



ASX and Media Release

Viralytics Presents CALM and STORM Clinical Trial Results at Oncolytic Virus Therapeutics Conference

Data Support Trials of CAVATAK in Combination with Checkpoint Inhibitors

17 June 2015, Sydney, Australia: [Viralytics Limited](#) (ASX: VLA, OTC: VRACY) today announced results from two [CAVATAK™](#) studies presented at the [9th International Conference on Oncolytic Virus Therapeutics](#), including updated results from the Phase 2 CALM biopsy extension trial and from the Phase 1/2 STORM trial of intravenous CAVATAK in advanced cancers. 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.

CALM Biopsy Extension Study

Results from the 13-patient Phase 2 CALM extension study demonstrate that CAVATAK is able to induce anti-cancer immune activity, according to a comparison of tumour tissue biopsies taken from the lesions of melanoma patients prior to and after the intratumoural administration of CAVATAK. Evidence from the study shows that CAVATAK causes key immune cells (such as cytotoxic T lymphocytes and PD-L1-expressing cells) to infiltrate the tumour tissue, including the lesions of patients who had previously progressed on other treatments such as ipilimumab, pembrolizumab or talimogene laherparepvec. An increase in the number of these cells indicates potential complementary activity when combining CAVATAK with new immunotherapies such as checkpoint inhibitors.¹

"These results point to the ability of CAVATAK to repopulate the tumour micro-environment with cancer-fighting T-cells, leading to immune activation and a mechanism for activity in distant non-injected lesions. Along with the upregulation of important receptors, such as PD-L1, these results identify CAVATAK as a strong candidate for use in combination with the anti-PD-1 antibodies and other checkpoint inhibitors," said Dr Robert Andtbacka, Lead Study Investigator of the CALM trial and a surgical oncologist at the Huntsman Cancer Institute, University of Utah.

The CALM extension study was undertaken to better elucidate the role of CAVATAK in triggering an immune response against cancer cells and continues at three US sites.

¹ Checkpoint inhibitors are an important new class of anticancer agent that take the brakes off the immune response to cancer and have application across a broad range of cancer types including melanoma, lung and bladder cancer. They include the anti-PD-1 antibodies such as nivolumab (Opdivo - Bristol Myers Squibb) and pembrolizumab (Keytruda, Merck) and the anti-CTLA-4 antibodies such as ipilimumab (Yervoy, Bristol Myers Squibb). Analysts forecast these 3 agents may achieve total annual revenues of more than US\$20Bn by 2020.



The presentation detailing the CALM extension study results, entitled **“Characterisation of the oncolytic kinetics of the immunotherapeutic agent, CAVATAK, delivered intratumorally in patients with advanced malignant melanoma,”** can be found on the Viralytics website at:

<http://www.viralytics.com/wp-content/uploads/2015/03/150616-CALM-OVC-2015-Poster.pdf>

STORM Clinical Trial – (Systemic Treatment Of Resistant Metastatic disease)

According to the initial results of the [Phase 1/2 STORM clinical trial](#), being conducted at three cancer centres in the United Kingdom, multiple intravenous infusions of CAVATAK have produced potential tumour viral replication in some advanced cancer patients. Moreover, additional indications of anti-tumour activity in some individual lesions have been associated with escalating doses of CAVATAK. The intravenous administration of CAVATAK has been well tolerated, with no grade 3 or 4 product-related adverse events. The third cohort of patients is now being studied using the highest dose of CAVATAK and will include assessment of tumour tissue biopsies. Initial results in the third cohort indicate the presence of CAVATAK in tumour biopsies from two melanoma patients.

“These early positive results offer the exciting possibility that tumour targeting, infection and immune activation mediated by CAVATAK may lead to increased anti-tumour activity. Given the promising results from preclinical studies exploring the use of intravenous CAVATAK in combination with checkpoint inhibitors, we are looking forward to the further clinical development of CAVATAK combined with important new immunotherapies in patients with various solid tumour types,” stated Professor Hardev Pandha of The University of Surrey and Principal Investigator of the STORM study.

The presentation discussing the STORM trial results, entitled **“Phase I/II STORM study: Intravenous delivery of a novel oncolytic immunotherapy agent, CAVATAK, in advanced cancer patients,”** can be found on the Viralytics website at:

<http://www.viralytics.com/wp-content/uploads/2015/03/150616-STORM-OVC-2015-poster.pdf>

About Viralytics Ltd:

Viralytics is developing oncolytic immunotherapy treatments for a range of cancers. Viralytics’ 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. 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.

Enquiries:

Dr Malcolm McColl
Managing Director
02 9988 4000

Mr Rudi Michelson
Monsoon Communications
03 9620 3333