ASX ANNOUNCEMENT 9 December 2019

Corporate Presentation in Relation to Sepsis

Melbourne, Australia; 9 December 2019: Australian stem cell and regenerative medicine company, Cynata Therapeutics Limited (ASX: CYP), has released the attached corporate presentation on sepsis and further information on the positive efficacy data from preclinical studies of its Cymerus™ mesenchymal stem cells (MSCs) in a model of sepsis, as announced to the ASX on 5 December 2019.

-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 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.

Corporate Presentation: Sepsis

Cynata Therapeutics Limited
9 December 2019

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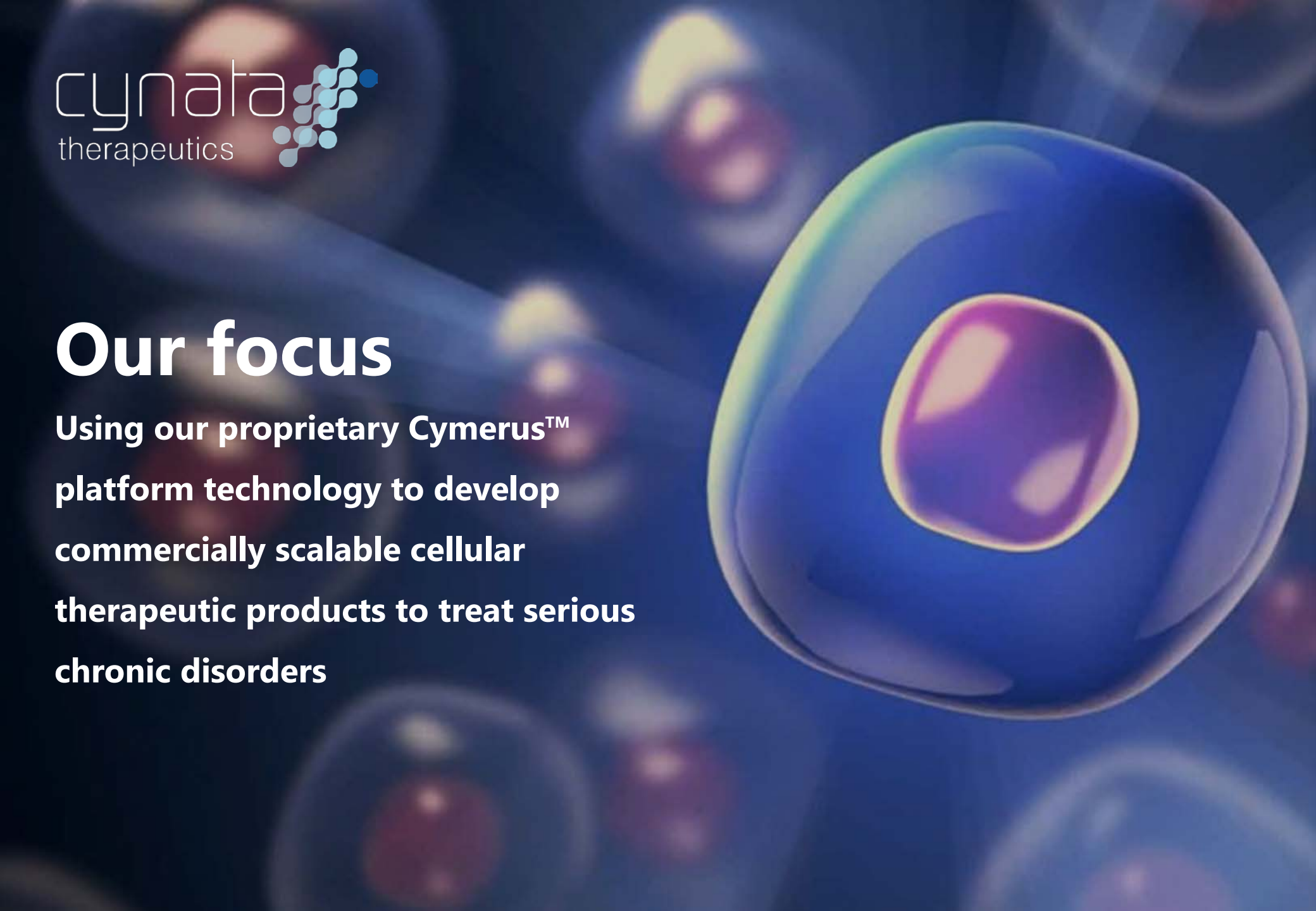
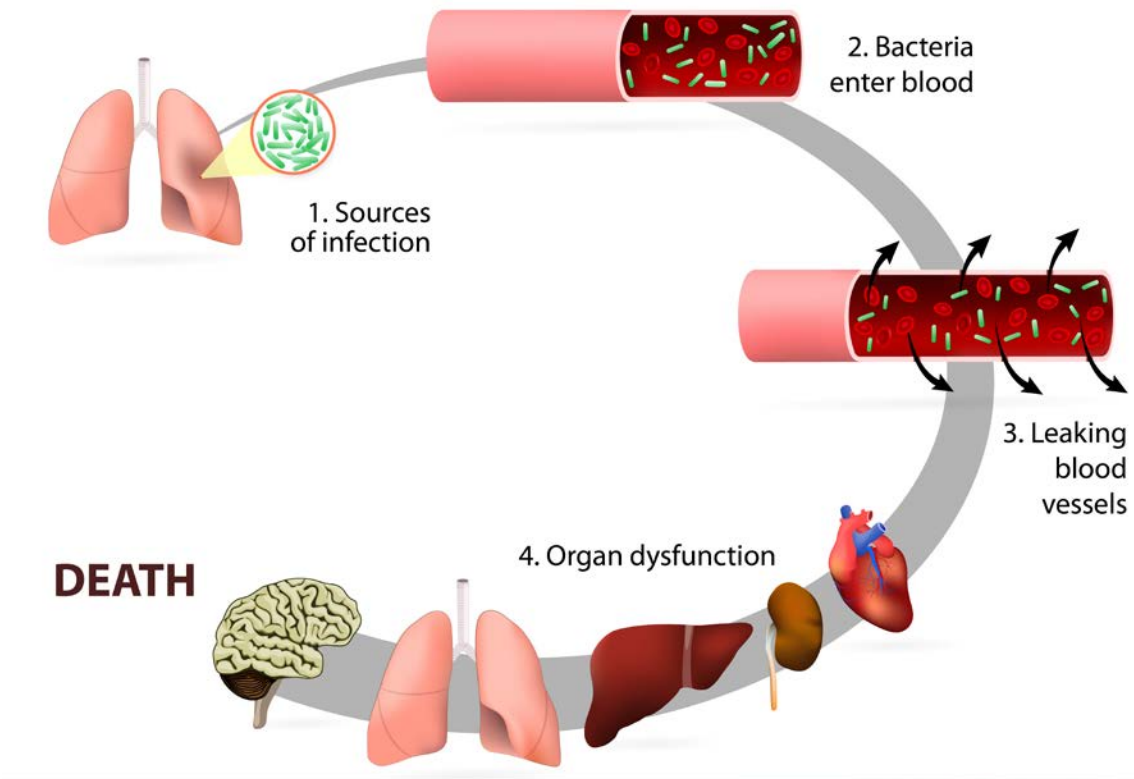


Our focus

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

What is sepsis?

Sepsis is a life-threatening condition caused by the body's response to an infection



- Sepsis is also known as blood poisoning, septicaemia, or in its most severe form, septic shock
- It affects ~**30 million** people worldwide each year, leading to up to **6 million deaths**
- Caused by an over-reaction of the immune system to infection, triggering changes that can damage multiple organs
- Initial symptoms are vague and not easily distinguished from less serious conditions
- Diagnosed based on mental status, blood pressure and breathing rate, in addition to presence of an infection

1. World Health Organization https://www.who.int/news-room/fact-sheets/detail/sepsis

Clinical significance

Enormous unmet medical need

- Sepsis is the most common cause of death in hospital Intensive Care Units
- Implicated in 1 in 20 deaths in the population as a whole and up to 50% of all hospital deaths
- Approximately 30% of patients diagnosed with severe sepsis do not survive[1]
- Sepsis has been identified as the most expensive in-patient cost in US hospitals[2], costing US$27 billion each year[1]
- Market opportunity for sepsis/septic shock across the 7 major pharmaceutical markets (US, France, Germany, Italy, Spain, UK and Japan) is estimated to reach US$5.9 billion by 2026[3]

Existing treatment options are limited

- Antibiotics – often used prior to identifying underlying infection, which makes selection of appropriate antibiotic difficult
- Intravenous fluids
- Organ support such as intubation and kidney dialysis

1. Sepsis Alliance. https://www.sepsis.org/
2. Agency for Healthcare Research and Quality, United States Department of Health and Human Services, Statistical Brief #204, May 2016
3. GlobalData report: Opportunity Analyzer: Sepsis and Septic Shock – Opportunity Analysis and Forecasts to 2026

Cynata/RCSI Development Partnership

RCSI Leading the world to better health

- The Royal College of Surgeons in Ireland is an international not-for-profit health sciences institution, founded in 1784, with its headquarters in Dublin
- RCSI is ranked among the top 2% of universities worldwide and its research is ranked first in Ireland for citations[1]

Cynata and RCSI commenced a development partnership in July 2018

- Focussed on the therapeutic potential of Cynata's Cymerus MSCs to treat sepsis
- Co-funded by Cynata and the RCSI Strategic Industry Partnership Seed Fund
- Led by Professor Gerard Curley (Chair of the Department of Anaesthesia and Critical Care at RCSI, and Consultant in Intensive Care Medicine at Beaumont Hospital, Dublin)

1. The Times Higher Education World University Rankings (2019))

Preclinical studies of Cymerus MSCs in sepsis – methods (1)

In vitro studies

- The ability of Cymerus MSCs to enhance phagocytosis, in comparison to bone marrow-derived MSCs (BM-MSCs) and a negative control, was assessed by co-culturing the cells with macrophages (white blood cells), in the presence of *E. coli* (bacteria)
- Phagocytosis is the process by which white blood cells ingest and remove bacteria and other harmful agents from the body
- The macrophages were exposed to MSCs either directly or indirectly:
  - Direct exposure was achieved by mixing the cells in the same culture vessel
  - Indirect exposure was achieved using Transwell plates, which keep the MSCs and macrophages apart but allow cell signalling molecules released by the MSCs to reach the macrophages
- The effects were assessed by measuring the amount of *E. coli* taken up by macrophages, and measuring the extent of phagocytosis

Preclinical studies of Cymerus MSCs in sepsis – methods (2)

In vivo studies

- Pneumonia-induced sepsis was caused in rats by instilling *E. coli* into the trachea (windpipe)
- Two versions of the model were used – mild and severe (the severity is adjusted by varying the dose of *E. coli* administered)
- This is a well-established, clinically relevant, preclinical model of sepsis, which has been used in numerous previous studies
- Animals were randomly assigned to groups as shown below:

Sepsis Severity	Sham	Placebo	Cymerus MSCs
Mild	N=5	N=14	N=14
Severe	N=5	N=14	N=14

Sham = healthy control animals in which no disease was induced

- Animals were monitored over a 24 hour period and then assessed for: blood oxygen levels; lung compliance (the ability of lungs to stretch and expand); alveolar neutrophil infiltration (which can lead to lung injury); barrier permeability (which allows harmful proteins into the lungs) and extent of inflammation

Preclinical studies of Cymerus MSCs in sepsis – results

In vitro studies

- Cymerus MSCs and BM-MSCs resulted in higher levels of *E. coli* in macrophages and a statistically significant increase in phagocytosis compared to negative controls ($p<0.05$)
- The effects were similar in both the direct and indirect assays

In vivo studies

- In the severe sepsis model, Cymerus MSC treatment resulted in the following statistically significant improvements in important biological parameters, in comparison to placebo control:
  - Increased blood oxygen levels ($p<0.01$)
  - Increased lung compliance (the ability of lungs to stretch and expand) ($p<0.01$)
  - Decreased alveolar neutrophil infiltration (which can lead to lung injury) ($p<0.05$)
  - Decreased barrier permeability (which allows harmful proteins into the lungs) ($p<0.05$)
  - Decreased inflammation ($p<0.05$)
- In the mild sepsis model, Cymerus MSC treatment also resulted in statistically significant improvements in blood oxygen levels ($p<0.01$) and lung compliance ($p<0.05$) and showed positive trends on other parameters
- Overall, MSC treatment resulted in more profound improvements in the severe model

Discussion

- Particularly encouraging that Cymerus MSC treatment was most effective in the severe sepsis model, as that is where greatest unmet need lies
- This finding is consistent with the known ability of MSCs to respond to their environment
- Cynata considers these highly encouraging preclinical results to be supportive of a clinical trial in patients with severe sepsis
- We are continuing to work with our partners at RCSI to plan the next steps for this program

"There is a critical need for new therapies to treat sepsis, which is a devastating condition that can affect people at any stage of life without warning. These exciting results give us grounds for optimism that Cymerus MSCs could provide a new treatment option for these patients." (Professor Gerard Curley, RCSI)

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

Conventional MSC processes

Cells from donors → MSC isolation → **Extensive** MSC culture expansion

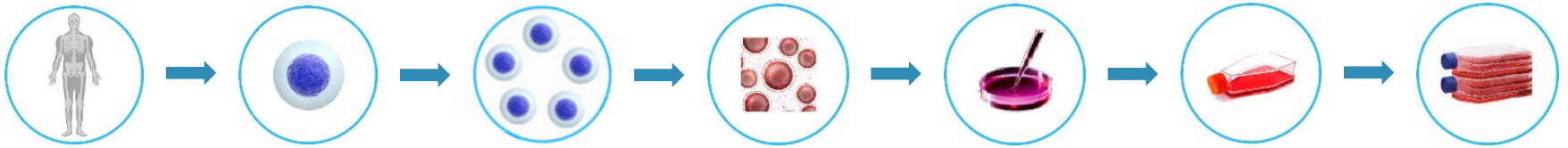
Substantial variability between donors	Very few MSCs per donation *(~20,000)*	Large number of MSCs required *(1bn + per patient)*

MSCs change when excessively expanded: loss of potency, senescence, decreased efficacy

- limits number of doses that can be produced per donation
- new donors required more frequently
- more variability

Cymerus iPSC-derived process

Cells from **one** donor → iPSC Derivation → iPSC Expansion → Induction of Mesoderm → Generation of MCA Colonies → Generation of MSCs → **Minimal** MSC culture expansion



Avoids inter-donor variability	Effectively **limitless** numbers	No need for extensive MSC culture expansion

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

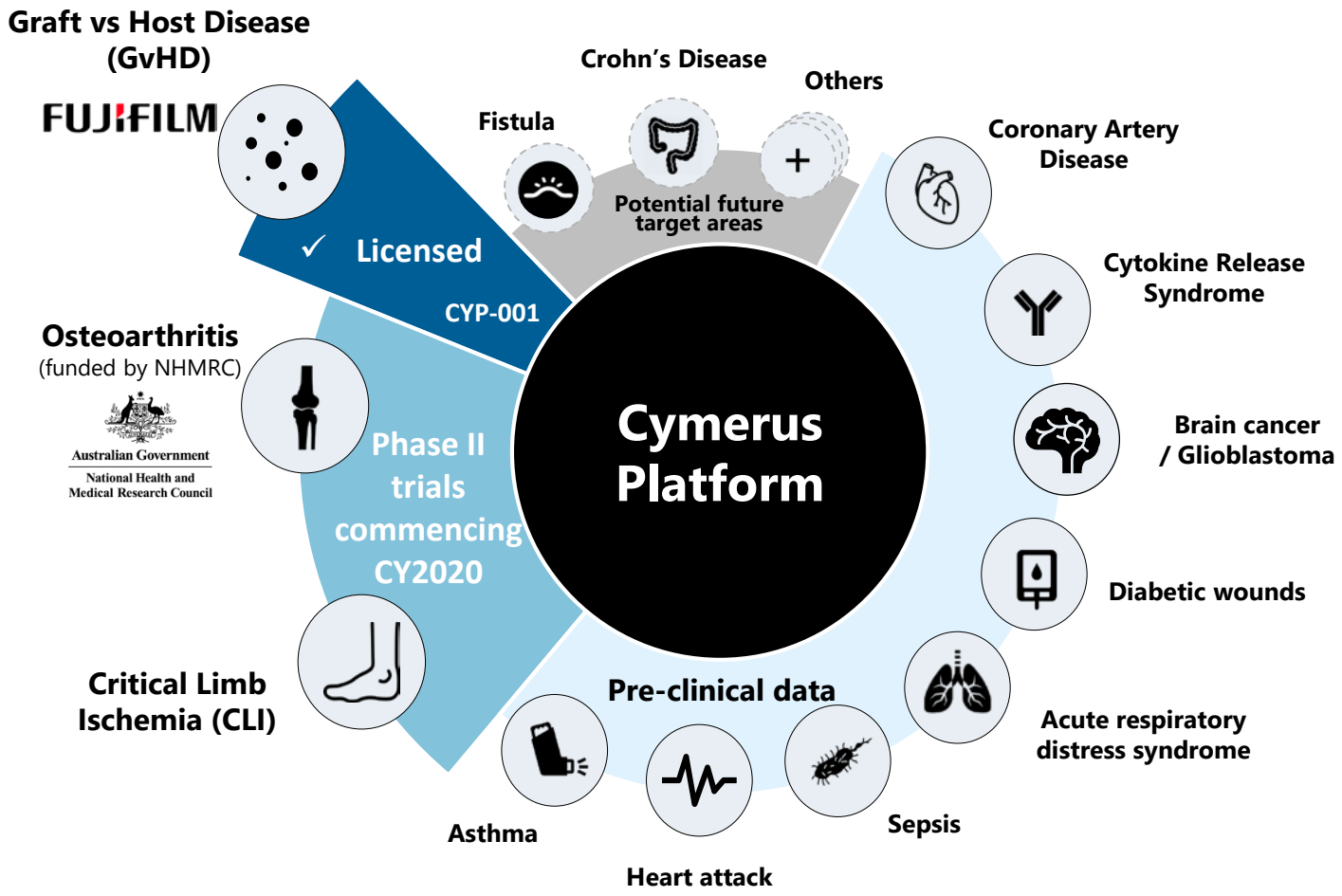
Key advantages of the platform:

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



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

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