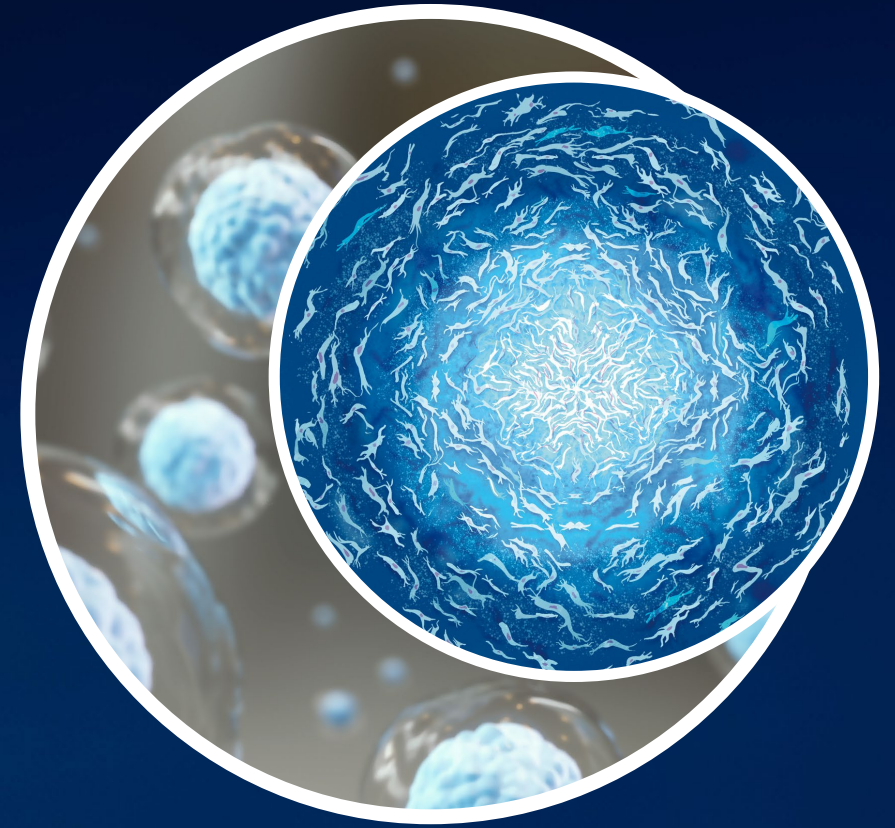
Study Conduct

- Conducted under IND from US FDA
- Clinical sites in USA, Europe and Australia
- First patient enrolled in March 2024; enrolment ~20% complete²
- Aiming to complete patient enrolment in 1H 2025

Results

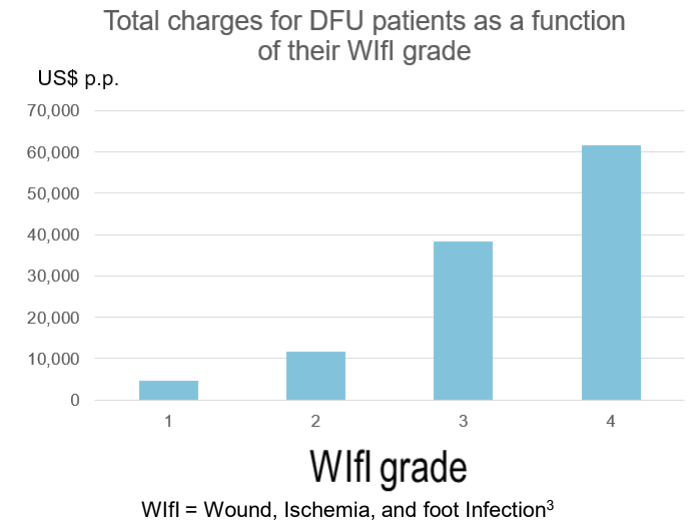
Results anticipated in 2H 2025 (primary evaluation)

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

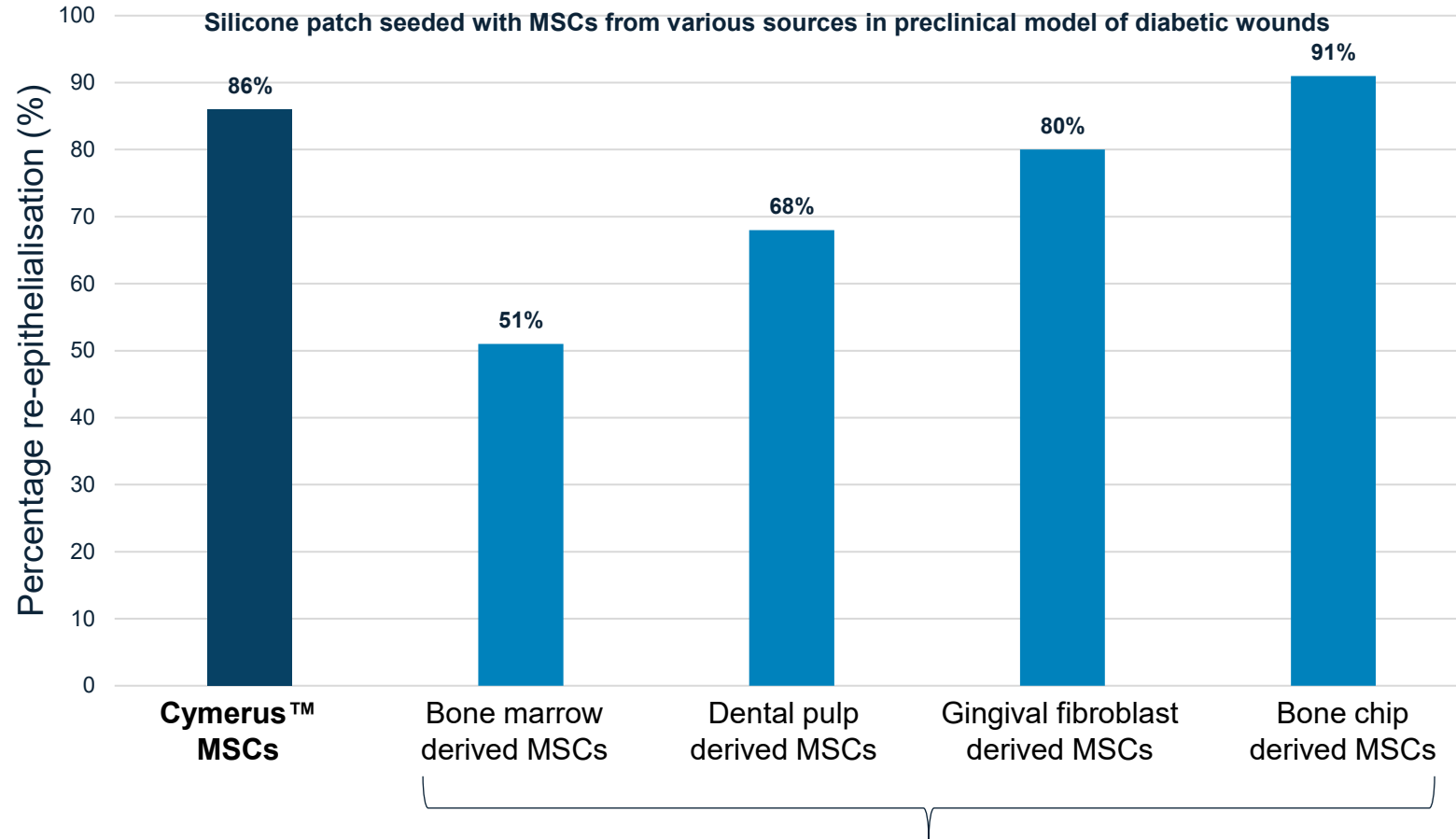
Estimated costs to US public and private payers **US\$9–13 billion** per year²

Diabetic foot ulcer examples



MSCs in DFU

MSCs have demonstrated strong success in pre-clinical DFU models



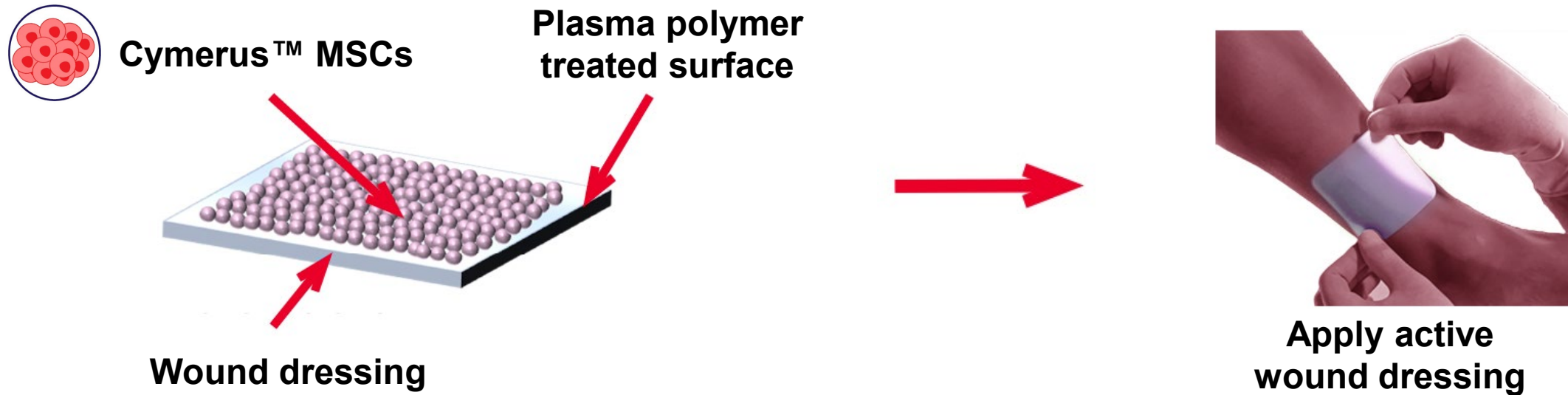
Major Challenges with manufacturing these MSCs consistently at scale

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)

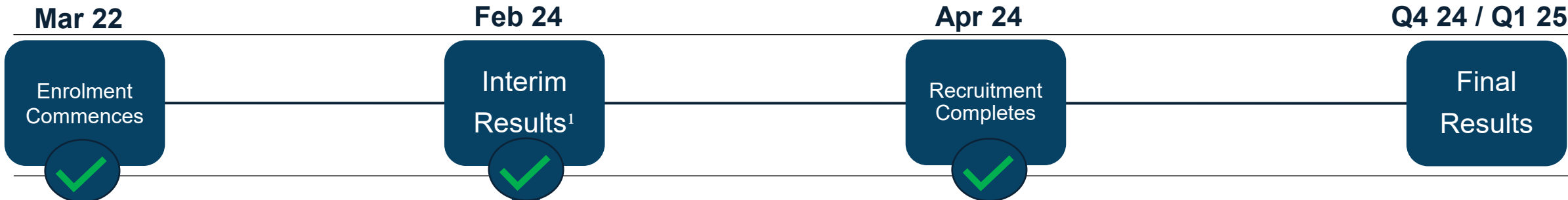
Results

- 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)**

DFU | timeline

Product: CYP-006TK

Phase I Study Timeline



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

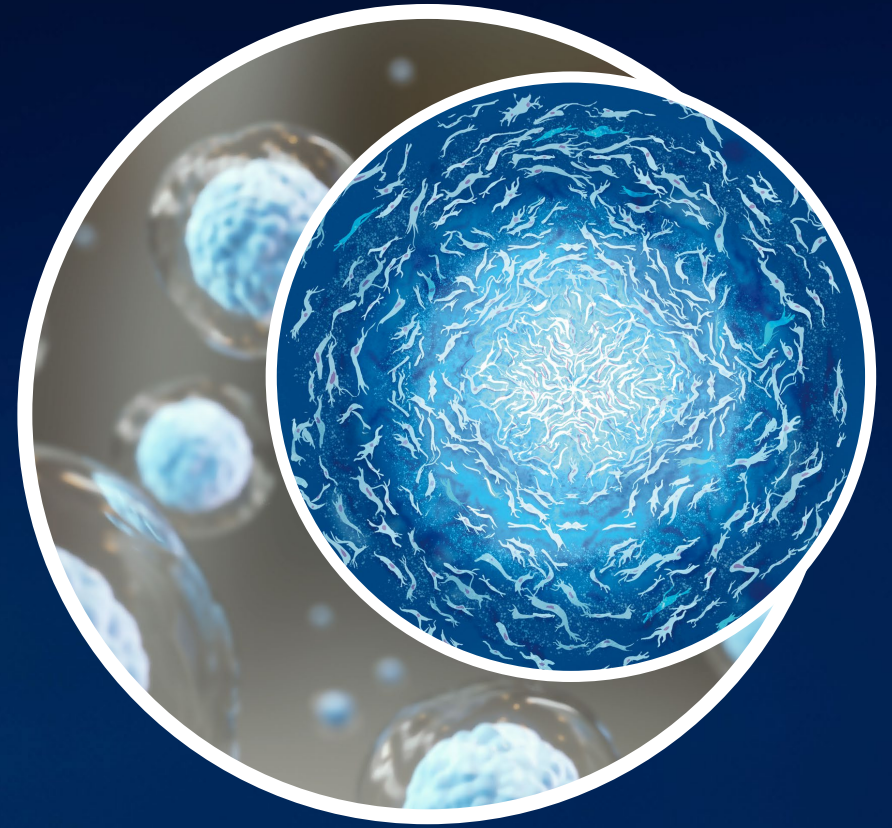


Day 28



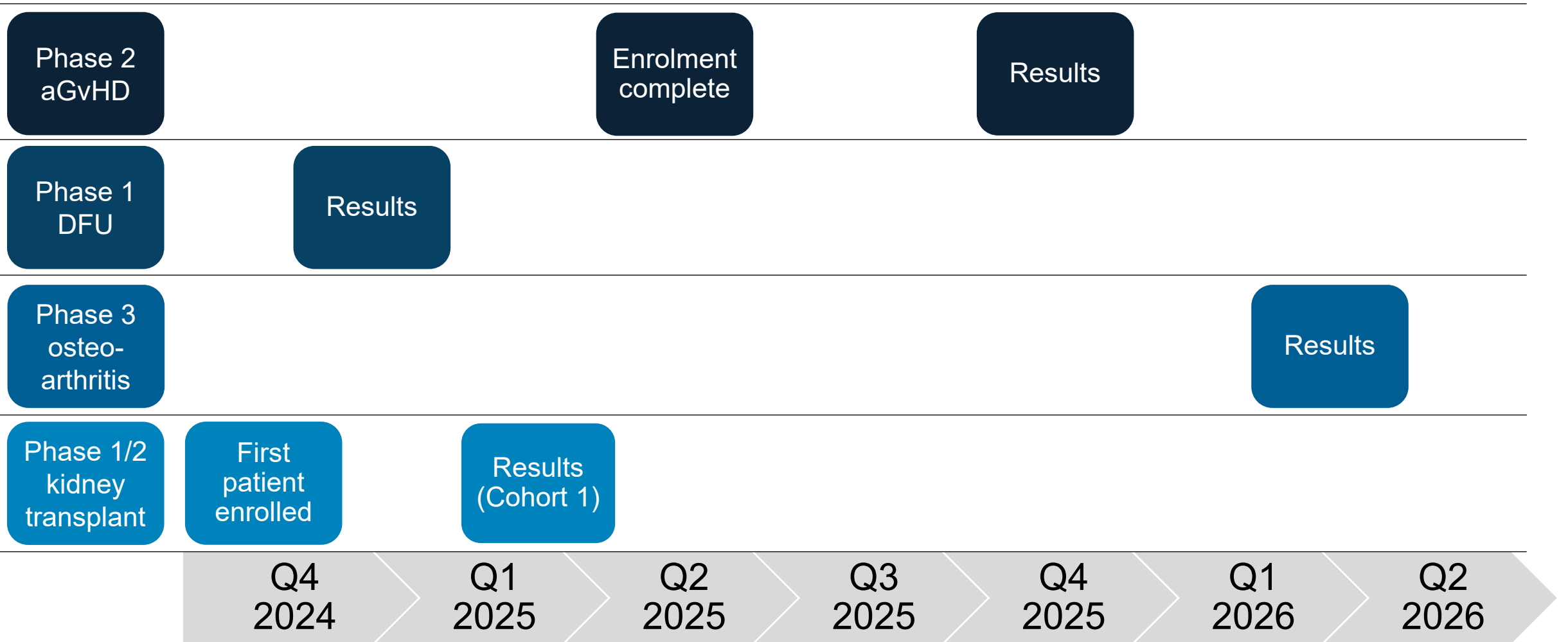
Example of ulcer healing in patient treated with CYP-006TK

Outlook and commercial potential

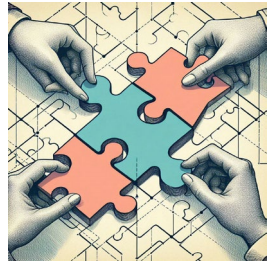


Upcoming catalysts*

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



Commercial attractiveness



Proprietary Platform Technology

- Ability to produce MSCs consistently and at scale allows for MSCs to be used in multiple indications = Platform Technology appeal



Platform Technology

- Platform Technology allows CYP to target multiple multi-billion dollar indications



Multiple Multi-Billion Dollar Indications

- 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

- 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 expects significant commercial interest following any positive read-outs
- Four read-outs expected by Q2 CY2026

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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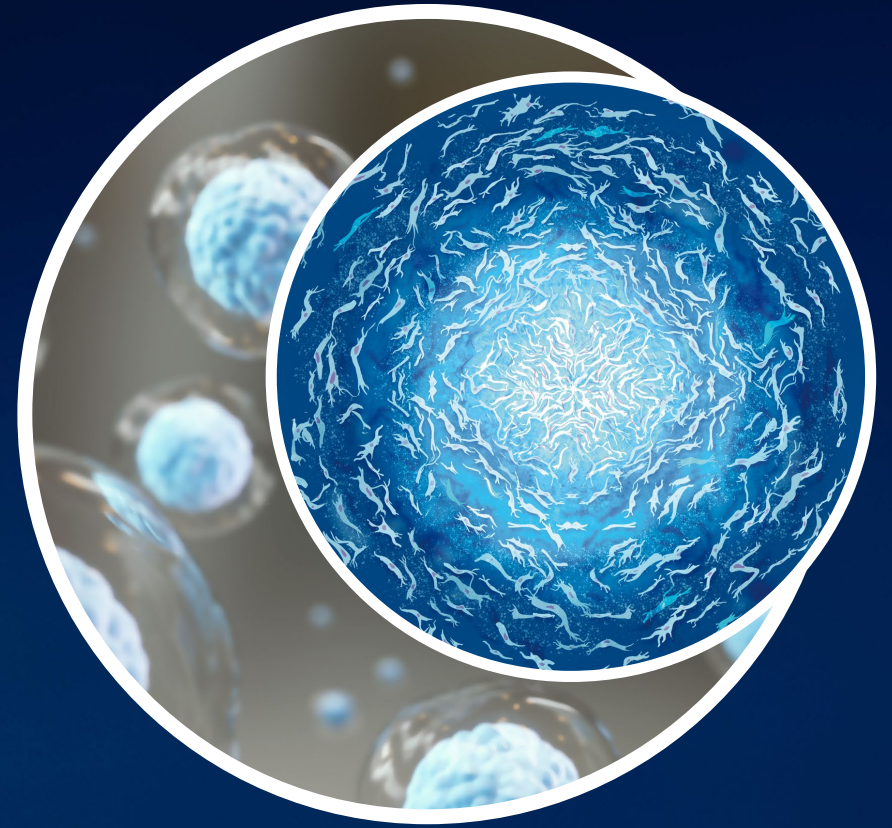


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[cynata-therapeutics](https://www.linkedin.com/company/cynata-therapeutics)

Annexure



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

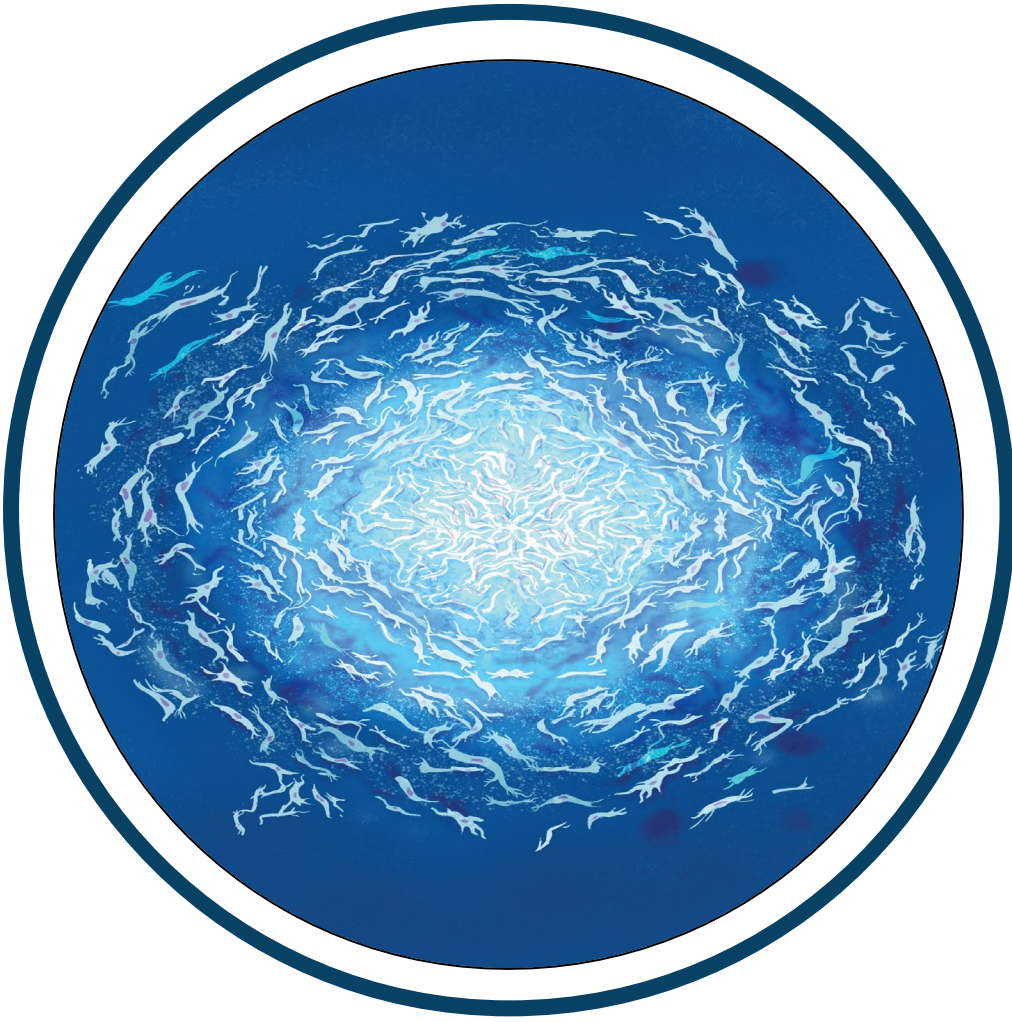


Dr Mathias Kroll

Chief Business Officer

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

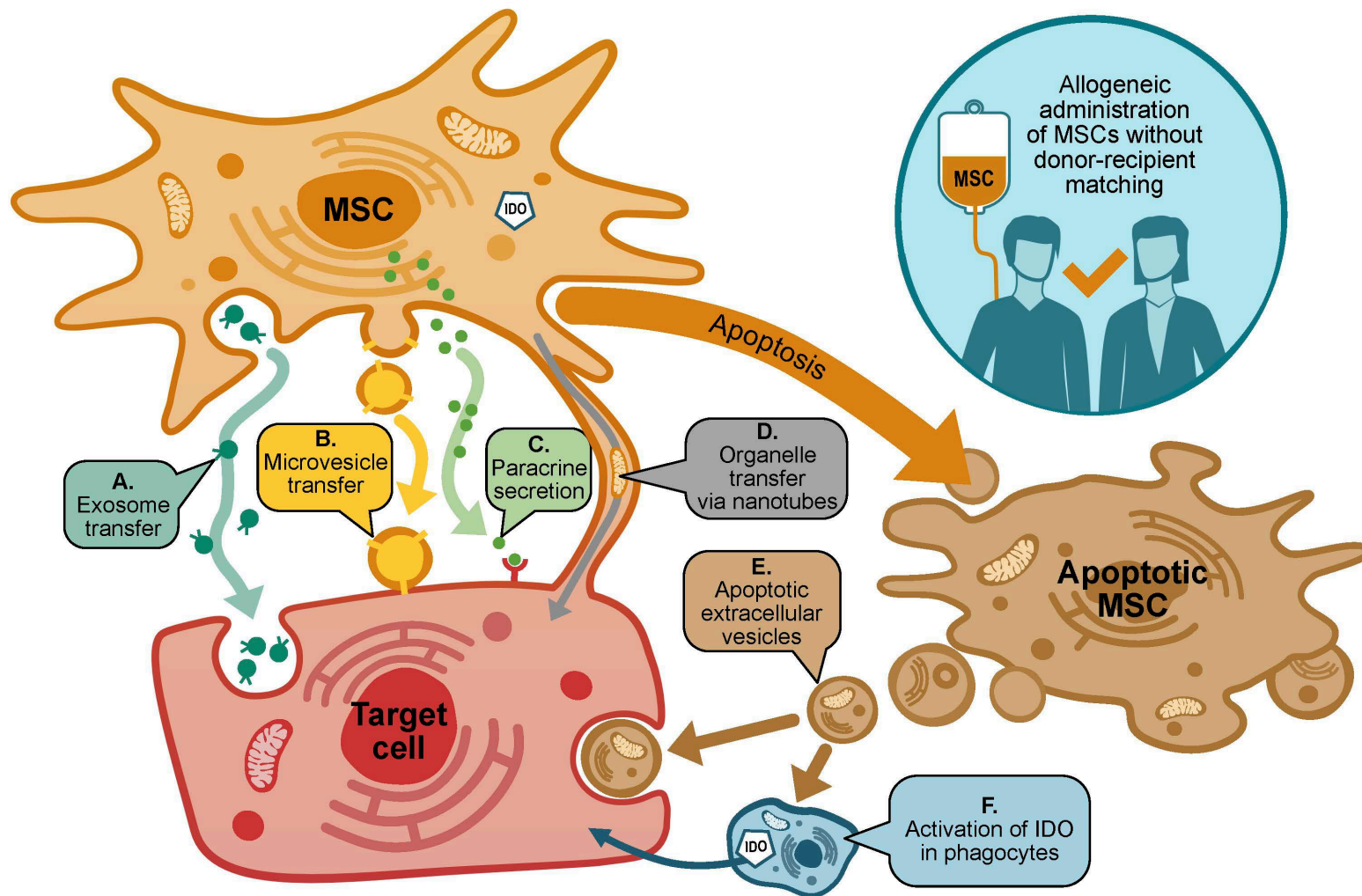
Advantages of iPSC-based platform



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

MSC mechanisms of action



MSCs may exert **many effects** on **target cells** via **diverse potentially-overlapping mechanisms**.

Target cells include (i) donor and host immune cells, including T cells, B cells, NK cells, monocytes and dendritic cells; and (ii) host cells susceptible to damage by GvHD, e.g. cells of the skin, gastrointestinal tract and liver.

Potential mechanisms through which MSCs may act include:

- (A, B): transfer of exosomes or microvesicles containing RNA and other molecules;
- (C) paracrine activity including secretion of proteins (including indoleamine dioxygenase [IDO]), peptides and hormones;
- (D) transfer of organelles via tunneling nanotubes;
- (E, F) MSC apoptosis results in the release of apoptotic extracellular vesicles that act on target cells, as well as induction of IDO production in recipient phagocytes.

Phase 2 trial of CYP-001 in aGvHD

Safer and more effective treatments for aGvHD

Although ruxolitinib is approved for SR-aGvHD, there is a substantial unmet need for a **safer and more effective** treatment option:

- Phase 1 results suggest that Cymerus™ MSCs could achieve better response and survival rates
- Cymerus™ MSCs have not been associated with any significant safety concerns

Running clinical trials

Now that there is an approved treatment option on the market for SR-aGvHD (ruxolitinib), it has become more challenging to **conduct clinical trials** in SR-aGvHD:

- In a trial of any new treatment in SR-aGvHD, doctors would have to be willing to withhold the approved treatment (and patients would have to agree)
- Key opinion leaders have advised that this could create a significant recruitment challenge

Cynata's Phase 2 study design

As a result, decision was taken to conduct Phase 2 trial in patients with **High Risk newly diagnosed** aGvHD:

- Patients not yet steroid resistant, but more likely to have a poor response than standard risk patients
- All patients receive steroids, then randomised to receive either MSCs or placebo as well
- These patients are **not** yet eligible to receive ruxolitinib (as they haven't yet been diagnosed with SR-aGvHD)

Potential to expand patient population

This trial potentially broadens the target patient population, to include those with newly diagnosed aGvHD, as well as those with SR-aGvHD

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



HSCI
HARVARD STEM CELL
INSTITUTE®

criticalcare
RESEARCH GROUP

SVI
St Vincent's Institute
MEDICAL RESEARCH

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