



ASX and Media Release

Viralytics receives MHRA approval for UK Clinical Trial

Phase I/II STORM study to soon commence

11 September 2013, Sydney, Australia: Viralytics Limited (ASX:VLA, OTCQX:VRACY) has received final approval from the UK Medicines and Healthcare products Regulatory Agency (MHRA) to undertake the Phase I/II clinical trial of CAVATAK™ in cancer patients.

The approved study will assess the multiple intravenous (systemic) delivery of CAVATAK™ in patients with late stage melanoma, prostate, lung or metastatic bladder cancers. This trial, referred to as the STORM (Systemic Treatment Of Resistant Malignancies) study will be undertaken at three prestigious cancer centres in the UK.

The lead study investigators are prominent oncologists Professor Hardev Pandha (The University of Surrey), Professor Kevin Harrington (The Institute of Cancer Research and The Royal Marsden, London) and Professor Alan Melcher (St James's University Hospital, Leeds).

In the first stage of the STORM study, CAVATAK™ will be administered as a monotherapy in late stage cancer patients.

In the second stage, CAVATAK™ will be administered in conjunction with docetaxel or carboplatin/paclitaxel targeting only one cancer type. That cancer type will be identified as the most promising target from the first stage of the study.

Viralytics' Chief Executive Officer Dr Malcolm McColl said, "2013 has been a year of important milestones for Viralytics. This approval from the MHRA and the commencement of the STORM study are key steps forward for our company. Clinical success in these important cancer types would significantly advance the commercial application of CAVATAK™ and benefit many more cancer patients."

The Phase I/II study is expected to soon commence.

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About Viralytics Ltd:

Viralytics is developing oncolytic virotherapy treatments for a range of cancers. Viralytics' lead product, CAVATAK™, is a proprietary formulation of the common cold Coxsackievirus Type A21 (CVA21). CVA21 binds to specific 'receptor' proteins highly expressed on multiple cancer types including, but not limited to: melanoma; prostate, lung, breast and bladder cancers; and multiple myeloma. CAVATAK™ acts to kill both local and metastatic cancer cells, by direct cytolysis and a possible immune response. The preferential targeting of cancer rather than healthy cells provides the potential for low toxicity in the patient. The company is actively enrolling a phase II clinical trial, of intratumourally administered CAVATAK™ in the treatment of Late stage Melanoma (the CALM study), at multiple prestigious cancer clinics in the US. Viralytics plans to commence a Phase I/II trial of CAVATAK™ being delivered systemically (intravenously). This trial referred to as the STORM (Systemic Treatment Of Resistant Malignancies) study will be undertaken in patients with melanoma, prostate, lung or metastatic bladder cancers. The second stage of the STORM trial will include combination treatments with existing chemotherapies in one of the above cancer types. Subject to regulatory approval the STORM trial will commence at three prominent UK sites later in 2013.

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.

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