



ASX and Media Release

Progress in CAVATAK Phase 2 Melanoma Trial

Updated data presented at Immunotherapy Session of American Society of Clinical Oncology (ASCO) Conference in Chicago

Highlights from the poster presentation included:

- 19 of 51 (37%) evaluable patients demonstrated immune-related Progression-Free Survival (irPFS)¹ at six months after first CAVATAK™ dose
- Preliminary overall response rate² of 26% (15/57)
- Anti-cancer activity in tumours at injected and non-injected sites, including lung and other distant tumour metastases
- Multiple CAVATAK™ administrations well tolerated by patients
- Very promising preclinical findings for combination of CAVATAK™ with anti-PD-1 monoclonal antibody, an emerging, potentially major class of cancer immunotherapy

3 June 2014, Sydney, Australia: Viralytics Limited (ASX:VLA, OTC:VRACY) reports that Dr Robert Andtbacka, Lead Study Investigator, Huntsman Cancer Institute, Utah, today presented additional positive interim results from the ongoing Phase 2 CALM clinical trial at ASCO, the world's foremost oncology conference.

The presentation, which was featured as a highlighted poster in the "Developmental Therapeutics – Immunotherapy" session is entitled:

Abstract 3031: "CALM study: A phase II study of an intratumorally delivered oncolytic immunotherapeutic agent, Cocksackievirus A21, in patients with stage IIIc and stage IV malignant melanoma"

The poster is now available on the Viralytics website.

Growing Body of Data

The primary endpoint of the CALM study was to have 10 or more patients from a total of 54 evaluable patients reporting irPFS at six months after the first dose of CAVATAK™. This endpoint was achieved in September 2013 in the first 30 patients (10/30 [33%]).

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 anytime 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%.

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Currently, there are now 19 of 51 (37%) evaluable patients achieving the six month irPFS endpoint.

CAVATAK™ continues to demonstrate anticancer activity in both injected tumours and non-injected tumours, such as at local and distant lymph nodes, lungs and distant sites. At present, investigators have reported overall responses in 15 of 57 (26%) patients. A number of patients currently on study are being continually monitored for the development of further overall responses, in addition to those already observed in 15 patients.

CAVATAK™ also continues to be well tolerated in patients. There have been no reports of serious adverse events³ and grade 3 or 4 adverse events⁴ related to the CAVATAK™ treatment in 57 patients on the study.

"Results to date in the CALM trial have been extremely encouraging with ongoing impressive activity in both injected and non-injected metastatic cancer lesions," said Lead Study Investigator, Dr Robert Andtbacka, "It is also notable that multiple doses of CAVATAK™ have been well tolerated by patients."

Preclinical anti-PD1 Immunotherapy Combination Data Also Presented

Dr Andtbacka also presented results from a preclinical study assessing CAVATAK™ with a new class of cancer immunotherapy, anti-PD-1 monoclonal antibodies (mAb). The study provided evidence of enhanced anti-cancer activity using a combination of CAVATAK™ and an anti-PD-1 mAb compared to the anti-PD-1 mAb or CAVATAK™ treatments alone.

Dr Andtbacka said, "The preclinical results from the combination of CAVATAK™ and the anti-PD-1 antibody are quite promising. Taken together with the clinical results seen in the CALM study, there is now a strong rationale for a clinical trial co-administering CAVATAK™ and an anti-PD-1 antibody. As a clinician, I would be keen to assess this combination as we try to find better ways to treat patients with metastatic melanoma."

Dr Malcolm McColl, Chief Executive Officer of Viralytics said, "We are very pleased to report to the international oncology community the further positive progress achieved in the CALM study. Additionally, the strong preclinical results of CAVATAK™ in combination with an anti-PD-1 antibody are also important, as this new class of cancer immunotherapy is forecast to have significant potential across many tumour types."

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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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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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