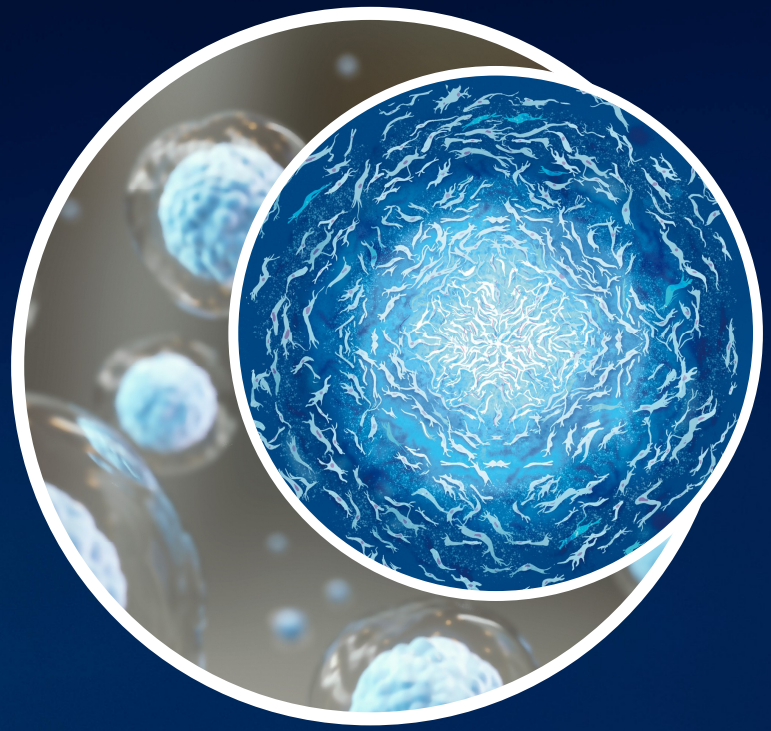
cynata therapeutics

A Clinical Stage Next Generation Stem Cell Therapeutics Company



BIOSHARES
18TH BIOTECH SUMMIT
THE ESSENTIAL BIOTECH INVESTMENT EVENT
12-13 JULY 2024 FREMANTLE, WA

Kilian Kelly, PhD
Chief Executive Officer and Managing Director

Important information

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Company highlights

Revolutionary Cymerus™ manufacturing platform

- **Mesenchymal stem cells** (**MSCs**)[1] have shown potential to treat a wide range of illnesses,[2] but standard manufacture requires ongoing supply of new donors → challenges with consistency, potency and scale
- The patented **Cymerus™** platform is based on **induced pluripotent stem cell** (**iPSC**) technology
- Overcomes major obstacle to commercialisation in this highly promising field, by enabling production of an **effectively limitless** quantity of **consistent**, **high-quality** MSC doses from a **single blood donation**

Compelling clinical data

- **Acute graft versus host disease (aGvHD) Phase 1:** 53% complete response; 87% overall response
- **Diabetic foot ulcer (DFU) Phase 1:** 88% median wound surface area reduction vs 51% in controls[3]

Rich clinical pipeline

- Three major randomised controlled clinical trial readouts upcoming:
  DFU (Ph 1) – late 2024/early 2025; **aGvHD** (Ph 2) – 2H 2025; and **osteoarthritis** (Ph 3) – early 2026
- New trial in kidney transplantation to commence in mid 2024

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1. Also known as mesenchymal stromal cells
2. Zhou, J., Shi, Y. Cell Mol Immunol 20, 555–557 (2023).
3. Initial data in first 16 patients (n=8 per group) after 10 weeks; final results in all 30 patients expected in late 2024/early 2025

FY 2024 – a year of progress

Completion of patient enrolment in two randomised controlled trials

- Phase 3 osteoarthritis – enrolment completed November 2023
- Phase 1 DFU – enrolment completed April 2024

Further encouraging clinical efficacy data

- Promising initial data from ongoing DFU trial released in February 2024

New trials adding to rich pipeline

- Global Phase 2 aGvHD trial – first patient enrolled in March 2024
- New kidney transplant trial approved and ready to commence

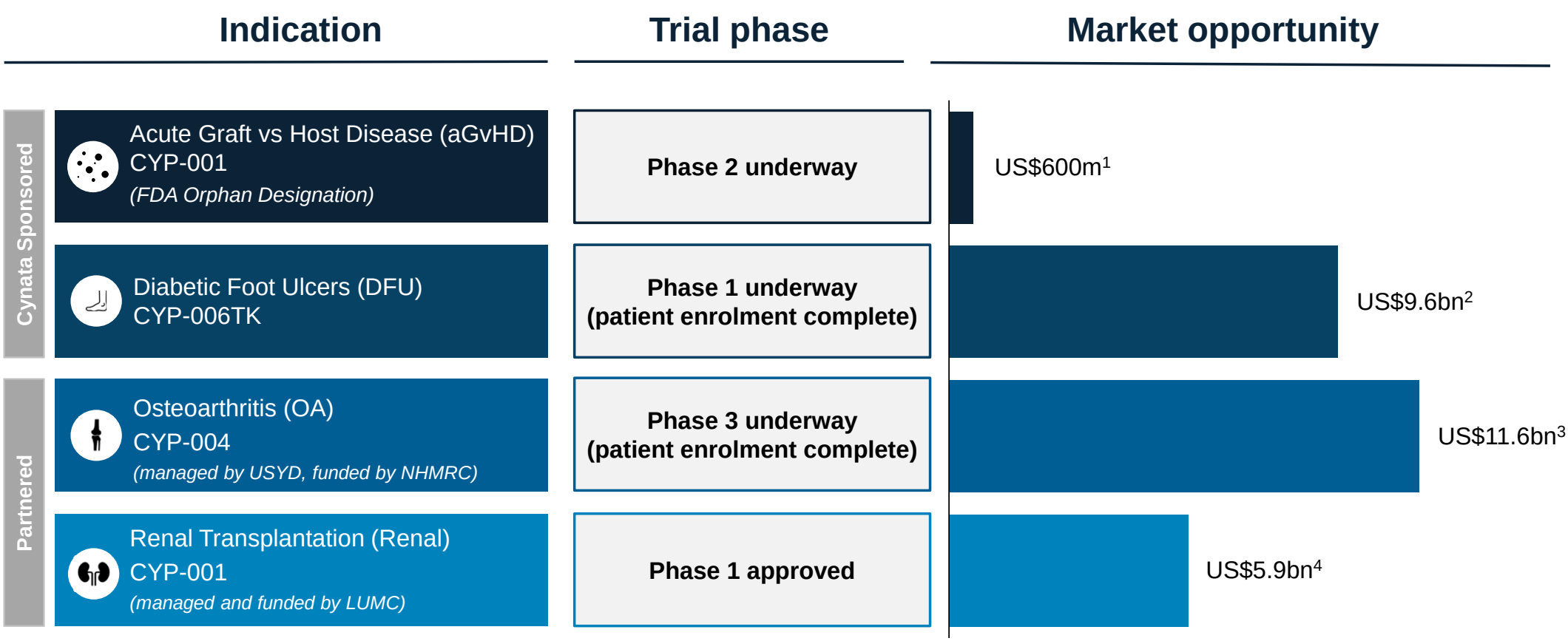
Senior management team strengthened

- New Chief Business Officer position created to drive next stage of commercial growth (Dr Mathias Kroll – commenced Apr 2024)

cynata therapeutics

1. Initial data in first 16 patients (n=8 per group) after 10 weeks; final results in all 30 patients expected in late 2024/early 2025

Advanced and diverse clinical pipeline



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

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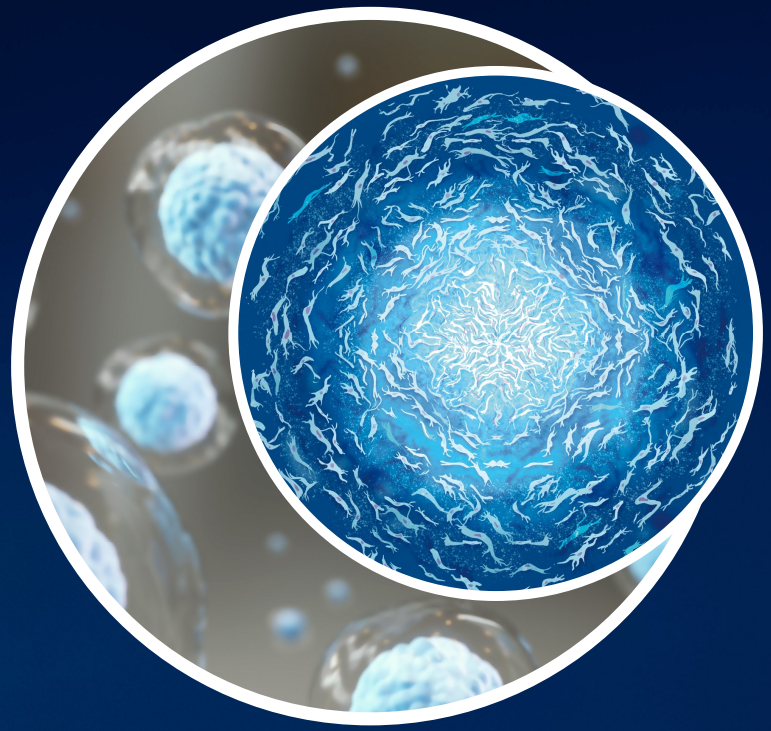
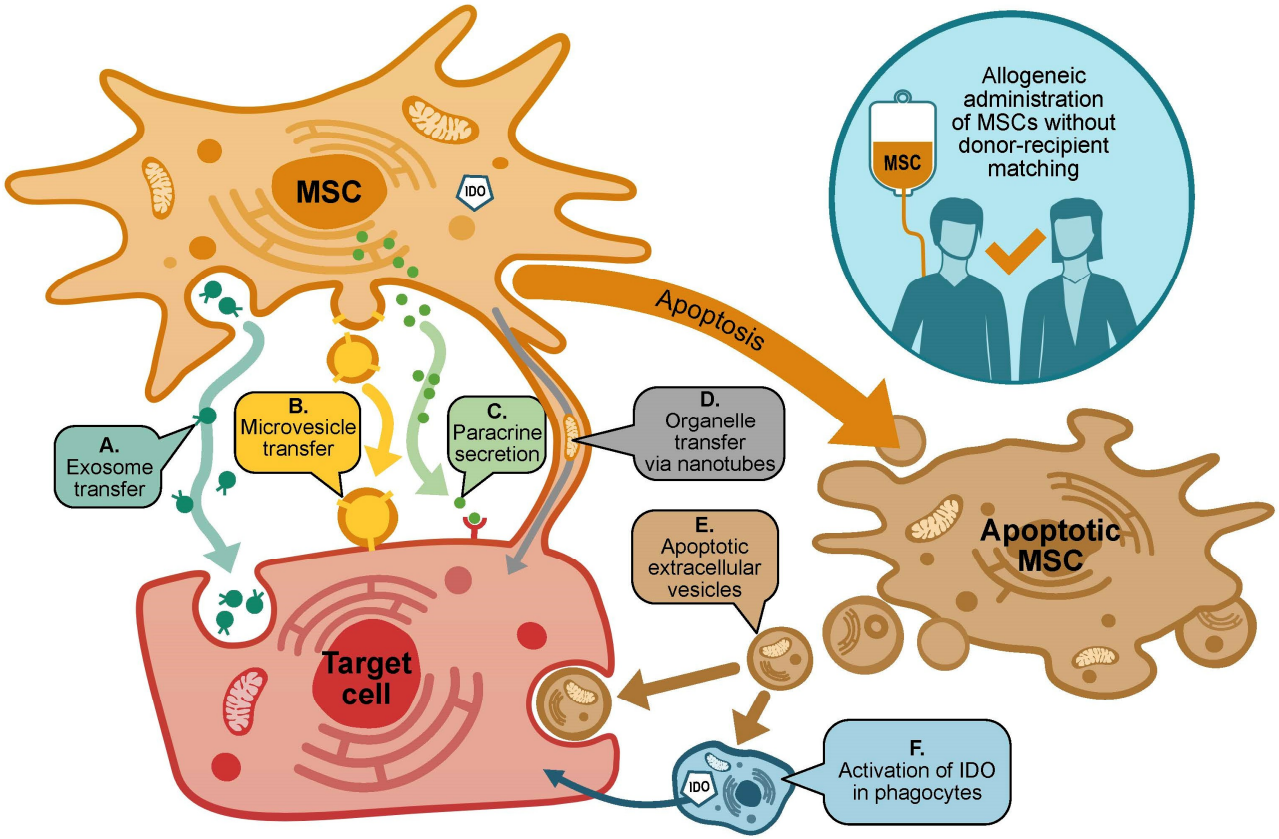
Revolutionary iPSC-based Cymerus™ Manufacturing Platform



Therapeutic potential of MSCs



Mesenchymal stem cells[1] (MSCs):

- Promote an **immunomodulatory** environment[2]
- The "sensor and switcher of the immune system"[3]
- Promote **tissue repair** and **regeneration**
- Can be used **without** matching donors to recipients
- Can be **engineered** to express other functional/therapeutic molecules
- However, with conventional manufacturing methods, there are consistency, potency and scalability challenges

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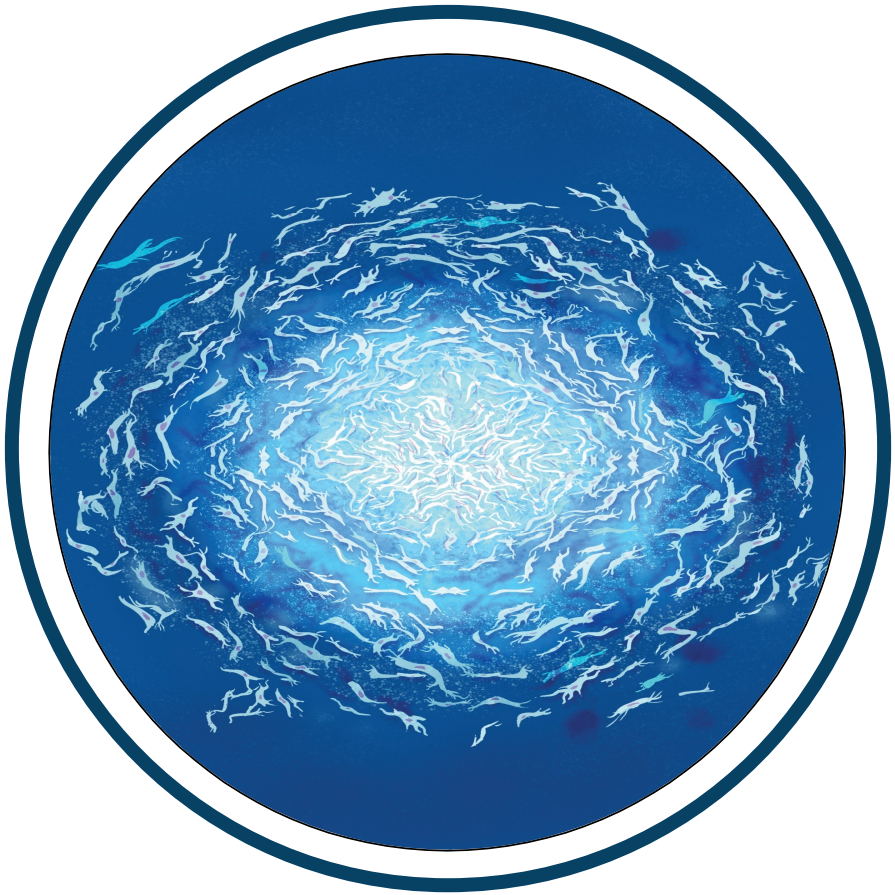
1. Also known as mesenchymal stromal cells
2. Kelly and Rasko, Front. Immunol. 12:761616 (2021)
3. Sarsenova et al, Front. Immunol.13:1010399 (2022)

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

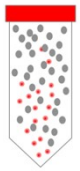
→ iPSCs are **ideal** starting material for commercial production of cellular products

Conventional MSC process

Ongoing need for new donors

Substantial inter-donor **variability**

MSC isolation



Small number of MSCs per donation

Culture expansion

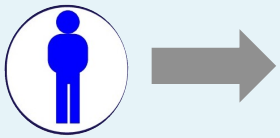
Extensive MSC culture expansion required

Major challenges:

- Logistically challenging
- Inter-donor **variability** – **inconsistent** activity in MSCs from different donors
- MSCs undergo **functional changes** and **loss of potency** during extensive culture expansion

Cymerus™ iPSC-based process

One donor, one time

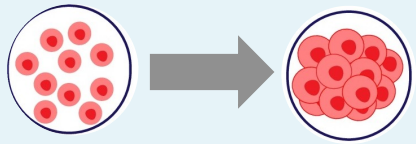


Avoids inter-donor variability

Reprogramming & iPSC expansion

Effectively **limitless** expansion potential

Differentiation into MSCs & culture expansion



Minimal MSC culture expansion

Robust patent protection

Advantages of **Cymerus™** platform:

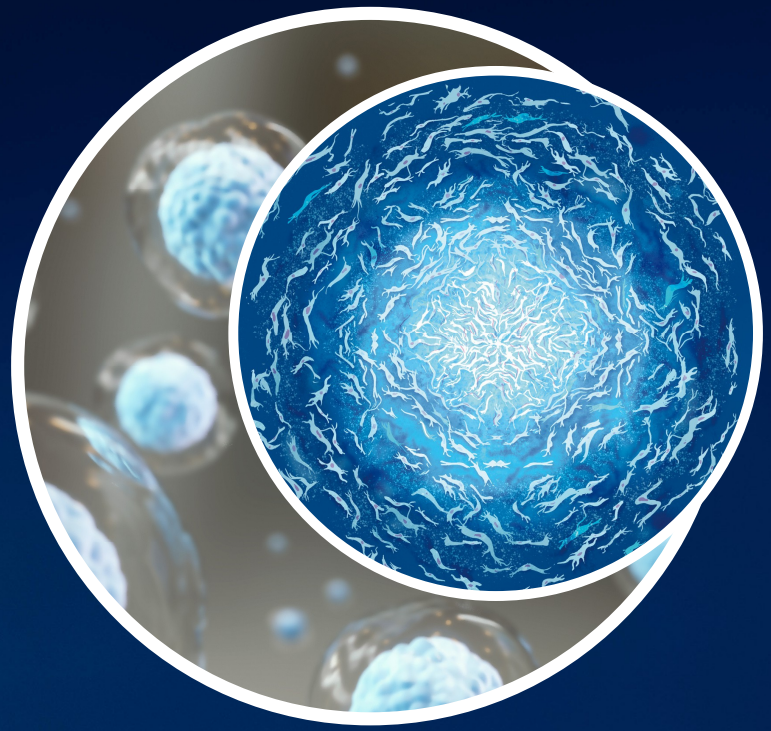
- **Effectively limitless** iPSC expansion potential
- **Avoids** need for new donors
- **Avoids** inter-donor variability
- **Avoids** extensive MSC expansion
- High level **potency**, **consistency** and **scalability**

Strategic partnership with Fujifilm

- Fujifilm: one of largest healthcare conglomerates globally, with significant assets in biotechnology sector, bolstered by recent multi-billion dollar investments
- Fujifilm Cellular Dynamics Inc (FCDI: subsidiary of Fujifilm) developed the original iPSC line used in Cynata's Cymerus™ manufacturing process
- Cymerus™ manufacturing process being established at FCDI, with Cynata's progress showcasing Fujifilm's iPSC platform
- Fujifilm holds a 4.5% shareholding in Cynata

FUJIFILM
Value from Innovation

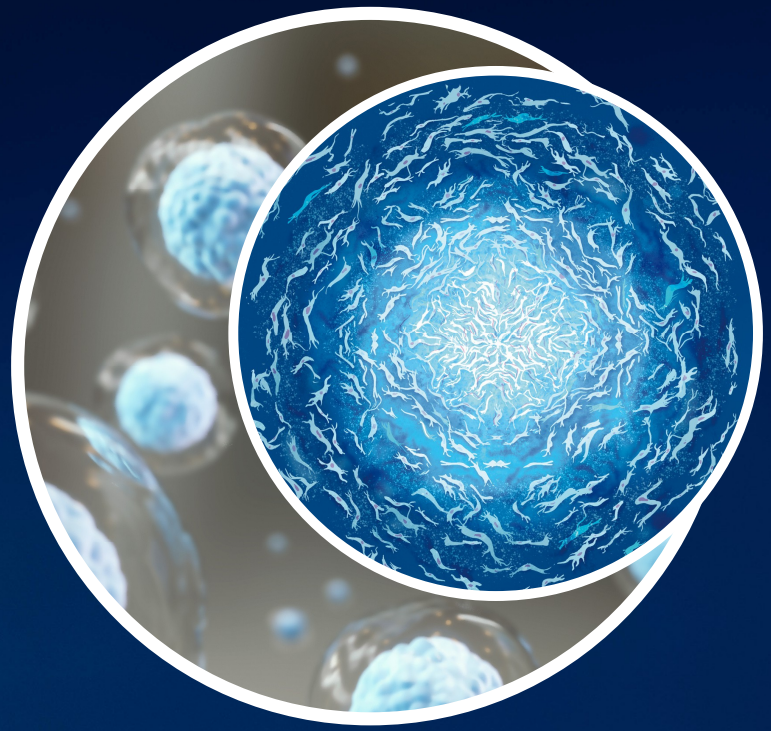
Regulatory pathway for novel iPSC-based product



Regulatory approach

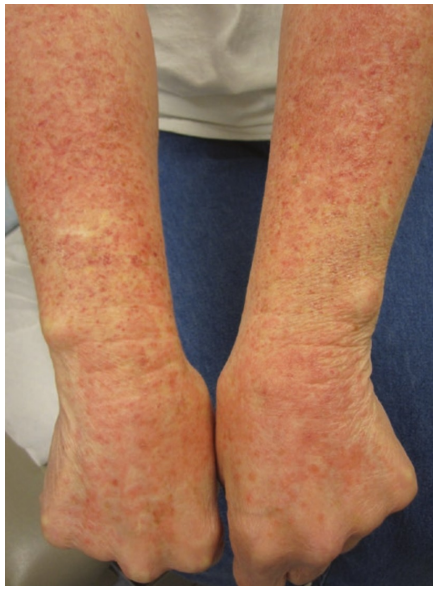
- When Cynata commenced development of Cymerus™ MSCs in early 2014:
  - No iPSC-based therapy had ever been used in a human anywhere in the world
  - No clinical-grade iPSC line existed
  - There was a lack of relevant regulatory guidelines, and no precedents to follow
- In Australia, iPSC-derived products are “Class IV biologicals”, which means clinical trials must be cleared via the CTA scheme rather than CTN unless certain exemptions apply (CTA is much more time consuming and costly)
- Opportunities/lessons learned:
  - Engaged with regulators worldwide (TGA, FDA, EMA and others) very early in development
  - “That’s how it has always been done” mentality does not apply with a novel class of therapies
  - Regulators offered opportunity to propose novel approaches based on scientific arguments
  - Overcame CTA requirement in Australia by gaining clinical trial approval overseas first

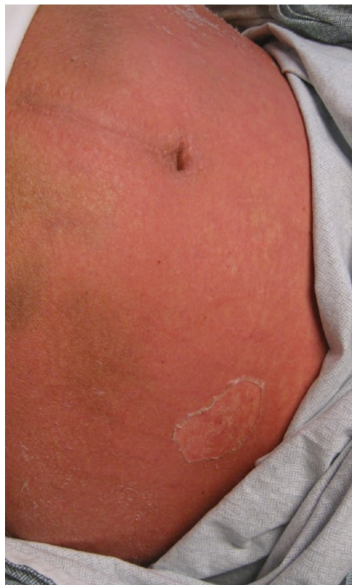
Graft versus host disease – background



Graft versus host disease (GvHD)

- Allogeneic haematopoietic stem cell transplantation (HSCT) is potentially curative for conditions such haematological malignancies (e.g. lymphoma, leukaemia)
- However, GvHD arises in ≥30% of patients, due to donor T cells attacking host tissues
- Categorised as acute (affects skin, GI tract and/or liver) or chronic (affects skin + potentially any other organ)
- Acute GvHD affects 3-4,000 patients per year in US
- First line treatment is with corticosteroids, but up to 50% of acute cases are steroid-resistant (SR-aGvHD)
- Prognosis in SR-aGvHD is very poor, with 2-year overall survival <20%[1]

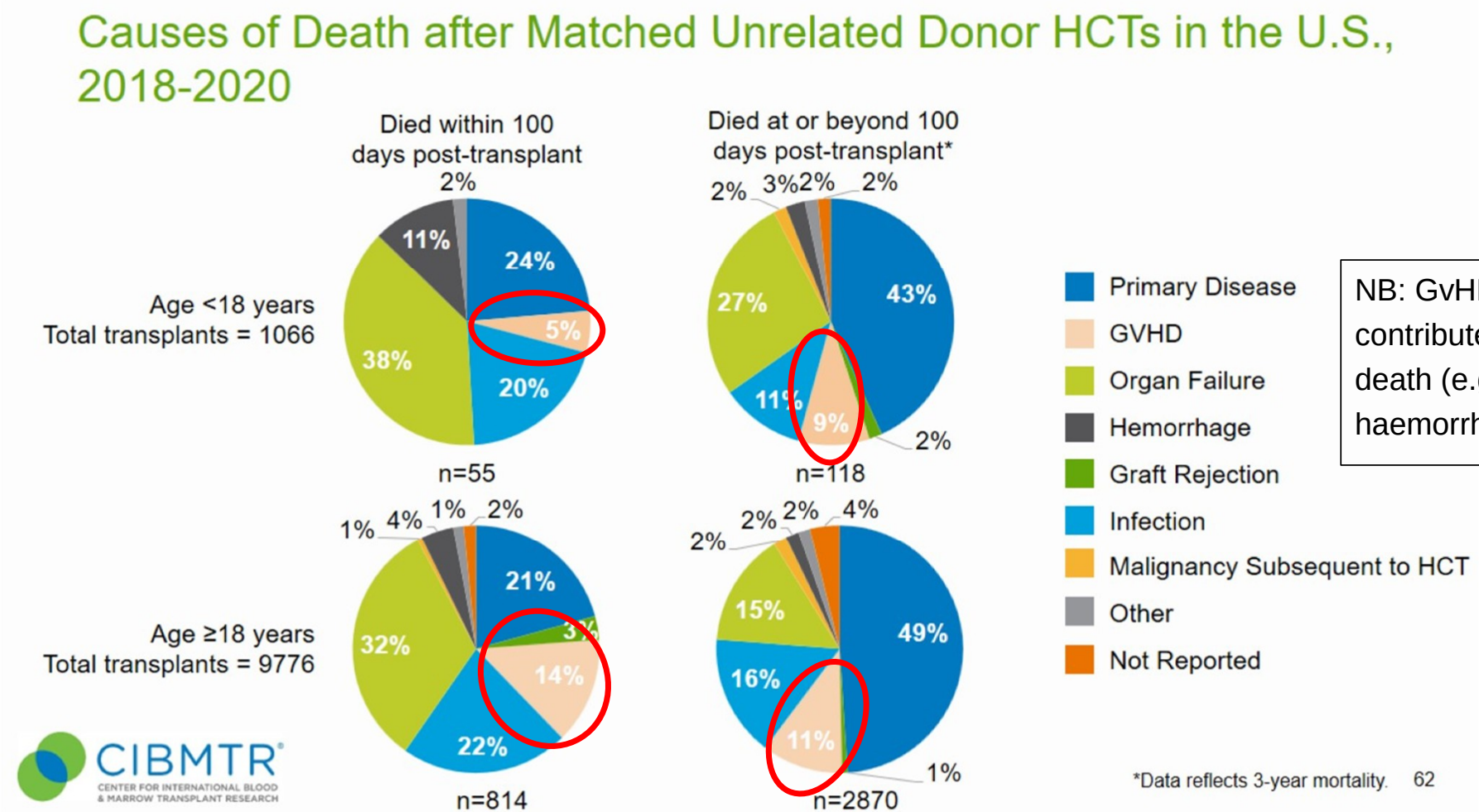




1. Westin JR, Saliba RM, De Lima M, et al. Steroid-Refractory Acute GVHD: Predictors and Outcomes. Adv Hematol. 2011; 2011:601953

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

GvHD is a significant cause of death after HSCT



NB: GvHD may also contribute to other causes of death (e.g. infection, haemorrhage, organ failure)

Source: Bolon YT, Atshan R, Allbee-Johnson M, Estrada-Merly N, Lee SJ. Current use and outcome of hematopoietic stem cell transplantation: CIBMTR summary slides, 2022

aGvHD treatment landscape

- First line treatment for aGvHD is corticosteroids – but up to 50% fail to respond – known as steroid-resistant aGvHD (SR-aGvHD)
- Numerous other therapies (e.g. immunosuppressants) have been investigated for SR-aGvHD, but most have limited efficacy and/or problematic safety profiles
- Ruxolitinib (a JAK kinase inhibitor):
  - Originally launched for treatment of myelofibrosis in 2012, followed by polycythemia vera in 2014, then SR-aGvHD in 2019, and chronic GvHD in 2021
  - Label extension for SR-aGvHD was approved in US based on single-arm trial in 71 patients, and in EU based on randomised controlled trial vs best available therapy (BAT) in 309 patients
  - Led to relatively good response rates in SR-aGvHD, but **no apparent improvement in overall survival**
  - Associated with a **high rate of potentially serious adverse reactions**
  - Ruxolitinib is priced at US$18k per month, and typically requires at least 6 months treatment for GvHD (i.e. >US$100k per patient). It has forecast sales of US$4.5b in 2024 across all indications.[1]

➔ There remains a **significant unmet need** for **safer** and **more effective** aGvHD treatments

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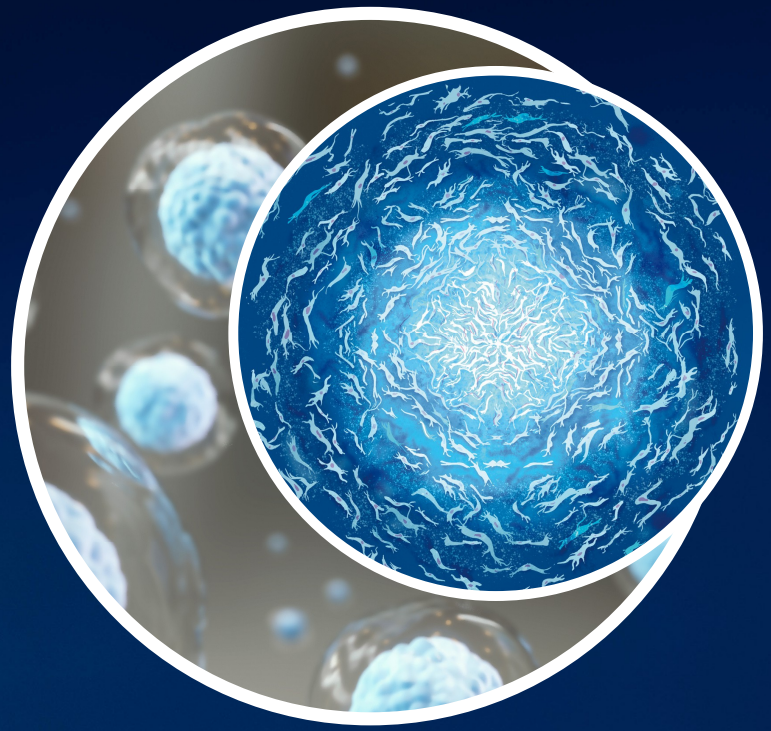
1. Note sales figures relate to all approved indications, including myelofibrosis, polycythemia vera, and GvHD

Compelling Clinical Data: Phase 1 clinical trial of CYP-001 for SR-aGvHD



CYP-001: Two *Nature Medicine* publications

Phase 1 trial of CYP-001 was the first completed clinical trial worldwide with **any iPSC-derived product**

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]

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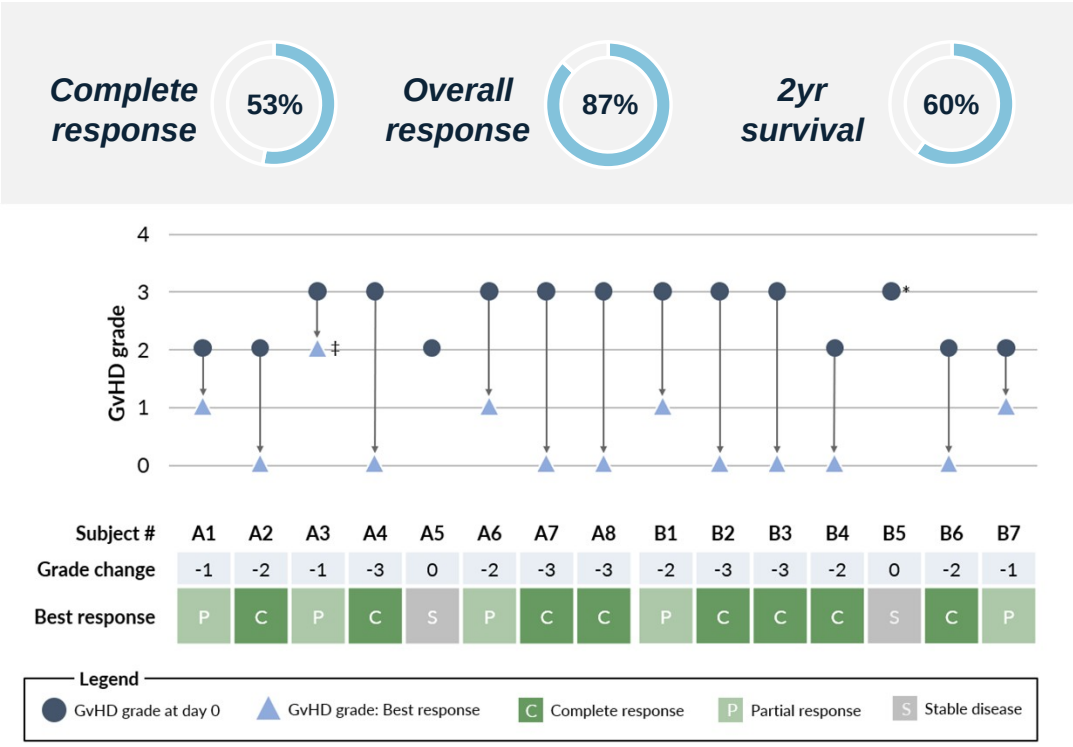
aGvHD | Phase 1 clinical trial - results

Product: CYP-001 (Cymerus™ MSCs for intravenous infusion)

Trial conducted in 15 patients with **steroid-resistant aGvHD**



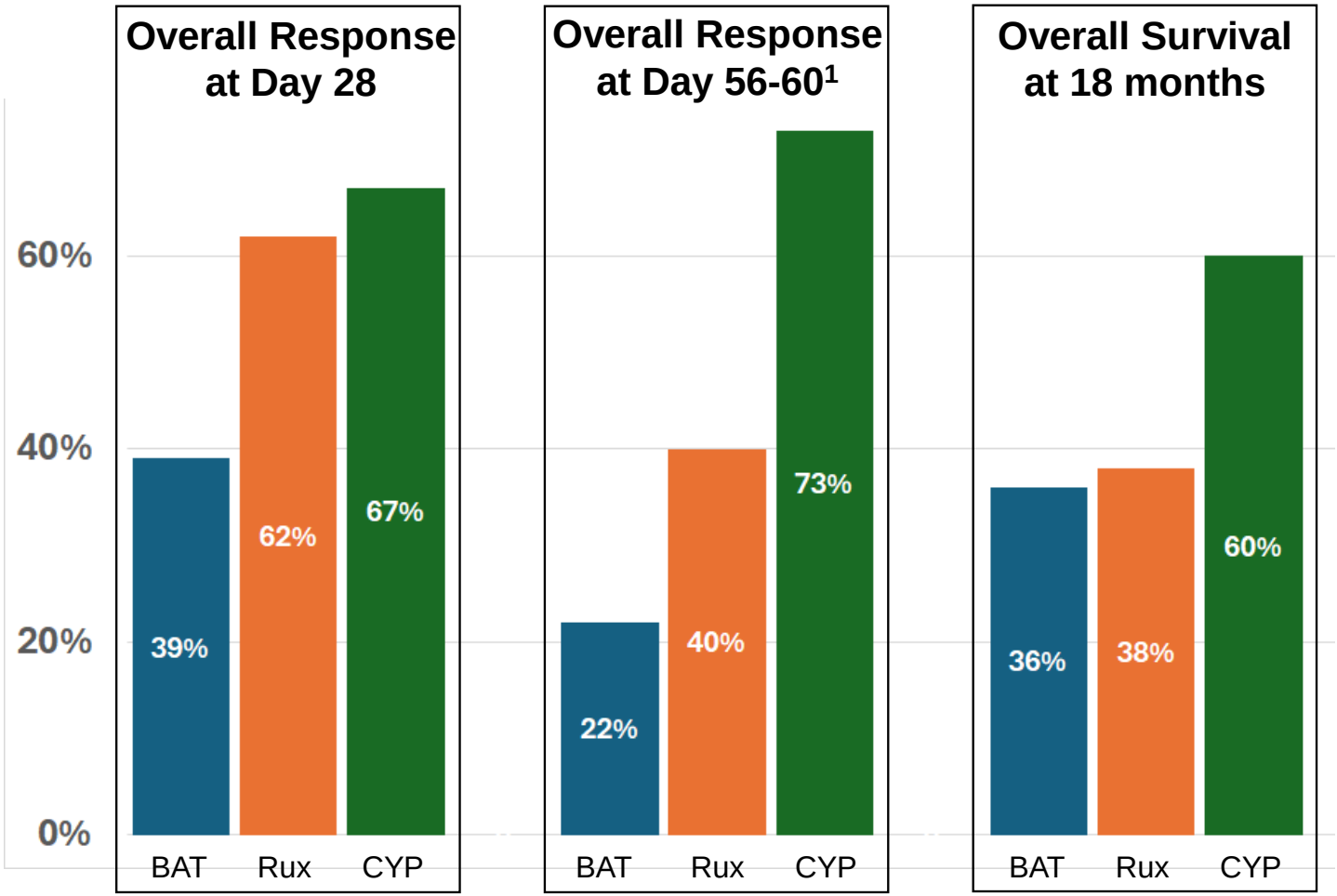
- CYP-001 was shown to be **safe and well tolerated**, with **sustained outcomes up to 2 years** after the first infusion
- **No serious adverse events or other safety concerns related to CYP-001**
- Very encouraging **response rates** and **overall survival**

- 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

Efficacy of CYP-001 vs other treatments in SR-aGvHD



- Overall response rates for BAT an Rux **declined** between D28 and D56
- Overall response rate for CYP-001 **increased** between D28 and D60
- Overall survival rate for CYP-001 was **60%** at **both 18 and 24 months**
- Overall survival rates for BAT and Rux were **36%** and **38%** at **18 months**, and **not evaluable at 24 months**

BAT = "best available therapy" in study NCT02913261 - other therapies commonly used in patients with steroid-resistant acute graft versus host disease (SR-aGvHD)

Rux = ruxolitinib (now approved for SR-aGvHD) in study NCT02913261

CYP = CYP-001 in study NCT02923375

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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).
1. Overall Response at Day 56-60 refers to Day 56 response for BAT & Rux, and Day 60 response for CYP-001.

Safety of CYP-001 vs other treatments in SR-aGvHD

- **No safety concerns related to CYP-001** have been identified
- Conversely, **adverse reactions to ruxolitinib are common**
- Grade 3-4 (**serious/life-threatening**) adverse reactions to ruxolitinib in aGvHD patients include:[1]

Adverse Reaction	Grade 3-4 Incidence
Infections (type of infection not specified)	41%
Bacterial infections	28%
Haemorrhage (bleeding)	20%
Fatigue	14%
Viral infections	14%
Hypertension (high blood pressure)	13%
Oedema (fluid retention)	13%
Thrombosis (blood clots)	11%
Blood disorders (thrombocytopenia, anaemia, neutropenia)	61%, 45%, 40%

1. JAKAFI® (ruxolitinib) tablets, for oral use, US FDA approved Prescribing Information, September 2021.

Grade 3 = Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care
Grade 4 = Life-threatening consequences; urgent intervention indicated.

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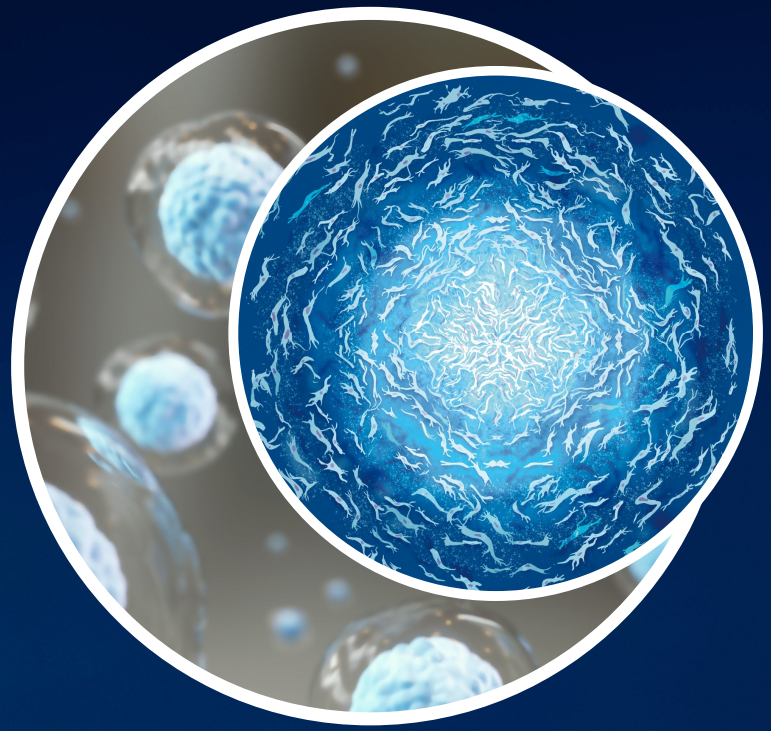
Now ongoing:
Phase 2 clinical trial of
CYP-001 for HR-aGvHD



aGvHD | Phase 2 clinical trial

Product	CYP-001 (Cymerus™ iPSC-derived MSCs for intravenous infusion)
Indication	High risk acute graft versus host disease (aGvHD)[1]
Study Design	• Randomised controlled trial in ~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	• Clinical sites in USA, Europe and Australia • Regulatory/ethics clearance secured in all participating jurisdictions – including IND from US FDA • First patient enrolled – March 2024 • Aiming to complete patient enrolment by end of calendar year 2024
Results	Primary evaluation results anticipated in 2H CY 2025

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1. aGvHD may occur after bone marrow transplantation/similar procedures, due to donor immune cells (from the “graft”) attacking the transplant recipient (the “host”)
For further information: https://clinicaltrials.gov/study/NCT05643638

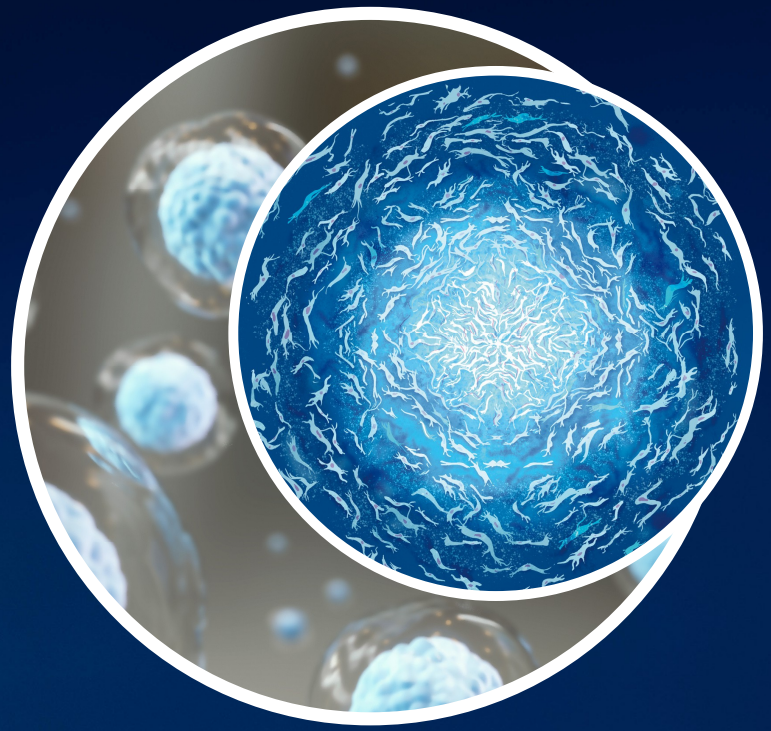
Phase 2 trial design

- SR-aGvHD is a life-threatening condition:
  - Very challenging to withhold approved agent in this setting, even though CYP-001 data so far compare very favourably with ruxolitinib
  - Consequently, KOLs advised there would be a significant recruitment challenge in a randomised trial of CYP-001 vs ruxolitinib in SR-aGvHD
- Consequently, Phase 2 trial is being conducted in patients with newly diagnosed High Risk aGvHD (HR-aGvHD; risk assessed based on refined Minnesota criteria)
- All patients will receive steroids (standard of care), and randomised to also receive either CYP-001 or placebo
- Newly diagnosed aGvHD patients are not yet eligible to receive ruxolitinib (they do not yet have SR-aGvHD), so the recruitment challenge related to ruxolitinib is avoided
- Also hypothesised that earlier intervention with CYP-001 maximises opportunity for benefit

Recruitment projection

- aGvHD is a rare condition, so a lot of clinical centres required to recruit in a reasonable timeframe
- Over 30 clinical centres are participating in Cynata's Phase 2 trial, which aims to recruit 60 patients – i.e. fewer than 2 patients per centre required on average
- Our recruitment projection is based on dates of each site opening, in addition to assumed recruitment rate per site:
  - Assumed recruitment rate per site is based on historical actual recruitment rates in similar trials – not simply an estimate provided by investigators
  - Start-up timelines at different clinical centres vary substantially – due to different regulatory & ethics timelines, as well as variations in administrative/logistical requirements
  - This leads to a staggered recruitment rate, ramping up as more sites come on board

Strategy, Outlook and Corporate Overview



Research partnerships

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

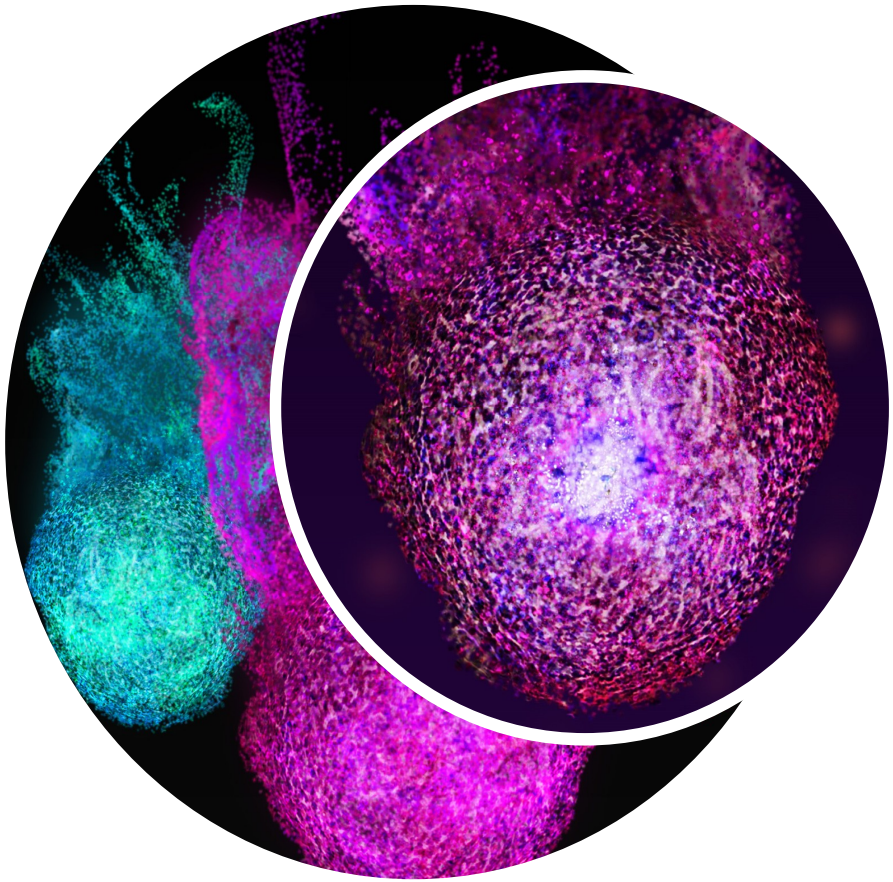
Cell Therapy Manufacturing Cooperative Research Centre

HSCI HARVARD STEM CELL INSTITUTE®

criticalcare RESEARCH GROUP

SVI St Vincent's Institute MEDICAL RESEARCH

Commercial partnering



Several distinct products in development → potential for multiple partnerships

Reinvestment of proceeds to maximise potential of the platform

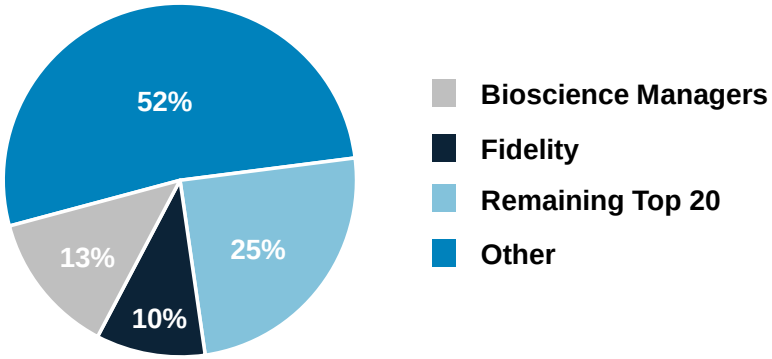
Platform also available to partners pursuing other indications and/or engineered MSC applications

cynata therapeutics

Corporate overview

Cynata has been listed on the Australian Securities Exchange (ASX) since 2013 (Ticker: CYP)

Shareholder distribution



Substantial shareholders (>5%)

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.

Fidelity INTERNATIONAL **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.

Financial information

Share price (10 July 2024)	A$0.26
Shares on issue	179m
Market capitalisation	**~A$47m**
Cash[1]	~A$9.0m

Source: IRESS
1. As at 31 March 2024

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

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Upcoming catalysts*

Results of **three randomised controlled clinical trials** expected between **early 2025 and early 2026**

Mid 2024

- Kidney transplant trial – start of enrolment

2H 2024

- Kidney transplant trial – results (Cohort A)
- aGvHD trial – completion of enrolment

1H 2025

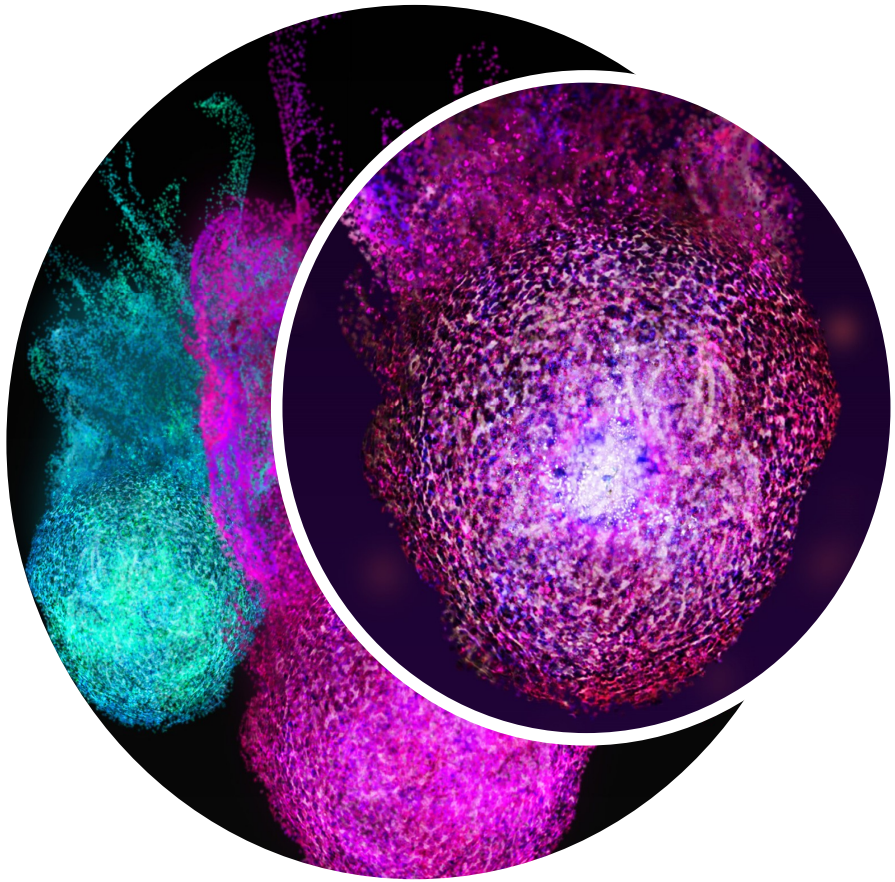
- Diabetic foot ulcer trial – results (potentially late 2024)

2H 2025

- aGvHD trial – results

1H 2026

- Osteoarthritis trial - results



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* Timing of events is approximate, and subject to change

Summary

Next generation stem cell company	• Leading platform technology in burgeoning stem cell sector • Diverse and highly credentialed leadership team with proven experience
Scalable manufacturing	• Cymerus™ manufacturing technology protected by robust patent portfolio • Enables scalable production of consistent MSCs from a single donation from a single donor, overcoming major challenges with conventional approaches
Compelling clinical data	• Very encouraging safety and efficacy results from aGvHD clinical trial (CYP-001) • Promising initial data from ongoing DFU clinical trial (CYP-006TK)
Rich clinical pipeline	• Broad pipeline with four active clinical programs • FDA cleared IND for Phase 2 aGvHD clinical trial; study underway • Patient enrolment complete in DFU & OA clinical trials • Commencement of renal transplantation clinical trial imminent
Significant growth potential	• Global estimated market opportunity across targeted indications of ~US$28bn[1] • Focus on indications with significant unmet need • Proactive B-2-B outreach to drive partnering strategy

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1. Refer to slide #20 for breakdown/sources

Contact Us

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