

ASX ANNOUNCEMENT

5 September 2024

Investor Webinar

Melbourne, Australia; 5 September 2024: Cynata Therapeutics Limited (ASX: “**CYP**”, “**Cynata**”, or the “**Company**”), a clinical-stage biotechnology company specialising in cell therapeutics, reminds shareholders that CEO and Managing Director, Dr Kilian Kelly, will host an investor webinar today, Thursday 5 September at 9:30am AEST.

Attendees are required to register in advance for the webinar – using the following link: https://us02web.zoom.us/webinar/register/WN_6EonNDzjQKG8-TXKkBc0Dg

Upon registration, attendees will receive a link to access the webinar.

A copy of the presentation to be delivered during the webinar is attached to this announcement.

-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.

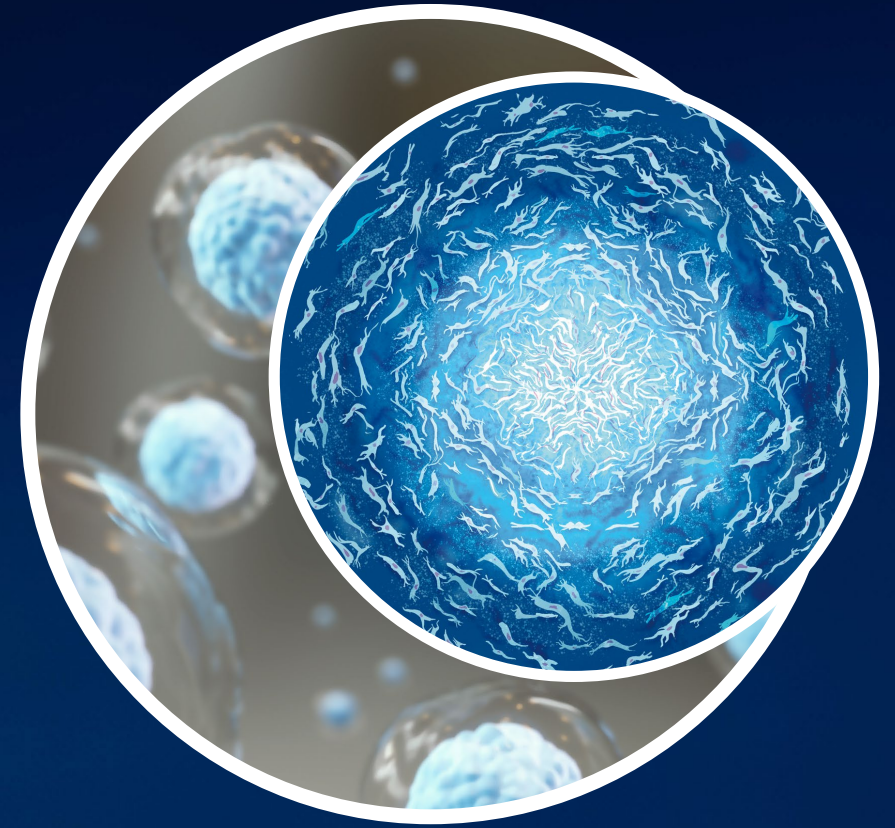
Cynata’s lead product candidate CYP-001 met all clinical endpoints and demonstrated positive safety and efficacy data for the treatment of steroid-resistant acute graft-versus-host disease (GvHD) in a Phase 1 trial. A Phase 2 clinical trial in GvHD under a cleared US FDA IND, as well as trials of Cymerus 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.



A Clinical Stage Next Generation Stem Cell Therapeutics Company

Investor Webinar
5 September 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 5 September 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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Company highlights

Revolutionary Cymerus™ manufacturing platform

- **Mesenchymal stem cells (MSCs)**¹ have shown potential to treat a wide range of illnesses²
- However, standard manufacture requires ongoing supply of donors → challenges with consistency, potency and scale
- The **induced pluripotent stem cell (iPSC)**-based Cymerus™ platform overcomes this major obstacle by enabling production of an **effectively limitless** number of **consistent** MSC doses **from a single blood donation**

Cynata is the leader of the burgeoning iPSC field

- **First completed iPSC clinical trial** worldwide
- **US FDA Orphan Drug Designation**³ and cleared **IND**⁴
- Compelling clinical data generated in **acute graft versus host disease (aGvHD)**⁵ and **diabetic foot ulcer (DFU)**⁶
- **Four active clinical programs** (including ongoing **Phase 2 & Phase 3** trials)
- **Three randomised controlled clinical trial readouts** upcoming between **late 2024** and **early 2026**

FY 2024 – a year of progress

Multiple clinical trials advanced

- Phase 3 osteoarthritis trial – patient enrolment completed in November 2023
- Global Phase 2 aGvHD trial – first patient enrolled in March 2024
- Phase 1 DFU trial – patient enrolment completed in April 2024
- New kidney transplant trial approved and ready to commence





Further encouraging clinical efficacy data

- Promising initial data from ongoing DFU trial released in February 2024
- Additional data from Phase 1 GvHD trial published in *Nature Medicine* in May 2024

Senior management team strengthened

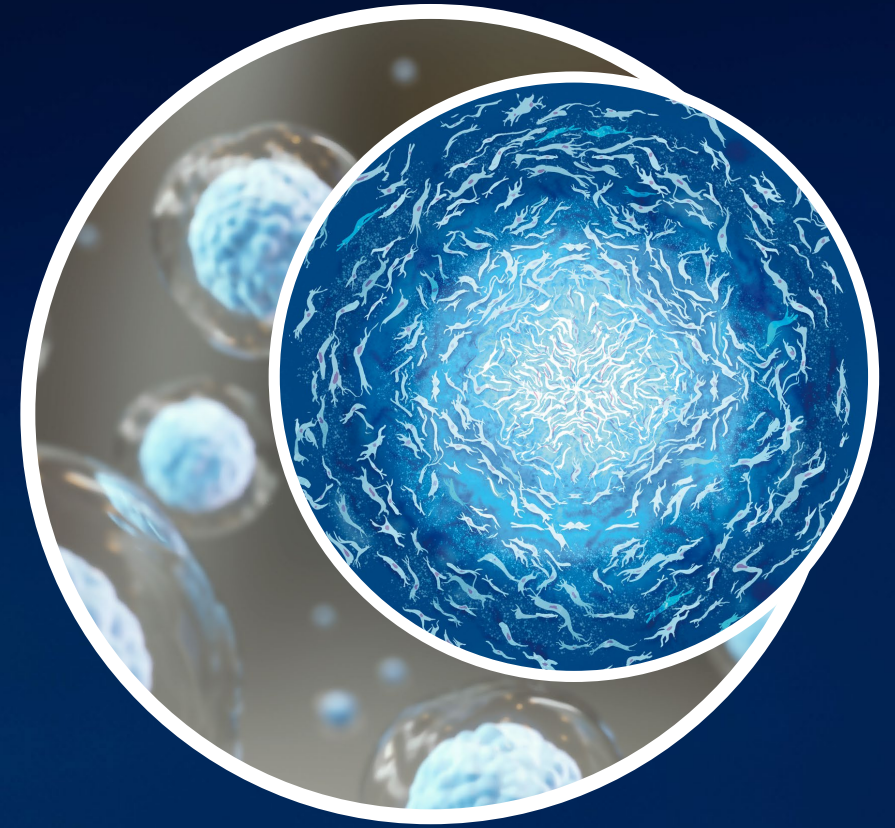
- Dr Mathias Kroll commenced in new position of Chief Business Officer in April 2024: position created to drive next stage of commercial growth

Advanced and diverse clinical pipeline

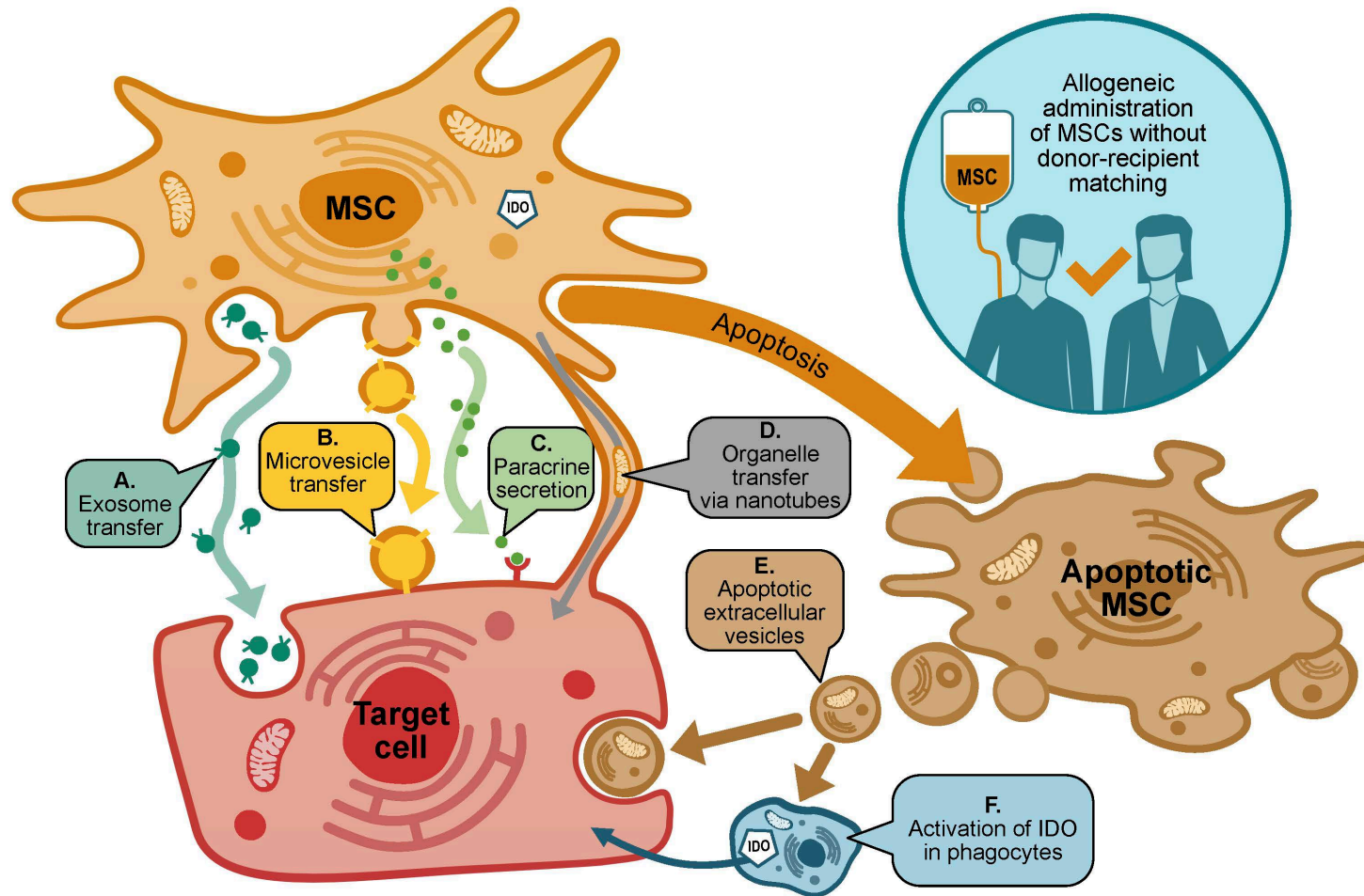
	Indication	Trial phase	Upcoming catalysts*	Market opportunity
Cynata Sponsored	 Acute Graft vs Host Disease (aGvHD) CYP-001 FDA Orphan Designation	Phase 2 ongoing	Enrolment completion – Q4 2024 Results – 2H 2025	US\$600m ¹
	 Diabetic Foot Ulcers (DFU) CYP-006TK	Phase 1 ongoing (enrolment complete)	Results – Q4 2024/Q1 2025	US\$9.6bn ²
Partnered	 Osteoarthritis (OA) CYP-004 <i>(managed by USYD, funded by NHMRC)</i>	Phase 3 ongoing (enrolment complete)	Results – 1H 2026	US\$11.6bn ³
	 Kidney Transplantation CYP-001 <i>(managed and funded by LUMC)</i>	Phase 1/2 approved	Enrolment start – Q3 2024 Cohort 1 results – Q1 2025	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

Revolutionary iPSC-based Cymerus™ Manufacturing Platform



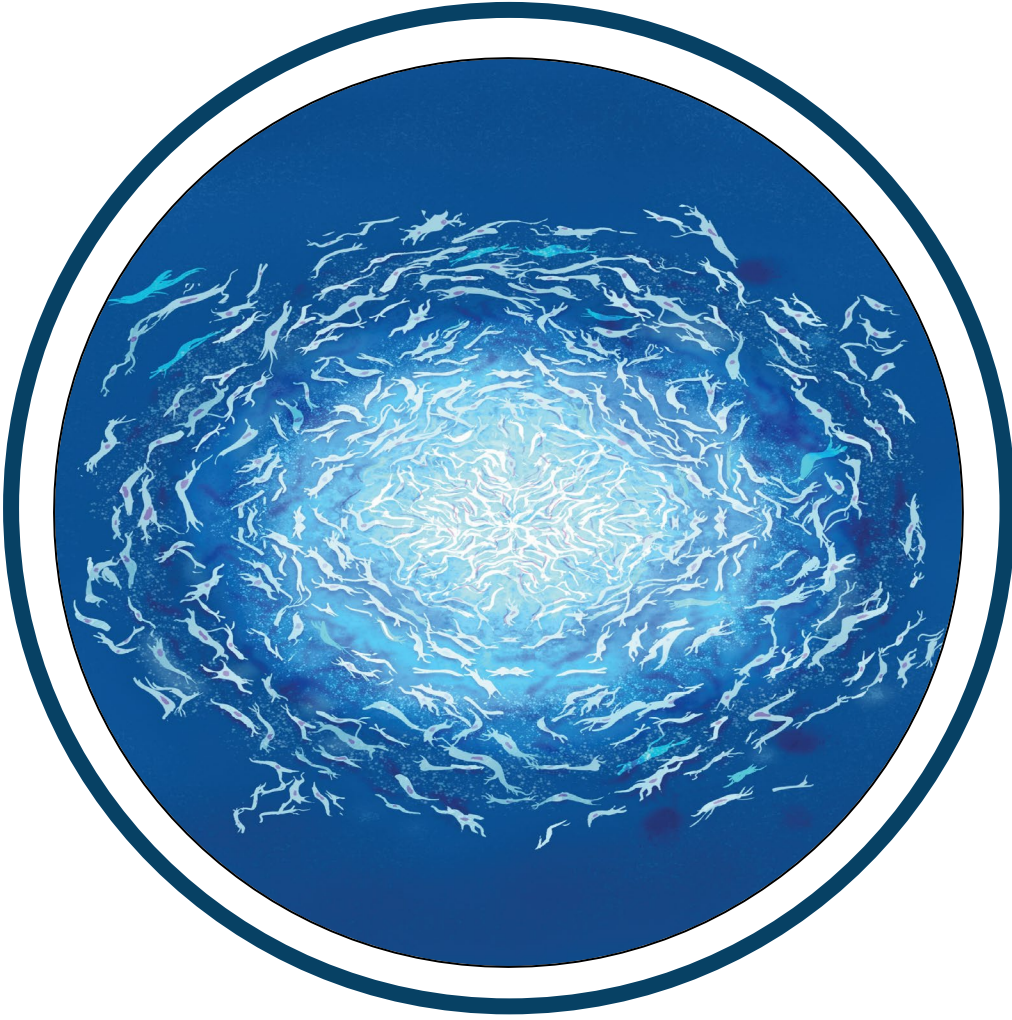
Therapeutic potential of MSCs



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

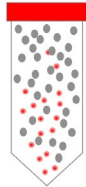
Conventional MSC process

Ongoing need for new donors



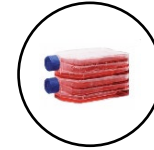
Substantial inter-donor **variability**

MSC isolation



Small number of MSCs per donation

Culture expansion



Extensive MSC culture expansion required

Major challenges:

- MSCs undergo **functional changes** and **loss of potency** during extensive culture expansion
- Continuously finding and testing new donors is **logistically challenging**
- Inter-donor **variability** – **inconsistent** activity in MSCs from different donors

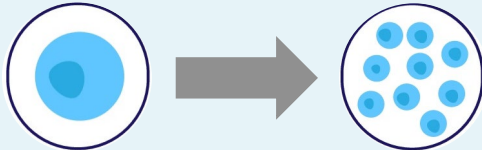
Cymerus™ iPSC-based process

One donor, one time



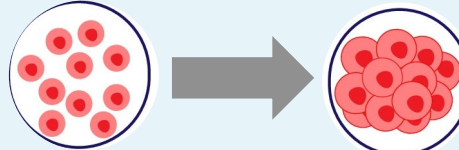
Avoids inter-donor variability

Reprogramming & iPSC expansion



Effectively limitless expansion potential

Differentiation into MSCs & culture expansion



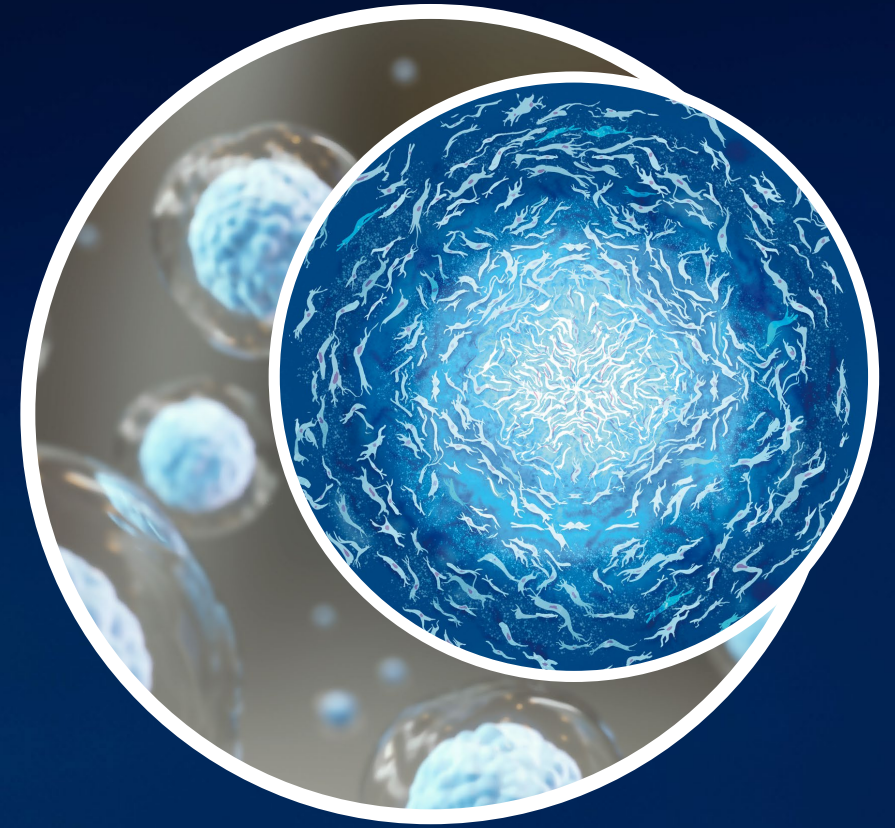
Minimal MSC culture expansion

Robust patent protection

Advantages of Cymerus™ platform:

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

Partnering Strategy



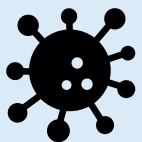
Commercial partnering



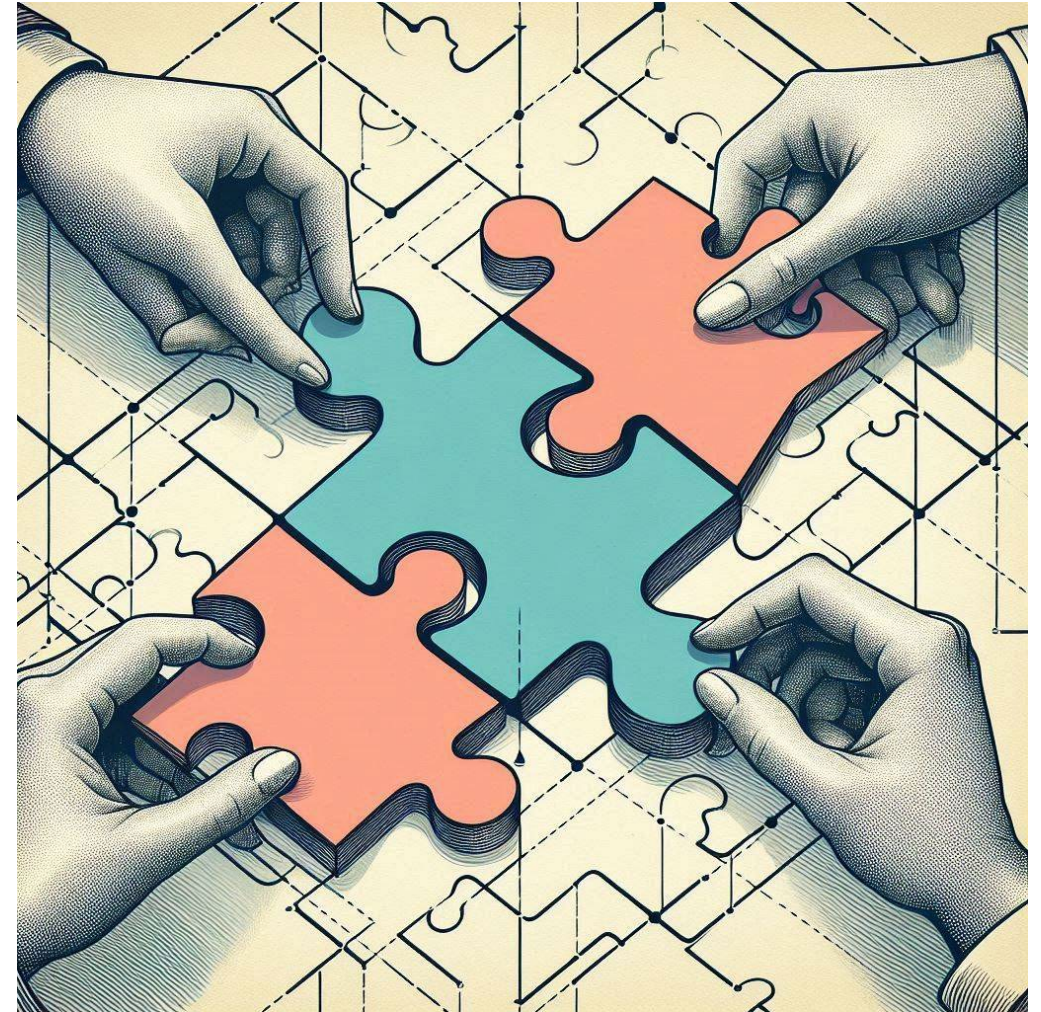
Commercial partnering potential underpinned by: (i) compelling clinical data; and (ii) scalable, commercial grade manufacturing platform



Several distinct products in development → potential for multiple partnerships



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



Industry connections

- We are enhancing our individual outreach to selected organisations, which will be accelerated by upcoming catalysts
- We attend leading conferences in our sector, to tell our story and open new discussions
- Following on from multiple events earlier this year (including Advanced Therapies, ISCT, BIO and bone marrow transplantation conferences), our six-month event outlook includes:



Alliance for Regenerative Medicine
Phoenix, October 2024

Company presentation and
partnering meetings



AusBiotech National Conference
Melbourne, October/November 2024

Chairing panel discussion on
iPSC opportunities



JP Morgan BioWeek/Biotech Showcase
San Francisco, January 2025

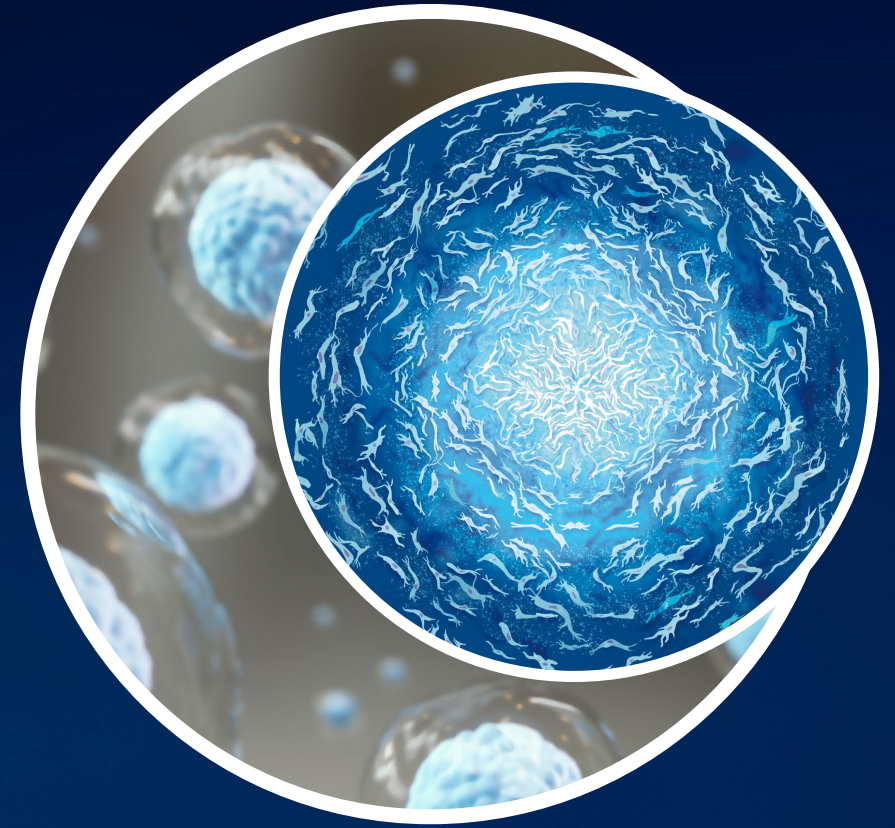
Company presentation and
partnering meetings



Advanced Therapies Congress
London, March 2025

Company presentation and
partnering meetings

Compelling Clinical Data: CYP-001 for aGvHD



CYP-001: Two *Nature Medicine* publications

- CYP-001 has been granted **Orphan Drug Designation** by the US FDA for the treatment of GvHD
- Phase 1 trial of CYP-001 was the first completed clinical trial worldwide with **any iPSC-derived product**



<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

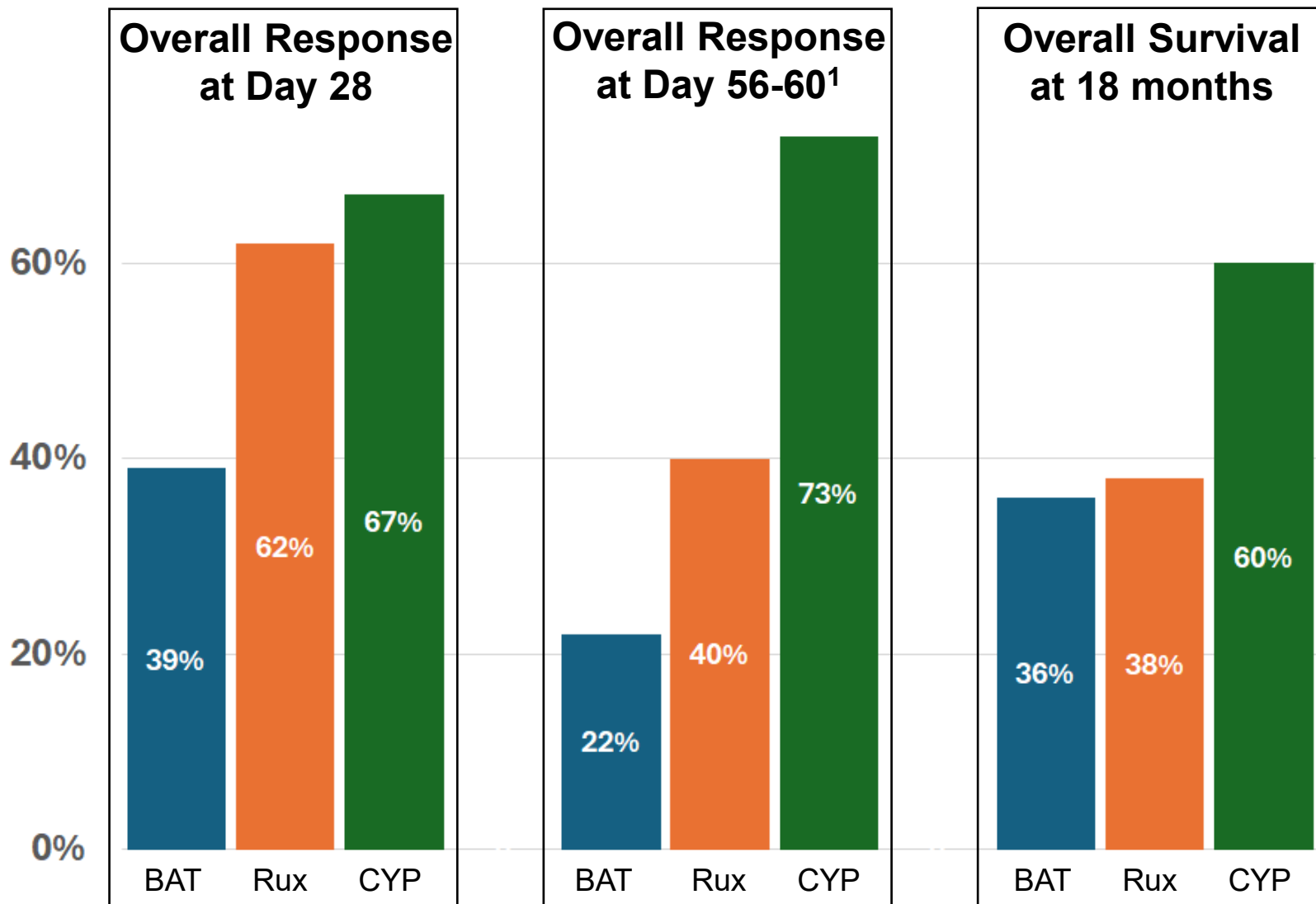
Nature Medicine 30, 1556–1558 (2024)

<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}

CYP-001 vs other treatments in SR-aGvHD



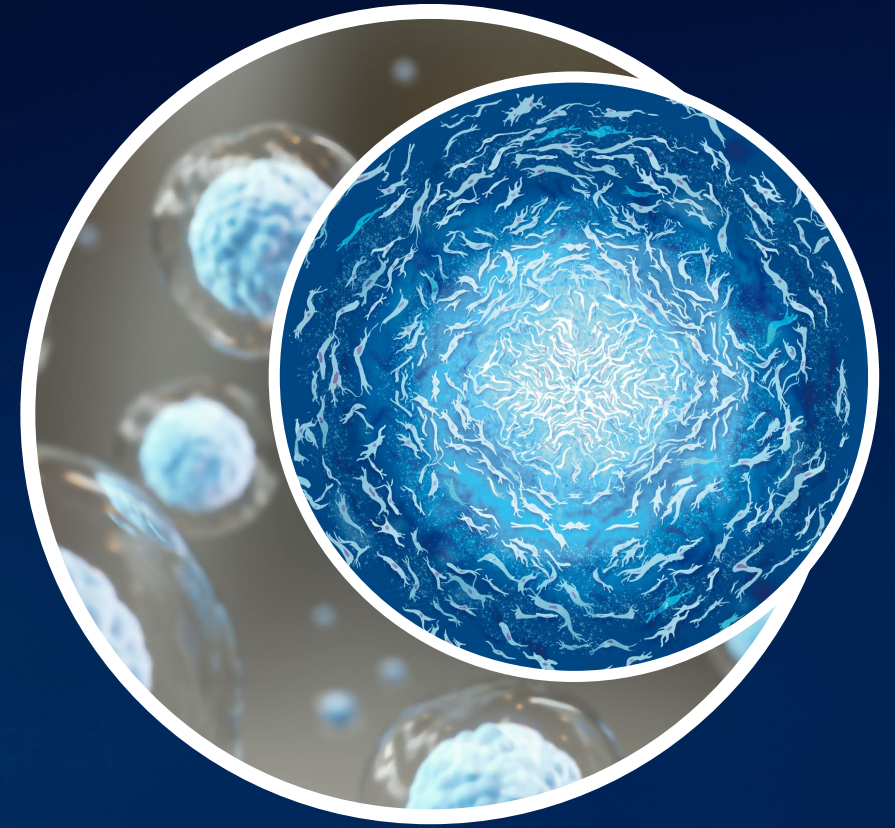
CYP = CYP-001 in Phase 1 trial (NCT02923375)

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)

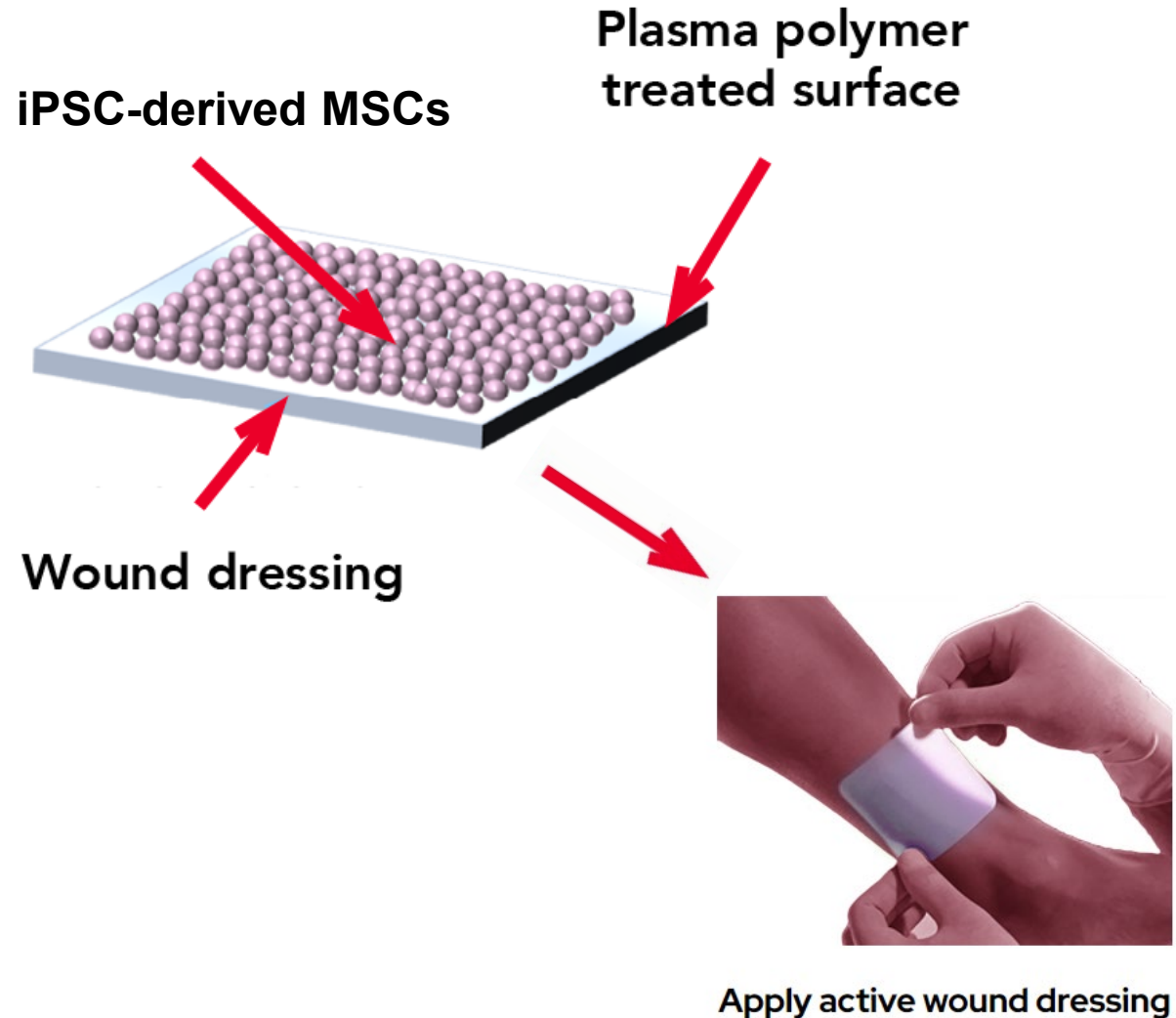
- Overall response rate for CYP-001 **increased** between D28 and D60
- Overall response rates for BAT and Rux **declined** between D28 and D56
- Overall survival rate for CYP-001 was **60%** at **both 18 and 24 months**
- Overall survival rates for BAT and Rux were **36%** and **38%** at **18 months**, and **not evaluable at 24 months**
- No serious adverse events/safety concerns related to CYP-001 identified, but **potentially serious adverse reactions to ruxolitinib are common**

CYP-006TK for DFU



CYP-006TK – a novel topical MSC product

- CYP-006TK utilises a proprietary surface-coating, optimised for the delivery of MSCs directly to the wound bed
- Technology exclusively licenced to Cynata by Tekcyte Limited (agreement for Cynata to acquire this IP outright announced 1 July 2024)



DFU | Phase 1 clinical trial – initial data

Product: CYP-006TK (topical Cymerus™ MSC wound dressing)

- Ongoing trial in non-healing diabetic foot ulcer (DFU)
- Patients randomised to receive standard of care (SoC) or CYP-006TK for 4 weeks, followed by SoC
- In the first 16 patients enrolled in the trial (8 per group), after 10 weeks' follow-up, the median reduction in wound surface area was:
 - **87.6%** in the active CYP-006TK group
 - compared to **51.1%** in SoC group

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

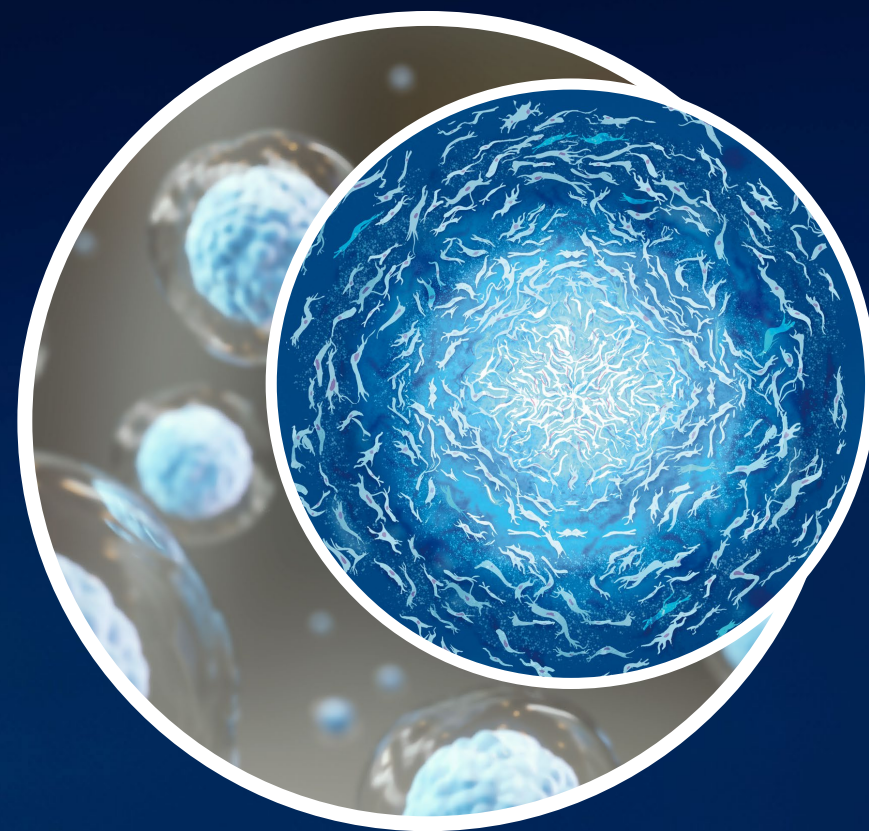
Day 0



Day 28

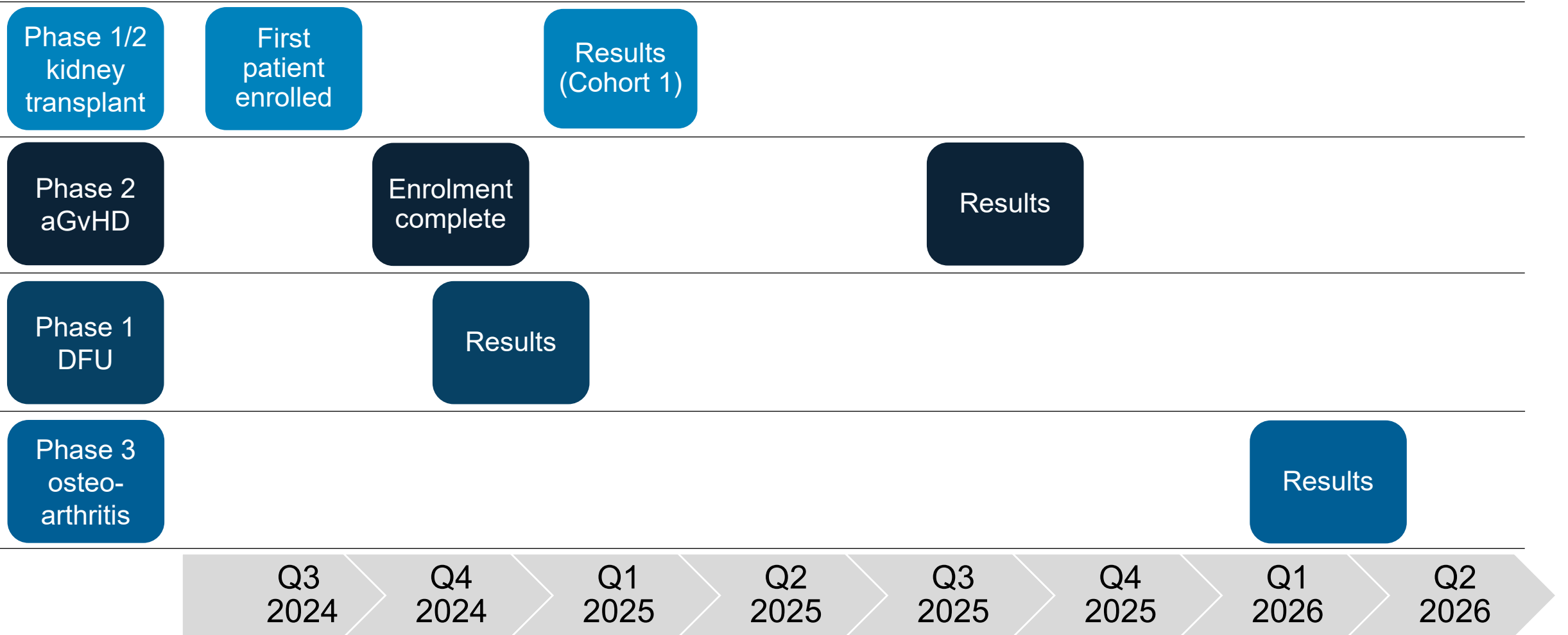


Outlook



Upcoming catalysts*

Results of three randomised controlled clinical trials expected between late 2024 and early 2026



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 kidney transplantation clinical trial imminent



Significant growth potential

- 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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