



## ASX and Media Release

### ALLOWANCE OF FDA INVESTIGATIONAL NEW DRUG (IND) APPLICATION FOR CAVATAK™ PHASE II MELANOMA TRIAL

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**27<sup>th</sup> June 2011** Viralytics Limited (ASX: VLA, OTC: VRACY)

Viralytics has received notification from the US Food and Drug Administration that the Clinical Trial Hold has been lifted and Viralytics is now able to immediately commence this Phase II trial within the USA.

The Phase II trial will comprise up to 63 patients (54 evaluable) and is a single arm intratumoral trial injecting CAVATAK™ to multiple tumours on up to 10 separate occasions over an 18 week period.

The primary end point of the trial will measure immune-related Progression-Free Survival at 6 months.

Full details of the Phase II CALM (**C**AVATAK in **L**ate Stage **M**elanoma) trial protocol are available on the Company's website.

Mr Dulhunty said "I would like to take this opportunity to thank all of the Viralytics staff and consultants "the Viralytics team" that have worked together over the past 18 months to enable the Company to achieve such a significant milestone."

The Company will now move forward with the appointment of an international Clinical Research Organisation, which will enable clinical site recruitment and commencement of the trial.

#### **Enquires**

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**About Viralytics Ltd:** Viralytics is listed on the Australian Stock 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, multiple myeloma and others. EV1 uses the receptor, integrin  $\alpha 2\beta 1$  (alpha 2 beta 1) receptor 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 and others

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