



ASX and Media Release

Positive CAVATAK™ Clinical Data Presented at 2016 European Association of Urology Congress

Latest results reported in non-muscle invasive bladder cancer CANON clinical trial

15 March 2016, Sydney, Australia: [Viralytics Limited](#) (ASX: VLA, OTC: VRACY) overnight announced positive data from the CANON¹ clinical trial of its lead drug candidate, [CAVATAK™](#)², at the 31st Annual European Association of Urology (EAU) Congress held in Munich, Germany.

Data were presented by Professor Hardev Pandha, University of Surrey and Principal Investigator of the CANON study, at the late breaking news session of the conference.

Professor Pandha provided commentary on the data from 14 patients on the Phase 1 CANON clinical trial, a two stage study expected to enrol approximately 25 non-muscle invasive bladder cancer (NMIBC) patients.

In the first stage, 9 patients were treated by intravesicular³ administration of monotherapy CAVATAK. In the second stage, to date, 5 patients have received a sub-therapeutic dose of the chemotherapy, mitomycin C, plus CAVATAK intravesically prior to routine surgical removal of the tumour tissue.

The study has generated evidence of CAVATAK targeting of tumour cells with viral (i.e. CAVATAK) replication and tumour cell death following either single or multiple administrations of CAVATAK to patients.

Anti-cancer activity including viral induced tumour inflammation has been demonstrated in both the monotherapy and combination therapy arms of the study. A complete response has been observed in one out of the 3 patients in the highest dose cohort of the monotherapy.

To date the intravesicular administration of CAVATAK has been generally well tolerated with no Grade 2, 3 or 4 product-related adverse events⁴.

¹ CAVATAK in **NON**-muscle invasive bladder cancer

² CAVATAK is an investigational novel cancer immunotherapy based on a proprietary bioselected common cold virus that has been shown to preferentially infect and attack cancer cells.

³ Intravesical delivery is the direct administration of drug into the bladder through a catheter.

⁴ Grade 2 adverse events are moderate with minimal, local or non-invasive intervention indicated; 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.



Commenting on the study Professor Hardev Pandha said, "I am very encouraged by the CAVATAK tumour targeting and anti-cancer activity observed in the CANON study. The observed tumour targeting and viral replication seen in this study is likely to provide a strong signal in generating a local and systemic anti-tumour immune response. There is an urgent need for new agents in the treatment of NMIBC and there is considerable potential for CAVATAK in this setting."

The poster detailing the CANON trial results can be found on the Viralytics website:

[Phase I/II CANON study: Novel oncolytic immunotherapy for the treatment of Non-Muscle Invasive Bladder Cancer using intravesical CAVATAK \(Coxsackievirus A21\)](#)

The Annual EAU Congress is Europe's largest annual conference for medical professionals and the pharmaceutical industry active in the urological field. More than 12,000 visitors are expected to attend the 31st Annual EAU Congress in Munich 11-15 March 2016.

About VIRALYTICS and CAVATAK™

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 prostate, bladder and lung cancers. Intratumoural, intravenous and intravesicular delivery routes are under investigation. Two combination studies with checkpoint inhibitors are underway in late-stage melanoma patients. A combination study of intravenous CAVATAK with KEYTRUDA in late-stage lung and bladder cancer patients will commence in 2016.

Further details on our clinical data can be found on our website at the following location:

<http://www.viralytics.com/our-pipeline/clinical-trials/>

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 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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