ASX and Media Release

Further strong progress in CAVATAK™ phase 2 CALM trial

- *Excellent progress with 12 of 35 (34%) evaluable patients reaching the six month irPFS target*
- *Primary endpoint already achieved with 10 of first 30 (33%) evaluable patients having reached six month irPFS target*[1]
- *Promising 12 month survival rate of 56% (9/16)*
- *Overall response rate in 9 from 38 (24%) assessable patients*
- *Encouraging activity in non-injected (metastatic) tumours*
- *49 patients enrolled in the study with full enrolment (54 patients) expected in December 2013*
- *Randomised phase 2 melanoma study next step towards registration*
- *No reports of drug-related grade 3/ 4 or serious adverse events*

---

8 November 2013, Sydney, Australia: Viralytics Limited (ASX:VLA, OTCQX:VRACY) continues to make strong progress on 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 at 11 US sites to investigate the safety and efficacy of intratumoral CAVATAK™ (Coxsackievirus A21) in 54 evaluable[2] patients with late stage (IIIc and IV) malignant melanoma.

Primary Endpoint

The trial achieved its primary endpoint in September 2013. 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

---

[1] The trial's primary endpoint is immune related Progression Free Survival (irPFS) at 6 months

2 Evaluable patients are those being on study for the six month tumour assessment visit or patients that have earlier withdrawn from the study due to progressive disease or for other reasons.

Suite 305, Level 3, 66 Hunter Street, Sydney 2000
T +61 2 9988 4000 F +61 2 8068 6038
www.viralytics.com

cancer without it worsening. It includes patients that achieve a complete tumour response[3], partial tumour response[4] or stable disease[5].

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 mid-September 2013 after only 30 evaluable patients, representing an irPFS rate of 33%.

There are now 12 of 35 evaluable patients reporting irPFS at six months representing an irPFS rate of 34%.

Other Trial Outcomes

A key performance measure is the one-year survival following initiation of treatment with CAVATAK™. Currently, 16 patients were evaluable by this measure with nine alive at the one-year endpoint (56%). The mean one-year overall survival rate based on a review of 42 Phase 2 melanoma trials in patients treated with a variety of agents is 25.5%[6]. One-year survival in the completed 50 patient Biovex Phase 2 OncoVex™ trial in late stage melanoma patients was 58%[7].

A further measure in the trial to assess CAVATAK™ activity is the best overall tumour response[8] which assesses both injected and non-injected tumours. In the 38 patients who have been on the study for at least 12 weeks, a confirmed response of either a complete or partial tumour response has been seen in 1 and 8 patients, respectively (9/38 or 24%).

Other study endpoints include durable response rate and overall survival. These will be reported as sufficient data is generated and analysed.

Dr Robert Andtbacka, Lead Study Investigator from the Huntsman Cancer Institute in the US said, *"CAVATAK™ continues to demonstrate very promising anti-cancer activity while being well tolerated in these late stage melanoma patients. Based on the robust interim results further clinical evaluation of CAVATAK™ in a randomised study as either a monotherapy prior to surgery or in combination with other new immunotherapies is warranted."*

---

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

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

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

6 Data from Korn et al, 2008. J. Clin.Oncol., (26):527-534

7 Senzer et al, 2009. J. Clin.Oncol., (34):5763-7

8 Best overall response is the best response (complete response, partial response, stable disease or progressive disease) received by the patient after initiation of treatment.

Commenting on the future prospects, clinical consultant to the program, Dr Keith Flaherty from the Henri and Belinda Termeer Center for Targeted Therapies at the Massachusetts General Hospital Cancer Center, said: *"Given the activity and tolerance profile witnessed to date, the combination of CAVATAK™ with other new targeted therapies has exciting potential in advanced stage melanoma patients. I would be eager to be involved in such a randomised study in the US."*

Dr Malcolm McColl, Chief Executive Officer of Viralytics said: *"We are very pleased with the further excellent progress and latest results in the CALM trial, our rapid advance toward full enrolment and the strong support of international key opinion leaders to further assess CAVATAK™. Our aim is to commence a randomised Phase 2 trial in melanoma patients in the second half of 2014."*

The study has now enrolled its 49th patient. Given the strong recent recruitment rates the study is forecast to enrol the final patient in December 2013.

As previously reported, 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™ has met the safety, tolerability and response[9] criteria and thus the study could progress to full enrolment. CAVATAK™ has been well tolerated by patients with no reports of serious adverse events[10] or grade 3/4 adverse events[11] related to the CAVATAK™ treatment.

Enquiries:
Dr Malcolm McColl
Chief Executive Officer
02 9988 4000

Mr Rudi Michelson
Monsoon Communications
03 9620 3333

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

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

10 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.

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

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.

Suite 305, Level 3, 66 Hunter Street, Sydney 2000
T +61 2 9988 4000 F +61 2 8068 6038
www.viralytics.com