

ASX and Media Release

**Viralytics moves into the Expansion Phase and Reports on Progress in the CAVATAK<sup>®</sup> and KEYTRUDA<sup>®</sup> Combination KEYNOTE-200 clinical trial at AACR Conference**

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**5 April 2017, Sydney, Australia:** [Viralytics Limited](#) (ASX: VLA, OTC: VRACY) today reported on progress in the ongoing Phase 1b KEYNOTE-200 (STORM<sup>1</sup> Part B) clinical trial evaluating [CAVATAK<sup>®2</sup>](#) in combination with KEYTRUDA (pembrolizumab) in patients with advanced non-small cell lung or metastatic bladder cancer at the [American Association for Cancer Research \(AACR\) Annual Meeting 2017](#), being held in Washington DC, USA.

The latest data from the study was the subject of a podium presentation by Dr. Charles Rudin, MD, PhD, Chief of the Thoracic Oncology Service, Memorial Sloan Kettering Cancer Center (New York, USA) in the *Novel Immuno-Oncology Agent Clinical Trials* plenary session. Dr. Rudin is the Principal Investigator for the KEYNOTE-200 trial.

Of the trial, Dr. Rudin said “We are keen to explore new investigational agents such as CAVATAK that have the potential to enhance the activity of KEYTRUDA in non-small cell lung and metastatic bladder cancer patients who have not been treated with checkpoint inhibitors as well as those who have progressed after checkpoint therapy. So far, the low rate and incidence of adverse events is encouraging and I am pleased we can now commence more rapid enrolment in the expansion stage.”

The KEYNOTE-200 trial (also known as Part B of the STORM clinical trial) is an ongoing study evaluating intravenously delivered CAVATAK in combination with KEYTRUDA (pembrolizumab) in patients with advanced non-small cell lung cancer (NSCLC) or metastatic bladder cancer. The key aims of the study are to establish a recommended dosing regimen and to evaluate anti-cancer activity and patient tolerability. The study is being conducted in collaboration with Merck (known as MSD outside the United States and Canada).

Enrolment of ten patients in the combination dose escalation phase of the study is now complete and recruitment of the expansion cohort of 80 patients is underway.

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<sup>1</sup> STORM - Systemic Treatment Of Resistant Metastatic disease

<sup>2</sup> CAVATAK is a novel investigational cancer immunotherapy based on a proprietary cold virus that has been shown to preferentially infect and kill cancer cells and can boost the natural anticancer immune response.

Patients enrolled in the dose escalation phase of the KEYNOTE-200 study had very advanced disease, been heavily pretreated and included patients who have received prior checkpoint therapies<sup>3</sup>.

In these first ten patients the combination of CAVATAK and KEYTRUDA (pembrolizumab) has been generally well tolerated with only one grade 3 CAVATAK-related and no grade 3 or higher pembrolizumab-related adverse events<sup>4</sup>. There have been no dose limiting toxicities.

Currently, all three patients in the third cohort assessing the highest dose of CAVATAK in combination with pembrolizumab are ongoing in the study.

The earlier completed STORM Part A study was designed to establish a safety profile and determine an intravenous dosing schedule for successful tumour targeting of CAVATAK given as a single agent. Data showed that CAVATAK was well tolerated, with no dose-limiting toxicities or grade 3 or higher CAVATAK-related adverse events. Biopsies of tumour tissue from patients with melanoma, non-small cell lung cancer (NSCLC) and metastatic bladder cancer confirmed successful tumour targeting by detecting CAVATAK in these samples following three intravenous doses of the agent. There was also evidence of potential tumour-specific secondary viral replication, which may lead to up-regulation of PD-L1 expression, a target for pembrolizumab.

“We are delighted to be advancing the KEYNOTE-200 expansion phase at leading sites in the USA and also plan to open sites in Australia and the UK,” said Dr Malcolm McColl, Managing Director of Viralytics. “Based on the earlier preclinical combination studies and the results from STORM Part A we are keen to assess the potential of the CAVATAK/ KEYTRUDA combination in these very important cancer indications.”

The presentation deck, entitled “Phase 1b KEYNOTE-200 (STORM study): A study of an intravenously delivered oncolytic virus, Coxsackievirus A21 in combination with pembrolizumab in advanced cancer patients,” is available from the Viralytics website at <http://www.viralytics.com/our-pipeline/scientific-presentations/>.

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<sup>3</sup> Checkpoint inhibitors are an important new class of anticancer agent that take the brakes off the immune response to cancer and have application across a broad range of cancer types including melanoma, lung and bladder cancer. They include the anti-PD-1 antibodies such as nivolumab (OPDIVO®, Bristol Myers Squibb) and pembrolizumab (KEYTRUDA®, Merck) and the anti-CTLA-4 antibodies such as ipilimumab (YERVOY®, Bristol Myers Squibb).

<sup>4</sup> Grade 3 adverse events are severe or medically significant but not immediately life-threatening; Grade 4 adverse events are life-threatening with urgent intervention indicated; Grade 5 is death related to an adverse event.



**About Viralytics Ltd:**

Viralytics is developing oncolytic immunotherapy treatments for a range of cancers. The company's lead investigational product, CAVATAK<sup>®</sup>, is currently being studied in Phase 1 and 2 clinical trials for the treatment of melanoma, as well as bladder and lung cancers. CAVATAK is a proprietary formulation of the common cold Coxsackievirus Type A21 (CVA21) that preferentially binds to specific 'receptor' proteins highly expressed on multiple cancer types. CAVATAK acts to kill both local and metastatic cancer cells through cell lysis and the potential generation of an immune response against the cancer cells – a two-pronged mechanism of action known as oncolytic immunotherapy.

Based in Sydney Australia, the company is listed on the Australian Securities Exchange (ASX: VLA) while Viralytics' ADRs also trade under VRACY on the US OTCQX International market. For more information, please visit [www.viralytics.com](http://www.viralytics.com).

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