ASX and Media Release

Viralytics Initiates Clinical Trial of CAVATAK™ in Combination with PD-1 Blocker Keytruda®

28 September 2015, Sydney, Australia: Viralytics Limited (ASX: VLA, OTC: VRACY) announced today that it has initiated a clinical trial to assess its oncolytic virus, CAVATAK™in combination with the checkpoint inhibitor Keytruda®[1] (pembrolizumab) in late-stage melanoma patients.

The company-sponsored 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 Howard Kaufman MD FACS, Associate Director for Clinical Sciences at the Rutgers Cancer Institute of 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.”

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

[1] Keytruda® is a trademark of Merck & Company Inc

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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 of 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.

About the Trial:
The trial referred to as the CAPRA (**CA**VATAK and **P**emb**R**olizumab in **A**dvanced Melanoma) study will use CAVATAK administered intratumourally in combination with Keytruda (pembrolizumab) in late stage melanoma patients.

Treatment with CAVATAK will be on days 1, 3, 5 and 8, and then at 3-weekly intervals (up to a maximum of 19 total injections), with intravenous pembrolizumab (2 mg/kg) starting on day 8 and continuing every 3 weeks for up to two years.

Further information is contained in the following trial synopsis.

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CAVATAK / Keytruda (pembrolizumab) COMBINATION TRIAL SYNOPSIS

Title of Study:	CAPRA (**CA**VATAK and **P**emb**R**olizumab in **A**dvanced Melanoma) Phase I Study of Intratumoral CAVATAK™ (Coxsackievirus A21) and Pembrolizumab in Patients With Advanced Melanoma
Objectives:	**VLA011** **Primary Objectives:** • Assess the safety and tolerability of intravenous pembrolizumab with intratumoral CAVATAK™ by incidence of dose-limiting toxicities **Secondary Objective:** • To assess the clinical efficacy of pembrolizumab in combination with intratumoral CAVATAK™ in terms of immune-related progression-free survival (irPFS) at 12 months, PFS hazard ratio, objective response rate (ORR), 1-year survival, overall survival (OS) and quality of life. • Assess the response of injected and non-injected melanoma deposits after CAVATAK™ and pembrolizumab. • Assess the time to initial response. • Assess the durable response rate • Assess peripheral blood for changes in T-cell phenotypes after CAVATAK™ and pembrolizumab. • Assess for T-cell immune response to known melanoma antigens during treatment.
Study Design:	This is a Phase I, single-site, open-label study designed to evaluate the safety and tolerability of intravenous pembrolizumab with intratumoral CAVATAK™. Treatment with CAVATAK™ will be on days 1, 3, 5 and 8, and then at 3-weekly intervals (up to a maximum of 19 total injections), with intravenous pembrolizumab (2 mg/kg) starting on day 8 and continuing every 3 weeks for up to two years. CAVATAK will be administered by intratumoral injection up to a total dose of 3 x 10^8 $TCID_{50}$. Pembrolizumab will be administered intravenously at the recommended dose of 2 mg/kg
Planned Sample Size:	This study is expected to enrol 30 patients

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 prostate, 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.

About Viralytics Ltd:

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