

ASX and Media Release

**Updated Positive Data from Phase 2 Trial of CAVATAK in
Late-Stage Melanoma
Report at the European Society of Medical Oncology (ESMO) 2014
Congress**

- *38.6% (22 of 57) patients met primary endpoint of immune-related Progression-Free Survival (irPFS)¹ at six months*
- *Preliminary overall response rate² of 28%*
- *73% (33 of 45) patients demonstrate one-year survival rate*
- *Activity demonstrated in both injected and non-injected sites, suggesting an anti-tumor immune response*

29 September 2014, Sydney, Australia: Viralytics Limited (ASX:VLA, OTC:VRACY) overnight announced strongly positive results from the US Phase 2 CALM trial of CAVATAK™ in late-stage melanoma at the European Society of Medical Oncology (ESMO) 2014 Congress in Madrid. CAVATAK is a novel cancer immunotherapy based on a proprietary cold virus that has been shown to preferentially infect and attack cancer cells.

To date, 22 of the 57 (38.6%) patients have achieved the irPFS¹ endpoint, significantly exceeding the initial target of 18.5%, or 10 of 54 evaluable patients reporting irPFS at six months after the first dose of CAVATAK.

Investigators also reported an overall response rate² in 16 of 57 (28%) patients, with an additional 3 patients remaining in the extension phase of the study and being monitored for the development of an overall response. Furthermore, CAVATAK continues to demonstrate activity in both injected tumours and non-injected tumours, including local and distant lymph nodes, lungs and other distant sites, suggesting an anti-tumour immune response.

An interim one-year survival rate of 73% (33 of 45) patients was achieved in this challenging population with advanced, difficult-to-treat disease.

¹ 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. irPFS includes patients who achieve a complete tumour response, partial tumour response or stable disease.

² Overall response rate includes either complete or partial responses that may occur at any time after initiation of treatment. A complete tumour response (irRECIST 1.1) is the disappearance of all tumour burden. A partial tumour response (irRECIST 1.1) is a reduction in the total tumour burden by greater than 30%.



CAVATAK™ treatment continues to be well tolerated in patients, with no reports of drug related serious adverse events³ or grade 3 or 4 adverse events⁴, and the majority of side effects being reported as grade 1.

“These latest results further demonstrate CAVATAK’s oncolytic immunotherapeutic activity,” said Dr Malcolm McColl, Chief Executive Officer of Viralytics. “Based on CAVATAK’s outstanding performance in this trial, and with strong support from leading oncologists, we plan to aggressively pursue our clinical development program. The commercial opportunity for CAVATAK, either as a monotherapy or in combination with other new agents, is reinforced by these very promising outcomes.”

Dr Robert Andtbacka, Lead Study Investigator from the Huntsman Cancer Institute, Utah, said: “CAVATAK’s activity and tolerability in these late-stage melanoma patients is impressive. Given this growing body of clinical and pre-clinical data, CAVATAK appears to be an excellent candidate for use, either as a single agent in earlier disease, or in combination with other new therapies, including anti-PD-1 and other checkpoint inhibitors. I look forward to contributing to the further clinical development of this promising immunotherapy agent.”

The poster reporting the updated CALM study results was presented by Dr Andtbacka as part of the melanoma session at the ESMO2014 Congress on Sunday, 28 September, in Madrid. The poster, awarded a best poster award at the ESMO2014 Congress, is entitled:

CALM study: Secondary endpoints of a Phase II study of a novel oncolytic immunotherapeutic agent, Coxsackievirus A21, delivered intratumorally in patients with advanced malignant melanoma.

The poster may be found on the Viralytics website at the following site:

<http://www.viralytics.com/wp-content/uploads/2014/09/140928-CALM-Study-Poster-ESMO.jpg>

The ESMO conference is the largest oncology conference held in Europe, with more than 16,000 expected to attend.

³ 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.

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

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Immunoprofiling Study Initiated

Viralytics will shortly initiate a recruitment extension to the CALM study to enable a deeper interrogation of the immunotherapeutic activity of CAVATAK. It will consist of an additional cohort of 12 patients from three sites in the US. Dr Andtbacka, along with Dr Brendan Curti from the Providence Cancer Centre in Portland, Oregon, and Dr Sigrun Hallmeyer from Oncology Specialists, Park Ridge, Illinois, will conduct the study. Biopsies taken from both injected and non-injected melanoma lesions will be examined in order to better understand the role of CAVATAK in triggering an immune response against cancer cells. The study is forecast to commence in October with preliminary results available in the first quarter of 2015.

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 immunotherapy treatments for a range of cancers. Viralytics' lead investigational 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 through cell lysis and the potential generation of an immune response against the cancer cells. Together this mechanism of action is known as oncolytic immunotherapy. CAVATAK's preferential targeting of cancer cells creates the potential for a more tolerable cancer treatment.

The company has completed enrolment in a single arm Phase 2 clinical trial of intratumourally administered CAVATAK in the treatment of Late-stage Melanoma (the CALM study), at multiple prestigious cancer clinics in the US. The study is being conducted in patients with late stage (IIIC and IV) malignant melanoma.

In addition, Viralytics has commenced a Phase 1/2 trial of CAVATAK delivered systemically (intravenously). This trial, referred to as the STORM (Systemic Treatment Of Resistant Malignancies) study, is enrolling 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. The STORM trial is being conducted at three UK cancer centres.

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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