



ASX and Media Release

## **Viralytics commences STORM phase 1/2 clinical trial**

*..Systemic CAVATAK™ delivery in cancer patients at 3 UK cancer centres  
..Initially as monotherapy in late stage cancer patients*

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**6 March 2014, Sydney, Australia:** Viralytics Limited (ASX:VLA, OTC:VRACY) has commenced the Phase 1/2 STORM (Systemic Treatment Of Resistant Malignancies) clinical trial in cancer patients in the UK.

The STORM study will assess the multiple intravenous (systemic) delivery of CAVATAK™ in approximately 30 patients with late stage melanoma, prostate, lung or metastatic bladder cancers.

The study is being conducted at three leading cancer centres in the UK. The lead study investigators are prominent oncologists Professor Hardev Pandha (The University of Surrey), Professor Kevin Harrington (The Institute of Cancer Research and The Royal Marsden, London) and Professor Alan Melcher (St James's University Hospital, Leeds).

In the first stage of the STORM study CAVATAK™ will be administered as a monotherapy in late stage cancer patients.

In the second stage CAVATAK™ will be administered in conjunction with commonly used chemotherapeutics, such as docetaxel or carboplatin/paclitaxel targeting only one cancer type. That cancer type will be identified as the most promising target from the first stage of the study.

Viralytics' Chief Executive Officer Dr Malcolm McColl said, "The commencement of the STORM clinical trial is another very significant milestone for Viralytics. We are encouraged by initial results following intravenous delivery of CAVATAK™ and the STORM study offers the opportunity to further explore this route of administration."

"Intravenous delivery of CAVATAK™ has the potential to broaden the commercial application and benefit many more cancer patients."



## STORM TRIAL SYNOPSIS

<b>Title of Study:</b>	A Dose-Finding and Signal-Seeking Study of the Safety and Efficacy of Intravenous CAVATAK™ (coxsackievirus A21, CVA21) Alone and in Combination with Cytotoxic Therapy in Patients with Late Stage Solid Tumours (NSCLC, Castrate-Resistant Prostate Cancer, Melanoma and Bladder Cancer)
<b>Objectives:</b>	<p><b>Primary Objectives:</b></p> <p><b>VLA009A (First stage)</b> To determine if CVA21 given intravenously is capable of tracking to malignant tumours.</p> <p><b>VLA009B (Second stage)</b> To assess the safety and efficacy of intravenous CVA21 and cytotoxic drug combination in solid tumours. To identify a safe and potentially effective Phase 2 dose for CVA21 in combination with cytotoxic drug(s).</p>
<b>Study Design:</b>	This trial will consist of 2 sequential parts: the first part (VLA009A) is a study of intravenous CVA21 as a single agent for the treatment of 4 different advanced solid tumours; the second part (VLA009B) is a study of intravenous CVA21 in combination with cytotoxic therapy appropriate for the solid tumour selected in the first part. Both parts will be open-label, multi-centre, ascending dose escalation (3+3 design) dose-finding and signal-seeking studies. In the final cohort for VLA009A, there must be a minimum of three subjects in each of the four solid tumours (NSCLC, prostate, bladder and melanoma) who have biopsy of an accessible lesion and complete one cycle of treatment before enrolment is completed.
<b>Planned Sample Size:</b>	VLA-009A: This part is expected to enrol from 18 to 27 subjects. VLA009B: This part is expected to enrol from 9 to 18 subjects.
<b>Treatment Duration:</b>	Patients will receive up to eight (8) 21-day courses of CVA21 without chemotherapy for VLA009A and with chemotherapy for VLA009B.

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### About Viralytics Ltd:

Viralytics is developing oncolytic immunotherapy treatments for a range of cancers. Viralytics' lead product, CAVATAK™, is a proprietary formulation of the common cold Coxsackievirus Type A21 (CVA21). CVA21 binds to specific 'receptor' proteins highly expressed on multiple cancer types including, but not limited to: melanoma; prostate, lung, breast and bladder cancers; and multiple myeloma. 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. Together this mechanism of action is known as oncolytic immunotherapy. CAVATAK™'s preferential targeting of cancer cells provides the potential for low toxicity in the patient.

The company has fully enrolled a phase 2 clinical trial of intratumourally administered CAVATAK™ in the treatment of Late stage Melanoma (the CALM study), at multiple prestigious cancer clinics in the US. Viralytics has commenced a Phase 1/2 trial of CAVATAK™ delivered systemically (intravenously). This trial, referred to as the STORM (Systemic Treatment Of Resistant Malignancies) study, will enrol patients with melanoma, prostate, lung or metastatic bladder cancers. The second stage of the STORM trial will include combination treatments with existing chemotherapies in one of the above cancer types. The STORM trial is being conducted at three UK cancer centres.



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.