

ASX and Media Release

Melanoma Phase I Clinical Trial Report Completed

19th January 2010, Sydney: Viralytics Limited (ASX: VLA, OTC: VRACY):

Viralytics is pleased to announce the report of its Phase I late stage melanoma trial of CAVATAK™ has been completed.

The Primary safety objective of this trial was to assess the safety and tolerability of two doses of CAVATAK™ when injected directly to a single tumour. The trial was successful with all patients tolerating the treatment and none of them exhibiting any product related serious adverse events.

The Secondary objective of the trial also monitored the injected tumour and other distant tumours for signs of CAVATAK™ activity against actively progressing metastatic melanoma. Injected tumours of one third of patients reduced in size, while the injected tumours of a further 22% of patients remained stable.

Measurement of other distant tumours in the patients showed that the overall disease was stabilized in two of the patients. It should be noted that as this trial was a safety trial the Company was only allowed to inject a single tumour. This restriction will not apply in Phase II trials.

All patients in the trial had late stage disease and had previously failed or rejected standard therapies.

The Principle Investigator for the study, Dr Mark Smithers from the Princess Alexandra Hospital, Brisbane said “A successful completion to this study was very important. We have now established a safety profile that allows the product to advance to Phase II efficacy evaluation. CAVATAK™ offers to be an exciting alternative in the attempt to establish successful immune therapy of Melanoma. Immune therapy, I believe, will play a significant role in the future treatment of this disease.”

The study conclusions also support the progress of development to Phase II where repeated dosing over a longer period of time would be used to establish the efficacy of CAVATAK™ in effectively treating Melanoma.

The formal conclusions drawn in the study report were as follows:

- All patients adequately tolerated the multiple single tumour injections up to a final dose of 2×10^9 TCID₅₀. There were no serious adverse events deemed to be probably, or highly probably, related to study drug.

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- Five of nine (55.55 %) patients experienced reductions in injected tumour volume or tumour stabilisation following multiple single tumour injections with CAVATAK™.
- The findings of potential anti-tumour activity and patient tolerability of intratumoural delivered CAVATAK™, provide a solid foundation for Phase II investigations employing a multi-dose administration schedule to further study the efficacy and safety of CAVATAK™ in patients with late stage melanoma and other advanced solid cancers.

Viralytics will use this report as a core source of data in the generation of its US FDA Investigational New Drug (IND) filing. The Company has chosen to conduct its planned Phase II melanoma trial under an IND filing, as a clinical trial conducted under an IND filing adds significantly greater value in future licensing agreements than a trial undertaken below this regulatory standard.

Viralytics will file an IND in two steps. The Company will hold a pre-IND meeting with the FDA allowing the FDA to review and comment on the Company's substantial clinical, manufacturing and toxicology data. Following this meeting and the provision of additional data (if requested), an IND filing will be lodged with the FDA. It is expected the pre-IND meeting will be held in the first quarter of 2010.

Enquiries

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About Viralytics Ltd

Viralytics is listed on the Australian Securities Exchange (ASX code: VLA). Viralytics' ADR trades under VRACY on the OTC market in the USA. Viralytics' principal asset is the intellectual property relating to CAVATAK™, an Oncolytic Virus technology. CAVATAK™ is the trade name for Viralytics' proprietary formulation of the Coxsackievirus Type A21 (CVA21). CVA21 is a virus that occurs naturally in the community. CVA21 attaches to the outside of a cell, using a specific 'receptor' on the cell's surface (like a key fitting a lock). CVA21 uses two receptors to infect cells, intercellular adhesion molecule-1 (ICAM-1) and/or decay accelerating factor (DAF). Both of these receptor proteins have been demonstrated to be highly expressed on multiple cancer types, including: melanoma, prostate cancer, breast cancer, multiple myeloma and others.