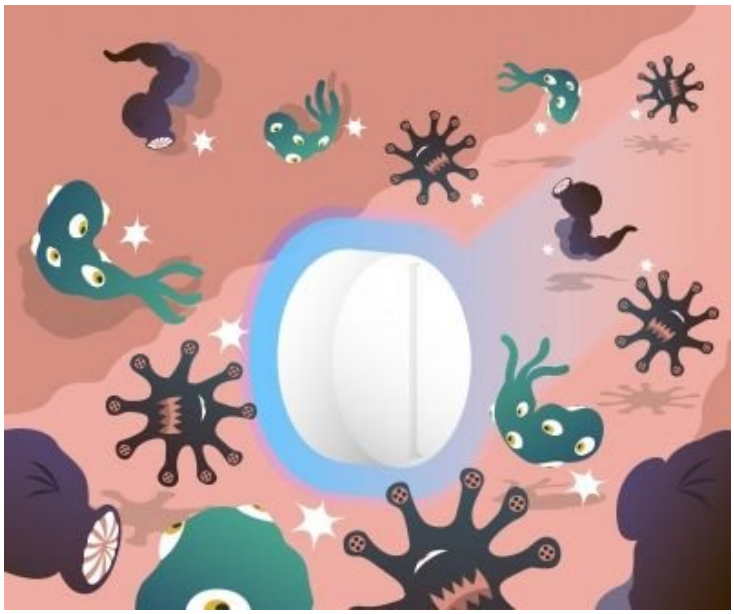
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Aussie firm trials combination therapy for melanoma

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Aussie firm trials combination therapy for melanoma



Singapore: Australia based Viralytics has initiated a clinical trial to assess its oncolytic virus, Cavatak, in combination with the checkpoint inhibitor Keytruda (pembrolizumab) in late-stage melanoma patients.

Phase 1b open-label study is designed to evaluate the safety and tolerability of the established dose of Cavatak in combination with Keytruda in 30 patients with advanced melanoma. Investigators will also assess evidence of anti- cancer activity, including response rates and bio-markers of anti-tumour immunity.

The lead investigator for the trial is Dr Howard Kaufman, associate director, clinical sciences, Rutgers Cancer Institute, New Jersey, New Brunswick. Dr Kaufman, whose research is focused on finding new treatments for melanoma and other related skin cancers, currently serves as the President of the Society for Immunotherapy of Cancer.

He was also an investigator in the recently concluded Phase 2 CALM trial assessing CAVATAK as a monotherapy in late-stage melanoma patients.

"Based on the positive results of the CALM trial, including data from the CALM extension study showing Cavatak's ability to increase the number of cancer-fighting immune cells present in tumour tissue, I am eager to explore the combination of CAVATAK and Keytruda in human trials," said Dr Kaufman. "Although Keytruda and other checkpoint inhibitors represent a major advance in the treatment of melanoma, there is great interest in the potential of oncolytic viruses such as Cavatak to improve upon these outcomes in patients with melanoma."

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Cavatak is an investigational novel cancer immunotherapy based on a proprietary bioselected cold virus that has been shown to preferentially infect and attack cancer cells. In preclinical studies, the combination of CAVATAK and the mouse homologue of pembrolizumab was well tolerated and produced greater anti-tumour activity and a greater survival benefit in a mouse melanoma model, compared to the use of either agent alone.

Keytruda (pembrolizumab) belongs to a new class of cancer immunotherapy agents called immune checkpoint inhibitors. Launched by Merck & Co in 2014 for the treatment of advanced melanoma, Keytruda was the first drug approved by the US Food and Drug Administration that blocks the PD-1 protein, which restricts the body's immune system from attacking cancer cells.

Dr Malcolm McColl, managing director, Viralytics said, "We are very pleased to be working with one of the leaders in immuno-oncology to assess the potential synergy of Cavatak and Keytruda, a key checkpoint inhibitor and potential blockbuster drug. The results of our preclinical studies provide encouragement that this combination may produce superior efficacy outcomes. Along with our MITCI clinical trial, initiated earlier this year to assess CAVATAK given along with ipilimumab, this study will provide valuable data about CAVATAK's potential as part of an immunotherapy combination strategy against major cancers."

Subject to satisfactory results from the Phase 1b study, Viralytics will proceed into a randomized Phase 2 combination trial of CAVATAK and Keytruda.