



ASX and Media Release

Target enrolment achieved in CAVATAK™ USA Phase 2 melanoma trial with excellent interim results

- *Target enrolment achieved in the US CALM trial with 54th patient injected with CAVATAK™*
- *Rapid enrolment reflects high interest from oncologists at leading US cancer centres*
- *Latest results show 14 of 40 (35%) evaluable patients reaching the six month irPFS target*
- *Further promising one year survival data with 12 of first 20 patients alive at one year (60%)*

08 January 2014, Sydney, Australia: Viralytics Limited (**ASX:VLA, OTCQX:VRACY**) can report that the 54th late stage melanoma patient has been injected with CAVATAK™, thus achieving the major milestone of target enrolment in the US Phase 2 CALM trial.

The Phase 2 trial is a single arm study being conducted at 11 US cancer clinics to investigate the safety and efficacy of intratumoral CAVATAK™ (Coxsackievirus A21) in patients with late stage malignant melanoma.

Dr Malcolm McColl, Chief Executive Officer of Viralytics said: "We are delighted to achieve this key enrolment milestone for the Company in our pathway towards commercialisation of CAVATAK™. The rapid enrolment in 2013 reflects excellent support from oncologists at our high calibre trial sites across the US and points to the need for better therapies to treat late stage melanoma."

It is also pleasing to report a highly encouraging overall irPFS (immune related Progression Free Survival) rate of 35% at 6 months (14 of 40 evaluable patients) and one year survival rate of 60% (12 of first 20 patients alive at one year).

The primary endpoint of the study required 10 patients from a total of 54 evaluable patients reporting irPFS at six months after the first dose of CAVATAK™. This was achieved in September after only 30 evaluable patients.

Dr Robert Andtbacka, Lead Study Investigator from the Huntsman Cancer Institute in the US said: "These interim results from the CALM trial are very encouraging with CAVATAK™ continuing to demonstrate promising anti-cancer activity while being well tolerated by patients. Investigational new drugs with this profile are excellent candidates for randomised studies."

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About Viralytics Ltd:

Viralytics is developing oncolytic virotherapy 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, by direct cytolysis and a possible immune response. The preferential targeting of cancer rather than healthy cells provides the potential for low toxicity in the patient. The company is actively enrolling a phase II 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 plans to commence a Phase I/II trial of CAVATAK™ being delivered systemically (intravenously). This trial referred to as the STORM (Systemic Treatment Of Resistant Malignancies) study will be undertaken in 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. Viralytics has received regulatory approval from the UK Medicines and Healthcare products Regulatory Agency and will commence the STORM trial at three prominent UK sites in early 2014.

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.

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