ASX and Media Release

# Viralytics' CAVATAK® in Combination with YERVOY® Provides Promising Results in Advanced Melanoma from the Phase 1b MITCI clinical study

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**5 April 2017, Sydney, Australia:** Viralytics Limited (ASX: VLA, OTC: VRACY) today reported updated positive clinical results from the ongoing Phase 1b MITCI[1] clinical trial evaluating the company's lead drug candidate, CAVATAK®[2], in combination with YERVOY®[3] (ipilimumab) in advanced melanoma patients at the American Association for Cancer Research (AACR) Annual Meeting 2017, being held in Washington DC, USA.

The latest MITCI results were the subject of a podium presentation in the *Novel Immuno-Oncology Agent Clinical Trials* plenary session by the study's principal investigator, Dr Brendan Curti MD, Director of the Biotherapy Program, Providence Cancer Center (Oregon, USA).

Regarding the trial data outlined in detail below, Dr Brendan Curti said "Although we are at an early stage in the study, I am impressed with these results demonstrating responses lasting greater than 6 months for a number of patients that have progressed after checkpoint therapy as well as those who have not yet been treated with these agents. The low incidence and low grade of adverse events are also encouraging."

"Furthermore there is a high unmet need for new therapies for the significant number of patients who progress following treatment with immune checkpoint antibodies," continued Dr Curti. "The results to date in this checkpoint refractory population are very encouraging and, given the urgent need for better therapies, I am pleased that we will expand the study to 70 patients."

## Response Rate of 50 Percent Including in Heavily Pretreated Patients

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.

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[1] MITCI (Melanoma Intra-Tumoral CAVATAK and Ipilimumab) study

[2] 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.

[3] YERVOY® is a trademark of the Bristol-Myers Squibb Company.

According to the data reported today, a Best Overall Response Rate (BORR) of 50% (11/22 patients) and a Disease Control Rate[4] (DCR) of 77% (17/22) has been achieved in the first 22 patients evaluable for efficacy in the study.

Of the 11 patients who had progressed on prior checkpoint therapy[5] there were 4 patients with responses; for a BORR of 36% (4/11). This compares favourably to published trial data where a BORR of 10-13%[6,7] was achieved in patients with advanced melanoma who received YERVOY alone following treatment failure with an anti-PD1 inhibitor. The DCR in these 11 prior checkpoint therapy MITCI patients was 82% (9/11).

In the MITCI trial, two responses were seen in patients with advanced stage IV M1c melanoma who had previously failed both ipilimumab and anti-PD-1 therapies.

Of the 11 patients who had not received prior checkpoint therapy, a BORR of 64% (7/11) was achieved. This compares favourably to a BORR of 11%[8] achieved in melanoma patients that had not received prior checkpoint therapy when treated with YERVOY alone. The DCR in the checkpoint therapy naïve patients was 73% (8/11).

A DCR of 95% (21 of 22 lesions in 10 patients) was seen across all patients on the trial with a BORR of 46% (6/13 lesions in 5 patients) and 67% (6/9 lesions in 5 patients) in non-injected visceral target lesions in patients with or without prior checkpoint therapies, respectively. Positive outcomes were also seen in non-injected visceral metastatic lesions including those in the lung and liver.

The durability of response across all 22 study patients is impressive with most ongoing. Four patients have complete responses (CR) with two patients having CR's continuing one year from the start of treatment.

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[4] Disease control rate includes patients that live with the cancer without it worsening. It includes patients that achieve a complete tumour response, partial tumour response or stable disease. A complete tumour response (immune related Response Criteria) is the disappearance of all tumour burden. A partial tumour response is a reduction in the total tumour burden by greater that 50%. Progressive disease is a 25% increase in tumour burden and all other cases are stable disease.

[5] 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).

[6] Bowyer et al; British Journal of Cancer (2016) 114, 1084–1089

[7] Long et al., 2016 Society Melanoma Research Abstract

[8] YERVOY® FDA approved label:http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/125377s0000lbl.pdf

At the data cut-off time for this presentation 25 patients were evaluable for safety. No dose-limiting toxicities, and no CAVATAK-related grade 3[9] or higher adverse events have been reported.

There have been only two grade 3 ipilimumab-related adverse events (fatigue and elevated liver enzymes). With no grade 4 or 5 treatment-related adverse events reported, the overall grade 3 adverse event rate is 8% (2/25). This compares favourably to ipilimumab monotherapy in advanced melanoma patients where the reported rate of grade 3 or higher treatment related adverse events is 23%[10].

"We are delighted with these initial results from the MITCI study and will increase the study size with a focus on the checkpoint refractory melanoma patient population," said Dr Malcolm McColl, Managing Director of Viralytics. "With continued strong response rates and low adverse event rate, there is the potential for this CAVATAK / ipilimumab combination to move into a pivotal registration study in patients who have failed prior checkpoint therapy."

The presentation, entitled "*The MITCI (Phase 1b) study: A novel immunotherapy combination of intralesional Coxsackievirus A21 and systemic ipilimumab in advanced melanoma patients with or without previous immune checkpoint therapy treatment*" is available from the Viralytics website at https://www.viralytics.com/our-pipeline/scientific-presentations/scientific-presentations-2017/.

**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.

[9] 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.

[10] Hodi et al. N Engl J Med. 2010; 363(8):711.

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