

ASX ANNOUNCEMENT

12 July 2024

Cynata to Present at Bioshares Biotech Summit

Melbourne, Australia; 12 July 2024: Cynata Therapeutics Limited (ASX: “CYP”, “Cynata”, or the “Company”), a clinical-stage biotechnology company specialising in cell therapeutics, announces that CEO and Managing Director, Dr Kilian Kelly will present at the Bioshares Biotech Summit in Fremantle, WA today, Friday 12 July 2024.

The Bioshares Biotech Summit is an event for fund managers, stockbrokers, investment bankers and retail investors active in the biotech sector. Dr Kelly was invited to present on Cynata’s Cymerus™ off-the-shelf iPSC¹-derived MSC² platform, with a particular focus on the acute graft versus host disease clinical program.

A copy of the presentation is attached.

-ENDS-

Authorised for release by Dr Kilian Kelly, CEO & Managing Director

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Lauren Nowak, Media Contact, +61 (0)400 434 299, lauren@littlebigdeal.au

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 – patient enrolment completed) and diabetic foot ulcers (DFU – patient enrolment completed) are currently ongoing, while a trial in renal transplant is expected to commence in the near future. 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.

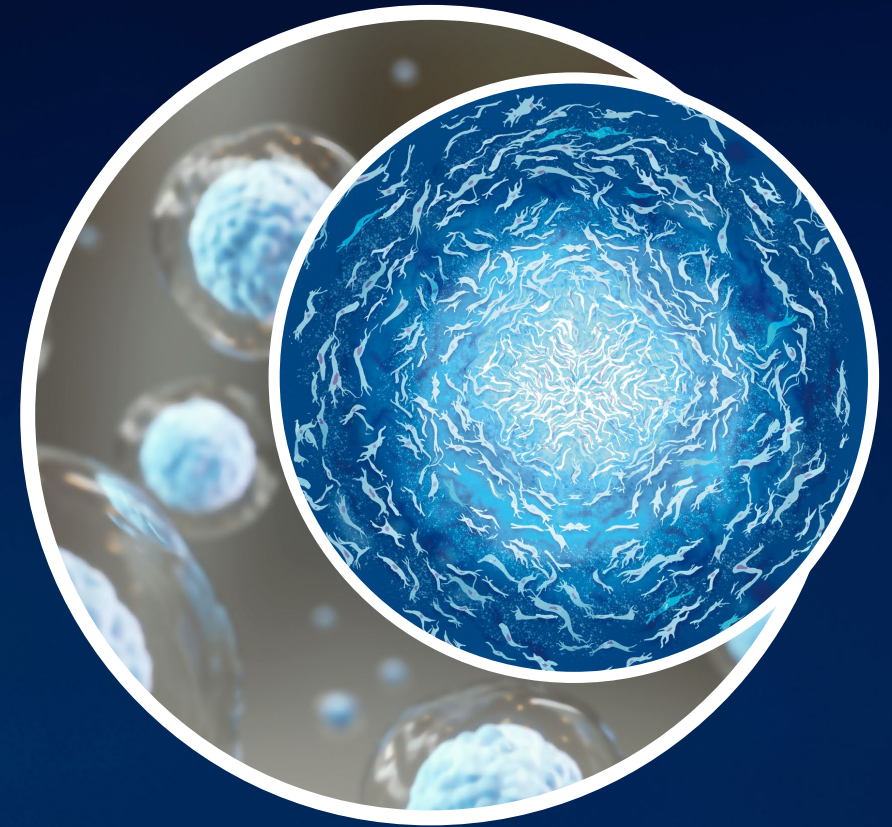
¹ iPSC = induced pluripotent stem cell

² MSC = mesenchymal stem (or stromal) cell



A Clinical Stage Next Generation Stem Cell Therapeutics Company

Kilian Kelly, PhD
Chief Executive Officer and Managing Director



Important information

Summary information

This Presentation contains summary information about Cynata Therapeutics Limited and its subsidiaries (CYP) which is current as at 10 July 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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Financial data

All financial information in this Presentation is in Australian currency (A\$) unless otherwise stated. This Presentation contains historical financial information based on the Company's results for the quarter to 31 March 2024. This information is disclosed in the Appendix 4C report lodged with the ASX on 30 April 2024. Any discrepancies between totals and sums of components in tables and figures in this Presentation are due to rounding.

Forward-looking statements

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, particularly in light of the current economic climate and the significant volatility, uncertainty and disruption caused by the outbreak of COVID-19.

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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 controls³

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

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)

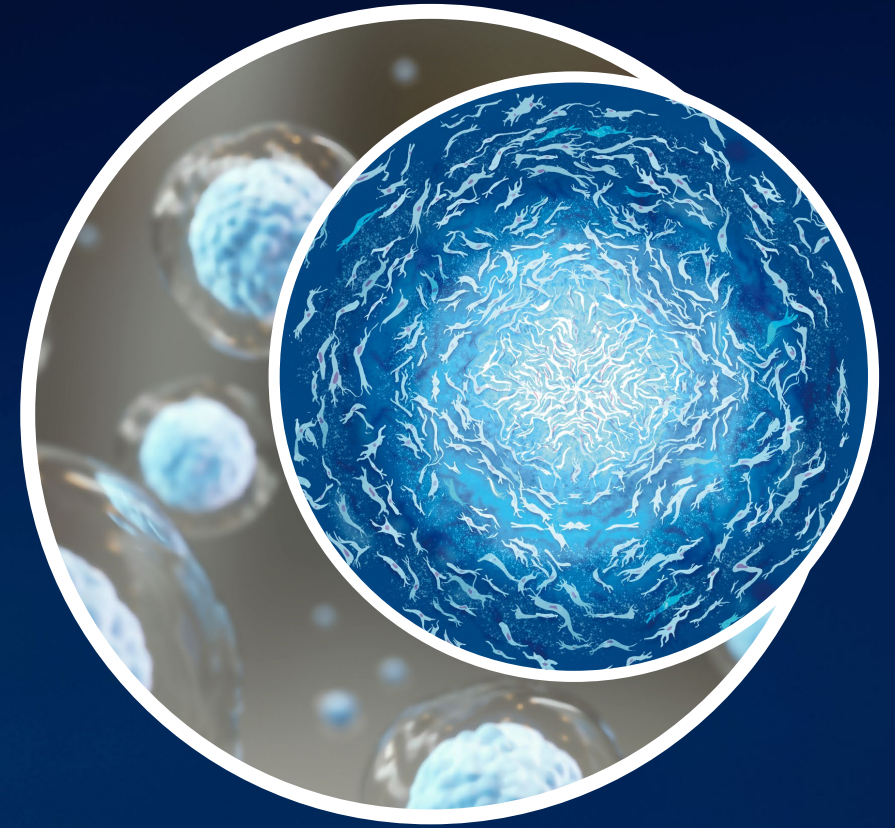
Advanced and diverse clinical pipeline

	Indication	Trial phase	Market opportunity
Cynata Sponsored	 Acute Graft vs Host Disease (aGvHD) CYP-001 <i>(FDA Orphan Designation)</i>	Phase 2 underway	US\$600m ¹
	 Diabetic Foot Ulcers (DFU) CYP-006TK	Phase 1 underway (patient enrolment complete)	US\$9.6bn ²
Partnered	 Osteoarthritis (OA) CYP-004 <i>(managed by USYD, funded by NHMRC)</i>	Phase 3 underway (patient enrolment complete)	US\$11.6bn ³
	 Renal Transplantation (Renal) CYP-001 <i>(managed and funded by LUMC)</i>	Phase 1 approved	US\$5.9bn ⁴

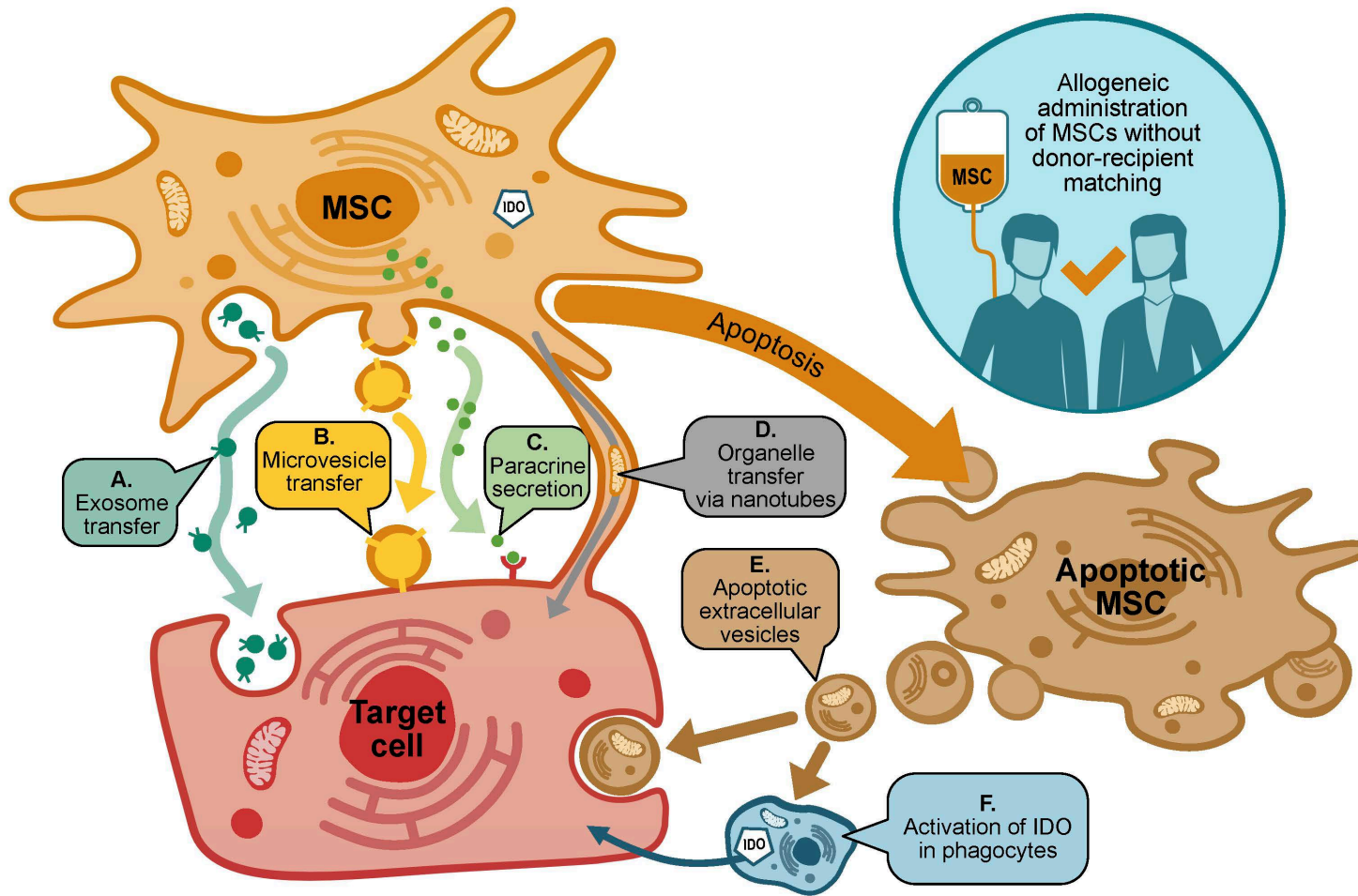
1. Global Graft versus Host Disease Market 2019-2029 (Reflects forecast market in 2026); 2. Zion Market Research, 2019 (represents global treatment market in 2025); 3. Persistence Market Research 2018 research report: "Osteoarthritis Treatment Market: Global Industry Analysis (2012-2016) and Forecast (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

Revolutionary iPSC-based Cymerus™ Manufacturing Platform



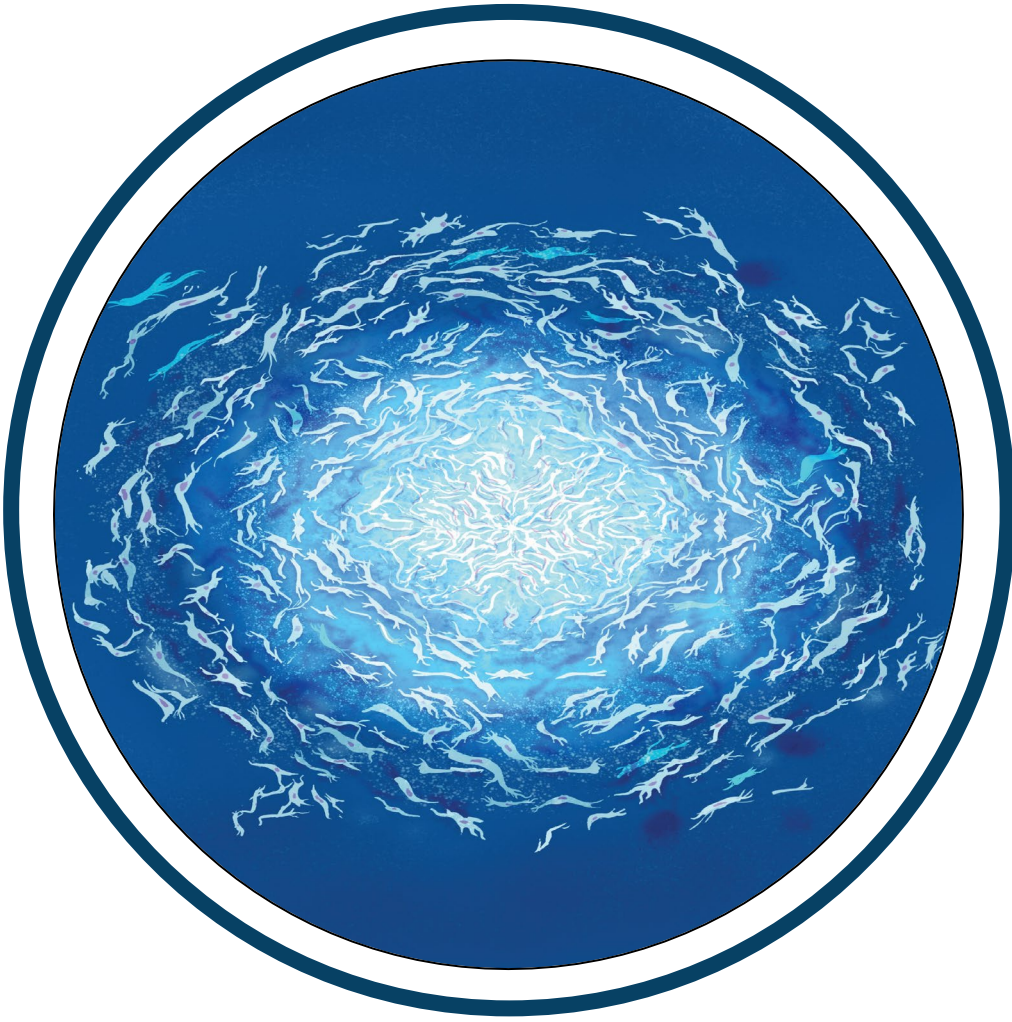
Therapeutic potential of MSCs



Mesenchymal stem cells¹ (MSCs):

- Promote an **immunomodulatory** environment²
- 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

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

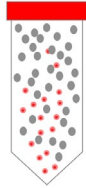
Conventional MSC process

Ongoing need
for new donors



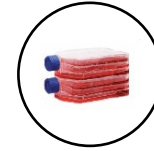
Substantial inter-donor **variability**

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**



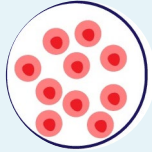
Avoids inter-donor
variability

Reprogramming &
iPSC expansion



Effectively limitless
expansion potential

Differentiation into MSCs
& culture expansion



Minimal MSC
culture expansion

Robust patent protection

Advantages of Cymerus™ platform:

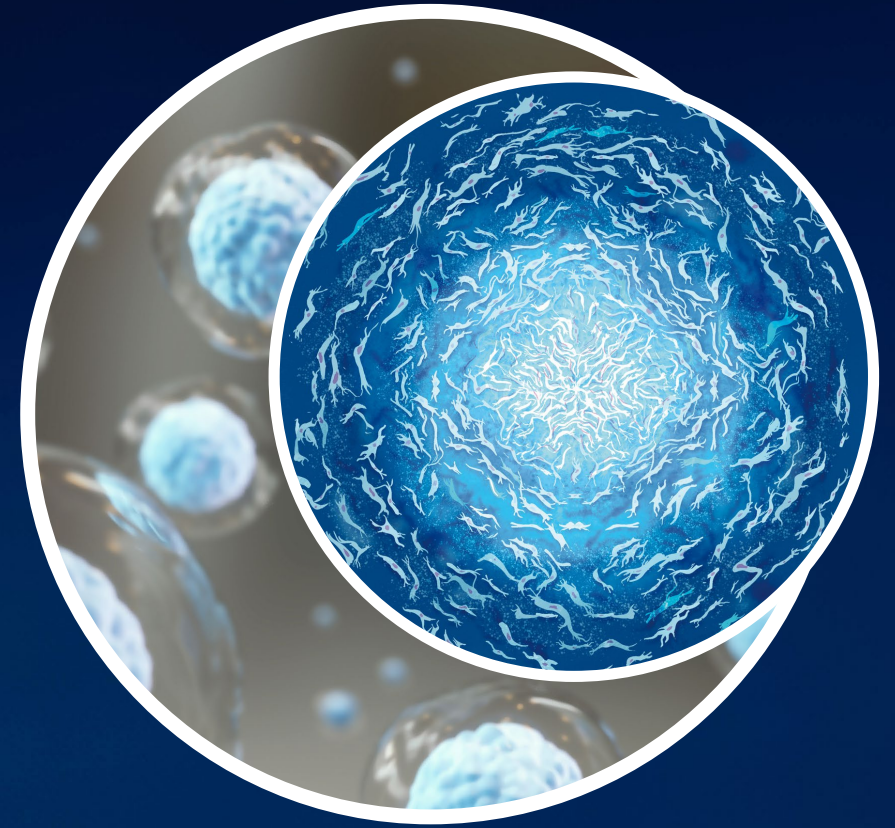
- **Effectively limitless** iPSC expansion potential
- **Avoids** need for new donors
- **Avoids** inter-donor variability
- **Avoids** extensive MSC expansion
- High level **potency, consistency** and **scalability**

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



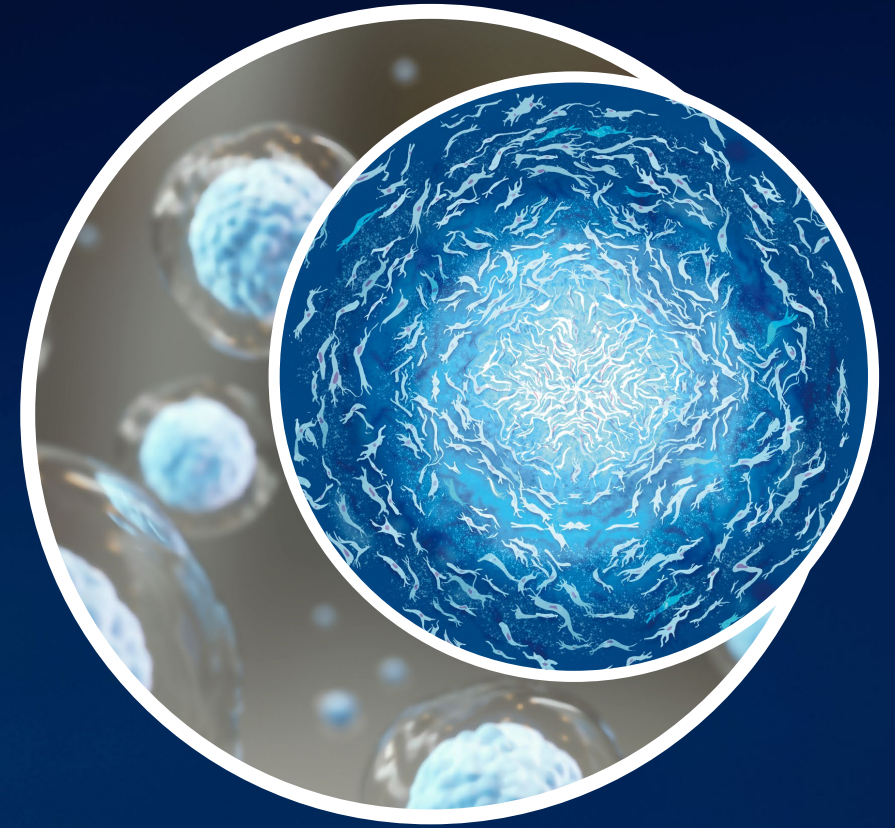
Regulatory pathway for novel iPSC-based product



Regulatory approach

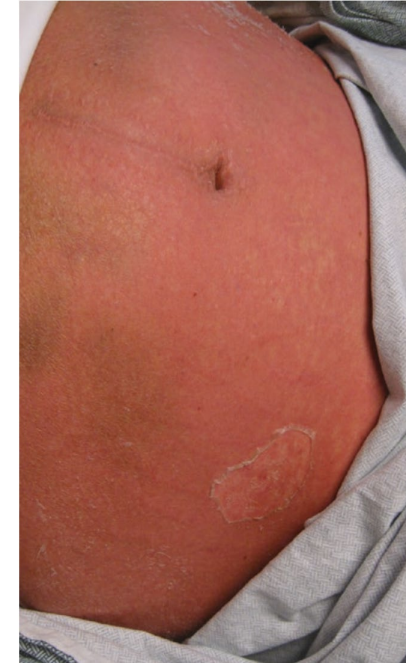
- When Cynata commenced development of Cymerus™ MSCs in early 2014:
 - No iPSC-based therapy had ever been used in a human anywhere in the world
 - No clinical-grade iPSC line existed
 - There was a lack of relevant regulatory guidelines, and no precedents to follow
- In Australia, iPSC-derived products 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



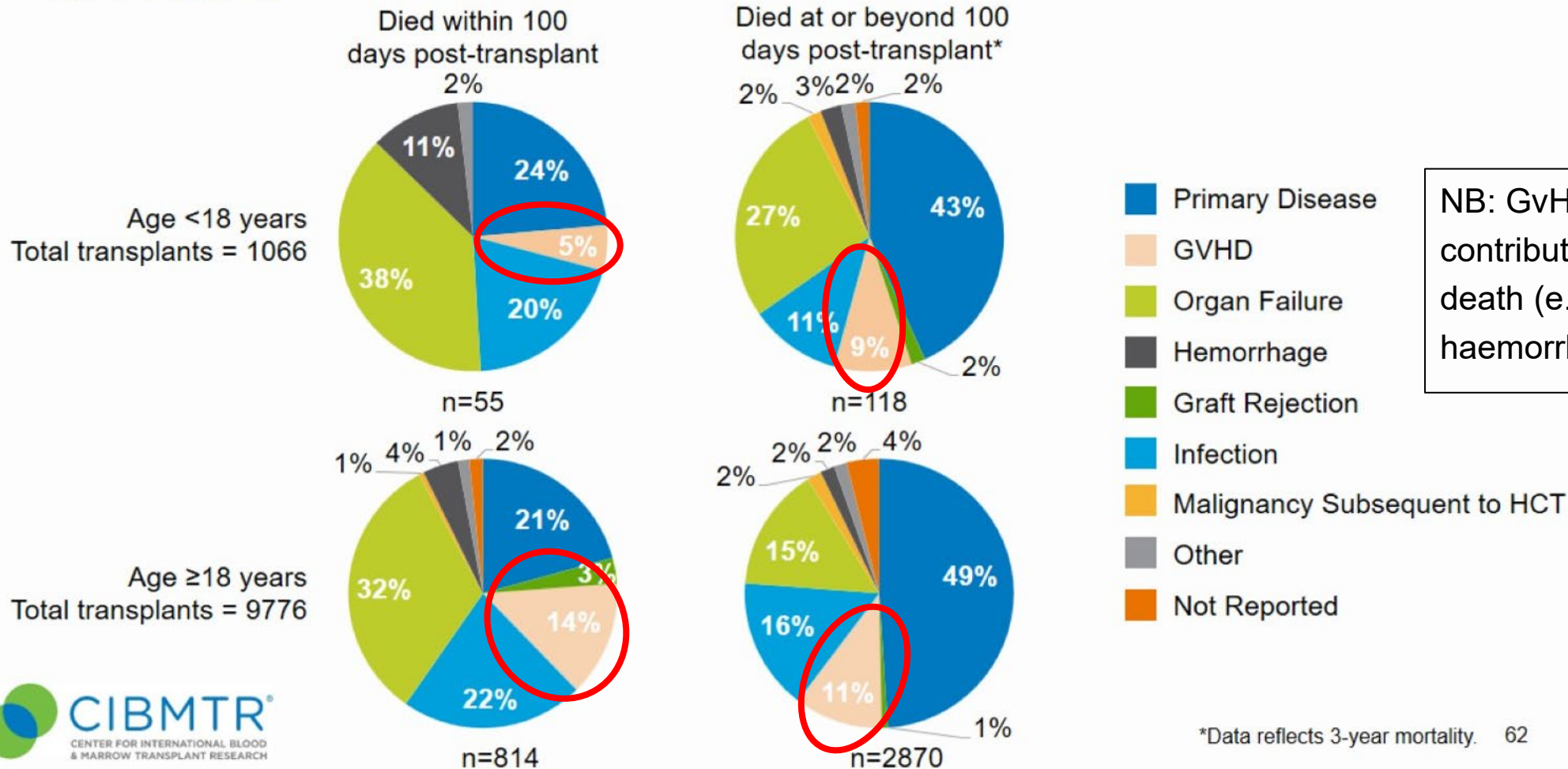
Graft versus host disease (GvHD)

- Allogeneic haematopoietic stem cell transplantation (HSCT) is potentially curative for conditions such haematological malignancies (e.g. lymphoma, leukaemia)
- However, GvHD arises in $\geq 30\%$ 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



GvHD is a significant cause of death after HSCT

Causes of Death after Matched Unrelated Donor HCTs in the U.S., 2018-2020

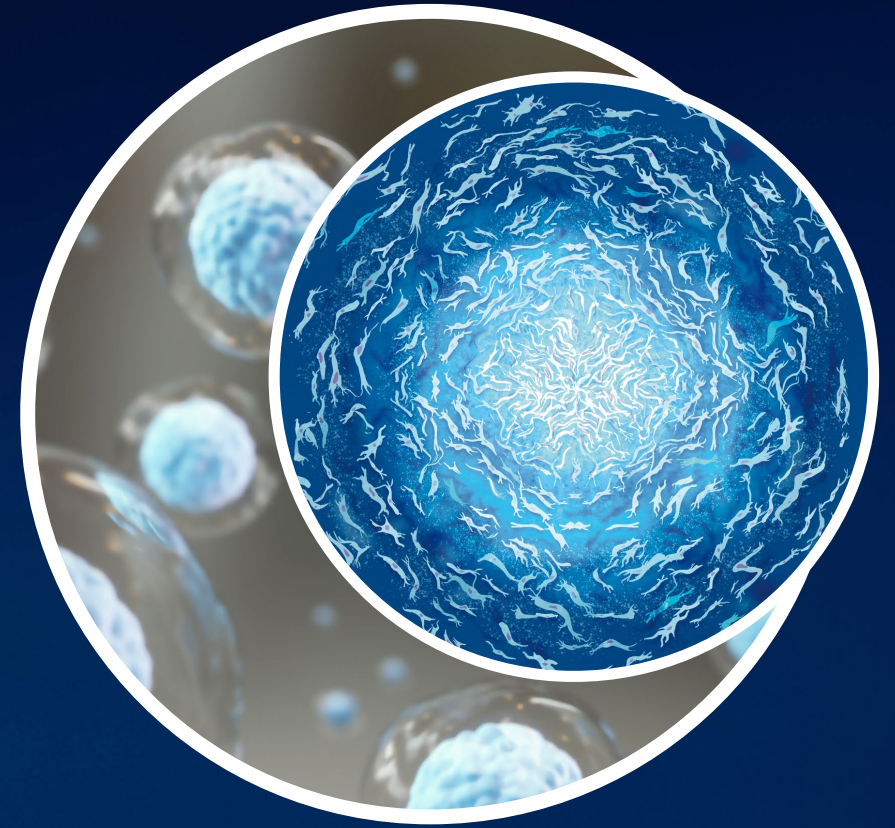


aGvHD treatment landscape

- 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

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 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>

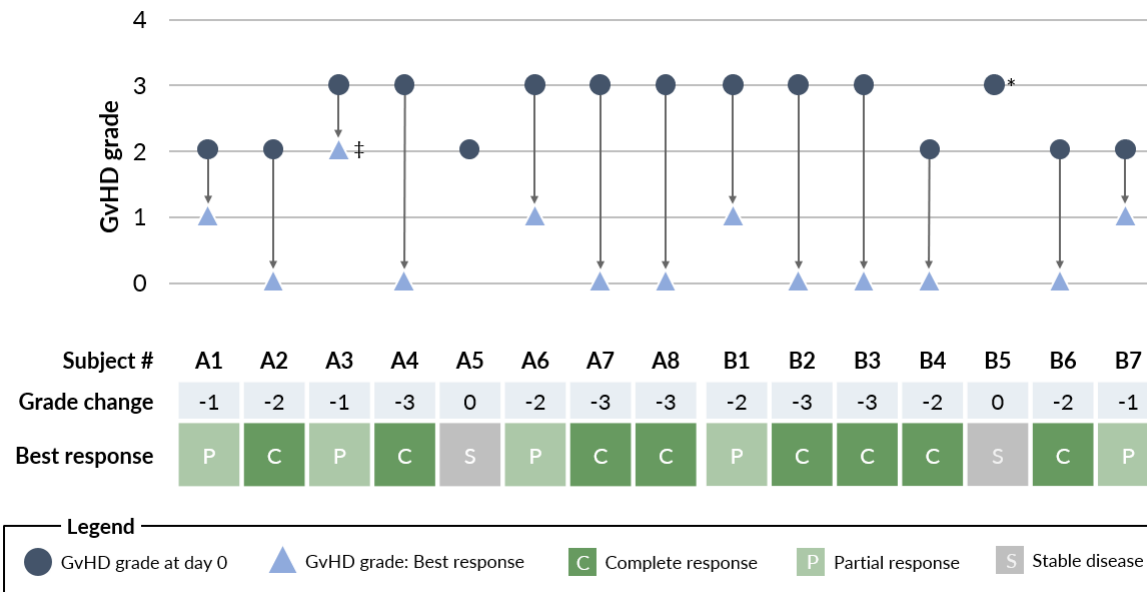
Two-year safety outcomes of iPS cell-derived mesenchymal stromal cells in acute steroid-resistant graft-versus-host disease

Kilian Kelly¹, Adrian J. C. Bloor², James E. Griffin³, Rohini Radia⁴, David T. Yeung^{5,6} & John E. J. Rasko^{7,8,9}✉

aGvHD | Phase 1 clinical trial - results

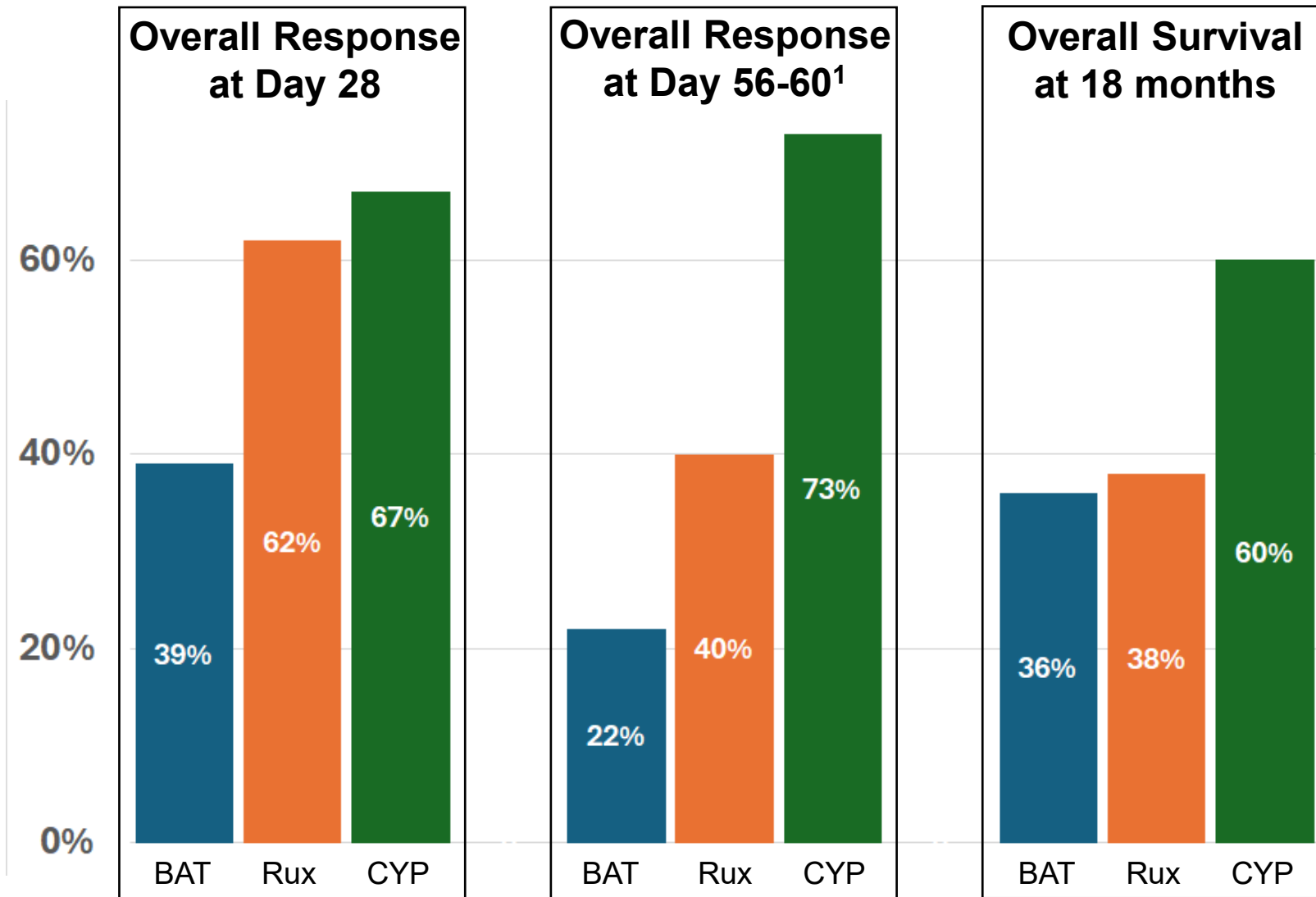
Product: CYP-001 (Cymerus™ MSCs for intravenous infusion)

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**

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



- Overall response rates for BAT and 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

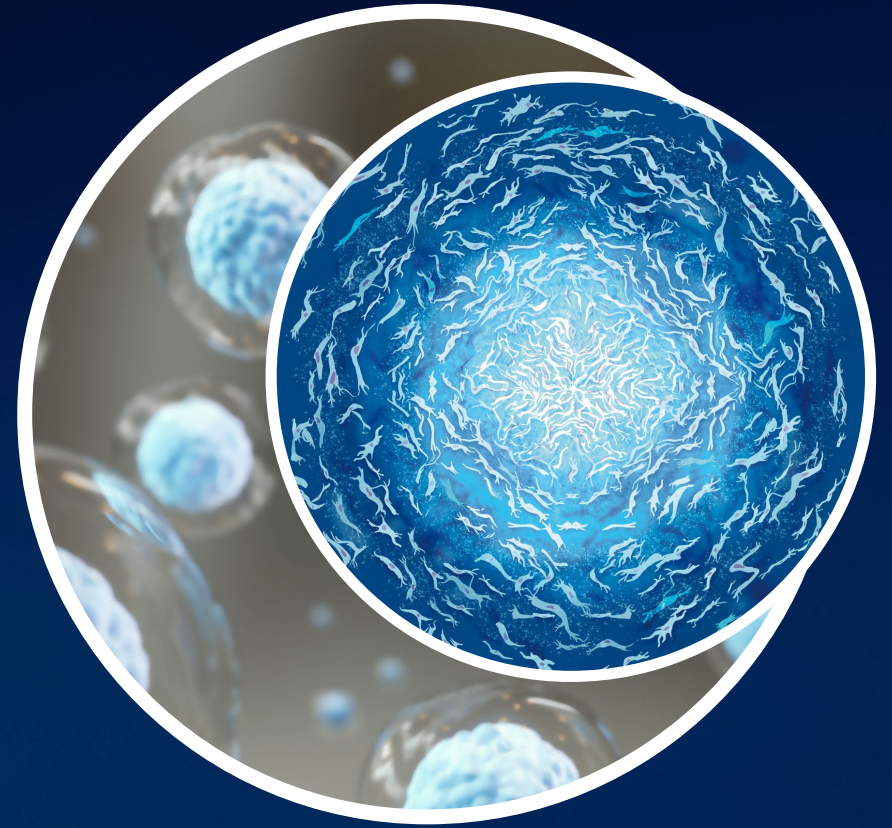
CYP = CYP-001 in study NCT02923375

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%

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

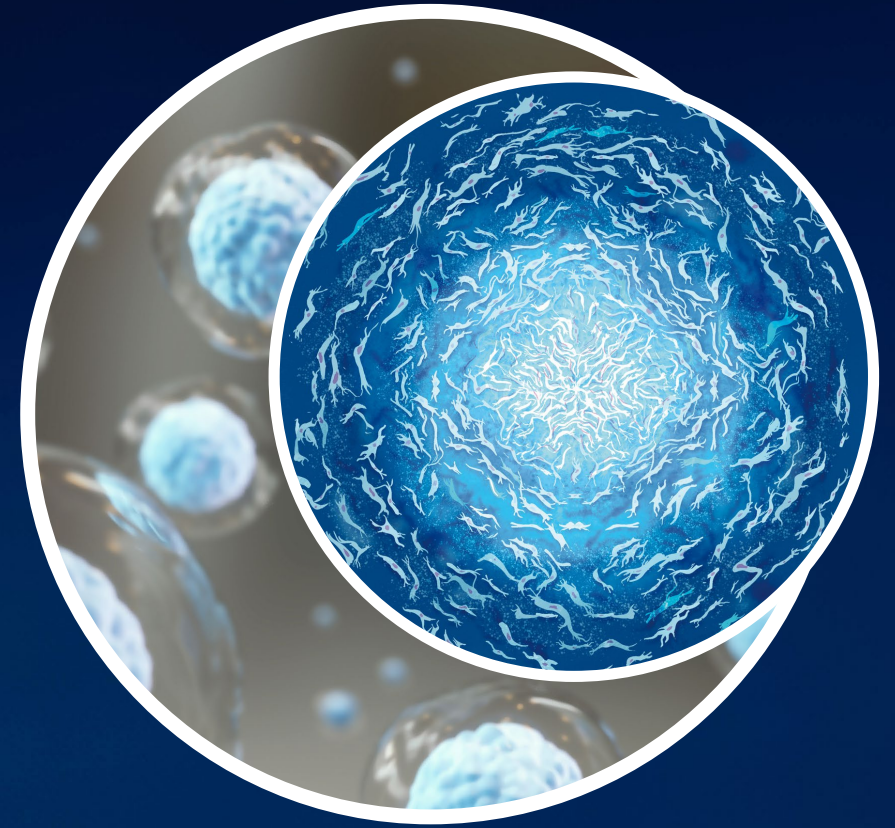
Phase 2 trial design

- 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:

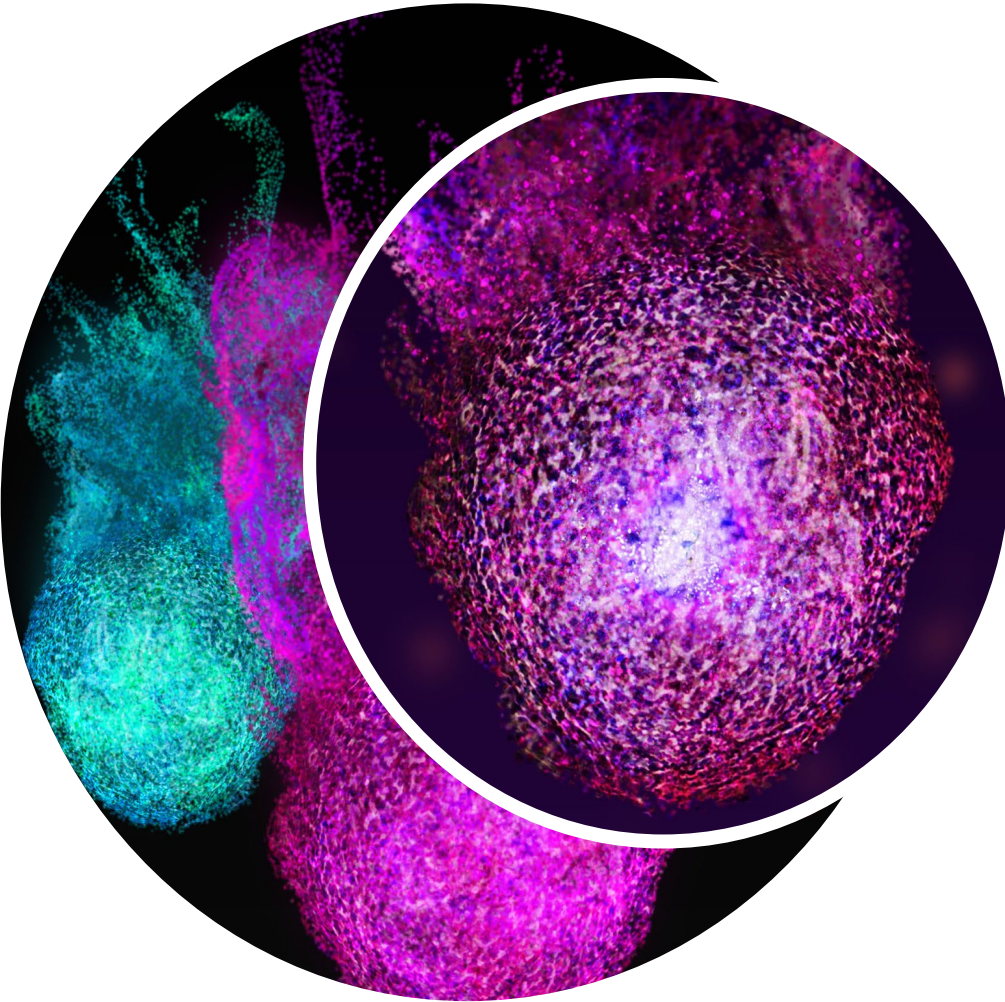
- GvHD
- Diabetic wounds
- Critical limb ischaemia
- Organ transplant rejection
- Osteoarthritis
- Respiratory disorders (including asthma, pulmonary fibrosis, acute respiratory distress syndrome)
- Sepsis
- Cardiovascular disorders (including coronary artery disease, myocardial infarction)
- Cytokine 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



Commercial partnering



Several distinct products in development → potential for multiple partnerships



Reinvestment of proceeds to maximise potential of the platform

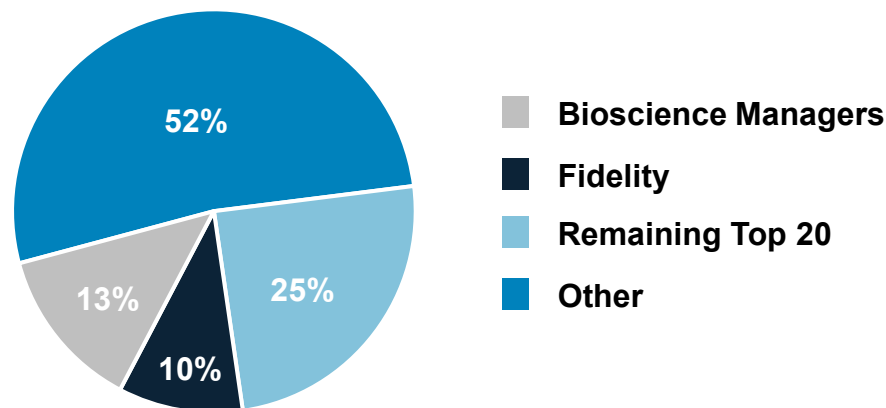


Platform also available to partners pursuing other indications and/or engineered MSC applications

Corporate overview

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

Shareholder distribution



Financial information

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

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.



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.

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

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

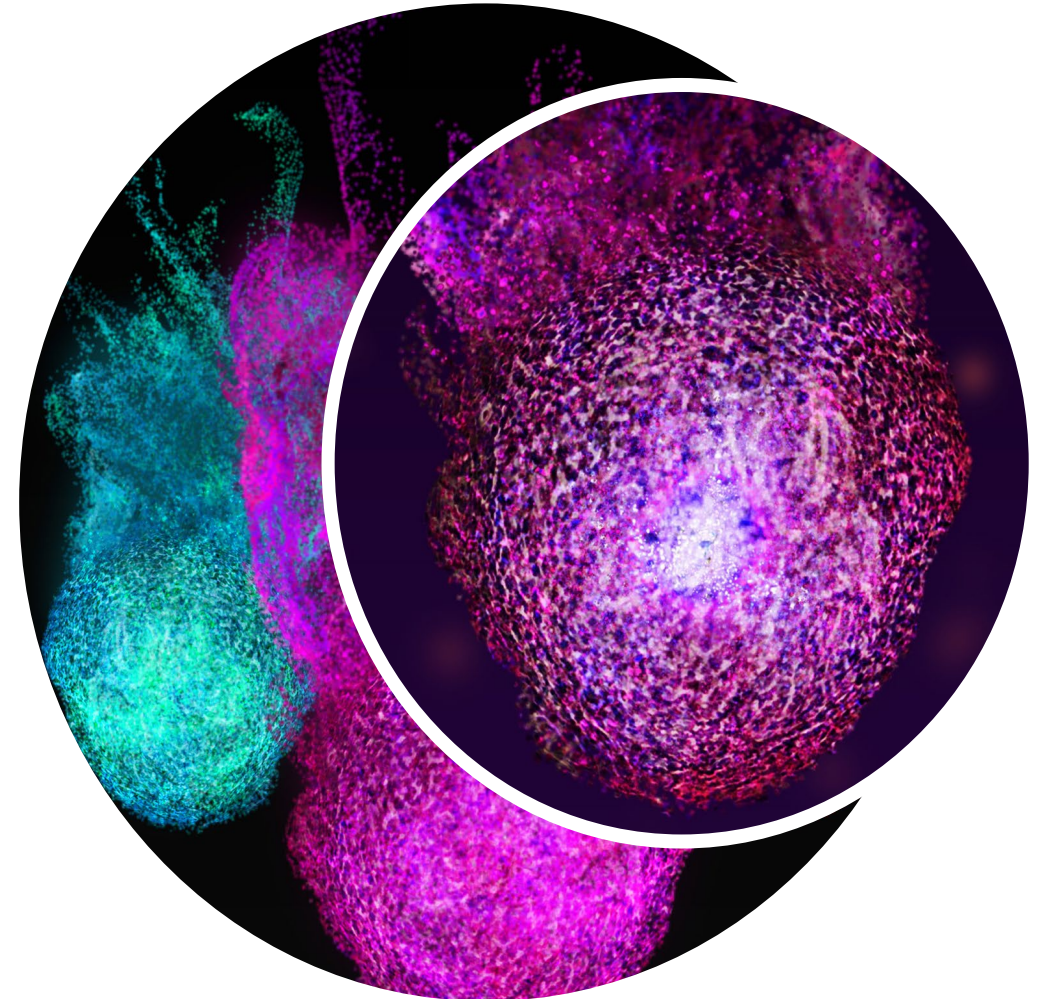
- Diabetic foot ulcer trial – results (potentially late 2024)

2H 2025

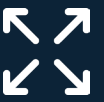




- aGvHD trial – results

1H 2026

- Osteoarthritis trial - results



Summary

 Next generation stem cell company	<ul style="list-style-type: none">• Leading platform technology in burgeoning stem cell sector• Diverse and highly credentialed leadership team with proven experience
 Scalable manufacturing	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• Global estimated market opportunity across targeted indications of ~US\$28bn¹• Focus on indications with significant unmet need• Proactive B-2-B outreach to drive partnering strategy



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