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Melanoma study reaches efficacy milestone

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Singapore: Australia-basedÃ?Â Viralytics in its ongoing US-based phase II melanoma trial of its virotherapy candidate Cavatak achieved an interim efficacy milestone of three Objective Responses (OR). This follows a recent review by the independent Data Monitoring Committee (DMC) of the trial.

The phase II trial protocol of the study comprises of two stages. The first stage involves recruiting 35 patients and demonstrating that CavatakTM is well tolerated and the second stage involves that at least three of those first 35 patients display an OR following treatment with Cavatak.Ã?Â An OR is defined as a reduction in total body tumor burden of greater

than 30 percent relative to baseline as assessed by CT scan analysis or a combination of CT scan analysis and physical calliper measurements.

When the trial achieves its interim efficacy milestone of three OR from 35 patients, then subject to the safety criterion also being satisfied, the trial can proceed to the second stage triggering further recruitment up to approximately 63 patients (54 of which are to be evaluable). In the event that three of 35 patients in the first stage fail to display an OR then the trial would be stopped, pending further DMC review.

Based on the recent assessment of the DMC, Cavatak treatment in the phase II study has produced three OR in the first 13 patients recruited, thereby already achieving its interim efficacy milestone well ahead of the 35 patient ceiling. The DMC will meet to assess stage I overall safety and tolerability when 35 patients are recruited, although Cavatak treatment until date has been well tolerated. When the stage I safety and tolerability criterion is met, the trial can formally proceed to stage II and full patient recruitment.

In relation to clinical endpoints in the trial, the rate of OR is a secondary endpoint. The primary endpoint of the study remains immune-related Progression Free Survival (irPFS) at six months and this endpoint will be met when 12-to-14 patients display irPFS at six months.