ASX and Media Release

Viralytics Update on CALM and STORM Clinical Trials at American Association for Cancer Research Annual Meeting

- *38.6% (22/57) of late-stage melanoma patients in the **Phase 2 CALM** clinical trial have achieved the irPFS[1] endpoint*
- *Initial results from the CALM biopsy extension study show immune activity against cancer cells*
- *Encouraging signs of anticancer activity in some individual lesions and good tolerability shown in **Phase 1/2 STORM trial** of intravenous CAVATAK in advanced cancers*
- *Further evidence of CAVATAK's potential benefit in combination with new immunotherapies such as checkpoint inhibitors*
- *Final clinical data from CALM trial to be presented at ASCO on June 1 2015*

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21 April 2015, Sydney, Australia: Viralytics Limited (ASX: VLA, OTC: VRACY) today presented two posters providing updated data from the Phase 2 CALM and Phase 1/2 STORM clinical trials of Viralytics' lead drug candidate, CAVATAK™, at the American Association for Cancer Research (AACR) Annual Meeting 2015 in Philadelphia, PA. CAVATAK is an investigational novel cancer immunotherapy based on a proprietary cold virus that has been shown to preferentially infect and attack cancer cells.

In the first poster presentation, Dr Robert Andtbacka of the Huntsman Cancer Institute, Utah, and Lead Study Investigator, provided further positive interim results from the Phase 2 CALM clinical trial in late-stage melanoma patients.

According to the CALM poster, 22 of the 57 (38.6%) patients have achieved the irPFS endpoint, more than doubling the initial target of 10 of 54 (18.5%) evaluable patients reporting irPFS at six months after the first dose of CAVATAK. Investigators also reported an overall response rate[2] in 16 of 57 (28%) patients, and an interim one-year survival rate of 75% (36 of 48 patients) was achieved in a challenging population with advanced, difficult-to-treat disease. In addition, activity was

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[1] The primary endpoint measured is immune-related Progression-Free Survival (irPFS) at six months after first dose of CAVATAK™. Progression Free Survival is the length of time, during and after treatment that the patient lives with the cancer without it worsening. irPFS includes patients who achieve a complete tumour response, partial tumour response or stable disease.

[2] Overall response rate includes either complete or partial responses that may occur at any time after initiation of treatment. A complete tumour response (irRECIST 1.1) is the disappearance of all tumour burden. A partial tumour response (irRECIST 1.1) is a reduction in the total tumour burden by greater than 30%.

demonstrated in both injected and non-injected sites, suggesting an anti-tumour immune response.

Preliminary results of the 13-patient CALM extension study were also reported, demonstrating that CAVATAK was able to induce anti-cancer immune activity in tumour tissue biopsies taken from melanoma lesions prior to and after CAVATAK administration. Evidence from the study includes the tumour infiltration of immune cells (such as T lymphocytes) and up-regulation of important receptors (such as PDL1) on cancer cells. This signals the potential for complementary activity when combined with other immunotherapies such as checkpoint inhibitors.

The extension study was undertaken to enable a deeper understanding of the role of CAVATAK in triggering an immune response against cancer cells and continues at three sites in the US.

“The biopsy results from the CALM extension study indicates that we have up-regulation of important immune cells that leads to immune activation and a mechanism for activity in distant non-injected lesions. Along with the elevation of PDL1 these results identify CAVATAK as a strong candidate for use in combination with the PD1 antibodies and other checkpoint inhibitors.” said Dr Robert Andtbacka.

Dr Andtbacka’s poster presentation is available on the Viralytics website and is titled:

Phase II CALM study: Changes in the tumor micro-environment induced by the immunotherapeutic agent, Coxsackievirus A21, delivered intratumorally in patients with advanced melanoma

In the second poster presentation, Viralytics Chief Scientific Officer Dr Darren Shafren reported on the intravenous delivery of CAVATAK in clinical and preclinical settings, including early results from the Phase 1/2 STORM clinical trial.

Initial results from the first six patients in the STORM study demonstrate that multiple intravenous doses of CAVATAK have been well tolerated, with no grade 2, 3 or 4 product-related adverse events. In addition, 4 patients have exhibited signs of secondary viral replication and escalating dose has been associated with indications of anti-tumour activity in some individual lesions. The third cohort is now being studied with the highest dose of CAVATAK and will include assessment of tumour tissue biopsies.

In a preclinical assessment of intravenous CAVATAK in combination with checkpoint inhibitors (anti-PD1, anti-CTLA4 or both agents), there was significantly greater anti-tumour activity when compared to the use of these agents alone.

Dr Hardev Pandha of The University of Surrey and Principal Investigator of the STORM study, said: "The early results from the STORM study and promising results from preclinical studies are strongly supportive of a clinical trial to assess intravenous CAVATAK in combination with checkpoint inhibitors in patients with solid tumour types, including lung or bladder cancer. I look forward to contributing to the further clinical development of this promising immunotherapy agent."

Dr Shafren's poster is available on the Viralytics website and is titled:

Intravenous delivery of a novel oncolytic immunotherapy agent, CAVATAK, in advanced cancer patients

"Based on these updated results, and with support from leading oncologists, we are optimistic about CAVATAK's potential synergy when combined with important new immunotherapies and targeted cancer drugs," stated Malcolm McColl, Viralytics Managing Director and CEO. "We look forward to initiating further combination studies."

About Viralytics Ltd:

Viralytics is developing oncolytic immunotherapy treatments for a range of cancers. Viralytics' 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.

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