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# **Doing the hard-cell for biotech**

### SARAH-JANE TASKER INNOVATION

A small Australian stem cell company is leading the world in the race to develop cells on a commercial scale and its chief Ross Macdonald says he is proud to "wave the flag" to show the country has a seat on the global stage.

Dr Macdonald, head of Cynata Therapeutics, is working the global conference circuit after the company received the green light from British regulators to progress a clinical study of its stem cell product, which the chief executive said was a "genuine world first".

"It has major impacts on cellbased medicine generally," he said from a conference in California.

"It will set a new program for many other companies in this space."

The company will study the use of induced stem cells to treat patients who have been diagnosed with graft-versus-host disease following a bone-marrow transplant.

That occurs when the donated cells/bone marrow attack the new body, which it views as foreign.

Dr Macdonald, who is also speaking at a major Japanese conference this week, said the use of cells as medicine had been the biggest directional change in the practice of medicine since antiviral drugs.

"Using the body's own cells in one form or another to treat disease is a very hot area at the moment," he said.

The earliest use of stem cells involved cells derived from embryos, but it wasn't a long-term solution for commercial purposes. Companies looked at alternatives, like extracting cells from bone marrow, but that also wasn't a viable approach commercially.

Dr Macdonald said that in the early 2000s scientists from Japan and the US developed an ap-

proach to manufacture cells similar to those extracted from an embryo - a discovery that saw the scientists involved awarded a Nobel prize in 2012.

The cell they manufactured is called an induced pluripotent stem cell (iPSCs). Pluripotent cells are able to give rise to different types of cells - they have the potential to become anything.

"We can in the laboratory coax any cell obtained from our body

to become what was essentially an embryo again — you induce a cell to become a pluripotent cell," Mr Macdonald said.

Cynata was formed in 2011 and listed on the Australian market in November 2013.

Dr Macdonald said the company had "got there very quickly", adding that to be starting a clinical trial in the next few months was a real achievement.

"We always thought we had something enormously important but we had to make investors and regulators think likewise."

The Cynata chief said its strategy was to license its technology to third parties.

"Our shareholders then get multiple shots on goal," he said.

The approval by the British regulator to progress a phase one clinical trial of its stem cell technology is expected to boost the interest from third parties.

The trial is expected to start in the next 12 months in Australia and Britain and will focus on patients who have had a bone-marrow transplant, or a similar procedure, and been diagnosed with graft-versus-host disease.

'We have the first approval for a clinical trial for a therapeutic product using the iPSCs," Dr Macdonald said.

"It is a landmark decision and

has ripples down the huge medical application of induced iPSCs derived products.'

Dr Macdonald said that despite an enormous amount of work in this space, no one else had reached the clinical trial phase.

"It's a good achievement given the vast resources the Japanese and American governments are throwing at it," he said.

"We are waving the flag loud and clear ... a major theme of Prime Minister Malcolm Turnbull's innovation statement was regenerative medicine.

"It is good to have a success story to say these things can happen in Australia."





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Ross Macdonald says using the body's own cells to treat disease is a 'hot area' of research



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