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Australia's Cartherics expands agreement with Catalent to focus on cancer and endometriosis treatment

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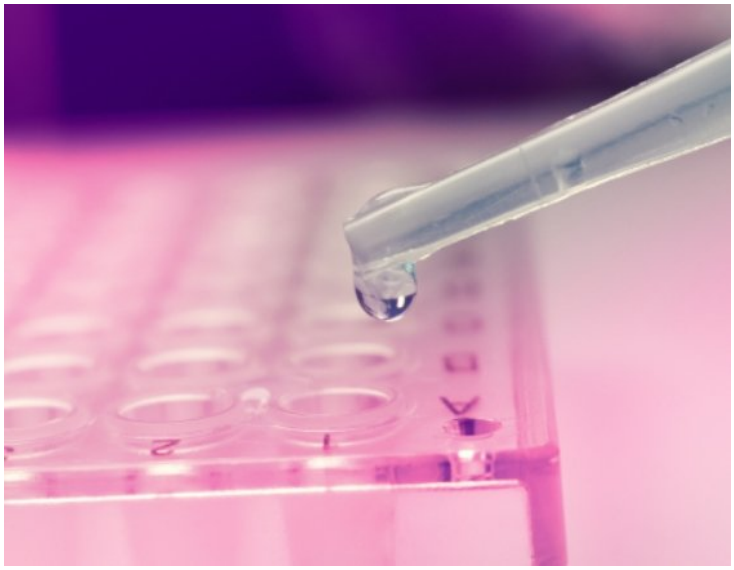
Supporting Carthericsâ?? mission to develop immune cell therapy products for the treatment of cancer and endometriosis



Cartherics, an Australia-based biotechnology company developing offâ??theâ??shelf immune cell therapies for highâ??impact women's diseases, including ovarian cancer and endometriosis, and Catalent, Inc., the leader in enabling the development and supply of better treatments for patients worldwide, have announced an enhanced partnership.

The companies have signed an amended commercial license agreement enabling the use of a Catalent cGMPâ??compliant induced pluripotent stem cells (iPSC) line for the manufacture and commercialisation of Cartherics' iPSC-derived Chimeric Antigen Receptor Natural Killer (CAR-NK) cell therapies. The agreement supports Cartherics' mission to develop immune cell therapy products for the treatment of cancer and endometriosis.

Under the terms of the agreement, Cartherics is granted rights to develop and commercialise multiple product candidates derived from a Catalent off-the-shelf cGMP iPSC line, including its lead CARâ??NK cell product, CTHâ??401. The licensed iPSC line is part of a broader portfolio of fully characterized, donorâ??consented, clinicalâ??grade iPSC lines generated under GMP conditions, supported by validated workflows for reprogramming, expansion, gene editing, differentiation and quality control.

With Catalent's support, Cartherics has already obtained approval from the US Food and Drug Administration (FDA) for use of the licensed iPSC line as the starting cell for generation of Cartherics' CTHâ??401. The two companies have also demonstrated full compatibility between CTH-401 and Catalent's iPSC-NK manufacturing platform.

The agreement enhances Cartherics' manufacturing capabilities by providing a robust framework for collaboration and incentives for utilising Catalent as its contract manufacturing organisation for late-stage clinical trials and commercial supply. Importantly, Cartherics retains the ability to manufacture clinical trial material and retains the right to participate in downstream

manufacturing as the partnership evolves.