



NEWS RELEASE

## **Viralytics and Merck & Co., Inc., Kenilworth, New Jersey, U.S.A. to Collaborate on Combination Clinical Trial of CAVATAK™ and KEYTRUDA® in Lung and Bladder Cancer**

**Sydney, Australia, 6 November 2015:** [Viralytics Limited](#) (ASX: VLA, OTC: VRACY) announced today that it has entered into a clinical trial collaboration agreement through subsidiaries of Merck & Co., Inc., Kenilworth, New Jersey, U.S.A. (known as MSD outside the United States and Canada) to evaluate the combination of Viralytics' investigational cancer immunotherapy CAVATAK™, with MSD's KEYTRUDA®, an anti-PD-1 (programmed death receptor-1) therapy.

The Phase 1b clinical trial will evaluate the safety and efficacy of this novel immunotherapy combination in patients with either advanced stage non-small cell lung cancer (NSCLC) or metastatic bladder cancer. Viralytics, in collaboration with MSD, will be the sponsor of the study, which is planned to begin in 2016.

As members of a new class of cancer treatments known as immunotherapies, both CAVATAK and KEYTRUDA are designed to enhance the body's own defences in fighting cancer. CAVATAK is an investigational agent based on a proprietary bioselected common cold virus that has been shown to preferentially infect and attack cancer cells. KEYTRUDA is a humanized monoclonal antibody that works by increasing the ability of the body's immune system to help detect and fight tumour cells. KEYTRUDA blocks the interaction between PD-1 and its ligands, PD-L1 and PD-L2, and may affect both tumour cells and healthy cells.

"We are excited to collaborate with MSD on this clinical trial, which is the first to explore the combination of an intravenously delivered oncolytic virotherapy with a checkpoint inhibitor such as KEYTRUDA in non-small cell lung and metastatic bladder cancer." said Dr Malcolm McColl, CEO and Managing Director of Viralytics. "We are pleased to have this opportunity to work with a leader in the immuno-oncology field to evaluate the potential synergy of these two novel immunotherapies in these very common cancer types."

"We believe that there may be potential benefit in combining CAVATAK with our anti-PD-1 therapy, KEYTRUDA – which have different, yet complementary approaches to engaging the immune system to fight cancer –and look forward to seeing results from this study." said Dr. Eric Rubin, vice president and therapeutic area head, oncology early-stage development, MSD Research Laboratories.

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The phase 1b combination trial will be the second stage of Viralytics' ongoing STORM clinical trial. The first stage of this study is focusing on assessing the intravenous administration of CAVATAK as a monotherapy in late-stage solid cancer patients. Initial results indicate that multiple intravenous infusions of CAVATAK have been well tolerated and have produced potential tumour viral replication in some advanced cancer patients, with anti-tumour activity seen in some individual lesions.

The second stage of the STORM trial has been re-designed to assess the intravenous delivery of CAVATAK in combination with KEYTRUDA in patients with advanced NSCLC or metastatic bladder cancer. The trial will be an open-label, multi-centre study with dose escalation of CAVATAK in combination with fixed doses of KEYTRUDA, followed by an expansion cohort phase. The final cohort will contain approximately 80 patients, across both indications. The aim of the study is to establish a recommended dose regimen for the CAVATAK/KEYTRUDA combination and to evaluate anti-cancer activity and patient tolerability. Patient biopsies will be assessed for changes in the tumour microenvironment that may provide a further signal of activity.

Viralytics will provide CAVATAK and sponsor the study; MSD will provide KEYTRUDA and conduct biomarker analysis. The agreement includes a provision where the parties may extend the collaboration to include a potential Phase 3 clinical trial. Additional details of the collaboration were not disclosed.

#### **About Non-Small Cell Lung Cancer (NSCLC) and Bladder Cancer**

According to the National Cancer Institute, lung cancer is the second most common type of cancer in the US with an estimated 221,200 new diagnoses per annum, and is by far the leading cause of cancer death. Of the various lung cancer types, NSCLC is the most prevalent, accounting for 85 to 90 percent of cases. Bladder cancer is the fifth most common cancer type in the US with over 74,000 new cases per annum, most of which affect men and people over the age of 55<sup>1</sup>.

#### **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. A combination study with the checkpoint inhibitor ipilimumab is underway in late-stage melanoma patients.

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.

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<sup>1</sup> <http://www.cancer.gov/cancertopics/types/commoncancers>



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).

### **Viralytics Forward-Looking Statements**

Certain statements made in this presentation are forward looking statements within the meaning of the safe harbour provisions of the United States Private Securities Litigation Reform Act of 1995. These forward looking statements are not historical facts but rather are based on Viralytics' current expectations, estimates, assumptions and projections about the industry in which Viralytics operates. Material referred to in this document that use the words 'estimate', 'project', 'intend', 'expect', 'plan', 'believe', 'guidance' and similar expressions are intended to identify forward looking statements and should be considered an at-risk statement. These forward looking statements are not a guarantee of future performance and involve known and unknown risks and uncertainties, some of which are beyond the control of Viralytics or which are difficult to predict, which could cause the actual results, performance or achievements of Viralytics to be materially different from those which may be expressed or implied by these statements. These statements are based on our management's current expectations and are subject to a number of uncertainties and risks that could change the results described in the forward-looking statements. Risks and uncertainties include, but are not limited to, general industry conditions and competition, general economic factors, the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally, and challenges inherent in new product development. Investors should be aware that there are no assurances that results will not differ from those projected and Viralytics cautions shareholders and prospective shareholders not to place undue reliance on these forward-looking statements, which reflect the view of Viralytics only as of the date of this presentation. Viralytics is not under a duty to update any forward-looking statement as a result of new information, future events or otherwise, except as required by law or by any appropriate regulatory authority.

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