



ASX and Media Release

## **Viralytics Commences Clinical Trial of CAVATAK in Bladder Cancer**

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**27 January 2015, Sydney, Australia:** Viralytics Limited (ASX: VLA, OTC: VRACY) has initiated its Phase 1 clinical trial of CAVATAK™ in patients with non-muscle invasive bladder cancer (NMIBC), also known as superficial bladder cancer.

This trial, titled the CANON (CAVATAK in **Non**-muscle invasive bladder cancer) study, has enrolled the first of an expected 30 - 40 patients in the two-part, open-label, dose-escalation study. The trial will take place in the UK and is designed to evaluate the safety and tolerability of CAVATAK administered alone directly into the bladder, as well as in combination with the standard chemotherapy, mitomycin C. The trial will also assess the pharmacodynamics of CAVATAK and document evidence of anti-tumour activity.

CAVATAK is a novel investigational cancer immunotherapy based on a proprietary cold virus that has been shown to preferentially infect and attack cancer cells. In preclinical studies, the combination of CAVATAK and mitomycin C synergistically increased cancer-killing activity in bladder cancer cell lines<sup>1</sup>.

"There is a real need for new therapies for bladder cancer that will improve the durability of response and reduce toxicities compared to current treatments," said Professor Hardev Pandha, Principal Investigator of the CANON study and Director of the Surrey Cancer Research Institute at the University of Surrey. "Based on the promising preclinical performance of CAVATAK in our studies, we are keen to explore this novel treatment in human trials."

Professor Pandha has been actively involved in the preclinical research of CAVATAK in bladder cancer cell lines<sup>1</sup> and is also Principal Investigator in the ongoing Phase 1/2 STORM trial assessing the intravenous (systemic) delivery of CAVATAK™ in approximately 30 patients with late-stage melanoma, prostate, lung or metastatic bladder cancers.

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<sup>1</sup> <http://www.viralytics.com/wp-content/uploads/2014/04/140411-Major-synergy-between-Coxsackievirus-A21-CAVATAK-TM-and-radiotherapy-or-chemotherapy-in-bladder-cancer-due-to-up-regulation-of-viral-receptors-ICAM-1-DAF..pdf>

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Dr Malcolm McColl, Managing Director of Viralytics said, "With the commencement of this study, we now have clinical trials underway to assess CAVATAK across a range of significant cancer indications and by several routes of administration. Leveraging our technology in this manner positions us well to advance new treatment approaches for several difficult-to-treat cancers, to the benefit of patients and investors, alike."

**About the Trial:**

According to the CANON trial protocol, CAVATAK will be given prior to standard therapy, to patients who are scheduled to undergo surgery (transurethral resection, or TUR) to treat their disease.

The first stage of the trial will evaluate CAVATAK delivered as a monotherapy via a catheter directly into the bladder. The second stage will examine CAVATAK given in conjunction with mitomycin C by the same route of administration, with a goal of demonstrating safety and tolerability, and establishing a recommended Phase 2 dosing regimen for the combination therapy.

**About Bladder Cancer:**

Bladder cancer is the sixth most common cancer type in the USA with over 74,000 new cases per annum, most of which affect men and people over the age of 55<sup>2</sup>. The standard of care for NMIBC for several decades has been the delivery of the live bacterial preparation Bacille Calmette Guerin (BCG) directly into the bladder.

Although BCG does lead to reduced rates of disease recurrence and an increase in progression-free survival, it may cause toxicities, which can be severe. Thus, there is a substantial unmet need for less toxic, more effective agents for the treatment of this common cancer type.

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**About Viralytics Ltd:**

Viralytics is developing oncolytic immunotherapy treatments for a range of cancers. Viralytics' lead investigational product, CAVATAK™, is a proprietary formulation of the common cold Coxsackievirus Type A21 (CVA21). CVA21 binds to specific 'receptor' proteins highly expressed on multiple cancer types including, but not limited to: melanoma; prostate, lung, breast and bladder cancers; and multiple myeloma. 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. Together this mechanism of action is known as oncolytic immunotherapy. CAVATAK's preferential targeting of cancer cells creates the potential for a more tolerable cancer treatment.

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<sup>2</sup> <http://www.cancer.gov/cancertopics/types/commoncancers>

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The company has the following clinical trials in progress, or due to commence shortly:

- Phase 2 clinical trial of intratumourally administered CAVATAK in the treatment of Late-Stage Melanoma (the CALM study), underway in the U.S.
- Extension to the CALM study focused on a deeper understanding of the immunotherapeutic activity of CAVATAK
- Phase 1/2 clinical trial of intravenously delivered CAVATAK in patients with melanoma, prostate, lung or metastatic bladder cancers, referred to as the STORM (Systemic Treatment of Resistant Malignancies) study, underway in the UK
- Phase 1 clinical trial of CAVATAK in bladder cancer, known as the CANON (CAVATAK for treatment of NON-muscle invasive bladder cancer) study, underway in the UK
- Phase 1b clinical trial of CAVATAK in combination with YERVOY® (ipilimumab) in late-stage melanoma patients, due to commence in Q1 in the U.S.

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).