

Cancer killer trial close

Robyn Riley

Victorian breakthrough on the line

The first trials of a ground-breaking treatment for ovarian cancer developed in Victoria are set for early next year.

Frustratingly stubborn to treat, ovarian cancer last year claimed more than 1000 lives in Australia.

Biotech company Cartherics announced last week it had a positive meeting with the US Food and Drug Administration as part of its final preparation for a formal application to start human studies of its unique cell therapy drug.

Called CTH-401, it is a natural killer cell product that seeks out and destroys the cells that cause ovarian cancer.

The natural killer cells come from stem cells taken from the donated cord blood of babies. Stem cells are nature's building blocks and can transform into any other type of cell.

The Melbourne company says this is the only treatment in the world to target and kill the ovarian cancer-associated cell molecule called TAG-72.

"The importance of the meeting with the FDA was that there were no red flags," Professor Alan Trounson said.

The Cartherics chief executive and renowned IVF and stem cell pioneer said the company now knew

what it needed to do to achieve a successful filing to begin the clinical trials.

"If this therapy works, we can manufacture the product very easily, because it is cloned from one single cell checked for genetic normality, so there are very few risk elements," Professor Trounson said.

He said the therapy should work in 95 per cent of ovarian cancers because all had the TAG-72 cancer cell the product was designed to target and kill.

"Sixty-five per cent of women don't survive (ovarian cancer)," he said.

"We need

something because there is not a lot of successful treatment available."

The company will file its application in February or March, advise the Therapeutic Goods Administration and then seek the approval of hospital ethics committees to do the trials in Australia.

"Clinical trials with Australian patients should start by the first quarter next year," Professor Trounson said.

"We know we have patients waiting in Melbourne and Sydney who want to be on the trial. We need to find out how well it works."

He said up to 30 patients would be recruited for the first study.

"It is a great treatment," Professor Trounson said. "It may not be perfect yet because we still may need to modify further, but this looks really good and safe in all our tests, and those two things are important."

"Natural killer cells have never shown up any adverse effects. We are making (the product) out of a single cell and we know exactly what we have genetically done and we multiply them into natural killer cells in very large numbers. That's the incredible value of stem cells."

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