ASX and Media Release

Viralytics Presents Phase 2 Melanoma Extension Cohort Data, updated CALM study survival and CAVATAK / Immune Checkpoint combination Preclinical Data at 2015 European Cancer Congress

28 September 2015, Sydney, Australia: Viralytics Limited (ASX: VLA, OTC: VRACY) today announced the presentation of positive clinical data from the Phase 2 CALM extension cohort clinical trial of its lead drug candidate, CAVATAK™, as well as updated overall survival from the main 57 patient CALM study and promising results of a preclinical study assessing the activity of intravenous CAVATAK given in combination with immune checkpoint inhibitors[1] at the 2015 European Cancer Congress (ECC) in Vienna, Austria.

CAVATAK™ is an investigational novel cancer immunotherapy based on a proprietary bioselected common cold virus that preferentially targets, infects and attacks cancer cells.

CALM Extension (Biopsy) Study Results

Dr Robert Andtbacka reported preliminary results from the 13-advanced melanoma patient CALM extension study, in which biopsies were taken from melanoma lesions prior to and after CAVATAK administration, yielding the following preliminary results:

- *5/12 patients (41.7%) achieved irPFS at 6 months.*
- *An objective response rate of 30.8% (4/13) was observed, including tumour responses in patients that had failed prior immunotherapies including the checkpoint inhibitors, ipilimumab and pembrolizumab.*
- *CAVATAK treatment mediated positive changes within the tumor microenvironment by inducing increases in immune response genes, immune cell infiltrates and expression of PD-L1.*

"The observation of CAVATAK-induced immune cell infiltration within the tumour, combined with the encouraging results seen in the CALM trial, point to CAVATAK as an investigational agent with real promise in combination with checkpoint inhibitors such as anti-CTLA-4 (ipilimumab) and/or anti-PD-1 (pembrolizumab)," said Dr Andtbacka. "In addition, CAVATAK treatment may have potential application in a

[1] Checkpoint inhibitors are an important new class of anticancer agent that take the brakes off the immune response to cancer and have application across a broad range of cancer types including melanoma, lung and bladder cancer. They include the anti-PD-1 antibodies such as pembrolizumab (Keytruda, Merck), nivolumab (Opdivo - Bristol Myers Squibb) and the anti-CTLA-4 antibodies such as ipilimumab (Yervoy, Bristol Myers Squibb). Analysts forecast these 3 agents may achieve total annual revenues of more than US$20Bn by 2020.

rescue strategy to reconstitute the immune cells within the tumor microenvironment of lesions resistant to immune checkpoint inhibitors. I look forward to further studies assessing CAVATAK by both the intralesional and intravenous delivery route in the combination setting in late stage melanoma patients."

Phase 1 MITCI Trial update

As the next stage in the clinical development of CAVATAK, Viralytics is conducting the MITCI (Melanoma Intra-Tumoral CAVATAK and Ipilimumab) study, which is designed to evaluate the activity of intralesional injection of CAVATAK in combination with systemic administration of ipilimumab[2] in patients with unresectable melanoma. The study is underway at three sites in the United States. Preliminary findings in the MITCI study indicate no serious adverse advents to the CAVATAK/ipilimumab combination to date, with a case report of one of the patients in the study showing early signs of anti-tumour activity in metastatic visceral and non-visceral lesions at 14 weeks post-treatment initiation.

Phase 2 CALM Trial update

Updated results from the Phase 2 CALM (CAVATAK in Late-stage Melanoma) clinical trial confirm previously reported positive treatment response data in difficult-to-treat, late-stage melanoma patients. In his oral and poster presentation, Dr Robert Andtbacka of the Huntsman Cancer Institute, University of Utah, and Lead Study Investigator, reported the following results:

- *The CALM study achieved its primary endpoint, with 22/57 patient (38.6%) achieving immune-related Progression Free Survival (irPFS[3]) at 6 months.*
- *Responses were observed in injected lesions, non-injected non-visceral lesions, and in distant non-injected visceral lesions, including lung and liver metastases.*
- *An objective response rate[4] of 28% (16/57) was demonstrated, with eight patients achieving complete response.*
- *A durable response[5] persisting for at least 6 months was seen in 21% of patients.*

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[2] Ipilimumab marketed by Bristol-Myers Squibb Company as Yervoy®.

[3] Progression Free Survival is the length of time, during and after treatment, that the patient lives with the cancer without it worsening. It includes patients that achieve a complete tumour response, partial tumour response or stable disease. 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 that 30%.

[4] Objective response rate includes either complete or partial responses that may occur at any time after initiation of treatment.

[5] Durable response occurs when a patient has at least a 30% decrease in the tumour burden continuous for at least 6 months. Patients who meet criteria for durable response demonstrate at least a partial response and some a complete response.

- *A one-year survival rate of 75.4% was achieved, with updated median overall survival[6] of 26.7 months.*

- *Multi-dose intralesional therapy with CAVATAK was generally well tolerated, with no grade 3 or 4 treatment related adverse events.*

CAVATAK Immunotherapy Combination Study

Results from a preclinical study assessing the activity of CAVATAK given in combination with immune checkpoint inhibitors (anti-PD-1 or anti-CTLA-4) in immunocompetent mice were presented in a poster by Dr Darren Shafren, Viralytics Chief Scientific Officer. The key results included:

- *Following gross examination, the CAVATAK and anti-PD-1 or anti-CTLA-4 mAb combination treatment appears to be generally well tolerated*

- *Intravenously delivered CAVATAK, when given in combination with anti-PD-1 or anti-CTLA-4, produced superior anti-tumour activity and offered greater survival benefits in a mouse melanoma model, compared to the use of either agent alone*

"Based on the results of this preclinical work and the excellent outcomes from the CALM study, we are excited about the prospects for CAVATAK given in combination with either a anti-PD-1 or anti-CTLA-4 blockade agent in melanoma patients," said Dr Malcolm McColl, Viralytics Managing Director and CEO. "Our MITCI study of intralesional CAVATAK in combination with ipilimumab is now well underway, and we have just initiated our CAPRA[7] study to assess CAVATAK in combination with the anti-PD-1 antibody Keytruda®[8] (pembrolizumab) in unresectable melanoma patients. We are also finalizing plans for a clinical trial to assess the intravenous delivery of CAVATAK in combination with immune checkpoint inhibitors in late-stage cancer patients."

The ECC presentation and posters may be found on the Viralytics website.

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 prostate, 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

[6] Median overall survival is the length of time from initiation of CAVATAK treatment that half of the patients are still alive.

[7] CAPRA (**CA**VATAK and **P**emb**R**olizumab in **A**dvanced Melanoma)

[8] Keytruda® is a trademark of Merck & Company Inc

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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