ASX and Media Release

Viralytics Reports Positive Final Results from CAVATAK™ Phase 2 Melanoma Trial

Presentation at American Society for Clinical Oncology Annual Meeting 2015

- *Primary endpoint achieved with 38.6% (22/57) of late-stage melanoma patients achieved the irPFS[1] endpoint*
- *Objective response rate of 28% (16/57) with eight patients achieving complete response[2]*
- *Durable response[3] persisting for at least 6 months in 21% of patients*
- *Activity in non-injected distant lesions, including lung and liver metastases*
- *One-year survival rate of 75.4% with median overall survival[4] of 26 months*
- *Well tolerated in 57 patients - no grade 3 or 4 treatment-related adverse events[5]*
- *Exciting results from biopsy study point to combination synergy with checkpoint inhibitors*
- ***Teleconference scheduled for 16 June (US time)***

---

2 June 2015, Sydney, Australia: Viralytics Limited (ASX: VLA, OTC: VRACY) today provided positive final data from the Phase 2 CALM clinical trial of Viralytics' lead drug candidate, CAVATAK™, at the American Society of Clinical Oncology (ASCO) Annual Meeting 2015 in Chicago, IL. 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.

Dr Robert Andtbacka of the Huntsman Cancer Institute, University of Utah, and Lead Study Investigator, presented a poster detailing the final results from the Phase 2

---

[1] The primary endpoint measured is immune-related Progression-Free Survival (irPFS) at six months after first dose of CAVATAK™. Progression Free Survival is the length of time, during and after treatment that the patient lives with the cancer without it worsening. irPFS includes patients who achieve a complete tumour response, partial tumour response or stable disease.

[2] A complete tumour response (irRECIST 1.1) is the disappearance of all tumour burden.

[3] 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.

[4] Median overall survival is the length of time from initiation of CAVATAK treatment that half of the patients are still alive. Currently this median is estimated time as more than half the patients are still alive.

[5] 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.

CALM clinical trial, confirming earlier promising results in difficult-to-treat, late-stage melanoma patients.

Final Results

The final CALM results showed that 22 of the 57 (38.6%) patients achieved the irPFS endpoint, more than doubling the target of 10 of 54 evaluable patients reporting irPFS at six months after the first dose of CAVATAK.

Investigators also reported an overall response rate[6] in 16 of 57 (28%) patients. Of these, eight patients achieved a *complete* response and disappearance of their total tumour burden and the other eight achieved a *partial* response being at least a 30% reduction in the tumour burden.

Durable responses, persisting for 6 months or more, were seen in 21% of patients. Notably, durable response was the FDA approved endpoint for the pivotal Phase 3 trial of Amgen's oncolytic virus talimogene laherparepvec (T-VEC) which recently gained recommendation for approval from the FDA's Cellular, Tissue and Gene Therapies Advisory Committee (CTGTAC) and the Oncologic Drugs Advisory Committee (ODAC) with a 16.3% durable response rate.

Responses have been observed in patients who have progressed on other agents such as T-Vec and the checkpoint inhibitor ipilimumab.

Promising anti-cancer activity was demonstrated in non-injected distant cancers, including lung and liver metastases. A response rate of 37.5% was recorded in individual target lesions at these sites – suggestive of CAVATAK's ability to trigger an anti-tumour immune response.

The one-year survival rate of 75% (43 of 57 patients) with a median overall survival of 26 months was achieved in a challenging population with advanced, intractable disease.

"These results mark CAVATAK as a new agent with significant promise in a range of settings, based on its performance in meeting the primary endpoint, its favourable tolerability profile, and its ability to produce durable responses. In addition, we are encouraged by initial interesting data showing that CAVATAK can reconstitute immune activity in the tumors of patients who have failed multiple other treatments -- suggesting a potential role in combination with other new immunotherapies," said Dr Andtbacka. "I look forward to a continuing role in studies which will help define

[6] 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%.

the optimal clinical settings for CAVATAK, both in combination therapies and as a single agent."

Extension (Biopsy) Study

Further results from the 13-patient CALM extension study were also reported. Biopsies were taken from melanoma lesions prior to and after CAVATAK administration. Results from the tumour tissue demonstrate that CAVATAK was able to induce anti-cancer immune activity. Specifically, there is evidence that CAVATAK induces key immune cells (such as cytotoxic T lymphocytes and PD-L1 expressing cells) to infiltrate the tumour tissue including into lesions of patients that have progressed on treatment ipilimumab, pembrolizumab or talimogene laherparepvec. Increases in the number of these cells are important signals of potential complementary activity in combination with important new immunotherapies such as checkpoint inhibitors[7].

Malcolm McColl, Viralytics Managing Director and CEO said "These results from our CALM trial represent a major milestone for Viralytics. We have demonstrated that CAVATAK has strong anti-cancer activity in late-stage patients, whilst being well tolerated. Durability of response and activity in non-injected sites are further indications of CAVATAK's substantial potential." He added "We are well funded and have excellent support from global thought-leading oncologists. With the excellent CALM results we have a solid platform for driving CAVATAK towards a commercial transaction."

Poster Presentation

- ***Final data from CALM: A phase II study of Coxsackievirus A21 (CVA21) oncolytic virus immunotherapy in patients with advanced melanoma (Abstract #9030)***
- Presenter: Dr Robert Andtbacka MD, CM, Associate Professor at the University of Utah-based Huntsman Cancer Institute and Lead Study Investigator for the CALM trial.

The poster is available on the Viralytics website.

[7] 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-PD1 antibodies such as nivolumab (Opdivo - Bristol Myers Squibb) and pembrolizumab (Keytruda, Merck) and the anti-CTLA4 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.

Teleconference to Recap Poster Presentation

Investors and analysts are invited to join a teleconference on 16 June (US) / 17 June (Australia) in which Dr Andtbacka will step through the ASCO poster and field questions.

The teleconference will be recorded and a link provided on the Viralytics website. Information regarding exact timing and dial in details will be provided in a separate market release.

About Viralytics Ltd:

Viralytics is developing oncolytic immunotherapy treatments for a range of cancers. Viralytics' 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 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.

Enquiries:
Dr Malcolm McColl
Managing Director
02 9988 4000

Mr Rudi Michelson
Monsoon Communications
03 9620 3333