



ASX and Media Release

Further Promising CAVATAK™ Trial Data to be presented at Association for Cancer Research Annual Meeting

Abstracts Published on Conference Website

18 April 2016, Sydney, Australia: [Viralytics Limited](#) (ASX: VLA, OTC: VRACY) today announced that abstracts for all three posters for presentation at the [American Association for Cancer Research \(AACR\) Annual Meeting 2016](#), have been released on the conference website and are also available on the [Viralytics website](#). The full posters will be presented on Monday, April 18 (US time) and available on the Viralytics website by 9am on Tuesday, April 19 Sydney time.

MITCI Clinical Trial

- ***Phase 1b study of a novel immunotherapy combination therapy of intralesional Coxsackievirus A21 and systemic ipilimumab in patients with advanced melanoma (Abstract CT021)***
- Poster Session: Phase I Clinical Trials in Progress
- Monday April 18, 2016, 8:00 AM – 12 noon (US Central Time)

The poster presentation will describe early results from the ongoing Phase 1b MITCI (Melanoma Intra-Tumoral CAVATAK™ and Ipilimumab) trial assessing [CAVATAK¹](#) in combination with YERVOY®² (ipilimumab) in late-stage melanoma patients. Underway at four US sites, the MITCI study is designed to evaluate the safety and anti-cancer activity of CAVATAK in combination with YERVOY.

The study has now treated eleven patients with the first six patients evaluable for tumour assessment at Day 106. Of five patients not previously treated with YERVOY there was a confirmed overall response in four patients, with all responses occurring by 3.5 months, and in both injected and non-injected lesions. Complete tumour responses were observed in 2 patients. A sixth patient that had progressed on earlier treatment with YERVOY and KEYTRUDA³ has stable disease at 3.5 months.

¹ CAVATAK is Viralytics' lead investigational drug candidate and a novel cancer immunotherapy based on a proprietary cold virus that has been shown to preferentially infect and attack cancer cells.

² Yervoy® is a trademark of the Bristol-Myers Squibb company

³ Keytruda® is a trademark of Merck & Company Inc



To date, no dose-limiting toxicities, and no CAVATAK-related grade 3 or higher adverse events⁴ have been reported. There has been one ipilimumab grade 3 adverse event (fatigue).

CALM Extension Study:

- ***Intratumoral Coxsackievirus A21 increases immune-cell infiltrates and up-regulates immune-checkpoint molecules in the tumor microenvironment of advanced melanoma patients: Phase II CALM Extension study (Abstract CT053)***
- Poster Session: Phase I Clinical Trials 1
- Monday, April 18, 2016, 1pm – 5pm (US Central time)

The poster presentation will report on the 13-patient CALM extension study assessing changes in tumour tissue following administration of CAVATAK in advanced melanoma patients. Intratumoral delivery of CAVATAK was shown to notably influence the dynamics of the tumor micro-environment as evidenced by increases in both immune cell infiltrates and levels of immune-checkpoint genes.

Preclinical Combination Immunotherapy Study:

- ***Elevated immune activity following an anticancer combination therapy of a novel oncolytic immunotherapeutic agent, CAVATAK (Coxsackievirus A21), and immune checkpoint blockade (Abstract 2341)***
- Monday, April 18, 2016, 1pm – 5pm (US Central Time)

The poster presentation will report on preclinical studies assessing the anti-cancer activity of the combination of intravenously delivered CAVATAK and checkpoint inhibitor antibodies in a melanoma and lung cancer immune competent mouse model.

Significant anti-tumor activity was seen with the combination of CAVATAK and checkpoint inhibitors, further supporting the clinical evaluation of such an immunotherapeutic combination treatment regimen.

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 cancers.

⁴ Grade 3 adverse events are severe or medically significant but not immediately life-threatening; Grade 4 adverse events are life-threatening with urgent intervention indicated; Grade 5 is death related to an adverse event.



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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