ASX and Media Release

Viralytics Presents CAVATAK™ Trial Results at Oncolytic Virus Therapeutics Conference

Updates of CALM and CANON Study Data

4 October 2016, Sydney, Australia: Viralytics Limited (ASX: VLA, OTC: VRACY) announced the presentation of the latest data from the completed Phase 2 CALM melanoma extension trial and Phase 1/2 CANON bladder cancer clinical trial of Viralytics' lead drug candidate, CAVATAK™ at the 10th International Meeting on Replicating Oncolytic Virus Therapeutics in Vancouver.

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

Phase 2 CALM Extension Trial

An overview of the latest results of the CALM (CAVATAK in Late-Stage Melanoma) extension trial will be provided in a podium presentation by Lead Investigator Robert Andtbacka, MD, CM, of the Huntsman Cancer Institute at the University of Utah.

The CALM extension trial was conducted in a 13-patient cohort of the 70-patient Phase 2 CALM clinical trial, designed to investigate the efficacy and safety of intralesional CAVATAK in advanced melanoma. The results of the larger trial included a confirmed overall response rate[1] (ORR) of 28.1 percent and a durable response rate[2] (DRR) of 21.1 percent. Tumour responses were observed in injected lesions; non-injected, non-visceral lesions, and in distant non-injected visceral lesions.

In the CALM extension study, biopsies were taken from melanoma lesions prior to and after the administration of CAVATAK. Results from the tumour tissue analysis demonstrate that CAVATAK was able to facilitate notable changes within the tumour microenvironment by:

[1] Overall response rate includes either complete or partial responses that may occur at any time after initiation of treatment. A complete tumour response (irRECIST 1.1) is the disappearance of all tumour burden. A partial tumour response (irRECIST 1.1) is a reduction in the total tumour burden by greater than 30%

[2] Durable response is a response lasting continuously for ≥ 6 months as assessed by irRECIST 1.1 criteria

- Inducing increases in immune cell infiltrates (CD3+ and CD8+ T cells) and greater expression of PD-L1, in particular within lesions displaying stable disease or response. Reconstitution of immune cell infiltrates was observed in a number of CAVATAK-treated lesions from patients failing prior treatment with checkpoint inhibitors[3].

- Significantly up-regulating a number of immune checkpoint inhibitory molecules in injected melanoma lesions, including CTLA-4, PD-L1, LAG-3, TIM-3 and IDO.

"The results of this study demonstrate the capacity of CAVATAK to modify the tumour micro-environment with the potential to then drive enhanced activity of the checkpoint inhibitors," said Dr Malcolm McColl, Managing Director of Viralytics. "This premise is supported by the early encouraging results from the CAVATAK and YERVOY®[4] combination in the Phase 1b MITCI[5] study as reported at the American Association of Cancer Research conference in April. We look forward to providing an update on the MITCI study at the upcoming ESMO conference and also advancing other CAVATAK and checkpoint inhibitor combinations across a range of cancer indications."

The slide presentation, "*Phase II CALM Extension study: Intratumoural Coxsackievirus A21 increases immune-cell infiltrates and up-regulates immune-checkpoint molecules in the tumour micro-environment,"* is available on the Viralytics website at: http://www.viralytics.com/our-pipeline/scientific-presentations/

Phase 1/2 CANON Trial

Updated results from the CANON (CAVATAK in NON-muscle invasive bladder cancer) trial of CAVATAK in bladder cancer will be reported in a podium presentation by Professor Hardev Pandha, Professor of Medical Oncology, University of Surrey and Principal Investigator of the CANON study.

The CANON study investigated the tolerance of escalating doses of CAVATAK delivered directly into the bladder through a catheter, a technique known as intravesicular administration, in 15 first-line patients with non-muscle invasive bladder cancer (NMIBC).

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[3] Checkpoint inhibitors include the anti-PD1 antibodies such as nivolumab (OPDIVO, trademark of Bristol Myers Squibb Company) and pembrolizumab (KEYTRUDA, trademark of Merck & Company Inc) and the anti-CTLA4 antibodies such as ipilimumab (YERVOY, trademark of Bristol Myers Squibb Company). Analysts forecast these three agents may achieve total annual revenues of more than US$20Bn by 2020.

[4] YERVOY, trademark of Bristol Myers Squibb Company

[5] MITCI (Melanoma Intra-Tumoural CAVATAK and Ipilimumab)

In the first stage, nine patients were treated by intravesicular administration of monotherapy CAVATAK. In the second stage, six patients received a sub-therapeutic dose of the chemotherapy, mitomycin C, plus CAVATAK delivered intravesically prior to routine surgical removal of the tumour tissue.

Clinical activity of CAVATAK was demonstrated by evidence of viral replication and notable signs of tumour inflammation following either single or multiple administrations of CAVATAK in multiple patients. A complete response was observed in one out of the three 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 or higher product-related adverse events[6].

Professor Pandha commented: "These data are very exciting, with evidence of CAVATAK tumour targeting, virus replication, tumour inflammation, and cancer cell death. It is also pleasing to report that CAVATAK has been well tolerated with no significant toxicity. These positive results suggest that CAVATAK is highly suited for application in non-muscle invasive bladder cancer and there is considerable opportunity for better therapies in this setting."

The slide presentation, "*Phase I/II CANON study: Oncolytic immunotherapy for the treatment of Non-Muscle Invasive Bladder Cancer (NMIBC) using Intravesical Coxsackievirus A21*," is available on the Viralytics website at: http://www.viralytics.com/our-pipeline/scientific-presentations/

Pre-clinical Investigation of CAVATAK as a Potential Treatment for Pancreatic Cancer

There is a high unmet need for better therapies for pancreatic cancer with the 5-year survival rate of 7%.

In general, metastatic pancreatic cancers express elevated levels of surface ICAM-1, the specific receptor targeted by CAVATAK. *In vitro* cultures of human pancreatic cells have been demonstrated to be susceptible to CAVATAK-mediated oncolysis.

[6] 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.

The poster presentation reported on the investigation of CAVATAK as a potential treatment for pancreatic cancer in an orthotopic mouse model both as a single agent and in combination with gemcitabine.

In this model, palpable tumors within the pancreas were intratumorally injected with CAVATAK twice over three weeks, and subsequently administered gemcitabine intraperitoneally four times over 12 days in the combination treatment arm.

CAVATAK as a single agent, and in combination with gemcitabine was well tolerated and induced notable tumor reduction and/or stabilisation as assessed by bioluminescent imaging in a number of animals.

Anti-tumor activity mediated from single agent or combination CAVATAK treatment regimens translated into statistically significant increases in survival rates compared to mice treated with gemcitabine alone.

The presented pre-clinical data suggest that CAVATAK may have potential anti-tumor activity in human pancreatic cancer.

The poster, "*Pre-clinical investigation of CAVATAK (Coxsackievirus A21) as a potential treatment for Pancreatic Cancer*," is available on the Viralytics website at: http://www.viralytics.com/our-pipeline/scientific-presentations/

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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