

ASX ANNOUNCEMENT

12 March 2021

Cynata Investor Presentation

Melbourne, Australia; 12 March 2021: Cynata Therapeutics Limited (ASX: CYP), a clinical-stage biotechnology company specialising in cell therapeutics, is pleased to release a Corporate Investor Presentation that will be used to update shareholders, investors and other parties at conferences in the near future.

Cynata continues its engagement with investors and potential strategic partners. The first conference that Cynata CEO, Dr. Ross Macdonald, is to present at is the virtual ASX Small and Mid-Cap Conference On-Demand segment from 16-17 March 2021. The conference provides Cynata the opportunity to showcase its unique Cymerus™ platform technology and the progress made in its broad clinical pipeline to a wide network of Australian investors. For more information, including registering for the event, please visit <https://www2.asx.com.au/investors/investment-tools-and-resources/events/smid>.

The 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. Clinical trials of Cymerus MSC products in osteoarthritis (Phase 3) and in severe complications arising from COVID-19 (Phase 2) are currently ongoing. Planning is also underway for further clinical trials of Cymerus MSC products in GvHD (through licensee Fujifilm), critical limb ischemia, idiopathic pulmonary fibrosis, renal transplantation, and diabetic foot ulcers. In addition, Cynata has demonstrated utility of its Cymerus MSC technology in preclinical models of numerous diseases, including the clinical targets mentioned above, as well as asthma, heart attack, sepsis, acute respiratory distress syndrome (ARDS) and cytokine release syndrome.

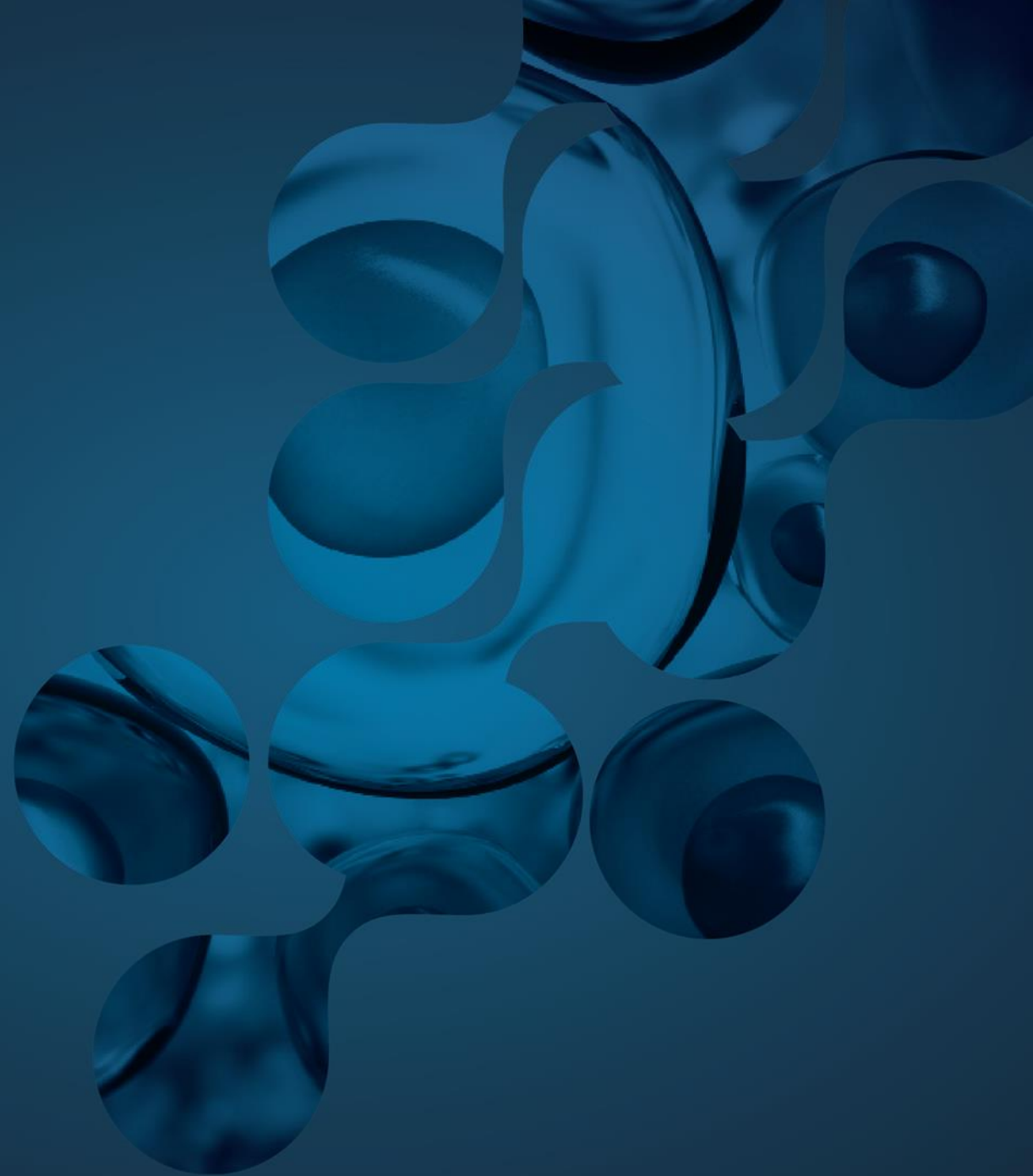
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A Next Generation Stem Cell Therapeutics Company

Investor Presentation: Cynata Therapeutics Limited
March 2021



Important information

Summary information

This Presentation contains summary information about Cynata Therapeutics Limited and its subsidiaries (CYP) which is current at 3 March 2021. 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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This Presentation contains historical financial information based on the Company's results for the half year to December 2020. This information is disclosed in the 4D report lodged with ASX on 26 February 2021. Any discrepancies between totals and sums of components in tables and figures in this Presentation are due to rounding.

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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',

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✓ Key recent highlights



Commencement of osteoarthritis Phase 3 clinical trial, funded by a NHMRC grant



Commencement of Phase 2 COVID-19 trial & assessment of options to accelerate recruitment



GvHD Phase 1 results published in prestigious journal, *Nature Medicine*



MoU signed with TekCyte to utilise wound dressing tech for Cynata's planned DFU trial¹



Well funded² for expansion of clinical development pipeline³ & executing US regulatory strategy



Actively pursuing discussions with potential partners and strategic parties

Company overview

Cynata is a clinical stage biotech developing its proprietary Cymerus™ platform technology for the scalable manufacture of mesenchymal stem cell (MSC) therapeutic products to treat serious disorders

About Cynata Therapeutics

- Stem cell and regenerative medicine company developing technology from the University of Wisconsin-Madison, USA
- Cymerus technology addresses critical shortcomings in existing methods MSC production, which is to achieve economic manufacture at commercial scale
- First product licensed to FUJIFILM for graft-versus-host-disease (GvHD)
- Compelling GvHD clinical trial results places Cynata in a strong position to accelerate clinical development, enabling other indications to progress directly to Phase 2 / 3 clinical trials (i.e. bypass Phase 1 studies)

Board and Management



Dr Geoff Brooke
Chairman



Dr Paul Wotton
Non-Exec Director



Dr Ross Macdonald
Managing Director / CEO



Dr Darryl Maher
Non-Exec Director



Dr Stewart Washer
Non-Exec Director



Dr Kilian Kelly
Chief Operating Officer



Financial information

Share price (8-Mar-21)	A\$0.64
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Shares on issue	143m
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Market capitalisation	~A\$92m
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Cash ¹	~A\$30m
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Debt	-
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Enterprise value	~A\$62m
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Top Shareholders

	10.3%
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	9.9%
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	5.8%
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Board and management	8.6%
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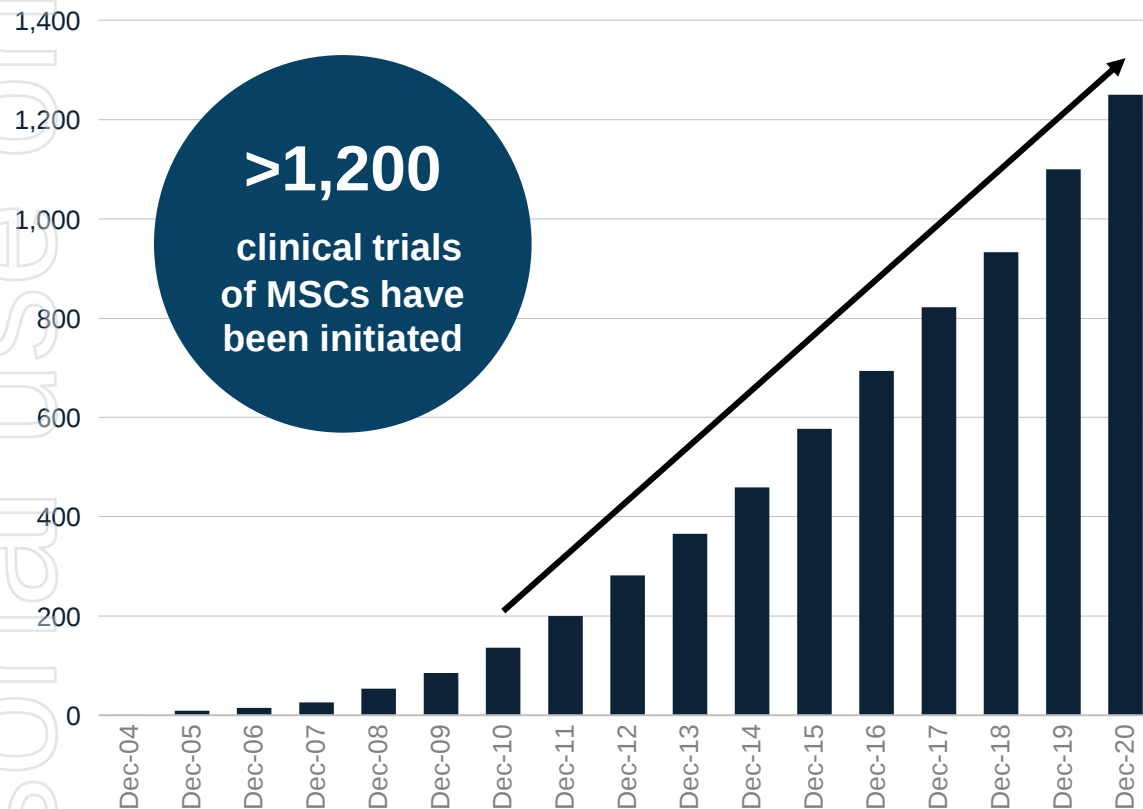
1. Cash as at 31 December 2020 (~A\$25m), adjusted for the proceeds of the entitlement offer and shortfall placement in Jan 21 (A\$3.3m), and the R&D Tax Incentive Refund received in Feb 21 (A\$1.4m)

Cynata well placed in the regenerative medicine market

Cynata is at the forefront of stem cell technology and ideally placed as global interest continues to grow in MSCs

Global interest in MSCs continues to grow

Number of MSC clinical trials¹ (cumulative)



Key driver of shareholder value for Cynata is ultimately the Cymerus MSC platform technology



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



Further successful trials in any of these indications will significantly **increase Big Pharma's interest** in MSCs



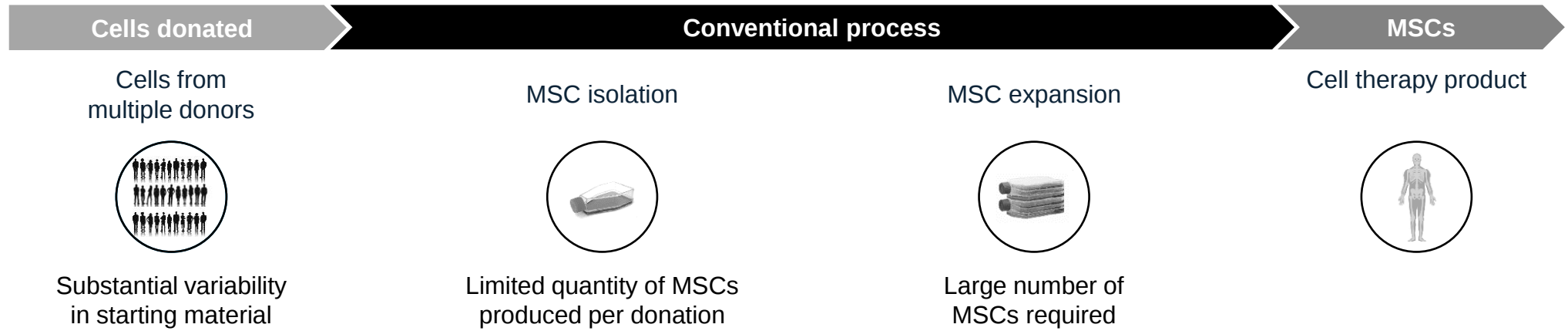
Demand for large quantities of product and regulatory scrutiny will focus attention on the **need for a better manufacturing solution**



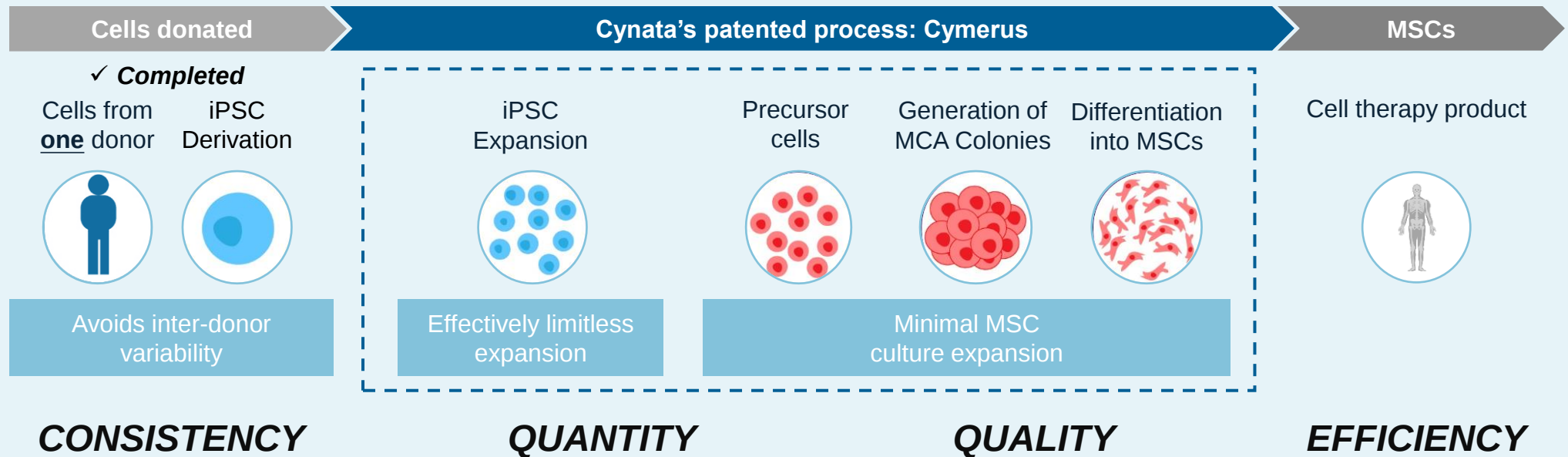
Cynata's uniquely scalable and consistent process is ideally placed to solve the manufacturing scalability challenges associated with conventional methods of MSC production

Conventional vs. Cynata's Cymerus MSC manufacturing process

The current conventional manufacturing process is **sub optimal**



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



FDA focus on manufacturing

Cynata's Cymerus process actively addresses some of the key areas that the FDA is likely to focus on

Potential issues raised

"The issue of reliable prediction of biological activity is particularly challenging for MSCs.

Substantial functional heterogeneity has been observed between MSC batches derived from different donors and expanded using different tissue culture conditions or duration, even though all of these batches meet the ISCT criteria for MSCs."

- Excerpt from FDA ODAC Briefing document for 13 August 2020

Key advantages underpinning Cymerus



Product derived from a **single donor** provides a **highly consistent product** and addresses regulatory concerns



Effectively limitless iPSC expansion *before* differentiating into MSCs, maintaining potency



MSCs represent a potential efficacious treatment in GvHD, **supporting Cynata's GvHD product CYP-001**

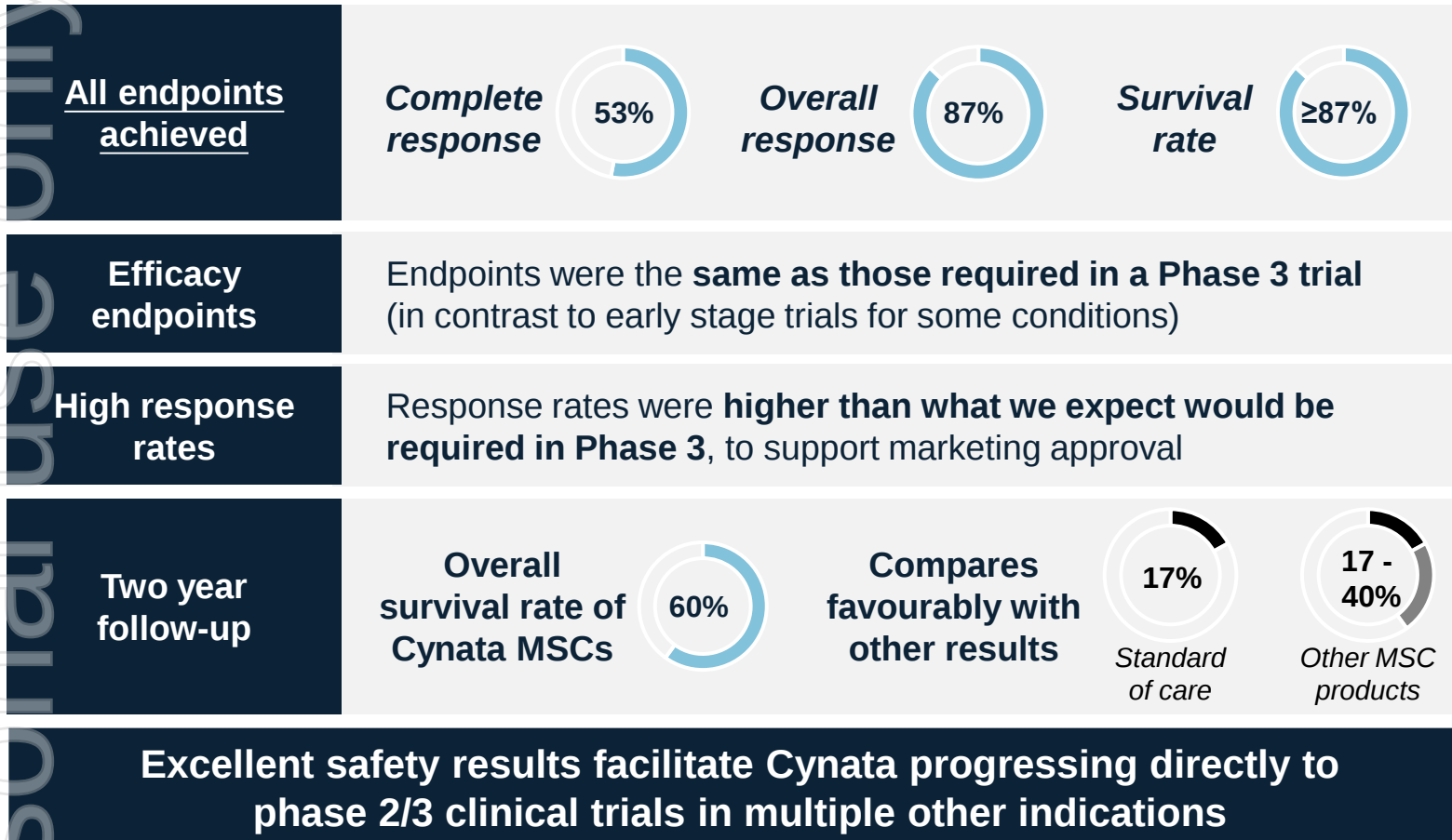


FDA advisory meeting observations to be leveraged to **optimise future CYP clinical trial design for FDA approval**

Phase 1 clinical trial results (CYP-001)

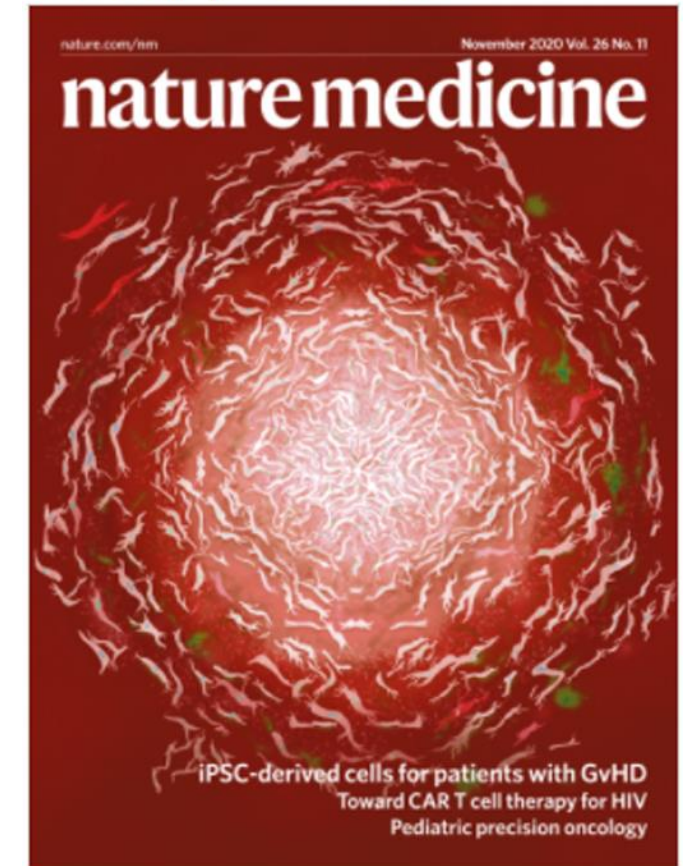
Outstanding results in the world-first allogeneic iPSC-derived therapy trial in steroid-resistant acute graft-versus-host disease (GvHD) places Cynata in a strong position to accelerate clinical development

Key clinical trial results¹ - demonstrating efficacy of our technology



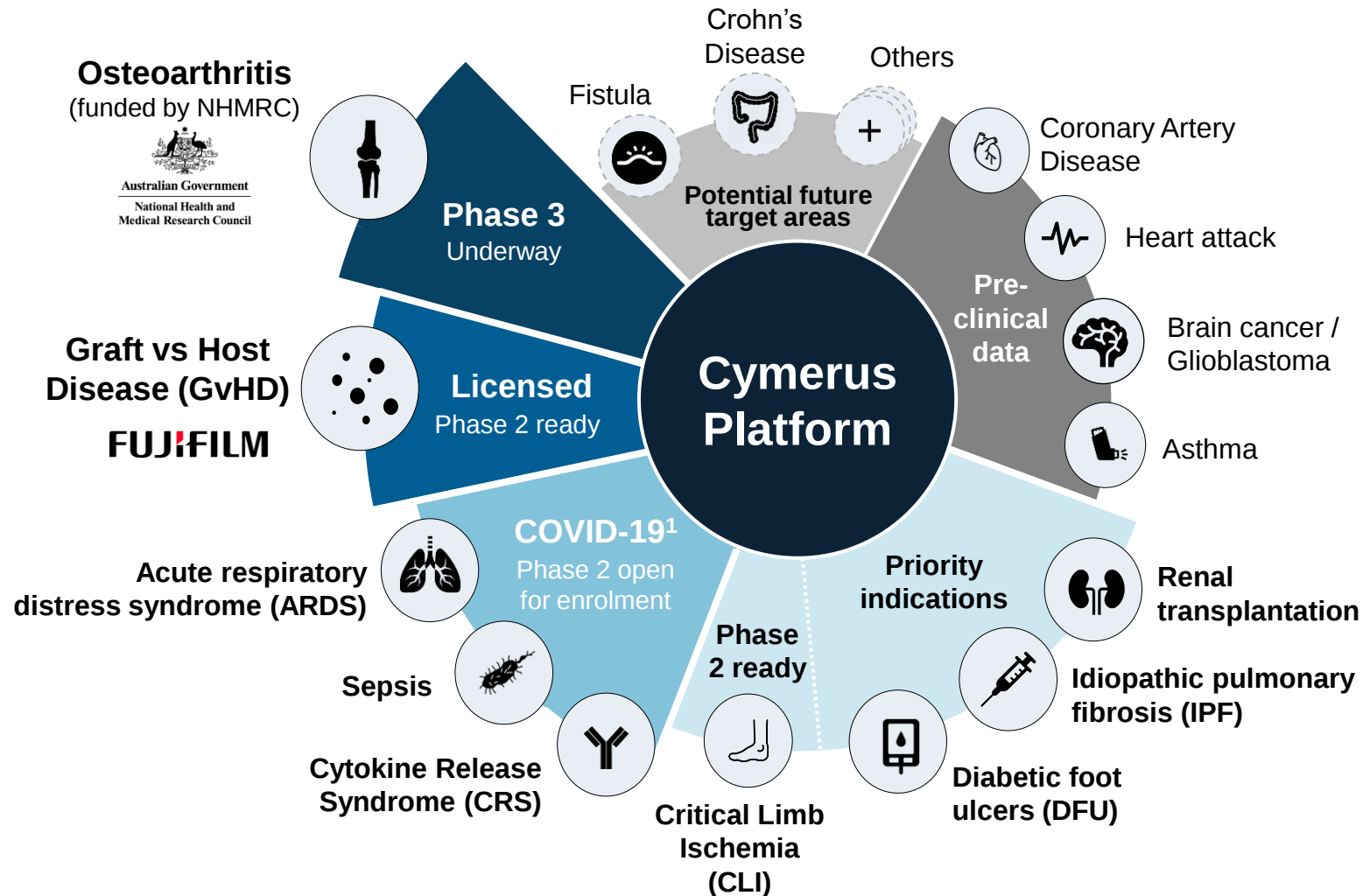
Published in prestigious journal²

Current Issue | November 2020



Cymerus platform

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



1. Investigating efficacy in patients admitted to ICU, commonly experiencing ARDS, sepsis and CRS

SCULpTOR¹ | Osteoarthritis Phase 3 clinical trial

Clinical trial underway, sponsored by the University of Sydney and funded by an NHMRC project grant



Significant opportunity

- **Osteoarthritis** occurs when the protective layer between bones (cartilage) in a joint wears away, which can cause pain, inflammation, swelling and difficulty with movement
- **There is no cure**, with current treatments centred on symptom management
- **Huge potential upside**, with OA estimated to affect >30m Americans with a global market of US\$11.6bn²



Clinical Trial Milestones

- ✓ **Preclinical research** shows MSCs can exert a number of important effects relevant to osteoarthritis, including potential to **improve the underlying disease** as well as alleviating pain
- ✓ **Funded** by an Australian Government NHMRC project grant³
- ✓ **Sponsored** by the University of Sydney⁴
- ✓ **Trial approved and commenced**, to assess the effect of CYP-004 (Cymerus MSC osteoarthritis product)



*“There is no cure for osteoarthritis, and current treatment options largely focus on alleviating pain rather than the underlying disease. We are delighted to commence this trial which will **evaluate the disease modifying potential of Cymerus MSCs.**”*

- Professor David Hunter, Principal Investigator⁴

SCULpTOR¹ | Osteoarthritis trial underway

Recruitment has commenced, seeking to enrol 440 patients with osteoarthritis of the knee to participate in the randomised, double-blind placebo-controlled phase 3 clinical trial

	Initial safety follow-up	<i>Four week safety follow-up of initial patients treated in November 2020</i>
	Recruitment	<i>University of Sydney to enrol 440 patients with osteoarthritis of the knee at study centres in Sydney and Tasmania</i>
	Treatment	<i>Each participant receives injections of Cymerus MSCs (or placebo) on three occasions over 1 year</i>
	Follow up	<i>Comparison from baseline up to 24 months in each participant</i>
	Results	<i>Final results expected in 2024²</i>

✓ **Complete**

Underway

Underway



	Endpoints	Co-primary endpoints: i. the proportion of participants achieving patient-acceptable symptom state (PASS) for knee pain at 24 months ii. central medial femorotibial (cMFT) cartilage loss from baseline at 24 months Secondary outcome measures: assessments of pain, other symptoms, physical function and quality of life
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Clinical Trial: Diabetic foot ulcers

Plans to undertake a clinical trial based on a solid pre-clinical foundations and utilising TekCyte technology



Diabetic Foot Ulcers (DFU)

Sores on the feet of patients with diabetes that occur in ~15-25% of patients sometime during their lifetime¹



Rationale for selection

- Among the most common and serious complications of patients who have diabetes, and is associated with significant morbidity and mortality and can lead to hospitalisation and lower limb amputation if not treated in a timely manner
- In Australia alone diabetic foot disease results in >27,000 hospitalisations, 4,400 amputations and 1,700 deaths annuals²
- ✓ Cymerus MSCs achieved encouraging efficacy results in a preclinical model of diabetic ulcers



Study design milestones

- MoU with TekCyte³, in anticipation of the parties entering into a license agreement for the use of TekCyte's wound dressing technology in the commercial development of Cynata's MSC product for DFU
- Planned clinical trial to be fully funded with available capital



Next steps

- Finalise license with TekCyte to utilise wound dressing tech
- Finalise clinical trial design and other preparation activities



Expanding the clinical development pipeline

Further Priority Indications, with preparations for clinical trials underway

Disease description

Rationale for selection

Next steps



Idiopathic pulmonary fibrosis

Incurable disease of unknown cause, which results in extensive scarring / fibrosis of the lungs.

- High unmet medical need; existing treatments have limited effects on disease progression or survival rates, with lung damage often advanced when first diagnosed and invariably progresses to respiratory failure with only 20-30% of patients surviving 5 years from diagnosis¹
- ✓ Efficacy of Cymerus MSCs demonstrated in preclinical rodent models of IPF + inflammatory lung disease: statistically significant improvements in multiple harmful effects of IPF, including interstitial fibrosis, dynamic lung compliance and airway resistance

- Finalise clinical trial plans (to be funded by available capital)
- Advance key elements (i.e. trial design; regulatory consultation; endpoint selection; KOL appointment; site selection)



Renal transplantation

Treatment for end-stage kidney disease, where the kidneys are no longer able to function and a transplant is required to eliminate patient's reliance on dialysis

- Current treatments (lifelong immunosuppression) are associated with significant morbidity
- ✓ Cymerus MSC treatment in a preclinical transplant model demonstrated immunoregulatory effects expected to prevent or reduce organ transplant rejection

Multiple options to create shareholder value

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



Build value in platform independently

Clinical trials – funded by Cynata, grants or collaborations, such as osteoarthritis and COVID-19 trials and advancing pre-clinical development programs

License / partner with big Pharma

License specific indications for development and commercialisation, such as GvHD (FUJIFILM); in active discussions with other parties across a range of indications

Strategic exit / merger

Monetisation via a strategic acquirer (e.g. big Pharma); interest demonstrated by previously announced proposal

Significant market opportunities

Cynata is targeting attractive market opportunities across a range of target indications

Target area

Trial Phase

Market opportunity



Osteoarthritis (OA)

Phase 3 underway

US\$11.6 bn¹



Graft vs. Host Disease (GvHD)

Phase 2 planning

US\$0.6 bn²



Acute Respiratory Distress Syndrome (ARDS)



Cytokine Release Syndrome (CRS)



Sepsis

Phase 2 underway
(COVID-19 Program)

US\$8.4 bn^{3,4,5}



Critical Limb Ischemia (CLI)

Phase 2 ready

US\$5.4 bn⁶



Idiopathic Pulmonary Fibrosis (IPF)

US\$4.5 bn⁷



Renal Transplantation

Planning for further
clinical development

US\$5.9 bn⁸



Diabetic Foot Ulcers (DFU)

US\$9.6 bn⁹

Valuation upside

Significant upside potential for Cynata when compared to other stem cell-therapy companies

Significant upside potential for Cynata



Market Capitalisation:

US\$0.07bn¹

US\$1.00bn²

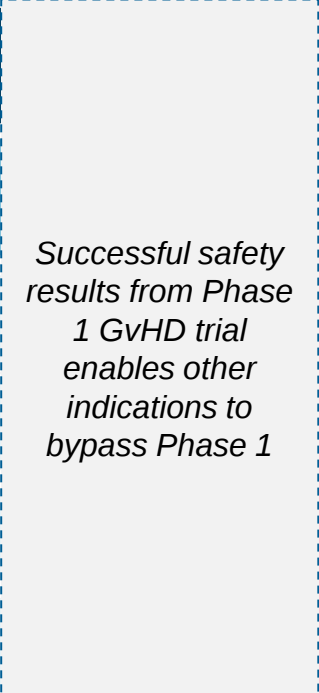
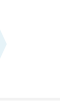
US\$1.15bn¹

US\$8.80bn³

Company				
Clinical stage targets	GvHD: Phase 1 complete (Two active Phase 2 / 3 trials; broad clinical pipeline)	Parkinson's disease (Entering early stage clinical)	Multiple targets (Clinical phase trials)	7 cancer immunotherapy targets (Phase 1 underway)
iPSC-derived product	✓	✓	X	✓

Development pipeline and outlook

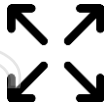
Broad and advanced clinical development pipeline, with multiple active trials and near-term catalysts

	Pre-clinical	Phase 1	Phase 2	Phase 3	<u>Key catalysts</u>
 GvHD				FUJIFILM	Fujifilm responsible for all updates and ongoing development via global license agreement US\$2m milestone payment on Phase 2 completion
 OA			Accelerated to Phase 3 based on study parameters		Recruitment underway seeking to enrol 440 patients in the phase 3 clinical trial funded by an NHMRC grant
 COVID-19 Program	Compelling pre-clinical data in ARDS, sepsis, CRS				Trial is currently open for patient recruitment; Cynata to execute strategy to accelerate recruitment
 CLI					Phase 2 ready , with regulatory and ethics approval received ¹
 Diabetic Foot Ulcers					Sign agreement with TekCyte to utilise wound dressing technology in planned clinical trial
 IPF					Expanding clinical development pipeline, with clinical trial planning underway
 Renal transplant²					
 Pre-clinical	Coronary artery disease; heart attack, asthma, cancer, other				Broad pre-clinical study results provide multiple opportunities for additional trials / partnering

1. Trial timing uncertain due to continued impact on recruitment due to COVID-19, and being assessed as part of broader clinical development strategy
2. Preclinical model of organ transplant rejection complete

Key objectives for 2021

Cynata is in a strong position going forward with ~A\$30m cash¹ to fund all planned clinical trials and advance development of its proprietary Cymerus platform technology



Execute on the expansion of the clinical pipeline and commence new clinical trials



Execute strategy to accelerate recruitment in the MEND (COVID-19) phase 2 clinical trial



Significant recruitment progress in the active SCULpTOR (OA) phase 3 clinical trial



Optimise manufacturing capabilities to enhance scale-up efficiencies



Execute US regulatory strategy, to assist in driving global commercialisation



Continue engagement in partnering discussions, and actively pursue new opportunities

Investment summary

	Scalable stem cell therapy technology	- Patented Cymerus platform technology enables commercial-scale production of mesenchymal stem cells from a single donor, overcoming multiple issues with today's on-market solutions - Value of platform to a range of diseases demonstrated across clinical and pre-clinical studies
	Successful clinical trial results	- All clinical endpoints achieved in Phase 1 trial of Cymerus MSCs in acute GvHD, with no safety concerns identified and highly encouraging efficacy - Endorsement by FUJIFILM via licence for GvHD supports further development of Cynata's products in other indications
	Broad and attractive pipeline	- Phase 3 osteoarthritis trial (funded by NHMRC) is underway and Phase 2 trial in COVID-19 patients open for recruitment - Preparations to commence further clinical trial in GvHD (via FUJIFILM license) and a Phase 2 trial in CLI; planning for clinical trial programs in idiopathic pulmonary fibrosis (IPF), renal transplantation, and diabetic foot ulcers (DFU) - Compelling pre-clinical data in other high-value target areas supports further clinical trials
	Significant growth potential	- Targeting significant commercial opportunities; global market opportunity in osteoarthritis alone is US\$11.6bn - FUJIFILM license granted on attractive terms, including A\$100m+ in milestone payments and royalties on product sales; and FUJIFILM responsible for further product development and commercialisation in GvHD
	Well positioned in regenerative medicine	- Cell therapeutics is an area of increasing interest among major pharmaceutical companies globally - Cynata's unique Cymerus technology ideally placed to solve current MSC manufacturing challenges - Well funded to advance clinical and process development, with ~A\$30m cash¹

Cynata Therapeutics Limited

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