



## ASX and Media Release

12 November 2012

# Viralytics' CAVATAK™ Phase I intravenous trial presentation

Viralytics Limited (ASX: VLA, OTC: VRACY)

A Viralytics paper on the Phase I clinical evaluation of CAVATAK™ in late stage melanoma, prostate, breast and colorectal cancer patients was presented at the annual meeting of the *EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics* on 9 November 2012 in Dublin, Ireland.

The poster entitled "Phase I, Open-Label, Cohort Study of CAVATAK™ (Coxsackievirus A21) Given Intravenously to Stage IV Patients Bearing ICAM-1 Expressing Solid Tumours" was presented by study investigator by Dr Winston Liauw, Cancer Care Unit, St George Hospital, NSW.

The Phase I dose escalation study administered CAVATAK™ via the intravenous route to 10 patients of which 8 were evaluable for assessment as per the protocol. Patients in this study received a single intravenous infusion of CAVATAK™ ranging from a dose of  $10^6$  to  $10^{10}$  infectious viral particles. The primary objective of this study was patient tolerance to intravenous infusion of CAVATAK™.

"The CAVATAK™ Phase I study met key endpoints required to justify moving the product into Phase II trials. CAVATAK™ was well tolerated for single-dose intravenous administration, demonstrated replication and presence inside some target cancers and some evidence for tumour stabilisation despite receiving only a single dose of oncolytic virus. The strongest signals came in melanoma patients and this would be an attractive target population in Phase II studies," said Dr Winston Liauw.

The poster presentation is available at: [www.viralytics.com](http://www.viralytics.com)

Viralytics has since advanced to a Phase II melanoma study using intratumourally injected CAVATAK™ under Investigational New Drug application allowed by the US Food and Drug Administration. In this study 13 subjects have so far been dosed in the Phase II CAVATAK™ trial with three demonstrating immune-related Progression-Free Survival at 6 months.

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**About Viralytics Ltd:** Viralytics is listed on the Australian Securities Exchange (ASX code: VLA), Viralytics ADR trades under VRACY on the OTC market in the USA. Viralytics' principal asset is the intellectual property relating to CAVATAK™, an Oncolytic Virus technology. CAVATAK™ is the trade name for Viralytics' proprietary formulation of the Coxsackievirus Type A21 (CVA21). EVATAK™ is the trade name for Viralytics' proprietary formulation of the Echovirus Type 1 (EV1). CVA21 and EV1 are viruses that occur naturally in the community. CVA21 and EV1 attach to the outside of cells using a specific 'receptor' on the cell's surface (like a key fitting a lock). CVA21 uses the receptors, intercellular adhesion molecule-1 (ICAM-1) and/or decay accelerating factor (DAF) to bind and infect target cells. Both of these receptor proteins have been demonstrated to be highly expressed on multiple cancer types including: melanoma, prostate cancer, breast cancer and multiple myeloma. EV1 uses the receptor integrin  $\alpha 2\beta 1$  (alpha 2 beta 1) to bind and infect target cells. Integrin  $\alpha 2\beta 1$  (alpha 2 beta 1) has been demonstrated to be highly expressed on multiple cancer types, including: prostate cancer, ovarian cancer.

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