ASX and Media Release

Positive results for Viralytics CAVATAK™ phase I intravenous study

..Positive results also for combination with docetaxel in preclinical study
..Phase I/II clinical study planned for second half 2013

---

9 April 2013, Sydney, Australia: Viralytics Limited (ASX:VLA, OTC:VRACY) has finalised the clinical study report on the Phase I evaluation of CAVATAK™ administered intravenously to late stage melanoma, prostate, breast or colorectal cancer patients. It is pleasing to report that CAVATAK™ was well tolerated with some evidence of stable disease despite most patients only receiving a single dose of CAVATAK™. Subject to regulatory approval, Viralytics is now well placed to initiate Phase I / II intravenous studies in patients with very common tumour types such as prostate, lung, melanoma and bladder cancer. A positive outcome in these studies would substantially broaden the potential application of CAVATAK™.

Patients in the Phase I dose escalation study received either a single intravenous (IV) infusion (9 patients) or two IV infusions (1 patient) of CAVATAK™ ranging from a dose of 10^6 to 10^{10} infectious units. Of the ten patients enrolled in the study, eight were evaluable for assessment as per the protocol. The primary objective of this study was patient tolerance to intravenous infusion of CAVATAK™.

Overall, CAVATAK™ was well tolerated for intravenous administration with no-treatment related serious adverse events observed and no subjects withdrawn due to adverse events.

Some patients displayed transient/stable reductions in lesion size and/or stable disease despite most receiving only a single dose of oncolytic virus. No objective responses were observed, however two subjects displayed stable disease at Day 84 as assessed by RECIST 1.1 criteria.

Study investigator, Associate Professor Winston Liauw of the Cancer Care Unit, St George Hospital, NSW said, “the CAVATAK™ Phase I Intravenous study met the key endpoint of patient tolerability. Single-dose intravenous administration CAVATAK™ was well tolerated, demonstrated secondary replication, presence inside some cancer tissue and provided evidence for some stable disease. Overall, the study observations provide strong foundations for Phase II investigations employing a multi-dose administration schedule to study the efficacy and safety of CAVATAK™ in patients with late stage solid cancers. I look forward to being involved with further clinical evaluations of CAVATAK™.”

Results of CAVATAK™ in combination with docetaxel

Furthermore Viralytics recently finalised *in vitro* laboratory studies demonstrating the oncolytic activity of CAVATAK™ in human lung cancer cell lines when used in conjunction with the important chemotherapeutic drug, docetaxel. Lung cancer cells were grown in culture and then treated with either a combination of CAVATAK™ and docetaxel, CAVATAK™ alone or docetaxel alone.

The combination of CAVATAK™ and docetaxel provided a moderately to strongly synergistic effect compared to the use of either product alone. Further *in vitro* experiments confirmed that

docetaxel had no negative effect on the rate of CAVATAK™ replication in human lung cancer cell lines. Overall, these results provide evidence that CAVATAK™ and docetaxel have the potential to be successfully used in combination therapy regimens.

The performance of CAVATAK™ in combination with docetaxel or paclitaxel/ carboplatin is planned to be assessed as part of the Phase I/II Multi-dose Intravenous CAVATAK™ STORM (**S**ystemic **T**reatment **O**f **R**esistant **M**alignancies) clinical trial to be conducted at three prestigious cancer centres in the UK.

In the first stage of this study CAVATAK™ will be administered as a monotherapy in late stage melanoma, non-small cell lung, metastatic bladder and castrate-resistant prostate cancer patients. In the second stage CAVATAK™ will be administered in conjunction with docetaxel or carboplatin/paclitaxel to the cancer type identified as the most promising target from the initial stage of the study.

Subject to review and approval of the clinical trial protocol by the UK Medicines and Healthcare products Regulatory Agency (MHRA) Viralytics aims to commence the study in the second half of 2013.

Viralytics' Chief Executive Officer Dr Malcolm McColl said, "the results of our Phase I clinical trial indicate CAVATAK™ is well tolerated in patients and our laboratory studies demonstrate that there may be compelling potential benefits from the combination of CAVATAK™ and docetaxel. We are very keen to achieve the necessary regulatory approvals and then get underway with our STORM clinical trial in these very important tumour types. Clinical success in this setting would significantly increase the potential commercial application of CAVATAK™ with benefits to many more cancer patients."

Docetaxel is a leading chemotherapy drug used to treat a wide range of solid tumour types including lung, breast and prostate cancer. It is marketed by Sanofi Aventis as Taxotere® and generated sales in excess of US$1 billion in 2011.

Enquiries:
Dr Malcolm McColl
02 9988 4000

Rudi Michelson
Monsoon Communications
03 9620 3333

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 and EV1 are viruses that occur naturally in the community. CVA21 and EV1 attach to the outside of cells, using a specific 'receptor' on the cell's surface (like a key fitting a lock). CVA21 uses the receptors, intercellular adhesion molecule-1 (ICAM-1) and/or decay accelerating factor (DAF) to bind and infect target cells. 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. EV1 uses the receptor, integrin α2β1 (alpha 2 beta 1) receptor to bind and infect target cells. Integrin α2β1 (alpha 2 beta 1) has been demonstrated to be highly expressed on multiple cancer types including prostate cancer, ovarian cancer and others.