



ASX and Media Release

Viralytics' CAVATAK® in Combination with KEYTRUDA® Provides Promising Results in the CAPRA Melanoma Clinical Trial

Study expansion to 50 patients

4 April 2017, Sydney, Australia: [Viralytics Limited](#) (ASX: VLA, OTC: VRACY) today reported updated interim clinical results from the ongoing Phase 1b CAPRA¹ clinical trial of the company's lead drug candidate, [CAVATAK®²](#), in combination with KEYTRUDA®³ (pembrolizumab) at the [American Association for Cancer Research \(AACR\) Annual Meeting 2017](#), being held in Washington DC, USA.

The latest clinical data from the CAPRA study was highlighted in a poster presentation by Dr Ann W. Silk Medical Oncologist and Assistant Professor at Rutgers Cancer Institute of New Jersey and Robert Wood Johnson Medical School (USA). The Phase 1b study currently has 20 patients enrolled and is designed to evaluate the tolerability and anti-cancer activity of intralesionally injected CAVATAK in combination with the systemic administration of KEYTRUDA in patients with unresectable melanoma.

"I am encouraged and impressed by this initial data from the CAPRA study in the first 15 evaluable patients which include a best overall response rate of 60% and stable disease in 27% of patients" stated Dr Silk. I am pleased with the patient's tolerability to the combination CAVATAK/KEYTRUDA treatment. We saw no dose limiting toxicities and no Grade 3 or higher treatment-related adverse events".

Added Dr Silk, "We are focused on looking for new combination therapies that will increase the proportion of patients that will benefit from checkpoint agents such as KEYTRUDA. The CAPRA results compare favourably to other combination studies and I look forward to expanding the study to enroll up to 50 patients, including patients that have failed prior checkpoint therapies."

The Best Overall Response Rate (BORR) is currently 60% (9/15 patients) in the evaluable patients. This result compares favourably to published trial data

¹ CAPRA (CAVATAK and Pembrolizumab in Advanced Melanoma) 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 KEYTRUDA® is a trademark of Merck Sharp & Dohme.



where a BORR of 33%⁴ was achieved in patients with advanced melanoma who received KEYTRUDA alone. Tumour responses are ongoing in all nine patients who have responded to the combination, with one patient's response lasting for one year after the initiation of therapy. To date two patients have demonstrated complete responses in the target lesions. In the sub-group of patients with the most advanced Stage IV M1c disease the BORR was 83% (5/6 patients).

There have been no Grade 3⁵ or higher treatment-related adverse events. This result compares favourably to KEYTRUDA monotherapy in advanced melanoma patients where the reported rate of Grade 3 or higher treatment related adverse events is 10.1%⁴.

"We continue to be very pleased with the ongoing results from the CAPRA study suggesting that CAVATAK may be able to enhance activity and reduce adverse events compared to KEYTRUDA alone," said Viralytics CEO Dr Malcolm McColl, "Based on these results, and with strong support from leading oncologists, we are delighted to continue exploring the potential of this combination therapy in an expanded cohort of patients."

The poster, entitled "*Phase 1b study of intratumoral oncolytic Coxsackievirus A21 (CVA21) and systemic pembrolizumab in subjects with advanced melanoma: Interim results of the CAPRA clinical trial*" 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.

⁴ Robert et al., N Engl J Med 2015; 372:2521-2532

⁵ 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.



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