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ASIA EDITION

Viralytics multi-cancer drug shows +ve results

April 9, 2013 | News | By BioSpectrum Bureau

Singapore: Viralytics has finalized the clinical study report on the phase I evaluation of Cavatak, which is administered intravenously to late stage melanoma, prostate, breast or colorectal cancer patients. Viralytics reported 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.

Patients in the phase I dose escalation study received either a single intravenous (IV) infusion (nine patients) or two IV infusions (one patient) of Cavatak ranging from a dose of 106-to-1010 infectious units. Of the ten patients who 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well tolerated for intravenous administration with no-treatment related serious adverse events observed and no subjects withdrawn due to adverse events.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 and stable reductions in lesion size and 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, New South Wales, 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."

He added, "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."