ASX and Media Release

Viralytics Receives UK Approval to Commence Clinical Trial of CAVATAK in Bladder Cancer

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14 November 2014, Sydney, Australia: Viralytics Limited (ASX: VLA, OTC: VRACY) announced today that it has received final approval from the UK Medicines and Healthcare Products Regulatory Agency (MHRA) to undertake a Phase 1 clinical trial of CAVATAK™ in patients with non-muscle invasive bladder cancer (NMIBC), also known as superficial bladder cancer.

The Phase 1 trial is a two-part, open-label, dose-escalation study designed to evaluate the safety and tolerability of CAVATAK administered alone, as well as in combination with the standard chemotherapy, mitomycin C, in patients with NMIBC. Investigators will also examine the pharmacodynamics of CAVATAK as well as document any evidence of anti-tumour activity.

This trial, referred to as the CANON (**CA**VATAK in **Non**-muscle invasive bladder cancer) study, will be undertaken by Professor Hardev Pandha, Director of the Surrey Cancer Research Institute at the University of Surrey as part of its ongoing research collaboration with Viralytics investigating CAVATAK's oncolytic activity in bladder cancer. CAVATAK is a novel 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 enhanced the cancer-killing activity in bladder cancer cell lines. In both the first and second stage of the trial, biopsies of the tumour tissue will be taken to assess the response to CAVATAK administration.

"Based on the significantly increased oncolytic activity of the CAVATAK/chemotherapy combination observed in bladder cancer cell cultures, we are excited to further explore this treatment in human trials, said Professor Pandha. "There is an urgent need for improved therapies for bladder cancer, and this combination appears promising."

According to Dr Malcolm McColl, Viralytics' Chief Executive Officer, "The approval is a significant milestone for Viralytics, which is pursuing the development of CAVATAK as a treatment for a variety of cancers, including late-stage melanoma, prostate and lung cancer. Success in this setting would further broaden the commercial opportunity for CAVATAK, either as a monotherapy or in combination with other treatments."

The CANON clinical trial is forecast to be initiated in Q1 2015.

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About the Trial:
According to the trial protocol, CAVATAK will be given in the frontline setting, or ahead of other therapies, to patients who are scheduled to undergo surgery (transurethral resection, or TUR) to treat their disease.

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

Further information is contained in the trial synopsis on the following page.

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[1]. 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 high unmet need for less toxic, more effective agents for the treatment of this common cancer type.

[1] http://www.cancer.gov/cancertopics/types/commoncancers

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Viralytics
Developers of Oncolytic Immunotherapies

CANON TRIAL SYNOPSIS

Title of Study:	A Phase I Study to Evaluate the Safety and Clinical Activity of Intravesicular CAVATAK (Coxsackievirus A21, CVA21) Alone and in Sequential Combination with Low-Dose Mitomycin C in Patients with Non-Muscle Invasive Bladder Cancer
Objectives:	**VLA012A (First stage)** **Primary Objectives:** • Evaluate the safety and tolerability of CAVATAK administered via intravesical instillation in patients with non-muscle invasive bladder cancer scheduled to undergo transurethral resection (TUR) **Secondary Objectives:** • Investigate the pharmacodynamics of CAVATAK, including analysis of biomarkers and immune response, in blood and urine collected after instillation and in tumour tissue collected at TUR • Document any evidence of anti-tumour activity • Evaluate viral replication, persistence and clearance in blood and urine collected after instillation and in tumour tissue collected at TUR **VLA012B (Second stage)** **Primary Objectives:** • Evaluate the safety and tolerability of CAVATAK™ administered in sequential combination with low-dose mitomycin C via intravesical instillation in patients with non-muscle invasive bladder cancer scheduled to undergo transurethral resection (TUR) • Establish a recommended Phase 2 dosing regimen for administration of CAVATAKTM in sequential combination with low-dose mitomycin C administered via intravesical instillation **Secondary Objectives:** • Investigate the pharmacodynamics of CAVATAK™ administered in sequential combination with low-dose mitomycin C, including analysis of biomarkers and immune response, in blood and urine collected after instillation and in tumour tissue collected at TUR • Document any evidence of anti-tumour activity • Evaluate viral replication, persistence and clearance in blood and urine collected after instillation and in tumour tissue collected at TUR
Study Design:	This is a Phase I, two-part, single-site, open-label, dose-escalation study designed to evaluate CAVATAK alone and in sequential combination with mitomycin C in patients with non-muscle invasive bladder cancer who are candidates for and are planning to undergo TUR for treatment of their disease. The study will consist of 2 sequential parts. Part 1 (VLA012A) is a study of the safety and tolerability of CAVATAK administered via intravesical instillation as a single agent in patients with non-muscle invasive bladder cancer scheduled to undergo TUR for treatment of their disease. Two dose levels and two schedules of administration will be evaluated in 3 cohorts of patients to evaluate the safety of CAVATAK in this patient population and establish a maximum tolerated dose (MTD) for incorporation into Part 2 (VLA012B).

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	Part 2 (VLA012B) will evaluate the safety and tolerability of CAVATAK administered in sequential combination with low-dose mitomycin C in the same patient population. Two dose levels and two schedules of administration of CAVATAK will be evaluated with a fixed dose of mitomycin C in 3 cohorts of patients. After the MTD of the combination is established in VLA012B, up to 10 additional patients will be enrolled at the MTD to further explore the safety and pharmacodynamics of the combination. Patients will be invited to participate at first presentation with non-muscle invasive bladder cancer and prior to scheduled TUR in order to give a relatively homogeneous study population and to facilitate collection of resected tumour tissue for histological, pharmacodynamics (PD) and pharmacokinetic (PK) analyses.
Planned Sample Size:	VLA012A: This part is expected to enrol from 9 up to a maximum of approximately 20 patients VLA012B: This part is expected to enrol from 19 up to a maximum of approximately 30 patients
Treatment Duration:	Patients will receive up to 2 instillations of CAVATAK on Days 1 and 2 of an 8-day cycle. A single instillation of mitomycin C will be given on Day 1 in VLA012B only.

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.

The company has extended enrolment to enable a deeper interrogation of the immunotherapeutic activity of CAVATAK, in a single arm Phase 2 clinical trial of intratumourally administered CAVATAK™ in the treatment of Late-stage Melanoma (the CALM study), at multiple prestigious cancer clinics in the US. The study is being conducted in patients with late stage (IIIC and IV) malignant melanoma.

In addition, Viralytics is progressing a Phase 1/2 trial of CAVATAK™ delivered systemically (intravenously). This trial, referred to as the STORM (Systemic Treatment Of Resistant Malignancies) study, is enrolling patients with melanoma, prostate, lung or metastatic bladder cancers. The second stage of the STORM trial will include combination treatments with existing chemotherapies in one of the above cancer types. The STORM trial is being conducted at three UK cancer centres.

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.

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