



ASX and Media Release

## Positive Clinical Data from CAVATAK™ and YERVOY® Combination presented at the 2016 AACR Annual Meeting

### Promising Response Rates and Good Tolerability in Late-Stage Melanoma Patients

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**19 April 2016, Sydney, Australia:** [Viralytics Limited](#) (ASX: VLA, OTC: VRACY) today presented positive initial data from its ongoing clinical trial evaluating the safety and anti-cancer activity of its investigational drug candidate [CAVATAK™](#) in combination with the checkpoint inhibitor YERVOY®<sup>1</sup> (ipilimumab) in late-stage melanoma patients. The results were reported in a poster presentation at the [American Association of Cancer Research \(AACR\) Annual Meeting 2016](#) in New Orleans, LA.

The Phase 1b clinical trial, known as the MITCI (Melanoma Intra-Tumoral CAVATAK and Ipilimumab) study, is being conducted at four US sites and has enrolled 11 advanced melanoma patients to date. According to data from the first six patients evaluable for tumour assessment, objective responses have been confirmed by the independent Data Monitoring Committee in four patients, with one additional patient showing stable disease at Day 106.

These results include two complete responses and two partial responses in patients with advanced melanoma, meaning their disease has spread to nearby lymph nodes (Stage III) or to other sites in the body (Stage IV). The patient with stable disease has Stage IV melanoma with multiple liver metastases and had previously failed multiple earlier therapies, including the checkpoint inhibitors YERVOY and KEYTRUDA<sup>2</sup> (pembrolizumab.)

“The preliminary finding that, out of five patients not previously treated with YERVOY, four had clinically meaningful tumor regressions in sites injected with CAVATAK as well as visceral, lymph node and subcutaneous sites that were not injected is notable in light of published objective response rates for monotherapy (CAVATAK: 28.1% and YERVOY: 11%<sup>3</sup>) in patients with advanced melanoma.” said Lead Investigator Dr Brendan Curti, MD, Director, Biotherapy Program, Earle A Chiles Research Institute at the Providence Cancer Center, Portland, Oregon. “These preliminary findings help to confirm that systemic immunity against melanoma can be achieved with this combination. Accrual to the MITCI study is ongoing and we look forward to updating our initial findings in the coming months.”

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<sup>1</sup> Yervoy® is a trademark of the Bristol-Myers Squibb Company.

<sup>2</sup> Keytruda® is a trademark of Merck & Company Inc

<sup>3</sup> [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2015/125377s074lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125377s074lbl.pdf)



To date, no dose-limiting toxicities, and no CAVATAK-related grade 3 or higher adverse events<sup>4</sup> have been reported. There has been one YERVOY-related grade 3 adverse event (fatigue).

Dr Malcolm McColl, Managing Director of Viralytics said, “These initial results suggest that CAVATAK may be beneficial as part of a combination therapy for patients with melanoma, adding to our growing body of clinical and preclinical evidence pointing to CAVATAK’s potential to enhance the activity of checkpoint inhibitors across a range of cancer indications, opening a considerable commercial opportunity.”

As members of a new class of cancer treatments known as immunotherapies, both CAVATAK and YERVOY are designed to enhance the body’s own defences in fighting cancer. CAVATAK is an investigational agent based on a proprietary bioselected common cold virus that has been shown to preferentially infect and attack cancer cells. YERVOY, an immune checkpoint inhibitor, is a humanized monoclonal antibody that works by taking the brakes off the body’s natural immune response to cancer.

In addition, a combination trial of CAVATAK and the checkpoint inhibitor KEYTRUDA is underway as part of a collaboration between Viralytics and Merck & Co. The Phase 1b study, known as the KEYNOTE-200 study (STORM Part B), is designed to explore the combination in patients with either advanced non-small cell lung cancer, or metastatic bladder cancer. Furthermore a potential clinical trial to assess the combination of CAVATAK with checkpoint inhibitors in patients with colorectal or breast cancer is currently being explored.

The abstract and poster presentation, entitled “*Phase 1b study of a novel immunotherapy combination therapy of intralesional Coxsackievirus A21 and systemic ipilimumab in patients with advanced melanoma*”, 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

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<sup>4</sup> 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.



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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