



ASX and Media Release

Viralytics presents Positive Bio-Marker Data from the CANON Bladder Cancer study

Presentation at 2017 EACR-AACR-SIC Special Conference, Florence, Italy

26 June 2017, Sydney, Australia: [Viralytics Limited](#) (ASX: VLA, OTC: VRACY) today announced that it presented a poster with additional promising bio-marker data from the completed Phase I/II CANON¹ clinical trial in non-muscle invasive bladder cancer (NMIBC) patients administered Viralytics' lead drug candidate, [CAVATAK®](#)² at the [EACR-AACR-SIC Special Conference](#), being held in Florence, Italy.

CANON Clinical Trial

The CANON clinical trial evaluated intravesical³ CAVATAK in 16 patients with non-muscle invasive bladder cancer (NMIBC). The objectives of the study were to evaluate the safety and tolerability of intravesical CAVATAK, first as monotherapy, and then in combination with sub-therapeutic doses of mitomycin C, in patients with NMIBC scheduled to undergo transurethral resection (TUR) for clinical treatment and disease staging. The additional CANON bio-marker results were reported in a poster presentation in the *Translational Research I* poster session (abstract 496).

Regarding the trial data presented, Prof. Hardev Pandha, University of Surrey and Principal Investigator of the CANON study, said "We detected notable levels of TRAIL (TNF-related apoptosis inducing ligand) in sequential urine samples of 10 of 12 (83.3%) monitored patients from the CANON study, suggesting that intravesically-delivered CAVATAK induces secretion of TRAIL. TRAIL is a cytokine that acts in inducing apoptotic cell death primarily in tumor cells. The increasing levels of TRAIL appear in general, to correlate with the kinetics of increasing CAVATAK replication."

Prof. Pandha further stated "This finding is potentially exciting, as detection of elevated levels of functional TRAIL in urine are believed to be one of the predictors of a beneficial immune response to Bacillus Calmette–Guerin

¹ CANON study (CAVATAK in **NON**-muscle invasive bladder cancer)

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 Intravesical delivery is the direct administration of drug unto the bladder through a catheter



(BCG) therapy mediating potential clinical benefit^{4,5}, and our preliminary data suggest intravesicular administration of CAVATAK similarly induces secretion of TRAIL in the urine.”

“These additional data fit nicely with our earlier observations that CAVATAK replication up-regulates target molecules for combination strategies with immune-checkpoint blockade therapies in NMIBC patients.” said Dr Malcolm McColl, Managing Director of Viralytics.

The poster, entitled “*Phase I/II CANON study: Oncolytic immunotherapy for Non-Muscle Invasive Bladder Cancer (NMIBC) using Intravesical Coxsackievirus A21*” 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.

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⁴ Ludwig A.T., Moore J.M., Luo Y. *Cancer Res.* 2004; 64:3386–3390.

⁵ Redelman-Sidi G, Glickman MS, Bochner BH. *Nat Rev Urol.* 2014 Mar; 11(3):153-62.