



ASX and Media Release

Combinations of Viralytics CAVATAK™ and Checkpoint Immunotherapy Demonstrate Anti-Cancer Activity in Preclinical Lung Cancer and Melanoma Studies

19 April 2016, Sydney, Australia: [Viralytics Limited](#) (ASX: VLA, OTC: VRACY) today reported preclinical data from studies assessing the combination of intravenously delivered [CAVATAK™](#) with checkpoint inhibitor (anti-PD-1 or anti-CTLA-4) antibodies in immune competent mouse models of non-small cell lung cancer and melanoma. The results were presented at the 2016 [American Association for Cancer Research \(AACR\) Annual Meeting](#) in New Orleans, LA.

In the orthotopic non-small cell lung cancer model, the combination of CAVATAK and the anti-PD-1 checkpoint inhibitor antibodies resulted in notable survival benefits over single agents alone. A significant survival benefit was seen at day 47, with five of 8 mice alive after treatment with the combination of CAVATAK and the anti-PD-1 antibody, compared to one of 8 mice surviving in the groups treated with either anti-PD-1 antibody or CAVATAK alone.

In the melanoma model, the combination of CAVATAK with each checkpoint inhibitor produced superior anti-tumour activity and offered increased survival benefits, compared to the use of either agent alone. The combination of CAVATAK with either anti-PD-1 and /or anti-CTLA-4 monoclonal antibodies was also 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.

“The significant anti-tumour activity resulting from the combination of CAVATAK with these leading checkpoint inhibitors in mouse models of lung cancer and melanoma strongly supports Viralytics’ current clinical trial evaluations of such immunotherapeutic treatment regimens in patients with these cancer types,” said Viralytics Chief Scientific Officer, Dr Darren Shafren.

The clinical evaluation of *intravenous* CAVATAK in combination with KEYTRUDA¹ (pembrolizumab) in patients with non-small cell lung cancer is to be assessed as part of the Phase 1b KEYNOTE-200 (STORM Part B) study. The study, conducted in collaboration with Merck and Co.², has been recently initiated in the US.

Viralytics is also assessing the combination of *intra-tumoural* CAVATAK with KEYTRUDA (the Phase 1b CAPRA³ study) and YERVOY®⁴ (ipilimumab, the Phase 1b MITCI⁵ study)

¹ Keytruda® is a trademark of Merck & Company Inc

² Merck & Co., Inc., Kenilworth, New Jersey, U.S.A. (known as MSD outside the United States and Canada)

³ CAPRA ((CAvatak™ and PembRolizumab in Advanced Melanoma)

⁴ Yervoy® is a trademark of the Bristol-Myers Squibb company

⁵ MITCI (Melanoma Intra-Tumoral CAVATAK™ and Ipilimumab)



- both underway in the US in late-stage melanoma patients. A study to assess intravenous CAVATAK with a checkpoint inhibitor in advanced melanoma patients is in the final planning stage.

As members of a new class of cancer treatments known as immunotherapies, CAVATAK, KEYTRUDA and YERVOY are designed to enhance the body's own defences in fighting cancer. CAVATAK is Viralytics lead investigational agent based on a proprietary bioselected common cold virus that has been shown to preferentially infect and attack cancer cells. KEYTRUDA (anti-PD-1) and YERVOY (anti-CTLA-4), known as immune checkpoint inhibitors, are humanized monoclonal antibodies that work by taking the brakes off the body's natural immune response to cancer.

The abstract and poster presentation, entitled "Elevated immune activity following an anticancer combination therapy of a novel oncolytic immunotherapeutic agent, CAVATAK (Coxsackievirus A21), and immune checkpoint blockade " are available from the Viralytics website at <http://www.viralytics.com/our-pipeline/scientific-presentations/>.

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. Intratumoral, intravenous and intravesicular delivery routes are under investigation. Two combination studies with checkpoint inhibitors are underway in advanced melanoma patients, as well as a combination study of CAVATAK and KEYTRUDA in late-stage lung and bladder cancer patients.

Further details on our clinical and pre-clinical data can be found at: <http://www.viralytics.com/our-pipeline/clinical-trials/>

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 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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