



ASX and Media Release

Positive CAVATAK™ Clinical Data Presented at 2015 Society for Immunotherapy of Cancer (SITC) Meeting

Results Reported in Melanoma, Lung, Prostate, and Bladder Cancers

9 November 2015, Sydney, Australia: [Viralytics Limited](#) (ASX: VLA, OTC: VRACY) today announced positive data from two clinical studies of its lead drug candidate, [CAVATAK™](#), at [the 30th Annual Meeting of the Society for the Immunotherapy of Cancer](#) (SITC) in National Harbor, Maryland, USA. These data included updated results from the Phase 1 STORM clinical trial of intravenous CAVATAK in advanced cancers and from the Phase 1 CANON clinical trial of intravesicular CAVATAK in non-muscle invasive bladder cancer.

CAVATAK is an investigational novel cancer immunotherapy based on a proprietary bioselected common cold virus that has been shown to preferentially infect and attack cancer cells.

Phase 1 STORM¹ Clinical Trial Update

In the ongoing [Phase 1 STORM clinical trial](#), multiple intravenous doses of CAVATAK are being administered to patients with late-stage non-small cell lung cancer (NSCLC), hormone refractory prostate cancer (HRPC), metastatic bladder cancer, and late stage melanoma. Initial results from the dose escalation phase in the first 12 patients, including six patients in the third cohort who have been administered the highest dose of CAVATAK, show that multiple infusions of CAVATAK are generally well tolerated with no Grade 3 or higher CAVATAK-related adverse events.

In addition, there is evidence of successful tumour targeting in two melanoma patients in Cohort 3 (i.e. highest dose), with CAVATAK replication and CAVATAK RNA evident in tumour biopsies. These biopsies also revealed the presence of immune cell infiltrates and notable levels of PD-L1 staining suggesting a potential benefit for CAVATAK with an immune checkpoint blockade agent such as KEYTRUDA^{®2} (pembrolizumab). Moreover, a number of patients have exhibited signs of possible tumour-specific secondary viral replication. Finally, several patients achieved a best overall response of stable disease, including one with a confirmed partial response.

Multi-dosing with single-agent CAVATAK in Cohort 3 of the STORM trial continues. The second stage of the trial, due to commence in 2016, will assess the intravenous

¹ Systemic Treatment Of Resistant Metastatic disease

² KEYTRUDA is a trademark of Merck and Co.

delivery of CAVATAK in combination with KEYTRUDA in patients with advanced non-small cell lung or metastatic bladder cancer.

“The STORM study continues to generate very promising data. Tumour targeting, along with the potential immune activation mediated by CAVATAK, provides considerable encouragement for potential synergy from the combination of intravenous CAVATAK with checkpoint inhibitors such as KEYTRUDA,” stated Professor Hardev Pandha, Director of the Surrey Cancer Research Institute at The University of Surrey and Principal Investigator of the STORM study. “We look forward to the initiation of the second stage of the trial to assess the combination of these two novel immunotherapies.”

“These updated positive findings are very supportive of the potential benefits from combining CAVATAK with KEYTRUDA,” said Dr Malcolm McColl, Viralytics Chief Executive Officer. “We are very excited about initiating the STORM trial’s second stage to look at this potentially complementary approach in two of the most common types of cancer.”

The poster presentation discussing the STORM trial results can be found on the Viralytics website:

[Phase 1 STORM Study: Intravenous Delivery of a Novel Oncolytic Immunotherapy Agent, CAVATAK, in Advanced Cancer Patients](#)

Phase 1 CANON³ Clinical Trial Update

The [Phase 1 CANON trial](#) is assessing the administration of CAVATAK via catheter directly into the bladder (intravesicular treatment) in patients with non-muscle invasive bladder cancer (NMIBC), also known as superficial bladder cancer. Initial results demonstrate that CAVATAK has been generally well tolerated with no Grade 2 or higher CAVATAK-related adverse events.

Evidence of targeting of tumour tissue, with viral replication and tumour cell death, has been seen in patients following single or double administrations of CAVATAK. Also, clinical activity of CAVATAK was demonstrated, with signs of viral replication and viral-induced tumour inflammation and a complete tumour response in one out of the 3 patients in the highest dose cohort.

The first stage of the CANON trial assessing CAVATAK as a single agent is complete. The second stage, evaluating CAVATAK in combination with a sub-therapeutic dose of the standard chemotherapy, mitomycin C, prior to the surgical removal of the tumour, is underway.

³CAVATAK in Non-muscle invasive bladder cancer



"These positive results, in particular the complete tumour response in one patient, represent a very encouraging outcome in the first stage of the study," said Professor Hardev Pandha, Principal Investigator of the CANON study. "We believe that the tumor targeting, viral replication and cancer cell death we are seeing in this trial can lead to both a strong local and systemic anti-tumour immune response. There is considerable potential for CAVATAK, either prior to surgical resection or in combination with the checkpoint inhibitors, as a new treatment approach to NMIBC, where there is a high unmet need for better therapies."

The poster detailing the CANON trial results can be found on the Viralytics website:

[Oncolytic Immunotherapy for the Treatment of NMIBC with CAVATAK](#)

Additional Posters

Two posters providing a recap of the Phase 2 CALM extension study and preclinical work assessing the combination of CAVATAK with checkpoint inhibitors were also presented at the conference and are available on the Viralytics website:

[Phase II CALM Extension Study: Coxsackievirus A21 Delivered Intratumorally to Patients with Advanced Melanoma Induces Immune-cell Infiltration in the Tumor Microenvironment](#)

[Combination of Intravenously Delivered CAVATAK \(Coxsackievirus A21\) and Immune-checkpoint Blockade Significantly Reduces Tumor Growth and Tumor Rechallenge](#)

About VIRALYTICS and CAVATAK™

Viralytics is developing oncolytic immunotherapy treatments for a range of cancers. The company's lead investigational product, CAVATAK™, is currently being studied in Phase 1 and 2 clinical trials for the treatment of melanoma, as well as prostate, bladder and lung cancers. Intratumoural, intravenous and intravesicular delivery routes are under investigation. Two combination studies with checkpoint inhibitors are underway in late-stage melanoma patients. A combination study of CAVATAK with KEYTRUDA in late-stage lung and bladder cancer patients will commence in 2016.

Further details on our clinical and pre-clinical data can be found on our website at the following locations:

<http://www.viralytics.com/our-pipeline/clinical-trials/>
<http://www.viralytics.com/our-pipeline/pre-clinical-studies/>
<http://www.viralytics.com/our-pipeline/scientific-presentations/>
<http://www.viralytics.com/our-pipeline/scientific-publications/>



CAVATAK is a proprietary formulation of the common cold Coxsackievirus Type A21 (CVA21) that preferentially binds to specific 'receptor' proteins highly expressed on multiple cancer types. 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 – a two-pronged mechanism of action known as oncolytic immunotherapy.

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. For more information, please visit www.viralytics.com.

Viralytics Forward-Looking Statements

Certain statements made in this presentation are forward looking statements within the meaning of the safe harbour provisions of the United States Private Securities Litigation Reform Act of 1995. These forward looking statements are not historical facts but rather are based on Viralytics' current expectations, estimates, assumptions and projections about the industry in which Viralytics operates. Material referred to in this document that use the words 'estimate', 'project', 'intend', 'expect', 'plan', 'believe', 'guidance' and similar expressions are intended to identify forward looking statements and should be considered an at-risk statement. These forward looking statements are not a guarantee of future performance and involve known and unknown risks and uncertainties, some of which are beyond the control of Viralytics or which are difficult to predict, which could cause the actual results, performance or achievements of Viralytics to be materially different from those which may be expressed or implied by these statements. These statements are based on our management's current expectations and are subject to a number of uncertainties and risks that could change the results described in the forward-looking statements. Risks and uncertainties include, but are not limited to, general industry conditions and competition, general economic factors, the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally, and challenges inherent in new product development. Investors should be aware that there are no assurances that results will not differ from those projected and Viralytics cautions shareholders and prospective shareholders not to place undue reliance on these forward-looking statements, which reflect the view of Viralytics only as of the date of this presentation. Viralytics is not under a duty to update any forward-looking statement as a result of new information, future events or otherwise, except as required by law or by any appropriate regulatory authority.

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