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ASIA EDITION

Viralytics' new CAVATEK study to be held in the UK

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Singapore: The next Viralytics clinical study evaluating multi doses of CAVATAK administered by the intravenous route (IV) is set to take place in the UK. The proposed intravenous signal seeking study will consist of approximately 30 patients with late stage non-small cell lung cancer, castrate resistant prostate cancer, metastatic bladder or melanoma.

Australia-based Viralytics is one of only two stock exchange listed companies in the world with technology that uses viruses to target and destroy cancer cells.

CAVATAK in trials to date has demonstrated that it selectively binds to the ICAM-1 receptors expressed in a broad range of cancers. CAVATAK then works its way into the cancer cells. Injected CAVATAK virus clears from circulation within about 48 hours with possible secondary viral replication. In other words, the mild virus keeps on working in patients persisting in targeting cancer cells.

The lead study investigators of the new IV study will be 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).

The clinical trial protocol is being finalized before submission to the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK. Subject to approval from the MHRA and the institutions involved, the trial will begin.

In the first stage of this proposed study, eligible patients will be administered multi-doses of CAVATAK up to a maximum of 109 infectious viral particles via the IV route. But in the later stage combination studies standard of care chemotherapy such as docetaxel will be assessed. Initial pre-clinical studies have not identified any adverse actions of such chemotherapy agents on the activity of CAVATAK.

The proposed study builds on the findings of the recently completed CAVATAK phase I intravenous study where key

endpoints were met justifying moving into more advanced clinical evaluation of intravenous CAVATAK delivery.

"Intravenous delivery of CAVATAK would instantly expand the range of potential target cancers. This would consequently make CAVATAK of heightened interest to the larger pharmaceutical companies," said Dr Jeffrey Weisberg, chief medical officer, Virlaytics.

In addition to the proposed intravenous trial, Viralytics is continuing its phase II melanoma study using intratumourally injected CAVATAK under Investigational New Drug application allowed by the US Food and Drug Administration. In this study 13 subjects have so far been dosed in the phase II CAVATAK trial with three so far demonstrating immune-related Progression-Free Survival at six months.