



ASX and Media Release

## **Viralytics to Present CAVATAK™ Clinical Data at American Association for Cancer Research Annual Meeting 2016**

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**17 March 2016, Sydney, Australia:** [Viralytics Limited](#) (ASX: VLA, OTC: VRACY) today announced that three Abstracts have been accepted for presentation at the [American Association for Cancer Research \(AACR\) Annual Meeting 2016](#), April 16 to 20. The meeting will be held in New Orleans (Louisiana, USA) with over 19,500 participants expected, including leading oncologists and representatives of the pharmaceutical industry.

### **Poster Presentation # 1**

- [\*\*\*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
- Location: Section 26
- Poster Board Number: 25

The poster presentation will report on preclinical studies assessing the anti-cancer activity of the combination of intravenous delivered CAVATAK™<sup>1</sup> and checkpoint inhibitor<sup>2</sup> (anti-PD-1 or anti-CTLA-4) antibodies in a melanoma immune competent mouse model.

Significant anti-tumour activity was seen in mice treated with the combination of CAVATAK and checkpoint inhibitors further supporting the clinical evaluation of such an immunotherapeutic combination.

The Abstract for Poster Presentation #1 is available on the AACR meeting and the Viralytics websites details below.

[Viralytics - Scientific Presentations 2016](#)

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<sup>1</sup> 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.

<sup>2</sup> 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 the checkpoint inhibitors may achieve total annual revenues of more than US\$20Bn by 2020.



## **Poster Presentation #2**

- ***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
- Location: Convention Center, Halls G-J, Poster Section 13, Poster Board Number: 9

The poster presentation will report on the CALM extension study<sup>3</sup> assessing changes in tumour tissue following administration of CAVATAK in advanced melanoma patients. Notably, intratumoral delivery of CAVATAK was shown to influence the dynamics of the tumor micro-environment as evidenced by increases in both immune cell infiltrates and levels of immune-checkpoint genes.

The full text of the abstract will be posted to the Meeting website on Friday, April 15 Eastern US time (Saturday, April 16 Sydney time).

## **Poster Presentation #3**

- ***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
- Location: Convention Center, Halls G-J, Poster Section 13, Poster Board 2

The poster presentation will describe early results from the ongoing Phase 1b MITCI<sup>4</sup> trial assessing CAVATAK in combination with YERVOY<sup>®5</sup> (ipilimumab) in late stage melanoma patients. Currently underway at three US sites, the MITCI study has been designed to evaluate the safety and anti-cancer activity of the combination of the established dose of CAVATAK in combination with YERVOY.

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<sup>3</sup> In the CALM extension study a cohort of 13 advanced melanoma patients received intratumoural CAVATAK on study Days 1,3,5 and 8 and then every three weeks for a further 6 injections. Sequential tumor biopsies of injected lesions (study Days 1 and 8) were monitored for evidence of viral-induced changes in immune cell infiltrates (Multi-spectral imaging) and immune checkpoint molecules (NanoString<sup>®</sup> PanCancer Immune profiling panel).

<sup>4</sup> MITCI (Melanoma Intra-Tumoral CAVATAK<sup>™</sup> and Ipilimumab)

<sup>5</sup> Yervoy<sup>®</sup> is a trademark of the Bristol-Myers Squibb company



The full text of the abstract will be posted to the [AACR meeting website](#) on Friday, April 15 Eastern US time (Saturday, April 16 Sydney time).

All poster presentations will be available from April 18 Eastern US time (April 19 Sydney time), and a link will be provided on the [Viralytics website](#).

**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 intravenous CAVATAK with KEYTRUDA in late-stage lung and bladder cancer patients will commence in 2016.

Further details on our clinical data can be found on our website at the following location:

<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](http://www.viralytics.com).

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