

## Cynata Corporate Presentation

**Melbourne, Australia; 30 October 2019:** Australian stem cell and regenerative medicine company, Cynata Therapeutics Limited (ASX: CYP), today released a presentation Cynata CEO, Dr Ross Macdonald, will use with investors to update on recent progress and public announcements.

-ENDS-

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### About Cynata Therapeutics (ASX: CYP)

Cynata Therapeutics Limited (ASX: CYP) is an Australian clinical-stage stem cell and regenerative medicine company focused on the development of therapies based on Cymerus™, a proprietary therapeutic stem cell platform technology. Cymerus overcomes the challenges of other production methods by using induced pluripotent stem cells (iPSCs) and a precursor cell known as mesenchymoangioblast (MCA) to achieve economic manufacture of cell therapy products, including mesenchymal stem cells (MSCs), at commercial scale without the limitation of multiple donors.

Cynata's lead product candidate CYP-001 met all clinical endpoints and demonstrated positive safety and efficacy data for the treatment of steroid-resistant acute graft-versus-host disease (GvHD) in a Phase 1 trial. Cynata plans to advance its Cymerus™ MSCs into Phase 2 trials for GvHD, critical limb ischemia and osteoarthritis. In addition, Cynata has demonstrated utility of its Cymerus MSC technology in preclinical models of asthma, diabetic wounds, heart attack and cytokine release syndrome, a life-threatening condition stemming from cancer immunotherapy.



# A Next Generation Stem Cell Therapeutics Company

Investor Presentation: Cynata Therapeutics Limited  
October 2019

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# Cynata Therapeutics is a Phase II-ready biotech with a highly scalable, proprietary platform for developing stem cell therapeutics

## Our focus

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

## About Cynata Therapeutics

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- 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

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Share price (28-Oct-19)	A\$1.32
Shares on issue	102.8m
<b>Market capitalisation<sup>1</sup></b>	<b>A\$135.7m ~(US\$92.8m)</b>
Cash <sup>2</sup>	A\$9.2m
Debt	-
<b>Enterprise value</b>	<b>A\$126.5m</b>

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## Top shareholders

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	9.3%
	7.9%
Board and management	6.0%

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# 2019 Highlights: Driving Clinical and Commercial Success



## Fujifilm license

- Fujifilm exercised license option for CYP-001 in (GvHD)
- Future development of CYP-001 being funded entirely by Fujifilm
- US\$3m upfront payment to Cynata + milestones + royalties

*Fujifilm endorsement validates Cynata's Cymerus platform*



## Phase II GvHD trial funded by Fujifilm

- Fujifilm to fund CYP-001 development and commercialisation with a Phase II clinical trial expected to commence in CY2020

*Phase II trial expected to commence in CY2020*



## Progressing Osteoarthritis to Phase II trial

- Advancing towards 448 patient Phase I clinical trial
- Funded by the National Health and Medical Research Council

*Phase II trial expected to commence in Q1 CY2020*



## Progressing CLI to Phase II trial

- Critical Limb Ischaemia (CLI): major clinical challenge and unmet need
- Severely impaired blood flow in the arteries: typically legs
- Clinical Trial Authorisation application filing expected imminently

*Phase II trial expected to commence in early CY2020*



## Advanced pre-clinical program

- Cymerus platform has therapeutic potential in numerous additional target areas of chronic disease
- Multiple preclinical studies successfully completed and data published

*Therapeutic potential in numerous additional target areas*



## Active commercial discussions

- Executing on the Company's commercial plan to unlock the value of its platform technology across a broad range of indications

*Focus on early commercialisation of Cynata's Cymerus MSC products*

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

## Key advantages of the platform:

### Scalability & Consistency

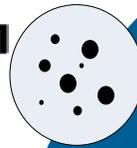
- ✓ Consistent product quality – single donor overcomes regulatory concerns
- ✓ Lower cost of goods on a per cell basis compared to conventional MSC products

### Fewer cells per patient

- ✓ Only 2 infusions per patient with Cymerus MSCs in GvHD, compared to 8-12 for bone-marrow derived products
- ✓ Greater convenience for patients and hospitals
- ✓ Lower costs incurred by healthcare system

## Graft vs Host Disease (GvHD)

**FUJIFILM**



✓ **Licensed**

CYP-001

## Osteoarthritis (funded by NHMRC)



Australian Government  
National Health and  
Medical Research Council

Phase II  
trials  
commencing  
CY2020

## Critical Limb Ischemia (CLI)



Crohn's Disease  
Fistula  
Others  
+  
Potential future target areas



## Coronary Artery Disease



## Cytokine Release Syndrome



## Brain cancer / Glioblastoma



## Diabetic wounds



## Acute respiratory distress syndrome

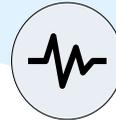


Pre-clinical data

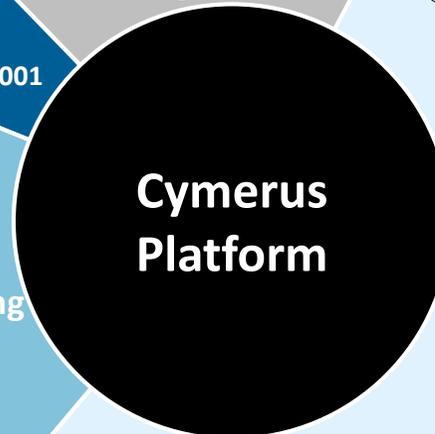
## Asthma



## Heart attack



## Sepsis



**Cymerus  
Platform**

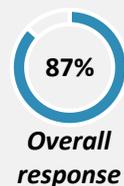
**Cynata has the only platform in the world to produce commercial quantities of MSCs from a single source**

# Value inflection point following clear data and first commercial transaction

## Successful clinical study data

### Demonstrating efficacy of our technology platform

- ✓ **World-first allogeneic iPSC-derived cell therapy clinical trial** in steroid-resistant acute GvHD
- ✓ **Successful clinical trial results** with all endpoints achieved



- ✓ **Clinically meaningful findings** validate progress to multiple Phase II trials
- ✓ **Endorsement by FUJIFILM** of Cynata's Cymerus platform supports the continued commercialisation of Cynata's cell therapeutic products in other indications

## Cynata's current focus

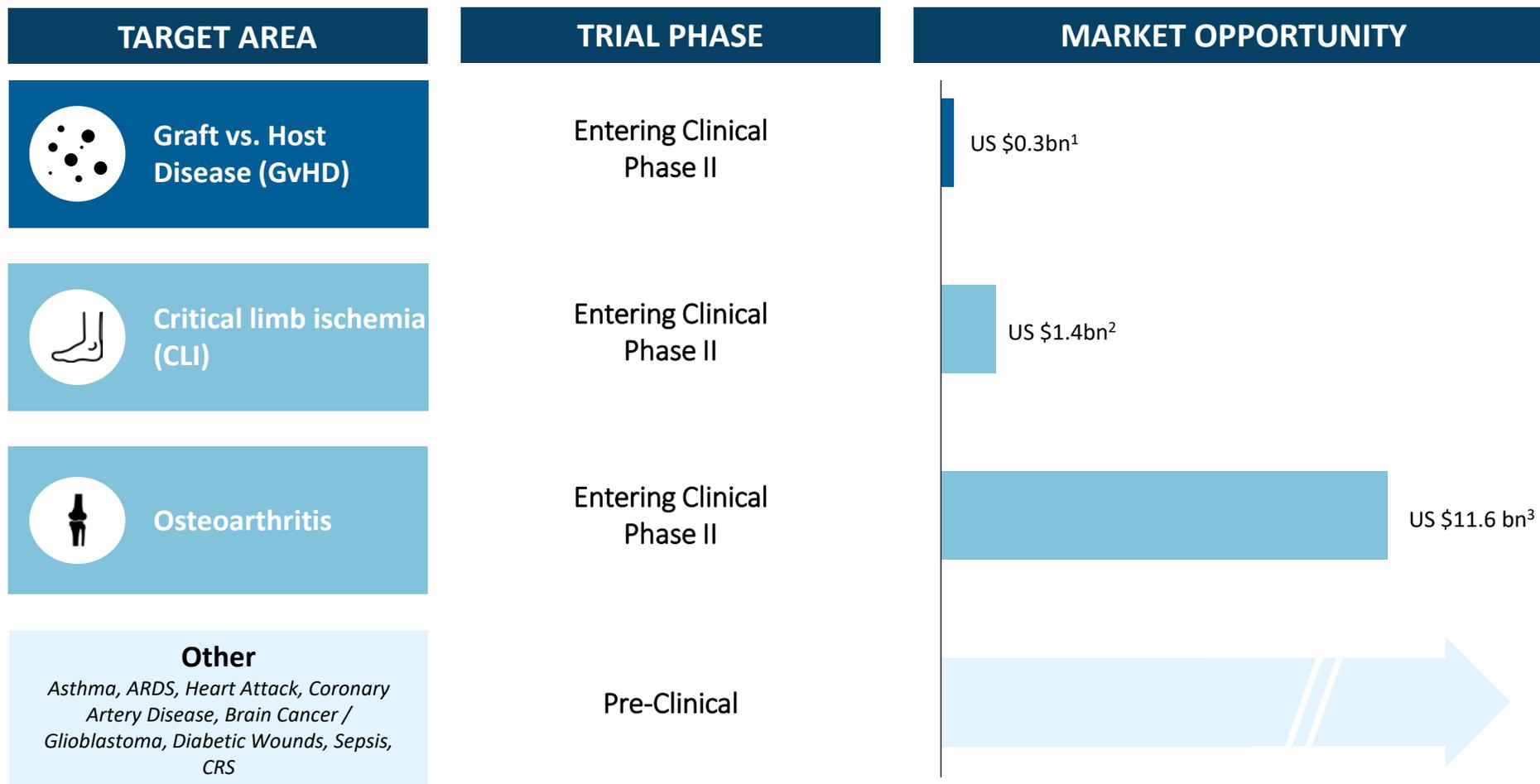
### Commercialise technology via further licence agreements

- **Critical Limb Ischemia:** Phase II trial commencing in early CY2020; licence available
- **Osteoarthritis:** Phase II trial commencing in Q1 CY2020; licence available
- **Pre-clinical studies** demonstrating attractive results in many other indications; licences available



- Cynata intends to maximise the value of its data package by licensing directly to Pharma or progressing indications to Phase II itself
- Cynata is in active ongoing commercial discussions with multiple pharma companies

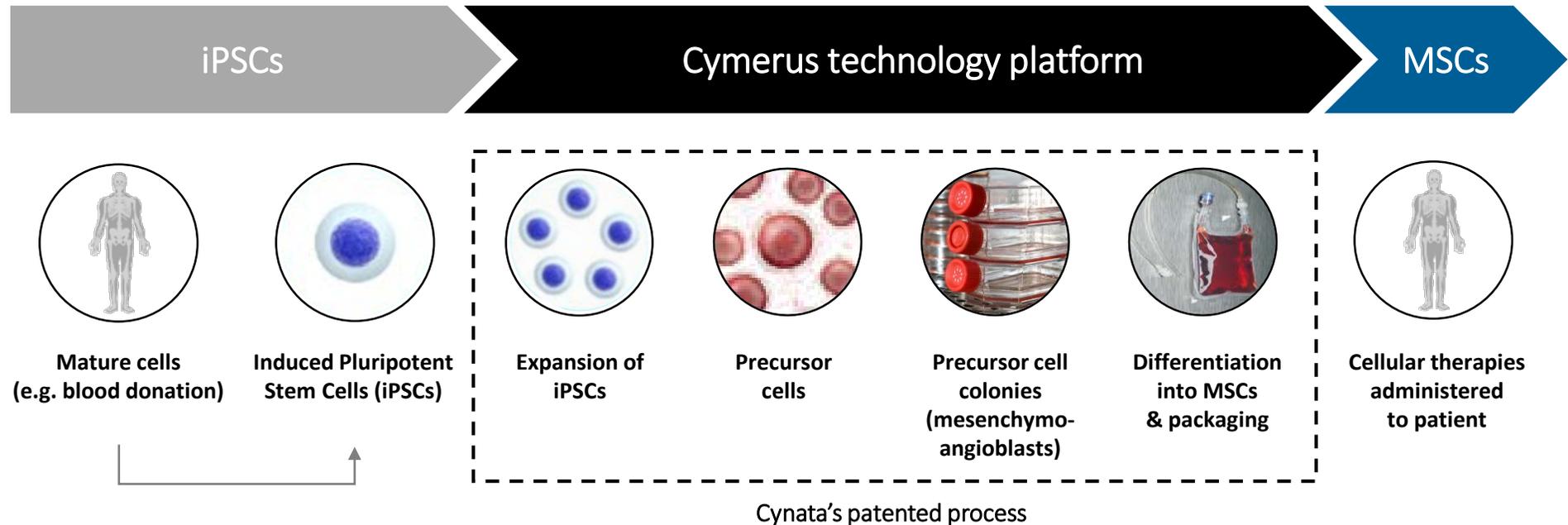
# Cynata is targeting significant market opportunities



1. Fujifilm's estimate of the peak annual global sales opportunity
2. ClearView's estimate of the peak annual global sales opportunity
3. Persistence Market Research 2018 research report: "Osteoarthritis Treatment Market: Global Industry Analysis (2012-2016) and Forecast (2017-2025)"

# Production and manufacturing process

Our patented Cymerus platform enables the production of iPSC-derived cellular therapeutics from a single adult donor



- Induced pluripotent stem cells derived directly from adult cells and can propagate indefinitely
- Give rise to every other cell in the body creating a huge opportunity in regenerative medicine
- Discovery of iPSCs awarded the Nobel Prize in Medicine in 2012

- Cymerus is the only platform in the world able to produce commercial quantities of Mesenchymal Stem Cells (MSCs) from a single source: iPSCs
- Mesenchymoangioblasts (MCAs) are produced from iPSCs and are readily able to expand and proliferate
- Bypasses complex and invasive surgeries and excessive MSC expansions with a scalable and cost effective process
- Overcomes regulatory hurdle as limitless quantities can be produced from a single donor

- MSCs have broad therapeutic potential
- Most widely studied type of adult stem cell, with potential treatments for a wide range of diseases

## GvHD clinical trial results

# Clinical trial design and key implications of clinical trial results

### What is GvHD?

Graft versus host disease (GVHD) is a condition where following a transplant the donor's immune cells in the transplant (graft) make antibodies against the patient's tissues (host) and attack vital organs. Organs most often affected include the skin, gastrointestinal (GI) tract and the liver.

## Clinical trial design

### Screening criteria

- Adults with steroid resistant acute GvHD
- Life expectancy of at least 1 month
- Other conditions screened out that may impact results



### Cohort A

May-17 – Dec-17  
n=8

1x10<sup>6</sup> cells/kg on Day 0 and Day 7<sup>1</sup>

28 day read-out ✓

100 day read-out ✓



Data and Safety Monitoring Board (DSMB) assessed Cohort A 28-day data and **approved commencement of Cohort B**

### Cohort B

Jan-18 – May-18  
n=7<sup>3</sup>

2x10<sup>6</sup> cells/kg on Day 0 and Day 7<sup>2</sup>

28 day read-out ✓

100 day read-out ✓

## Key implications of clinical trial results

### Endpoints

- Endpoints in this trial were the **same as those required in a Phase 3 trial** (in contrast to early phase trials for some other conditions)

### Response rates

- Response rates were **higher than what we expect would be required in Phase 3**, to support marketing approval

### Number of patients

- Although the Phase 1 trial involved just 15 treated subjects, **even late stage trials in this condition do not necessarily involve large numbers**
- For comparison, recently completed Phase 3 trials in Japan and US have involved just 25 and 55 patients, respectively

# GvHD clinical trial results

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

## Phase I clinical trial data – all endpoints achieved<sup>1</sup>



**Complete Response<sup>2</sup> rate**

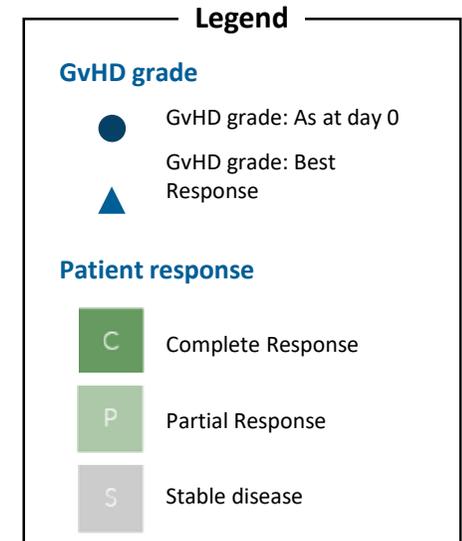
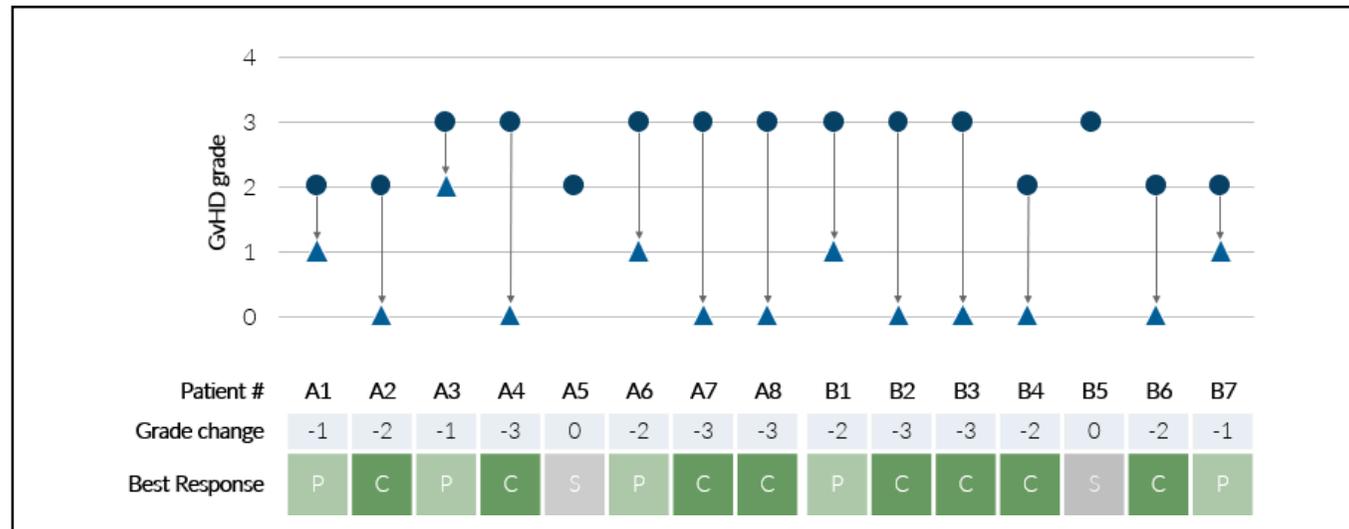


**Overall Response<sup>3</sup> rate**



**Overall survival<sup>4</sup> rate**

## Patient data



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

## Fujifilm licensing agreement

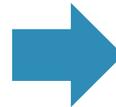
Cynata is executing on a clear scientific and commercial vision and continually assesses pathways to optimise shareholder value

### 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

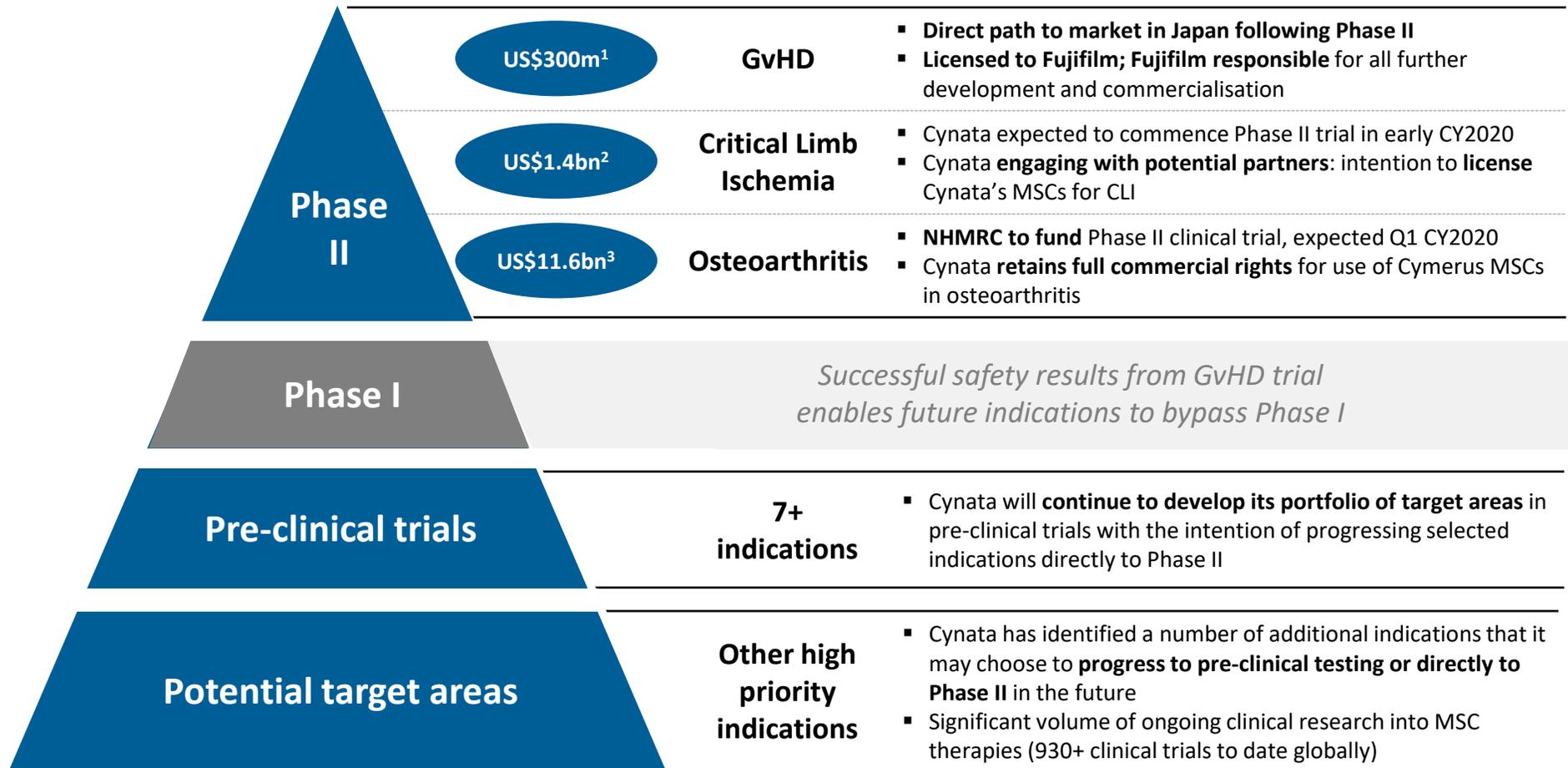
- ✓ Exclusive global licence in GvHD
- ✓ Multiple cash flow events:
  - US\$3m equity @ 35% premium
  - US\$3m upfront license fee received
  - US\$40m in potential milestone payments
  - Double digit royalties (worth potentially >US\$30m p.a.)
- ✓ Represents a major endorsement by Big Pharma
- ✓ Ongoing relationship with potential for further commercial agreements

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

## Path to commercialisation

Strong clinical pipeline and program supports Cynata's commercial objectives

### New enhanced pipeline and clear pathway to commercialisation



# Pipeline and Catalysts

Cynata has a large pipeline of indications with upcoming catalysts

		H2 CY2018	H1 CY2019	H2 CY2019	Upcoming catalysts / status
Phase II ready	<b>Graft vs Host Disease</b>	Phase I trial  Phase I trial completed		<b>FUJIFILM</b> Value from Innovation <b>license</b>	Phase II trial expected to commence in CY2020
	<b>Critical Limb Ischemia</b>			Phase II trial planning	Phase II trial expected to commence early CY2020
	<b>Osteoarthritis</b>	Phase II announced		Phase II trial planning	Phase II trial expected to commence in Q1 CY2020; funded by NHMRC
Pre-Clinical	<b>Acute Respiratory Distress Syndrome</b>			Results expected	Project on track for completion
	<b>Heart attack</b>	Completed			Expressions of interest being sought from potential partner companies
	<b>Brain Cancer/ Glioblastoma</b>		Completed		Further engineered MSC pipeline developments in planning stage
	<b>Diabetic wounds</b>	Completed			Ongoing discussions with study partner (CRC-CTM) to commence a clinical trial
	<b>Coronary Artery Disease</b>		Completed		Next steps being determined in collaboration with UNSW
	<b>Asthma</b>		Completed		In discussion with potential partners to support progress to a clinical trial
	<b>Cytokine Release Syndrome</b>		Completed		Expressions of interest being sought from potential partner companies
	<b>Sepsis</b>	Commenced			Program on track with results expected Q1 CY2020

## 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**



**Mr Peter Webse**  
Non-Exec Director  
Company Secretary

- +25 years' company secretarial experience
- Managing Director of Platinum Corporate Secretariat Pty Ltd, a company specialising in providing company secretarial, corporate governance and corporate advisory services

**25+ years company secretarial and management experience**



**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**

# Investment Summary

<p><b>1 Scalable, globally applicable technology</b></p>	<ul style="list-style-type: none"> <li>▪ Cymerus platform technology enables commercial-scale production of mesenchymal stem cells</li> <li>▪ Fully patented process overcomes multiple issues with today's on-market solutions</li> <li>▪ Value of platform to a range of diseases demonstrated across multiple clinical and pre-clinical studies</li> </ul>
<p><b>2 Attractive licensing business model</b></p>	<ul style="list-style-type: none"> <li>▪ A 'hub and spoke' model: intention to license Cymerus technology across a range of target areas</li> <li>▪ Licence granted to FUJIFILM for GvHD on highly attractive terms, including US\$3m upfront fee, &gt;US\$40m in milestone payments, double digit royalties on product sales and FUJIFILM responsible for all further product development activities and costs</li> <li>▪ Cynata in active commercial discussions with multiple other parties</li> </ul>
<p><b>3 Successful clinical trial results</b></p>	<ul style="list-style-type: none"> <li>▪ First in-human trial of Cymerus MSCs in GvHD successfully completed in 2018</li> <li>▪ All trial endpoints achieved: no safety concerns identified; highly encouraging efficacy</li> <li>▪ Endorsement by FUJIFILM of Cynata's Cymerus platform supports the continued commercialisation of Cynata's cell therapeutic products in other indications</li> </ul>
<p><b>4 Clear pipeline of high potential target areas</b></p>	<ul style="list-style-type: none"> <li>▪ Phase II clinical trial program commencing in Critical Limb Ischemia (CLI) in 2020</li> <li>▪ Phase II clinical trial in Osteoarthritis (OA) commencing in 2020, funded by NHMRC</li> <li>▪ Phase II clinical trial in GvHD commencing in 2020 (Fujifilm)</li> <li>▪ Compelling pre-clinical data in multiple other high-value target areas supports further clinical trials</li> </ul>
<p><b>5 Well positioned in regenerative medicine</b></p>	<ul style="list-style-type: none"> <li>▪ Cell therapeutics is an area of increasing interest from major pharmaceutical companies</li> <li>▪ Global market opportunity of US\$1.4bn for CLI and US\$11.6bn for OA</li> <li>▪ Over 930 clinical trials investigating the efficacy of MSCs in treating diseases have been initiated globally</li> </ul>

Thank you for your attention

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# Appendix

# Critical Limb Ischemia | Overview of Cynata-led Phase II program



## Estimated market size

230,000  
Addressable events per year

~US\$1.4B<sup>1</sup>  
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 II program in Critical Limb Ischemia has commenced; trial expected to begin in early CY2020

# Osteoarthritis | New Phase II 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<sup>1</sup>

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

- 448-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<sup>2</sup> and will retain full commercial rights to the use of Cymerus MSCs in osteoarthritis



## Key milestones

- Phase II clinical trial in Osteoarthritis expected to commence in 1Q CY2020

## Pre-clinical studies | Ongoing value-creating program

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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		✓		Study to commence to evaluate effectiveness of Cymerus MSCs in sheep with ARDS in association with the Prince Charles Hospital in Brisbane.	US\$2.5bn by 2018 <sup>2</sup>
Heart attack		✓	✓	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 <sup>3</sup>
Brain Cancer / Glioblastoma		✓	✓	Research collaboration in genetically modified MSCs in cancer: involves modifying stem cells to target cancer	US\$3.3bn by 2024 <sup>4</sup>
Diabetic Wounds		✓	✓	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 <sup>5</sup>
Coronary Artery Disease		✓	✓	Research collaboration for the development of MSC therapies to treat coronary artery disease	US\$22.5bn by 2021 <sup>6</sup>
Asthma		✓	✓	Cymerus MSCs demonstrated significant beneficial effects on three key components of asthma: airway hyper-responsiveness, inflammation and airway remodelling	US\$25.6bn by 2024 <sup>1</sup>
Cytokine Release Syndrome		✓	✓	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) <sup>7</sup>
Sepsis		✓		Development partnership with RCSI (Royal College of Surgeons in Ireland), one of the foremost health sciences research institutions in Europe, to investigate the utility of Cymerus MSCs in sepsis, the leading cause of death in ICU's	US\$5.9bn by 2026 <sup>8</sup>

### 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