

Cynata Therapeutics Ltd

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Cynata Therapeutics aims for commercial production of cutting-edge STEM cell products

Cynata Therapeutics Ltd (ASX:CYP) is ready to move up to scalable production of its graft-versus-host disease (GvHD) drug after a clinical trial proved the safety and efficacy of the drug.

Cynata managing director and chief executive officer Dr Ross Macdonald told Proactive that showing the product had a desirable clinical effect in people was an excellent result for the company.

He said: "We achieved all of the study endpoints, demonstrating primarily the safety of the product but also efficacy, and therein lies one of the secrets to success in biotech land, which is demonstrating that the product or technology works in humans."

The trial results included a 54% complete response rate, an 87% overall response rate and a greater than 87% survival rate of patients using the GvHD drug.

Not only is the technology safe and effective, it also bypasses complex and invasive surgeries for patients and hospitals, and lowers costs incurred by healthcare systems.

Cutting edge-technology

Cynata's Cymerus technology overcomes the challenges of other production methods to achieve economic manufacture of cell therapy products, including mesenchymal stem cells (MSCs), at commercial scale without the limitation of multiple donors.

Macdonald said this put Cynata ahead of the pack in terms of commercial product development.

He said: "For a small Aussie company with a hundred million or so market cap to be the leader in the world in this area - and there's no dispute about that as for this particular type of cell therapy we are well and truly the leader as first company to complete a clinical study - it's really a very exciting place to be.

"The technology provides a consistent manufacturing process - and that consistency and reproducibility is a vital element of successful drug product development."

Fuji Film partnership

The company now has the full support and resources to achieve commercial production after signing on the dotted line with new partner, pharmaceutical giant, Fuji Film.

Macdonald said: "Australia is a great place for medical research and development, but it has some limitations when it comes to access to the amount of capital that's required to fully develop a drug product.

"Instead of trying to squeeze blood out of a stone, our strategy was to access the necessary resources through

Price: 0.69

Market Cap: \$71.08 m

1 Year Share Price Graph



April 2019 October 2019 March 2020

Share Information

Code: CYP

Listing: ASX

| | | |
|----------------|-------------|------------|
| 52 week | High | Low |
| | 1.87 | 0.58 |

Sector: Pharma & Biotech

Website: www.cynata.com

Company Synopsis:

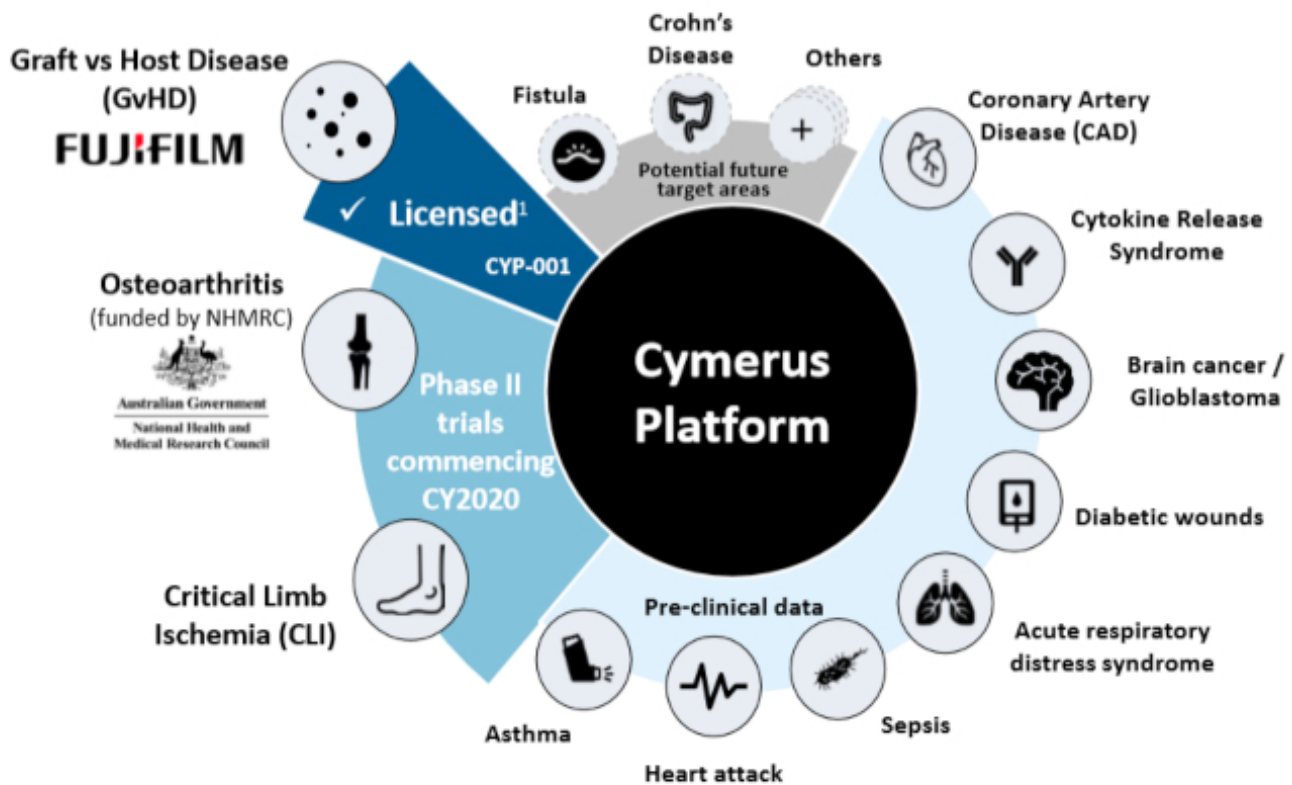
Cynata Therapeutics Ltd (ASX:CYP) is a clinical-stage stem cell and regenerative medicine company.

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partnership.

"Fuji Film is very active in pharmaceuticals and in the manufacture of drug products and that's what drew us together.

"It's also consistent with our strategy of partnering our technology with global players who have the capacity and the access to resources that are necessary to ultimately bring our drug product to market."



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

Advancing the product to market

Fuji Film now has global rights to Cynata's first product, GvHD, and has already paid a US\$3 million licence fee, bought US\$3 million worth of stock at a 35% premium, and will pay further US\$40 million in milestones plus a double-digit royalty on product sales.

Macdonald said: "This year they expect to start a phase two clinical trial.

"In Fuji Films hands, GvHD is expected to get to market sometime late in 2022 or early 2023."

Further trials in 2020

Cynata has three fully-funded clinical trials upcoming, one is the phase two GvHD trial with Fuji Film, one is in Osteoarthritis (OA) which is funded by the Australian Government and one is in critical limb ischemia (CLI).

Macdonald said: "You can cure cancer in rats but if you can't cure cancer in humans you don't have a product.

"It comes down to being able to generate really good, solid data from clinical trials that prove that your product is safe and effective - that's the sort of data we are seeking to generate to really drive shareholder value and become catalysts for shareholders to enjoy a significant uplift.

"Data is what drives value in biotech land."

Market opportunities

The company states that GvHD has an estimated market opportunity of US\$0.3 billion, CLI has an estimated market opportunity of US\$1.4 billion and OA has an estimated market opportunity of US\$11.6 billion.

Consequently, interest from major pharmaceutical companies in these areas of cell therapeutics is increasing.

Macdonald said this was one of the reasons Cynata recently knocked back a takeover bid which it believed undervalued the company.

He said: "Last year the company received takeover bids, one of which was disclosed to the market at \$2 per share.

"Ultimately, we decided not to go ahead with that, but it's a nice position to be in when a global, major pharmaceutical company decides that the technology looks exciting enough that they're prepared to pay a couple of hundred million dollars for it.

"That was also important validation of our technology and our strategy."

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