ASX ANNOUNCEMENT 10 June 2020

Cynata Investor Presentation

Melbourne, Australia; 10 June 2020: Cynata Therapeutics Limited (ASX: "**CYP", "Cynata",** or the **"Company"**), a clinical-stage biotechnology company specialising in cell therapeutics, has today released a new investor presentation. The Company will use this presentation to brief investors at upcoming investor events.

Cynata's recent highlights:

- **Ethics approval for COVID-19 clinical trial**
- **Balance sheet strengthened through successful placement and share purchase plan**
- **Advancing clinical development for multiple upcoming Phase 2 ready clinical trials**

The Investor Presentation is attached to this announcement.

-ENDS-

Authorised for release by Dr Ross Macdonald, Managing Director & CEO

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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 severe complications arising from COVID-19, 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, sepsis, acute respiratory distress syndrome (ARDS) and cytokine release syndrome.

A Next Generation Stem Cell Therapeutics Company

Investor Presentation: Cynata Therapeutics Limited
June 2020

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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

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 Phase 2 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

COVID-19 clinical development strategy

- Assessing opportunities to expand COVID-19 trial to other jurisdictions
- Current internal focus; Cynata is accelerating the COVID-19 clinical program

Opportunity to accelerate clinical development program

Progressing clinical development

- FUJIFILM endorsement via license validates Cymerus platform; Fuji funding development and commercialisation; Phase 2 GvHD clinical trial expected end 2020
- Osteoarthritis advancing towards 448 patient Phase 2 clinical trial, funded by the NHMRC; CLI Phase 2 clinical trial approved by MHRA

Multiple Phase 2 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

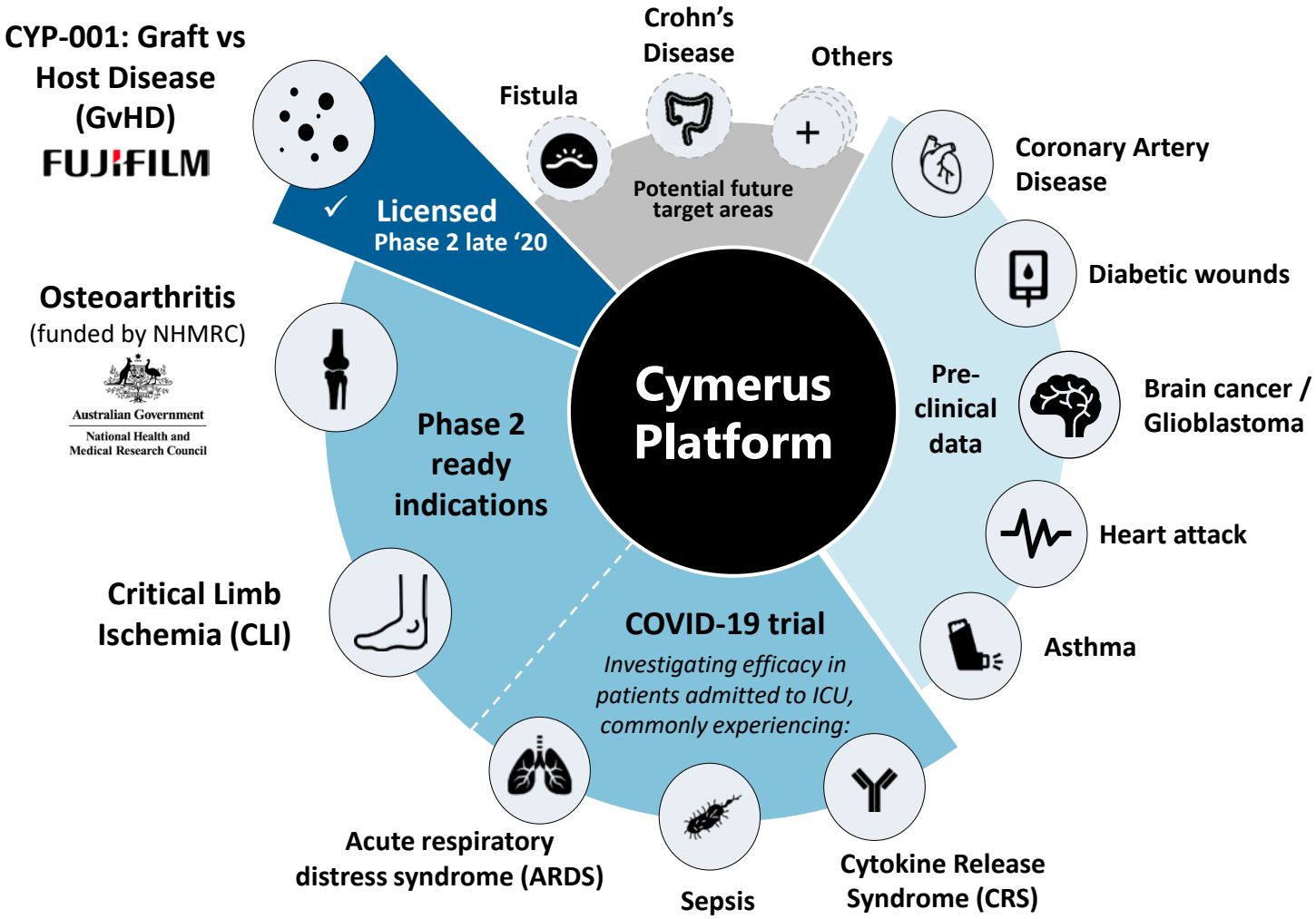
Preliminary program design

- 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
Graft vs. Host Disease (GvHD)[1]	Clinical Phase 2 ready	US$0.3 bn
Critical limb ischemia (CLI)[2]		US$1.4 bn
Osteoarthritis (OA)[3]		US$11.6 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	

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). **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

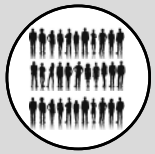
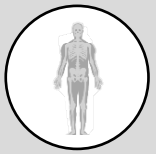
Demand for large quantities of product will focus attention on the **major manufacturing challenges** associated with conventional production methods

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

Conventional vs. Cynata's Cymerus MSC manufacturing process

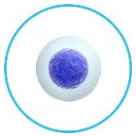
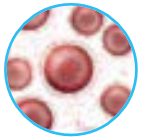
Current conventional MSC manufacturing process is impractical

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

Cells from multiple donors	MSC isolation	MSC expansion	Cellular therapies administered
			
Substantial variability in starting material	**Limited quantity of MSCs produced per donation**	**Large number of MSCs required**	**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	iPSC Derivation	iPSC Expansion	Precursor cells	Generation of MCA Colonies	Differentiation into MSCs	Cellular therapies administered
						
1 **Avoids inter-donor variability**		**2** **Effectively limitless expansion**			**3** **Minimal MSC culture expansion**	**4** **Only 2 infusions per patient[1]**

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* 1
Comparability testing	Required every time a new donation is used	N/A	✓ *Lower cost, minimised risk[1]*
Number of clinical doses per donation	Limited to several thousand	Effectively limitless	✓ *Lower cost; simplified logistics; comparative ease of scalability* 2
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]* 3
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* 4
Risk of contamination[3]	Medium to high, depending on process	Negligible	✓ *Lower risk of adverse reaction in patients; significant regulatory*

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

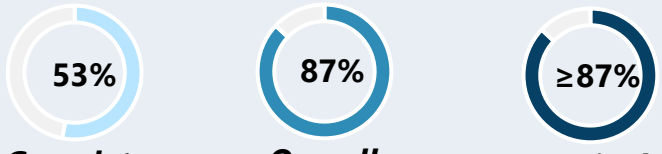
World-first allogeneic iPSC-derived cell therapy clinical trial in steroid-resistant acute GvHD completed, with compelling results

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): *1x10^6 cells/kg on Day 0 and Day 7*[1] ▪ Cohort B (n=7[4]) : *2x10^6 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 1x10^8 cells. 2. Max 2x10^8 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 I**
- **Clinically meaningful findings validate progress** to multiple Phase 2 trials across multiple indications
- Indications now **Phase II trial ready include GvHD, osteoarthritis and CLI**
- 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:**
  - **US$3m** equity @ 35% premium
  - **US$3m** upfront license fee received
  - **US$43m** 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

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 >US$43m 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; osteoarthritis (funded by NHMRC); GvHD (via FUJIFILM license); critical limb ischemia (CLI) ▪ 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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