



ASX and Media Release

Viralytics Presents New CAVATAK® Data at the 11th International Oncolytic Virus Conference

11 April 2018, Sydney, Australia: [Viralytics Limited](#) (ASX: VLA, OTCQX: VRACY) today reported updated positive clinical trial results for [CAVATAK®](#), an oncolytic virus and the company's lead investigational product, at the 11th International Oncolytic Virus Conference (OVC) in Oxford, UK. The new data represent progress in the ongoing CAPRA, MITCI and KEYNOTE-200 clinical studies assessing CAVATAK in combination with leading cancer immunotherapy agents. The oral presentation was given by Professor Hardev Pandha MB ChB FRCP FRACP PhD FRSB from the Royal Surrey County Hospital (UK), who is currently participating in the KEYNOTE-200 study.

Regarding the trial data, outlined in more detail below, Professor Pandha said "The data from all the CAVATAK/checkpoint combination studies, although in a relatively small number of patients, is impressive. The low incidence and low grade of adverse events are encouraging. For KEYNOTE-200, in particular, there are encouraging signals for this study, however, the data needs to mature and I look forward to seeing the updated information as it becomes available."

CAVATAK Clinical Trial Update

In the OVC presentation entitled *Clinical evaluation of a novel oncolytic immunotherapy agent, CAVATAK® in combination with immune checkpoint therapy in advanced cancer patients*, Professor Pandha highlighted CAVATAK as a very promising oncolytic virus which is backed by a growing body of clinical evidence.

Professor Pandha gave an overview of updated results from the **Phase 1b CAPRA¹** clinical trial, in late-stage melanoma patients being treated with a combination of intralesional CAVATAK and KEYTRUDA®² (pembrolizumab). Results to date include good tolerability and a preliminary Best Overall Response Rate (BORR) of 59 percent (16/27 patients) and a disease control rate of 81 percent (22/27). 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 percent³). There are now 31 patients enrolled in the study.

An update from the **Phase 1b MITCI⁴** clinical trial was also included in Professor Pandha's discussion, which showed that a combination of intralesional CAVATAK and YERVOY®⁵ (ipilimumab) is well tolerated and has activity in advanced

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

melanoma patients whether or not they have been previously treated with anti-PD-1 therapies such as KEYTRUDA. In the 16 patients who had not been previously treated with KEYTRUDA or other anti-PD-1 therapies, the response rate is 50 percent. In the 9 patients who had failed earlier single line anti-PD-1 treatment, responses have been seen in 33% (3 of 9) patients—promising results in a setting where there is a high unmet need for new therapies. There are now 46 patients enrolled in the study.

Professor Pandha further reported preliminary results from the eighty-five patient **KEYNOTE-200** Phase I 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. Enrolment to this trial is now complete.

Systemic administration of CAVATAK with pembrolizumab has mediated encouraging clinical signals of activity.

Preliminary results from the assessment of study patients were presented. Of the 45 patients who were naïve to prior checkpoint therapy, 4 patients were not evaluable for target lesion response assessment by CT scan due to, withdrawal of consent, early disease progression or study discontinuation. For the remaining 41 evaluable patients, there was target lesion response (not all yet confirmed) in 5 of 16 NSCLC and 7 of 25 metastatic bladder cancer patients. Sixteen of these 41 patients currently remain on the study and are being monitored for response.

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

Prolonged stable disease has been the best response observed to date in 16 evaluable patients previously treated with immune checkpoint inhibitors.

The CAVATAK/pembrolizumab combination has been generally well tolerated. At present only 8 percent (7 of 85) patients have displayed treatment related Grade 3 adverse events with no Grade 4/5 treatment related 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 notable intratumoral induction of PD-L1 at Day 15 relative to baseline in patients with negative/low baseline PD-L1 treated with CAVATAK and pembrolizumab.

Professor Pandha's presentation included previously released background information on CAVATAK as well as details of completed CAVATAK clinical trials. For further details, the OVC presentation can be found on the company website at www.viralytics.com.



About Viralytics Ltd

Viralytics is developing oncolytic immunotherapy treatments for a range of cancers. The company's lead investigational product, CAVATAK[®], 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.

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