



ASX and Media Release

Viralytics Updates CAVATAK™ and KEYTRUDA® Combination Clinical Trials at ESMO 2016

10 October 2016, Sydney, Australia: [Viralytics Limited](#) (ASX: VLA, OTC: VRACY) today presented updates of two ongoing Phase 1b combination clinical trials of [CAVATAK™](#), its lead drug candidate, and KEYTRUDA®¹ (pembrolizumab), Merck's anti-PD-1 checkpoint inhibitor, at the [European Society for Medical Oncology 2016 Congress](#) in Copenhagen, Denmark.

CAVATAK is a novel cancer immunotherapy based on a proprietary cold virus that has been shown to preferentially infect and attack cancer cells.

STORM (KEYNOTE 200) Trial Update

An update of the ongoing two-part Phase 1b STORM (KEYNOTE 200) clinical trial evaluating the safety and efficacy of CAVATAK, both as a monotherapy and in combination with KEYTRUDA, was provided in a poster presentation led by Professor Hardev Pandha, MD, PhD, Director of the Surrey Cancer Research Institute at the University of Surrey in the UK.

Part A of the STORM (Systemic Treatment of Resistant Metastatic Disease) trial is complete. The trial was designed to establish a safety profile and determine an intravenous dosing schedule for successful tumour targeting for CAVATAK given as a single agent to patients with advanced solid tumours. CAVATAK was well tolerated in this trial, with no dose-limiting toxicities. In addition, clinical data from biopsies of tumour tissue from patients with melanoma, non-small cell lung cancer (NSCLC) and metastatic bladder cancer confirmed successful systemic tumour targeting by detecting CAVATAK in these samples following three intravenous doses of the agent.

Enrolment in the first two cohorts (6 patients) in Part B of the STORM study, known as the KEYNOTE 200 trial, is now complete. The expansion phase (approximately 80 patients) will commence once successful enrolment of the three patients in the third cohort is complete.

Part B of the trial, being undertaken in collaboration with Merck (known as MSD outside the United States and Canada), is evaluating intravenously delivered CAVATAK in combination with KEYTRUDA in patients with advanced NSCLC or metastatic bladder cancer. The trial is an open-label, multi-center study with dose escalation of CAVATAK in combination with fixed doses of KEYTRUDA.

¹ KEYTRUDA is a trademark of Merck & Company Inc

The aim of the study is to establish a recommended dosing regimen for the CAVATAK/KEYTRUDA combination and to evaluate anti-cancer activity and patient tolerability. To date, this immunotherapy combination has been well tolerated with no grade 3 or higher treatment-related adverse events.

The poster presentation, entitled *"Intravenous coxsackievirus A21 in combination with pembrolizumab in advanced cancer patients: Phase 1b KEYNOTE 200 study"* is available from the Viralytics website at <http://www.viralytics.com/our-pipeline/scientific-presentations/>.

CAPRA Trial Update

An update of the Phase 1b CAPRA (CAVATAK and Pembrolizumab in Advanced Melanoma) clinical trial led by Howard Kaufman, MD, FACS, Associate Director for Clinical Sciences at the Rutgers Cancer Institute of New Jersey in New Brunswick was also provided in a poster presentation.

The CAPRA trial is designed to evaluate the safety and tolerability of the established dose of intratumoral CAVATAK in combination with KEYTRUDA in 30 patients with advanced melanoma for whom KEYTRUDA would be considered standard of care. Investigators are also assessing evidence of anti-cancer activity, including response rates and bio-markers of anti-tumour immunity.

Preliminary observations of the first eight evaluable patients have revealed reductions in a number of injected and non-injected visceral and non-visceral lesions, with a number of patients displaying evidence of post-injection systemic exposure to CAVATAK. Overall, this immunotherapy combination has been well tolerated, and no grade 3 or higher treatment-related adverse events have been observed.

The poster presentation, entitled *"Phase 1b study of intratumoral oncolytic coxsackievirus A21 (CVA21) and pembrolizumab in subjects with advanced melanoma"* is available from the Viralytics website at: <http://www.viralytics.com/our-pipeline/scientific-presentations/>.

Dr Malcolm McColl, Managing Director of Viralytics said: "We are pleased with enrolment in both studies and the potential benefits from the CAVATAK and KEYTRUDA combination in these important cancer indications. We look forward to providing further updates at the upcoming Society for Immunotherapy of Cancer conference in November."



About Viralytics Ltd:

Viralytics is developing oncolytic immunotherapy treatments for a range of cancers. The company's lead investigational product, CAVATAK™, 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 Cocksackievirus 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.

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