



ASX and Media Release

## **Viralytics Presents New CAVATAK® Data at the 2017 SITC Annual Meeting, Announces New Clinical Studies**

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**13 November, Sydney, Australia:** [Viralytics Limited](#) (ASX: VLA, OTCQX: VRACY) today reported updated positive clinical and preclinical trial results for [CAVATAK®](#), an oncolytic virus and the company's lead investigational product, at the [32<sup>nd</sup> Annual Meeting of the Society for Immunotherapy of Cancer](#) (SITC) in National Harbor MD, United States. The new data represent progress in the ongoing CAPRA, MITCI and KEYNOTE-200 clinical studies assessing CAVATAK in combination with leading cancer immunotherapy agents.

"Based on these promising results and our growing clinical momentum, we are now planning an aggressive expansion of our clinical trial programme," said Viralytics Managing Director Malcolm McColl. "In the next three to six months, we intend to initiate four new Phase 1b clinical studies of CAVATAK across a range of indications and treatment settings, including new trials of CAVATAK in head and neck cancer, colorectal cancer, uveal melanoma and IV melanoma. In addition, our preclinical work on combining CAVATAK with IDO inhibitors points to a potential new opportunity for Viralytics in the clinic."

### **CAVATAK Clinical Trial Update**

In a podium presentation entitled "Oncolytic Viruses in Combination with Immunotherapy Approaches," Howard L. Kaufman, MD, FACS, and immediate past President of the SITC, highlighted CAVATAK as a very promising oncolytic virus which is backed by a growing body of clinical evidence.

Dr. Kaufman gave an overview of updated results from the Phase 1b CAPRA<sup>1</sup> clinical trial, in late-stage melanoma patients being treated with a combination of CAVATAK and KEYTRUDA®<sup>2</sup> (pembrolizumab). The study was presented in more detail in a poster presented by Dr. Ann Silk, MD, MS, Medical Oncologist, Rutgers Cancer Institute of New Jersey. Results to date include good tolerability and a preliminary Best Overall Response Rate (BORR) of 61 percent (14/23) and a disease control rate of 78 percent (18/23), with very promising durability of response in seven of eleven patients with the most advanced Stage IV M1c disease. These response rates, albeit in the relatively small CAPRA study, exceed the published rates for either agent used alone in patients with late-stage melanoma (CAVATAK: 28 percent and KEYTRUDA: ~33 percent<sup>3</sup>). There are now 26 of 50 planned patients enrolled in the study.

An update from the MITCI<sup>4</sup> clinical trial was also included in Dr. Kaufman's discussion, which showed that a combination of CAVATAK and YERVOY®<sup>5</sup> (ipilimumab) is well tolerated and has activity in advanced melanoma patients whether or not they have been previously been treated with anti-PD-1 therapies such as KEYTRUDA. In the 14 patients who had not been previously treated with KEYTRUDA or other anti-PD-1 therapies, the response rate is 57 percent. In the seven patients who had failed earlier single line anti-PD-1 treatment, responses have been seen in two of seven patients—

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1 CAPRA (CAVATAK and Pembrolizumab in Advanced Melanoma)

2 KEYTRUDA® is a trademark of Merck and Co.

3 Merck KEYTRUDA package insert: ipilimumab naïve patients treated with 10mg/kg pembrolizumab every 3 weeks.

4 MITCI (Melanoma Intra-Tumoral CAVATAK and Ipilimumab)

5 YERVOY® is a trademark of Bristol-Myers Squibb

promising results in a setting where there is a high unmet need for new therapies. There are now 38 of 60 planned patients enrolled in the study.

The MITCI study is now focussed on a subset of melanoma patients who have progressed on prior single line anti-PD-1 therapy, with the potential to advance into a pivotal trial in this setting.

Dr. Kaufman further reported preliminary results from the ninety patient KEYNOTE-200 trial being conducted in collaboration with Merck (known as MSD outside the United States and Canada) to investigate intravenous CAVATAK in combination with KEYTRUDA in patients with advanced non-small cell lung cancer (NSCLC) or metastatic bladder cancer.

Results from the early assessment of checkpoint naïve patients were presented. Of the 28 patients, nine patients were not evaluable for target lesion response assessment by CT scan due to early disease progression or study discontinuation. For the remaining 19 evaluable patients, there was response (not all yet confirmed) in three of six NSCLC and five of 13 metastatic bladder cancer patients. 12 of these 19 patients currently remain on the study.

Twenty eight percent and 56 percent respectively of the advanced bladder and NSCLC cancer patients had received 2 or more prior therapies.

To date, the combination therapy has been well tolerated with no dose-limiting toxicities. Seven of 64 patients (11%) have experienced treatment-related Grade 3 or higher adverse events

In addition, initial data from an assessment of the tumour microenvironment, following biopsy of tumour tissues before and after CAVATAK/pembrolizumab administration, demonstrate promising changes in the levels of the important biomarker PD-L1, including a significant increase to positive PDL-1 levels from a group of five patients who previously had negative or weak levels. In general, elevated levels of PD-L1 correlate with improved outcomes with anti-PD-1/PDL-1 checkpoint therapy in lung and bladder cancer.

### **Preclinical Study: Triple Combination of CAVATAK, Anti-PD-1, and IDO Inhibitor**

The results of a melanoma preclinical study of a novel immunotherapy combination consisting of CAVATAK, an anti-PD-1 monoclonal antibody (mAb), and an IDO inhibitor were discussed in a poster presentation at the SITC meeting, suggesting a potential new clinical application for CAVATAK going forward.

The study data demonstrate a notable positive trend in both the reduction of the overall tumour burden as well as a survival benefit in mice treated with either the triple combination or the double combination of CAVATAK and an anti-PD-1, compared with mice receiving anti-PD-1 and IDO inhibition without CAVATAK. The triple combination was tested in an immune-competent mouse melanoma model and appears to be generally well tolerated. These results support the potential clinical evaluation of this novel immunotherapy combination.

### **Expansion of the CAVATAK Clinical Programme**

Based on CAVATAK's promising clinical results to date, Viralytics announced that it plans to initiate four new Phase 1b combination clinical trials in the coming three to six months in the US, expanding into new cancer indications and treatment settings for CAVATAK. These trials will investigate:



- Intralesional CAVATAK and KEYTRUDA in advanced head and neck cancer (ITCAHN study)
- Intravenous CAVATAK and YERVOY in uveal melanoma metastatic to the liver (CLEVER study)
- Intravenous CAVATAK and KEYTRUDA in advanced melanoma (PaCKMAN study)
- CAVATAK and a checkpoint inhibitor in colorectal cancer metastatic to the liver

**NOTE:** For further details, copies of the SITC presentations can be found on the company website at [www.viralytics.com](http://www.viralytics.com).

An updated Investor Presentation, including the new data, is also available on the home page of our website [www.viralytics.com](http://www.viralytics.com).

#### **About the SITC**

The Society for Immunotherapy of Cancer (SITC) is the world's leading member-driven organization specifically dedicated to improving cancer patient outcomes by advancing the science and application of cancer immunotherapy. Regarded as the premier destination for knowledge exchange, education and networking in the cancer immunotherapy field, the SITC Annual Meeting provides an unrivalled opportunity to present to, and connect with, key opinion leaders.

#### **About Viralytics Ltd**

Viralytics is developing oncolytic immunotherapy treatments for a range of cancers. The company's lead investigational product, CAVATAK<sup>®</sup>, is currently being studied in clinical trials for the treatment of melanoma, as well as 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](http://www.viralytics.com).

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