ASX and Media Release

Viralytics presents updates on the Combination of CAVATAK® with YERVOY® (MITCI trial) and KEYTRUDA® (KEYNOTE-200 trial) at the 2017 ASCO Annual Meeting Conference

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5 June 2017, Sydney, Australia: Viralytics Limited (ASX: VLA, OTC: VRACY) today announced that it has presented posters updating recent progress on the ongoing Phase 1b MITCI[1] and Phase 1b KEYNOTE-200 (STORM[2] - Part B) clinical trials evaluating Viralytics' lead drug candidate, CAVATAK®[3] in combination with checkpoint inhibitors at the American Society for Clinical Oncology (ASCO) Annual Meeting 2017, being held in Chicago (USA).

MITCI Clinical Trial

The MITCI clinical trial is evaluating intratumoral CAVATAK®, in combination with YERVOY®[4] (ipilimumab) in subjects with advanced melanoma. The latest MITCI results were reported in a poster presentation in the *Developmental Therapeutics-Immunotherapy* poster session (abstract 3014).

Regarding the trial data presented, Dr Brendan Curti, Director of the Biotherapy Program, Providence Cancer Center (Oregon, USA) and the Principal Investigator, said "Although the number of patients treated on the trial are small at this point, I am impressed with these results in heavily pre-treated patients."

Dr Curti further stated "Checkpoint inhibitors have provided a significant change in the treatment of an ever-increasing number of tumor types, however most patients do not respond and some eventually fail after an initial response. The issue then, is what to offer these patients? The combination of an oncolytic virus such as CAVATAK with an anti-CTLA-4 represents a new option if our early results are confirmed with further investigation."

The objective of the ongoing MITCI trial is to evaluate the safety and anti-cancer activity of CAVATAK in combination with ipilimumab in late-stage melanoma patients. The MITCI trial is now focussing on a subset of melanoma patients who have progressed on prior anti-PD1 with or without previous treatment with ipilimumab (anti-CTLA-4) therapy.

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[1] MITCI (Melanoma Intra-Tumoral CAVATAK and Ipilimumab) study
[2] STORM - Systemic Treatment Of Resistant Metastatic disease
[3] CAVATAK is a novel investigational cancer immunotherapy based on a proprietary cold virus that has been shown to preferentially infect and kill cancer cells and can boost the natural anticancer immune response.
[4] YERVOY® is a trademark of the Bristol-Myers Squibb Company

From the ongoing preliminary data reported today, a Best Overall Response Rate (BORR) of 67% (8/12) was observed in advanced melanoma patients naïve to prior checkpoint therapy.

Of interest, in a randomised study of ipilimumab with or without Imlygic®[5] (talimogene laherparepvec) in a population of melanoma patients that were 98% checkpoint treatment naïve, a BORR of 38.8% (38/98) in the Imlygic® with ipilimumab arm was reported in the melanoma-skin cancer session at ASCO 2017.

In a subgroup of patients who received prior single agent PD-1 blockade therapy, when treated on the MITCI trial, preliminary data showed a confirmed BORR of 33% (2/6) and a disease control rate (DCR) of 67% (4/6).

Again of interest, in a recently published study by Long *et al* (2016, SMR) reported a 13% BORR and a 45% DCR in a checkpoint refractory patient population treated with ipilimumab monotherapy.

In a further subset of MITCI patients that had progressed on both anti-PD1 and anti-CTLA-4 therapies, a BORR of 14% (1/7) was observed, with a DCR of 57% (4/7). One patient from this group previously identified as an unconfirmed responder, subsequently progressed and as a consequence has been withdrawn from the study and the previous reference to PR changed to PD in the data analysis.

Particularly encouraging are the ongoing responses observed for MITCI in non-injected liver and lung lesions of 38% (6/16) with a stable disease rate of 56% (9/16).

It is very promising that such tumour responses are occurring in an environment of very acceptable treatment tolerability with only one Grade 3[6] treatment-related adverse event (ipilimumab-related Grade 3 fatigue) being observed, resulting in an overall Grade 3 adverse event rate of 7% (1/15). This rate compares favourably to that consistently observed in the published data on ipilimumab monotherapy in advanced melanoma patients of 23% Grade 3 or higher treatment related adverse events.

“We are encouraged by these early results in the MITCI study in patients who have failed prior anti-PD1 therapy and we have focused further enrolment in

[5] IMLYGIC® is a trademark of Amgen Inc

[6] 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.

this population," said Dr Malcolm McColl, Managing Director of Viralytics. "Clinically important response rates, combined with the low adverse event rate observed with this combination, opens the possibility for this CAVATAK with ipilimumab combination to move into a pivotal registration study in patients who have failed prior checkpoint inhibitor therapy."

The poster was also selected for review at the Poster Discussion Session on Monday June 5.

The poster, entitled "*Activity of a novel immunotherapy combination of intralesional Coxsackievirus A21 and systemic ipilimumab in advanced melanoma patients previously treated with anti-PD1 blockade therapy"* is available from the Viralytics website at https://www.viralytics.com/our-pipeline/scientific-presentations/scientific-presentations-2017/.

KEYNOTE-200 (STORM) Trial

The KEYNOTE-200 (STORM) clinical trial is an ongoing Phase 1b study evaluating intravenously-delivered CAVATAK® in combination with KEYTRUDA[7] (pembrolizumab) in patients with advanced non-small cell lung or metastatic bladder cancer. The aims of the study are to establish a recommended dosing regimen and to evaluate anti-cancer activity and patient tolerability of the combination. The study is being conducted in collaboration with Merck (known as MSD outside the United States and Canada).

The latest data from the study was the subject of a poster presentation in the *Developmental Therapeutics-Immunotherapy* poster session by the study's principal investigator, Dr Charles Rudin, MD, PhD, Chief of the Thoracic Oncology Service, Memorial Sloan Kettering Cancer Center (New York, USA; abstract TPS3108).

Of the trial, Dr Rudin said "The KEYNOTE-200 expansion phase is enrolling well, and the low incidence of adverse events continues to be encouraging."

Enrolment in the KEYNOTE-200 dose escalation phase of the study was completed earlier this year and recruitment in the expansion cohort of 80 patients is ongoing. While the dose-escalation phase was conducted solely in the US, additional sites in Australia and the United Kingdom have either commenced, or soon to commence, recruitment.

To date, 17 subjects have been treated at the highest CAVATAK dose in combination with KEYTRUDA, with fifteen subjects still on trial. Only one Grade 3 CAVATAK-related adverse event (hyponatremia) and no Grade 3 or higher

[7] KEYTRUDA® is a trademark of Merck Sharp & Dohme

pembrolizumab-related adverse events have been reported. It should be noted that there have been no dose limiting toxicities for any of the CAVATAK doses tested on any study, whether as monotherapy or in a combination treatment.

"We are delighted that enrolment in the KEYNOTE-200 multinational expansion phase is progressing well." said Dr Malcolm McColl, Managing Director of Viralytics. "Based on encouraging results from the use of CAVATAK in combination with other checkpoint inhibitors in patients with advanced melanoma, we are keen to assess the potential of the CAVATAK/ KEYTRUDA combination in these two important cancer indications; bladder and lung."

The poster, entitled "*KEYNOTE-200 phase 1b: A novel combination study of intravenously delivered Coxsackievirus A21 pembrolizumab in advanced cancer patients*," is available from the Viralytics website at:
http://www.viralytics.com/our-pipeline/scientific-presentations/

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 Phase 1 and 2 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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