



ASX and Media Release

CAVATAK™ Presentations at Oncolytic Virus Therapeutics Conference Reinforce Potential in Bladder Cancer and Melanoma

Viralytics Presents Positive Monotherapy and Combination Data

16 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 positive early data from a Phase 1/2 clinical trial in bladder cancer and promising results from a preclinical assessment of CAVATAK given in combination with leading checkpoint inhibitors. 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.

CANON Clinical Trial – (CAVATAK in Non-muscle invasive bladder cancer)

According to the initial results of [the Phase 1/2 CANON trial](#), being conducted at the Surrey Cancer Research Institute at the University of Surrey in the UK, a single administration of CAVATAK via catheter directly into the bladder (intravesicular treatment) was able to produce tumour viral targeting and replication, as well as viral-induced cancer cell death in the first cohort of three patients. In addition, the intravesicular administration of CAVATAK has been well tolerated with no greater than Grade 1 product-related adverse events.

“These data demonstrate proof of concept of intravesicular delivery of CAVATAK, and are very exciting considering that they were achieved at the lowest planned doses,” said Professor Hardev Pandha, Principal Investigator of the CANON study and Director of the Surrey Cancer Research Institute. “We believe that the overall observed tumour targeting and viral replication is likely to provide a strong signal in generating both a strong local and systemic anti-tumour immune response.”

Recruitment of the second cohort is underway in the CANON trial, which is designed to evaluate the safety and tolerability of CAVATAK administered alone, as well as in combination with a sub-therapeutic dose of the standard chemotherapy, mitomycin C. The trial will also assess the pharmacodynamics of CAVATAK and document evidence of anti-tumour activity. Preclinical research of CAVATAK has shown that the combination of CAVATAK and mitomycin C synergistically enhanced the cancer-killing activity in bladder cancer cell lines.

There is a substantial unmet need for less toxic, more effective agents for the treatment of bladder cancer, a common cancer type also known as superficial bladder cancer, or non-muscle invasive bladder cancer (NMIBC).



The poster detailing the CANON trial results, entitled **“Oncolytic immunotherapy for the treatment of Non-Muscle Invasive Bladder Cancer using intravesical Coxsackievirus A21: Phase 1/2 CANON study,”** can be found on the Viralytics website at:

<http://www.viralytics.com/wp-content/uploads/2015/03/150615-CANON-OVC-poster.pdf>

CAVATAK Immunotherapy Combination Study

The results of a preclinical study assessing the activity of CAVATAK given in combination with immune checkpoint inhibitors¹ (anti-PD-1 or anti-CTLA-4) demonstrate that the combination of CAVATAK with each checkpoint inhibitor produced superior anti-tumour activity and offered greater survival benefits in a mouse melanoma model, compared to the use of either agent alone.

“Of particular interest was the finding that the combination of CAVATAK with either anti-PD-1 and /or anti-CTLA-4 monoclonal antibodies was able to noticeably delay the onset of palpable tumour development following a re-challenge with mouse melanoma cells when compared to all other single treatment regimens,” said Viralytics Chief Scientific Officer, Dr Darren Shafren in an oral presentation of the study results.

“The significant anti-tumour activity mediated by the combination of CAVATAK with these leading checkpoint inhibitors shown in this mouse melanoma model supports clinical evaluation of such an immunotherapeutic treatment regimen in patients with advanced melanoma,” added Dr Shafren.

Accordingly, Viralytics has commenced a Phase 1b clinical trial in late-stage melanoma patients to evaluate the safety and tolerability of the established dose of intratumoural CAVATAK in combination with an anti-CTLA-4 monoclonal antibody (ipilimumab, marketed by Bristol-Myers Squibb Company as Yervoy®). The MITCI (Melanoma Intra-Tumoral Cavatak and Ipilimumab) trial, being conducted at the Providence Cancer Centre, Portland, Oregon, and at Oncology Specialists, Park Ridge, Illinois, is also designed to assess evidence of anti-cancer activity, including response rates and bio-markers of anti-tumour immunity.

“Overall, CAVATAK is a well-tolerated oncolytic virus, making it a strong candidate for use in combination with ipilimumab,” stated Malcolm McColl, CEO and Managing

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.



Director of Viralytics. "Based on these results, we are exploring the potential of this combination treatment to improve response rates and the durability of response."

The presentation discussing the combination study results, entitled "**Combination of a novel oncolytic immunotherapeutic agent, CAVATAK (Coxsackievirus A21) and immune-checkpoint blockade significantly reduces tumor growth and improves survival in an immune competent mouse melanoma model,**" can be found on the Viralytics website at:

<http://www.viralytics.com/wp-content/uploads/2015/03/Pre-clinical-blockade-combination-OVC-2015.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.

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