



## **ASX and Media Release**

27th April 2011

### **CAVATAK™ PHASE II - FDA INVESTIGATIONAL NEW DRUG (IND) APPLICATION UPDATE**

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Viralytics Limited (ASX: VLA, OTC: VRACY)

On 22 April 2011 (US 21<sup>st</sup> April 2011) Viralytics lodged a reply to the questions raised by the US Food and Drug Administration (FDA) following the FDA's initial review of the Company's investigational new drug (IND) application.

The Company's reply known as a "Complete Response to Clinical Hold Letter" will now be reviewed by the FDA. The FDA has 30 days from the date of lodgement of the reply to either:

- Write to Viralytics removing the current Clinical Hold. The removal of the clinical hold means that Viralytics is able to proceed immediately with its planned Phase 2 intratumoural 54 patient melanoma trial; or
- Write to Viralytics with further questions/clarification and/or request additional information. If the FDA is not fully satisfied with the information supplied or further questions are raised by the additional information that Viralytics has supplied, the FDA may ask additional questions while maintaining the clinical hold.

Viralytics will update the market on the occurrence of either of the abovementioned events.

#### **Enquiries**

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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