A Next Generation Stem Cell Therapeutics Company

Investor Presentation: Cynata Therapeutics Limited
June 2020

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Cynata Therapeutics is a clinical stage biotech with a highly scalable, proprietary platform for developing stem cell therapeutics

Our focus

Utilise our proprietary Cymerus™ platform technology to develop commercially scalable cellular therapeutic products to treat serious chronic disorders

About Cynata Therapeutics

- Cynata is an Australian stem cell and regenerative medicine company that is developing a therapeutic stem cell platform technology, Cymerus, using discoveries made at the University of Wisconsin-Madison
- Cynata has licensed its first product, CYP-001 for graft-versus-host-disease (GvHD) to Fujifilm, with the intention to license Cymerus technology across a range of serious disorders
- Cynata's proprietary Cymerus technology addresses a critical shortcoming in existing methods of production of mesenchymal stem cells (MSCs) for therapeutic use, which is the ability to achieve economic manufacture at commercial scale

Financial information

Share price (9-June-20)	A$0.665
Shares on issue	117m
Market capitalisation[1]	A$77.8m ~(US$53m)
Cash[2]	A$15.2m
Debt	-
Enterprise value	A$62.6m

Top shareholders

Fidelity INTERNATIONAL	9.9%
FUJIFILM	7.4%
Board and management	5.8%

1. USD/AUD = 1.46; 2. Cash incorporates A$6.9m as at 31 Mar 2020, adjusted for the A$3.55m Placement announced 22 Apr 2020 and A$4.8m SPP announced 27 May 2020

Recent Developments: Optimising clinical programs

Ethics approval for COVID-19 clinical trial

- Accelerated planning and rapidly achieved ethics approval
- MEND[1] clinical trial will build on Cynata's strong pre-clinical results in ARDS, sepsis and CRS, all of which are common hallmarks of severe COVID-19 cases

Building on strong pre-clinical results

FUJIFILM partnership driving GvHD Phase 2

- FUJIFILM endorsement via license validates Cymerus platform; Fuji funding development and commercialisation
- Phase 2 GvHD clinical trial expected end 2020

Fully funded GvHD product development

Progressing clinical development

- Osteoarthritis 440 patient Phase 3 clinical trial approved; funded by the NHMRC
- CLI Phase 2 clinical trial approved by MHRA
- COVID-19 Phase 2 approved

Multiple Phase 2/3 ready indications

Active commercial discussions ongoing

1. MEND = MEseNchymal coviD-19 trial

MSCs have potential utility in complications arising from a COVID-19 infection

- **Increased global interest** in the potential of MSCs to treat complications of COVID-19, **representing external validation and early studies demonstrating potential utility**[1]
- COVID-19 is a respiratory virus that in some patients causes severe complications, **particularly involving the lungs**
- **ARDS and sepsis, together with cytokine release syndrome (CRS), are the leading causes of death in COVID-19 patients**
  - **ARDS** is an inflammatory process leading to build-up of fluid in the lungs and respiratory failure; ARDS makes up ~10% of all ICU admissions and almost 25% of patients requiring mechanical ventilation[2]; death occurs in more than one-third of patients
  - **Sepsis**, commonly referred to as blood poisoning, is an over-reaction of the immune system to infection, leading to ~6m deaths every year[3]
  - **CRS** is a systematic inflammatory immune response, with reactions ranging from mild to life threatening
- Cynata has generated compelling data from pre-clinical studies investigating the potential of its MSCs in these indications, as they each represent significant unmet needs with **broader applications to Cynata's clinical development beyond COVID-19**

Cynata plans to leverage recent increased interest to accelerate its development program and validate its technology for multiple indications and in multiple regions

Note: MSCs are not inherently antiviral and are not a vaccine.
1. Leng, G. et al., Aging & Disease, 11: 216 April 2020; 2. Bellani G,, et al.. Jama. 2016;315(8):788.E 3. Not COVID-19 induced deaths (Source: World Health Organization)

Cynata's COVID-19 clinical development program is underpinned by strong pre-clinical and clinical results

Cynata's data supports utility of Cymerus MSCs, confirming that they:

- Significantly reduce levels of pro-inflammatory cytokines
- Increase both anti-inflammatory proteins and regulatory T cells
- Have a strong safety profile

Compelling pre-clinical results in diseases which can arise from a COVID-19 infection:

ARDS

Study demonstrated effectiveness of Cymerus MSCs in acute respiratory distress syndrome (ARDS)

Sepsis

Results show that Cymerus MSCs are highly effective in a model of pneumonia induced sepsis

CRS

Model demonstrated Cymerus MSCs significantly ameliorate the effects of cytokine release syndrome (CRS)

Cynata is now engaging with multiple parties, and considering collaboration and partnering opportunities as they arise

MEND trial | Overview of Phase 2 clinical trial COVID-19 patients

Target population

- 24 adult patients with COVID-19 admitted to intensive care with compromised lung function, which can ultimately progress to ARDS

Rationale for selection

- Respiratory distress (+ CRS and sepsis) represent significant unmet needs as consequence of a severe COVID-19 infection, as well as other causes beyond COVID-19
- Strong pre-clinical results in indications that can arise from a severe case of COVID-19
- Increased market interest, allowing accelerated program planning and approval

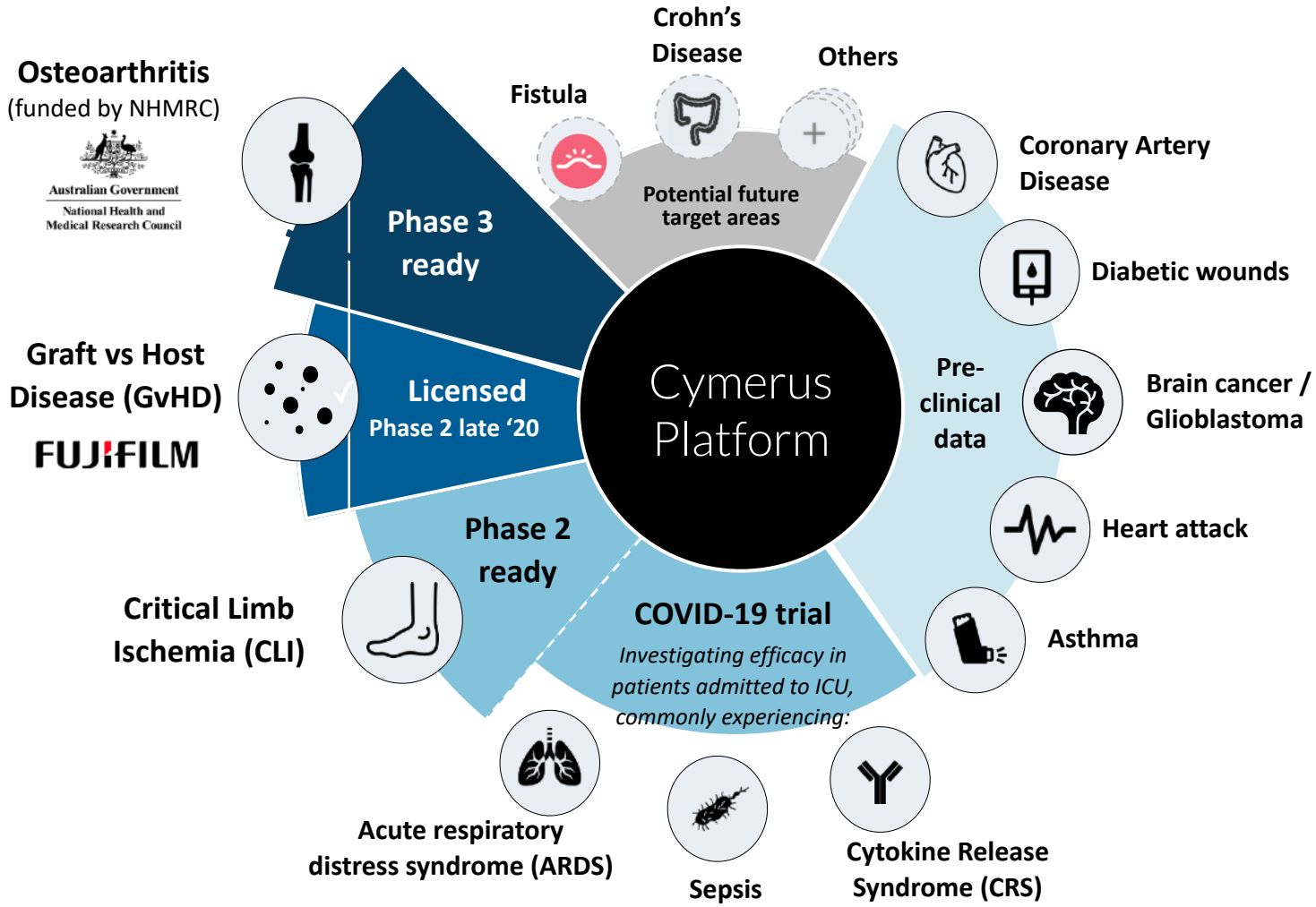
Preliminary program design

- In collaboration with CPA Research Institute[1] and COVID-19 Stem Cell Treatment Group
- Open-label, randomised controlled clinical trial based in NSW, Australia
- Twelve patients randomised to receive Cymerus MSC infusions with standard care; twelve patients randomised as the control group, to receive current standard of care
- Primary endpoints: an improvement in PaO_2/FiO_2 ratio, and safety & tolerability

Key milestones

- Ethics approval obtained
- Recruitment expected to commence subject to finalisation of relevant agreements with study centres
- Cynata assessing opportunities to expand this program to other jurisdictions

Cynata's Cymerus platform has potential applications across a wide range of diseases



Cynata is targeting significant market opportunities

TARGET AREA	TRIAL PHASE	MARKET OPPORTUNITY
Osteoarthritis (OA)[1]	Phase 3 ready	US$11.6 bn
Graft vs. Host Disease (GvHD)[2]	Phase 2 ready	US$0.3 bn
Critical limb ischemia (CLI)[3]		US$1.4 bn
Acute respiratory distress syndrome (ARDS)[4]	COVID-19 Phase 2 program	US$2.5 bn
Cytokine Release Syndrome (CRS)[5]		US$4.5 bn
Sepsis[6]		US$5.9 bn
Other *Asthma, Heart Attack, CAD, Brain Cancer / Glioblastoma, Diabetic Wounds*	Pre-Clinical	US$15.3 bn

1. Persistence Market Research 2018 research report: "Osteoarthritis Treatment Market: Global Industry Analysis (2012-2016) and Forecast (2017-2025). 2. Fujifilm's estimate of the peak annual global sales opportunity. 3. ClearView's estimate of the peak annual global sales opportunity. 4. Vasomune Therapeutics company announcement, 2018 (Reflects total global market opportunity in 2018) 5. Evaluate Pharma, 2017 (Reflects total global market opportunity in 2022); 6. GlobalData 2017 (Reflects total global market opportunity in 2026)

Cynata is well placed amid expected MSC marketing approvals globally

~30 Phase 3 trials with MSC-based therapies currently active

Indications include:

- Heart failure
- Heart attack
- Stroke
- Type II diabetes
- Degenerative disc disease
- Peripheral artery disease
- Diabetic foot ulcer
- Non-healing fractures
- Chronic GvHD
- Chronic obstructive pulmonary disease
- Crohn's disease

Cynata is uniquely placed in the MSC-based therapy market

Many ongoing Phase 3 trials involve very common conditions, representing **multi-billion** dollar market opportunities

Approvals in any of these indications will significantly **increase Big Pharma's interest** in MSCs

Demand for large quantities of product will focus attention on the **major manufacturing challenges** associated with conventional production methods

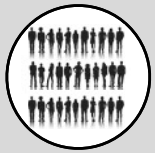
Cynata's uniquely scalable and consistent process is ideally placed to solve these manufacturing challenges

Conventional vs. Cynata's Cymerus MSC manufacturing process

Current conventional MSC manufacturing process is impractical

Cells donated → **Conventional process** → **MSCs**

Cells from multiple donors



Substantial variability in starting material

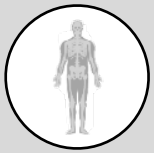
MSC isolation

Limited quantity of MSCs produced per donation

MSC expansion

Large number of MSCs required

Cellular therapies administered



8-12 infusions per patient[1]

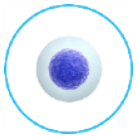
Cynata's Cymerus iPSC-derived process optimises manufacturing for scalability

Cells donated → **Cynata's patented process: Cymerus™** → **MSCs**

Cells from **one** donor

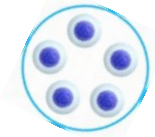
Avoids inter-donor variability

iPSC Derivation



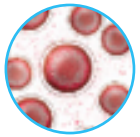
Consistency

iPSC Expansion



Effectively limitless expansion

Precursor cells



Quantity

Generation of MCA Colonies

Differentiation into MSCs

Minimal MSC culture expansion

Quality

Cellular therapies administered

Only 2 infusions per patient[1]

Efficiency

iPSC: Induced Pluripotent Stem Cells. iPSC's derived directly from adult cells and can propagate indefinitely.
MCA: Mesenchymoangioblasts. These are produced from iPSCs.

1. In GvHD clinical trials/practice

Cynata has the only platform in the world able to produce commercial quantities of MSCs from a single source

	Conventional process	Cymerus™	*Significance for Cynata*
Donors	Continuous supply of new donors required	One donor, one time *(completed)*	✓ *Lower cost; simplified logistics; highly consistent product*
Comparability testing	Required every time a new donation is used	N/A	✓ *Lower cost, minimised risk*[1]
Number of clinical doses per donation	Significantly limited	Effectively limitless	✓ *Lower cost; simplified logistics; comparative ease of scalability*
Extent of MSC expansion	High (>25 population doublings)	Low (10 population doublings)	✓ *Minimised expansion and low "age" ensures Cynata 's product is consistently highly potent, with potency maintained*[2]
Cellular "age"	Variable	Low: iPSC-derived MSCs are more primitive	
Infusions per patient	8-12	~2	✓ *Greater convenience for patients and hospitals; lower costs incurred by healthcare system*
Risk of contamination[3]	Medium to high, depending on process	Negligible	✓ *Lower risk of adverse reaction in patients; significant regulatory benefit*

Cymerus produces a consistent and scalable product, with lower cost of goods on a per cell basis and fewer cells required per patient compared to conventional methods

1. MSC product from different donors must be proven to be the same: highly risky given every donor is different
2. Conventional manufacturing process requires extensive MSC culture expansion. MSCs change when excessively when expanded, causing a loss of potency and decreased efficacy
3. Contamination with off-target cell types – isolation of MSCs in original sample is associated with risk of carry-over of other cell types

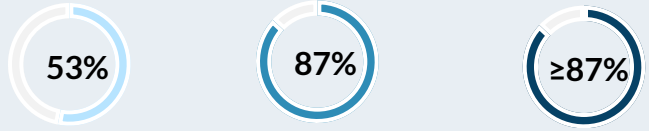
World-first allogeneic iPSC-derived cell therapy clinical trial in steroid-resistant acute GvHD completed, with compelling results

Phase 1 Clinical trial design

Target population	▪ Adults with steroid resistant acute graft-versus-host disease (GvHD) ▪ Donor's immune cells in a transplant (graft) react against and damage the patient's tissues (host)
Trial design[3]	▪ Read outs on day 28 and 100 ▪ Cohort A (n=8): *1x10⁶ cells/kg on Day 0 and Day 7[1]* ▪ Cohort B (n=7[4]) : *2x10⁶ cells/kg on Day 0 and Day 7[2]*

Key clinical trial results

All endpoints achieved



Efficacy endpoints	▪ Endpoints were the **same as those required in a Phase 3 trial** (in contrast to early stage trials for some conditions)
High response rates	▪ Response rates were **higher than what we expect would be required in Phase 3**, to support marketing approval

No treatment-related serious adverse events or safety concerns were identified

1. Max 1x10⁸ cells. 2. Max 2x10⁸ cells 3. Note: late stage trials in this condition do not necessarily involve large numbers (for comparison - recently completed Phase 3 trials in Japan / US have involved just 25 and 55 patients, respectively). 4. One patient withdrew from trial prior to dosing; trial was intended to have 8 participants

Successful clinical data places Cynata in a strong position

Successful study data → Accelerates clinical development

Demonstrating efficacy of our technology platform

- ✓ **Successful clinical results;** all endpoints achieved in Phase 1 GvHD clinical trial, with strong safety profile
- ✓ **Successful pre-clinical data in multiple indications;** provide rationale for further development
- ✓ **Endorsement by FUJIFILM** of Cynata's Cymerus platform via GvHD license supports the continued commercialisation of Cynata's cell therapeutic products in other indications

Unlocks multiple indications and an accelerated clinical development pathway

- Successful safety results from GvHD trial enables **future indications to bypass Phase 1**
- **Clinically meaningful findings validate progress** to multiple Phase 2 trials across multiple indications
- Indications now **Phase 2 trial ready include GvHD and CLI; Phase 3 ready include osteoarthritis**
- Pre-clinical studies demonstrating attractive results in other indications present a **broad range of opportunities for future clinical trials**

Cynata is executing on a clear scientific and commercial vision and continually assesses pathways to optimise shareholder value

Multiple options to create shareholder value

Build value in platform independently
(e.g. continue running clinical trials)

License / partner with big Pharma to develop specific target areas
(e.g. Fujifilm license for GvHD)

Strategic exit/merger
(e.g. Strategic acquirer)

FUJIFILM case study

- ✓ **Exclusive global licence in GvHD**
- ✓ **Multiple cash flow events:**
  - **A$4m** equity @ 35% premium
  - **A$100m+** in upfront license fee & potential milestone payments and royalties[1]
    - **A$2.86m** on completion of planned Phase 2
- ✓ **Represents a major endorsement by Big Pharma**
- ✓ **All development costs met by FUJIFILM**
- ✓ **Ongoing relationship with potential for further commercial agreements**

FUJIFILM transaction provides validation of the Cymerus platform and supports the licensing of additional target areas

1. $1 AUD = $0.7 USD

Investment Summary

Scalable, globally applicable technology	▪ Cymerus platform technology enables commercial-scale production of mesenchymal stem cells ▪ Fully patented process overcomes multiple issues with today's on-market solutions ▪ Value of platform to a range of diseases demonstrated across clinical and pre-clinical studies
Attractive licensing business model	▪ A 'hub and spoke' model: intention to license Cymerus technology across a range of target areas with Cynata in active commercial discussions with multiple parties ▪ Licence granted to FUJIFILM for GvHD on attractive terms, including A$100m+ in milestone payments, royalties on product sales, and FUJIFILM responsible for further product development
Successful clinical trial results	▪ All clinical endpoints achieved in trial of Cymerus MSCs in GvHD, with no safety concerns identified and highly encouraging efficacy ▪ FUJIFILM endorsement supports further development of Cynata's products in other indications
Clear pipeline of high potential target areas	▪ Multiple Phase 2 clinical trials with preparations underway to commence in 2020: COVID-19; GvHD (via FUJIFILM license); critical limb ischemia (CLI) ▪ Phase 3 Osteoarthritis trial (funded by NHMRC) preparations underway to commence in 2020 ▪ Compelling pre-clinical data in other high-value target areas supports further clinical trials
Well positioned in regenerative medicine	▪ Cell therapeutics is an area of increasing interest from major pharmaceutical companies ▪ Global market opportunity of US$1.4bn for CLI and US$11.6bn for OA ▪ Cynata's unique Cymerus technology ideally placed to solve current MSC manufacturing challenges

Thank you for your attention

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Appendix

Globally experienced board and management team

Dr Paul Wotton
Chairman

- CEO, Obsidian Therapeutics
- Former CEO of Ocata Therapeutics (NASDAQ: OCAT) acquired by Astellas Pharma, in a US$379m transaction
- Previous executive roles with Antares Pharma Inc. (NASDAQ: ATRS), Topigen Pharmaceuticals and SkyePharma
- Founding CEO, Sigilon Therapeutics; board member of Vericel Corp and Veloxis; past Chairman of the Emerging Companies Advisory Board of BIOTEC Canada

Expertise running and monetising Ocata Therapeutics, acquired by Astellas

Dr Ross Macdonald
Managing Director / CEO

- 30 years' experience and a track record of success in pharmaceutical and biotechnology businesses
- Previous senior management positions with Hatchtech, Sinclair Pharmaceuticals, Connetics Corporation (Palo Alto, CA), and Stiefel Laboratories, the largest independent dermatology company in the world and acquired by GSK in 2009 for £2.25b

Track record of success in pharmaceutical and biotechnology businesses

Dr Stewart Washer
Non-Exec Director

- 20+ years of CEO and Board experience in medical technology, biotech and agri-food companies
- Exec Chairman of Emerald Clinics, Chairman of Orthocell Ltd, Director of Botanix Ltd and Zelda Therapeutics Ltd
- Previously CEO roles with Calzada (ASX:CZD), Phylogica (ASX:PYC) and Celentis and managed the commercialisation of intellectual property from AgResearch in New Zealand with 650 Scientists and $130m revenues

Deep experience growing companies as CEO and on the Board

Dr Geoff Brooke
Non-Exec Director

- 30+ years venture capital experience
- Co-founded GBS Venture Partners
- Formerly President of Medvest, a US-based early-stage venture capital group he founded with Johnson & Johnson
- Other Board experience include non-executive director of Acrux Limited and Chairman of Actinogen Media Limited

Extensive life sciences and financial expertise in US and Australia

Dr Darryl Maher
Non-Exec Director

- 23+ years experience at CSL Limited, one of the world's most successful developers of biologic Pharmaceutical products
- Previously Vice President of R&D and Medical Affairs at CSL Behring Australia, where he was responsible for the development of multiple successful drug products from initiation through clinical development and ultimately to commercialisation

Former R&D Executive at CSL, with global development expertise

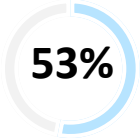
Dr Kilian Kelly
Chief Operating Officer

- 15 years' experience in pharmaceutical / biotechnology research and development, in both commercial and academic settings
- Previous appointments include Senior Director, Drug Development at Biota Pharmaceuticals (NASDAQ: BOTA), Vice President, Regulatory and Clinical at Mesoblast Limited (ASX:MSB)

Extensive academic, commercial and management experience

Highly successful outcome, with majority of patients reporting a Complete Response from a devastating disease

Phase 1 clinical trial data – all endpoints achieved[1]

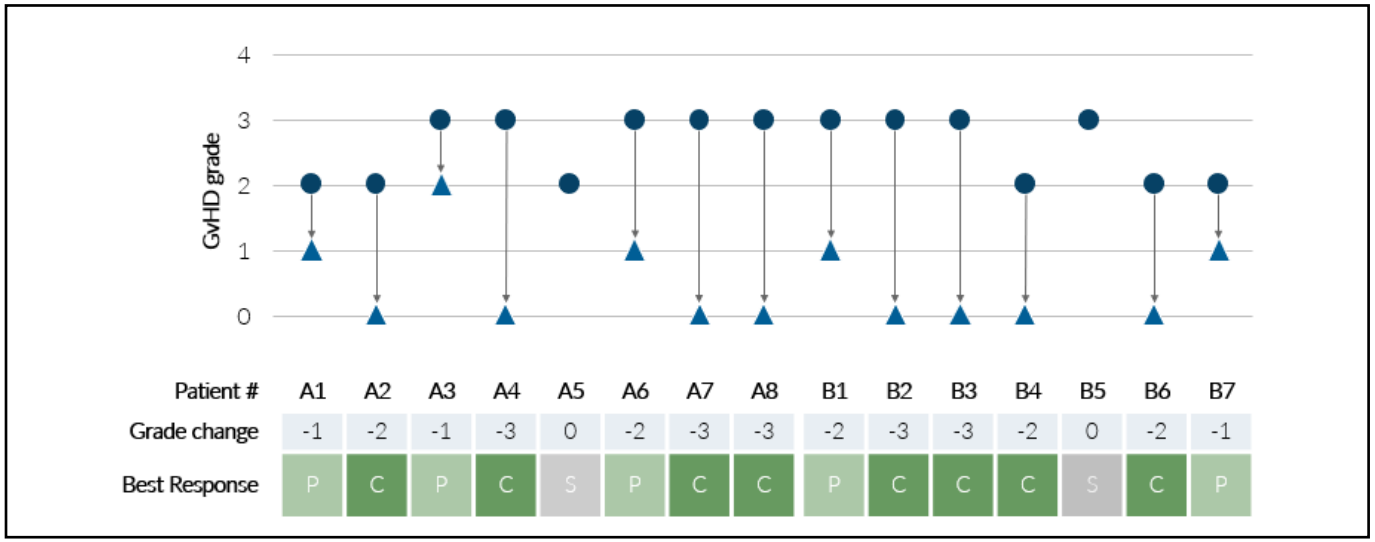


Complete Response[2] rate

Overall Response[3] rate

Overall survival[4] rate

Patient data



Legend

GvHD grade

- GvHD grade: As at day 0
- GvHD grade: Best Response

Patient response

- C — Complete Response
- P — Partial Response
- S — Stable disease

No treatment-related serious adverse events or safety concerns were identified

1. Pooled Cohort A/B results at 100 days. 2. Absence of GvHD. 3. Overall Response is either a Complete or Partial Response (improvement by 1+ grade).
4. One patient in Cohort A died of pneumonia (unrelated to treatment), one patient in cohort B withdrew from trial on Day 22 to commence palliative care.

Critical Limb Ischemia | Overview of Cynata-led Phase 2 program

Estimated market size

230,000	~US$1.4B[1]
Addressable events per year	Forecast annual global market sales

Critical Limb Ischemia (CLI)	▪ MSC therapy for effective treatment of critical limb ischemia patients who are ineligible for revascularization, to promote angiogenesis and reduce inflammation
Rationale for selection	▪ Cymerus preclinical studies were compelling, animals treated with Cymerus MSCs experienced improved blood flow ($p<0.006$) and faster blood flow recovery ($p<0.001$) when compared to the control group treated with saline ▪ Development timeline is relatively rapid
Preliminary program design	▪ Pivotal trials may last 1–2 years and require 50–100 revascularisation-ineligible patients (patients not eligible for surgery intended to restore blood flow) ▪ Endpoints likely to include amputation-free survival and ankle-brachial index, ulcer healing, and pain (reviewed over 6–12 months)
Key milestones	▪ Planning for Phase 2 program in Critical Limb Ischemia has commenced; MHRA approval received; preparations for commencement in 2020

Source: ClearView Analysis

1. ClearView's estimate of the peak annual global sales opportunity

Osteoarthritis | New Phase 3 program
Funded by National Health and Medical Research Council

Estimated market size

30,000,000
People in the USA affected by osteoarthritis

~US$11.6B[1]
Forecast global market opportunity by 2025

Osteoarthritis	▪ Assess the effect of Cymerus MSCs on clinical outcomes and knee joint structures of patients with osteoarthritis of the knee (compared to a placebo)
Rationale for selection	▪ Preclinical research showed MSCs can exert a number of important effects, including release of cytokines and growth factors that reduce inflammation and promote tissue repair, new blood vessel formation, and regeneration of compromised cartilage which may result in improved outcomes for patients
Preliminary program design	▪ 440-patient trial funded by an NHMRC project grant and in-kind contributions from participating institutions (no cash contribution from Cynata) ▪ Cynata to supply Cymerus MSCs for use in the trial[2] and will retain full commercial rights to the use of Cymerus MSCs in osteoarthritis
Key milestones	▪ Phase 3 clinical trial in Osteoarthritis expected to commence in CY2020

1. Persistence Market Research 2018 research report: "Osteoarthritis Treatment Market: Global Industry Analysis (2012-2016) and Forecast (2017-2025)."
2. Subject to ethics/regulatory approval and execution of a satisfactory material transfer agreement with the University of Sydney

Pre-clinical studies | Ongoing value-creating program

Pre-clinical studies are intended to provide a rational basis for investigating the potential safety and efficacy of an experimental drug in particular disease indications

Demonstrate potential of MSCs	• MSCs have already shown promising therapeutic potential in a wide range of pre-clinical models (as well as in human patients)
Validate Cymerus technology	• Cynata has sought to collaborate with experts in various therapeutic areas to validate the potential clinical utility of the Cymerus technology
Cost-effective	• An important element has been to leverage expenditure as much as possible through grants and joint projects

The successful outcomes from these studies, combined with the clinical data in GvHD have facilitated a number of ongoing commercial discussions in these and other clinical indications

Pre-clinical studies | Existing target areas

Disease target area	Partner	Pre-clinical trials started	Proof of concept completed	Key highlights	Global market opportunity*
ARDS	Critical Care Research Group	✓	✓	Study demonstrated effectiveness of Cymerus MSCs in sheep with ARDS in association with the Prince Charles Hospital in Brisbane.	US$2.5bn by 2018[2]
Heart attack	The University of Sydney	✓	✓	Data indicates that Cymerus MSCs may have the potential to restore cardiac function and reduce scar size after a heart attack	US$18.2bn by 2019[3]
Brain Cancer / Glioblastoma	Harvard	✓	✓	Research collaboration in genetically modified MSCs in cancer: involves modifying stem cells to target cancer	US$3.3bn by 2024[4]
Diabetic Wounds	Cell Therapy Manufacturing	✓	✓	Independent study by CRC for Cell Therapy Manufacturing generated positive data which demonstrates the efficacy of Cymerus MSCs in a preclinical model of diabetic wounds	US$4.9bn by 2024[5]
Coronary Artery Disease	UNSW Sydney	✓	✓	Research collaboration for the development of MSC therapies to treat coronary artery disease	US$22.5bn by 2021[6]
Asthma	Monash University	✓	✓	Cymerus MSCs demonstrated significant beneficial effects on three key components of asthma: airway hyper-responsiveness, inflammation and airway remodelling	US$25.6bn by 2024[1]
Cytokine Release Syndrome	University of Massachusetts Amherst	✓	✓	Pre-clinical model demonstrating Cymerus MSCs significantly ameliorate the effects of Cytokine Release Syndrome, a potentially severe and life-threatening adverse reaction to cancer immunotherapy	US$4.5bn by 2022 (CAR-T)[7]
Sepsis	RCSI	✓	✓	Development partnership with RCSI (Royal College of Surgeons in Ireland), demonstrated utility of Cymerus MSCs in sepsis, the leading cause of death in ICU's	US$5.9bn by 2026[8]

Successful outcomes open many other disease targets potentially benefiting from MSCs

Notes

*Reflects total global market opportunity for the relevant therapeutic category

1. Grand View Research, 2016; 2. Vasomune Therapeutics company announcement, 2018 3. GBI Research, 2013; 4. Global Data, 2016; 5. Transparency Market Research, 2018; 6. Smithers Apex, 2015 ; 7. Evaluate Pharma, 2017; 8. GlobalData 2017