ASX and Media Release

Primary Endpoint Achieved in CAVATAK Phase 2 Melanoma Trial

- *Primary endpoint achieved while still recruiting*
- *Measure is immune related Progression Free Survival (irPFS) at six months after first CAVATAK™ dose*
- *10 of first 30 evaluable patients reach six month irPFS target*
- *Continuing to full enrolment to build safety and efficacy data*
- *Data Monitoring Committee previously reported that CAVATAK™ met required safety, tolerability and response criteria*
- *44 patients now enrolled, full recruitment forecast by end 2013*
- *Randomised melanoma study next step towards registration*

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18 September 2013, Sydney, Australia: Viralytics Limited (ASX:VLA, OTCQX:VRACY) has achieved the primary endpoint in its Phase 2 clinical trial of CAVATAK™ in the treatment of late stage melanoma patients (the CALM study).

The Phase 2 trial is a single arm study being conducted at 10 US sites and is designed to investigate the safety and efficacy of intratumoral CAVATAK™ (Coxsackievirus A21) in 54 evaluable[1] patients with late stage (IIIc and IV) malignant melanoma.

The primary endpoint measured is immune related Progression Free Survival (irPFS) at six months after first dose of CAVATAK™. Progression Free Survival is the length of time, during and after treatment, that the patient lives with the cancer without it worsening. It includes patients that achieve a complete tumour response[2], partial tumour response[3] or stable disease[4].

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[1] Evaluable patients are those being on study for the six month tumour assessment visit or patients that have earlier withdrawn from the study due to progressive disease or for other reasons.

2 A complete tumour response (irRECIST 1.1) is the disappearance of the tumour burden.

3 A partial tumour response (irRECIST 1.1) is a reduction in the total tumour burden by greater that 30%.

4 Stable disease (irRECIST 1.1) is cancer that is neither decreasing nor increasing in extent or severity.

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The primary endpoint of the study was to have 10 patients from a total of 54 evaluable patients reporting irPFS at six months after the first dose of CAVATAK™. This was achieved after only 30 evaluable patients, representing an irPFS rate so far of 33%.

"Achieving the primary endpoint of the CALM study before patient recruitment has been completed is very encouraging. In addition to the positive irPFS data we have observed responses in both injected and non-injected lesions." said Dr Robert Andtbacka, Lead Study Investigator from the Huntsman Cancer Institute in the US.

Dr Malcolm McColl, Chief Executive Officer of Viralytics said: "We are delighted to achieve this major milestone in the development of CAVATAK™. Given the excellent progress achieved to date and the encouraging feedback from key opinion leaders in the melanoma field we also believe it is now timely to consider the design of a randomised study in melanoma patients."

Other study endpoints include durable response rate, one year survival and overall survival. These will be reported on as sufficient data are generated and analysed.

As reported on 19 July, the independent Data Monitoring Committee (DMC) of the trial met to review data from the first 35 patients in the study (Stage 1). It concluded that CAVATAK™ had met the safety, tolerability and response[5] criteria and thus the study could progress to full enrolment. CAVATAK™ has been well tolerated by patients with no reports of serious adverse events[6] or grade 3/4 adverse events[7] related to the CAVATAK™ treatment.

There are now 44 patients enrolled in the study with full enrolment forecast by the end of 2013.

About the Phase 2 CALM Clinical Trial

CALM study: A Phase II single arm study of intratumoral CAVATAK™ (Coxsackievirus A21) in patients with stage IIIc and stage IV malignant melanoma.

The CALM study is designed to investigate the efficacy and safety of intratumoral administered CAVATAK™ in approximately 63 patients (54 evaluable patients) with treated or untreated unresectable Stage IIIC, IV M1a, M1b, M1c melanoma. To date 26%

5 At least 3 partial or complete responses (modified RECIST 1.1) in the first 35 patients.

6 A Serious Adverse Event is defined as any Adverse Event or Suspected Adverse Reaction that, in the view of the investigator or sponsor, results in any of the following outcomes: Death, Life-threatening AE, Inpatient hospitalization or prolongation of existing hospitalization, Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, Congenital anomaly/birth defect, Any "other" important medical event.

7 Grade 3/4 Adverse Events related to study treatment are events which can indicate toxicity to the study treatment.

and 74% of patients recruited have Stage IIIc or Stage IV disease respectively with an average of 2.9 prior treatments before the first dose of CAVATAK™.

The study has a 2-stage Simon's minimax design. The first stage involves recruiting 35 patients and demonstrating that (a) at least three of the first 35 patients display an objective response (modified RECIST 1.1 complete response or partial response) following treatment with CAVATAK™ and (b) CAVATAK™ is well tolerated.

The independent Data Monitoring Committee (DMC) reported in December 2012 that the first hurdle had been achieved with three objective responses in the first 13 patients recruited. The second hurdle was achieved in July 2013 following review of patient data by the DMC.

Patients are treated with up to 3 x 10^8 $TCID_{50}$ CAVATAK™ intratumourally on study days 1,3,5,8 and 21 then every three weeks for an additional five injections.

Key eligibility criteria are ≥ 18 years old, ECOG 0-1, and at least 1 injectable cutaneous, subcutaneous, or nodal tumour >1.0cm

The primary endpoint is immune related Progression Free Survival (irPFS) at 6 months following first treatment.

A target of overall irPFS at 6 months of 22.5% versus a projected rate of 10% in the target population was selected. This decision was based on data from previous trials and literature. With an alpha level of 5% and 80% power, a total of 54 evaluable patients will be required to test the null hypothesis that the true irPFS rate is <10% versus the alternative hypothesis that the true irPFS rate is at least 22.5%. The null hypothesis will be rejected if 10 or more of 54 patients meet the target of irPFS at 6 months after the first CAVATAK™ treatment. According to the protocol, if at least 10/54 patients are alive and progression-free at 6 months, then further clinical investigation of CAVATAK™ is warranted.

Secondary endpoints include durable response rate, one year survival and overall survival.

The study is being conducted at 10 sites in the US. Efficacy and safety is investigator assessed.

Full details of the clinical trial design can be found at the following website:

http://clinicaltrials.gov/show/NCT01227551

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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 later in 2013.

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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