



## ASX and Media Release

# Strong interim results of CAVATAK in Phase 2 Trial

## Data presented at prestigious World Congress of Melanoma

### KEY POINTS:

- *Interim results from the first 35 melanoma patients in the Phase 2 CAVATAK™ CALM trial presented at the World Congress of Melanoma*
- *23 patients have so far reached the point where they can be assessed against the trial's primary endpoint of immune related Progression Free Survival (irPFS) at 6 months*
- *Strong progress with 8 of these 23 patients having achieved the primary endpoint of irPFS at 6 months*
- *The trial target will be met if 10 of 54 evaluable patients achieve the primary endpoint of irPFS at 6 months*
- *2 complete and 6 partial tumour responses have been observed from a total of 30 assessable patients*
- *These results achieved in advanced melanoma sufferers with an average of nearly 3 prior treatments before CAVATAK™*
- *Encouraging results with activity in non-injected (metastatic or secondary) as well as the injected tumours*
- *Data Monitoring Committee reports CAVATAK™ has met the required safety and tolerability criteria and study is proceeding to full enrolment*
- *Full recruitment may occur by end 2013*

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**19 July 2013, Sydney, Australia:** Viralytics Limited (ASX:VLA, OTC:VRACY) today announced strong interim results from its Phase 2 clinical trial of CAVATAK™ treatment in late stage melanoma patients.

The interim data shows solid progress towards achieving the primary endpoint of the study and strengthens the evidence of the tolerability of CAVATAK™ in late stage melanoma patients.

Earlier today, Dr Robert Andtbacka, the lead study investigator from the Huntsman Cancer Institute in the USA, presented on the safety and investigator

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assessed efficacy data from the first 35 patients in the CALM study at the 8<sup>th</sup> World Congress of Melanoma, Hamburg, Germany.

The primary endpoint measured is immune related Progression Free Survival (irPFS) at 6 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<sup>1</sup>, partial tumour response<sup>2</sup> or stable disease<sup>3</sup>.

Currently, there are 23 patients who have met the protocol criteria for assessment of the primary endpoint of irPFS at 6 months. 8 of these 23 (35%) have achieved this endpoint. The trial target will be realised if 10 of 54 patients meet the primary endpoint.

30 patients qualified for assessment of the irPFS endpoint at 12 weeks. 18 patients (60%) have achieved an irPFS at 12 weeks, with 7 of these patients currently between the 12 week and 6 months response monitoring timepoints.

A further measure in the trial to assess CAVATAK™ activity is the best overall tumour response<sup>4</sup> which assesses both injected and non-injected tumours. In the 30 patients who have been on the study for at least 12 weeks, a best response of either a complete or partial tumour response has been seen in 2 and 6 patients, respectively (total of 8 /30 or 27%).

Five patients have entered the extension study and received further doses of CAVATAK™. Two patients have been on the study for a total of twelve months and have completed the extension study with both achieving a partial response. Follow up surgery to remove the residual injected tumour tissue resulted in a surgical complete response in both patients.

To date CAVATAK™ has been well tolerated by patients with no reports of serious adverse events<sup>5</sup> or grade 3/4 adverse events<sup>6</sup> related to the CAVATAK™ treatment. Toxicity is a recognized shortcoming of traditional chemotherapy drugs and some new therapies in development for the treatment of melanoma.

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1 A complete tumour response is the disappearance of the tumour burden.

2 A partial tumour response is a reduction in the total tumour burden by greater than 30%.

3 Stable disease is cancer that is neither decreasing nor increasing in extent or severity.

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

<sup>5</sup> 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.

<sup>6</sup> Grade 3/4 Adverse Events related to study treatment are events which can indicate toxicity to the study treatment.

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The independent Data Monitoring Committee (DMC) of the trial met recently to review data from the first 35 patients in the study (Stage 1). It reported that CAVATAK™ has met the safety and tolerability criteria and thus the study is progressing into Stage 2, full enrolment and its conclusion.

It is also pleasing to report that there are now 38 patients enrolled in the study. On the basis of the current recruitment rates it may be possible to fully enrol the study by the end of 2013.

Dr Andtbacka commented: "These interim results with CAVATAK™ are encouraging and it is pleasing to see activity in both injected and metastatic tumours. Oncolytic immunotherapy is a promising new class of investigational agents with potential future application either as a monotherapy, a pre-treatment prior to surgery or use in combination with other new frontline therapies".

Dr Malcolm McColl, Chief Executive Officer of Viralytics said: "We are very pleased to present these encouraging interim results to oncologists from the global melanoma community. The results to date are very promising both with regard to tolerability and our solid progress towards the primary endpoint. These interim results have been achieved in advanced melanoma patients with 74% at Stage IV disease and an average of 2.9 prior treatments before the first dose of CAVATAK™, reinforcing how difficult it is to successfully treat melanoma."

Dr Andtbacka's presentation is entitled:

"CALM study: A phase II study of intratumoral coxsackievirus A21 in patients with stage IIIc and stage IV malignant melanoma"

The presentation is available on the Viralytics website:

[http://www.viralytics.com/pages/technology-overview/scientific-presentations-publications\\_.php](http://www.viralytics.com/pages/technology-overview/scientific-presentations-publications_.php)

The World Congress of Melanoma is the premier international conference devoted to melanoma with over 1,000 attendees from the global oncology community.

**Enquiries:**

**Dr Malcolm McColl**  
**02 9988 4000**

**Rudi Michelson**  
**Monsoon Communications**  
**03 9620 3333**

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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

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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. Subject to regulatory approval the STORM trial will commence 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 OTC market.

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