

Trial of cancer killing virus-based drug is a success

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Singapore: Viralytics Biotech and Amgen, released top line results on its oncolytic virotherapy investigational product, Talimogene Laherparepvec (TVec).

Amgen reported that its phase III study in over 400 late stage melanoma patients met the primary endpoint of superior durable response rate defined as the rate of complete or partial response lasting continuously for at least six months in T-Vec versus control treated patients.

T-Vec is an investigational product based on a genetically modified cancer killing herpes virus injected directly into the tumour. Amgen acquired the technology through its purchase of BioVex in 2011 for up to \$1 billion including a \$425 million upfront payment.

Viralytics CEO, Dr Malcolm McColl, said that, "This is a milestone event for the field of oncolytic virotherapy with success in meeting the primary endpoint in a controlled phase III study. Amgen's achievement reflects well on our sector of targeted cancer biologics, encouraging further pivotal clinical evaluation of such novel oncolytic agents."

Viralytics' lead investigational product is CAVATAK, a proprietary formulation of the genetically unmodified human Coxsackievirus A21 (involved in common cold infection). Cavatak is currently under assessment at multiple sites in the US in a phase II Calm (Cavatak in Late Stage Melanoma) trial with 25 patients presently enrolled. The Calm study interim efficacy milestone of 3 or more complete or partial response responses in the first 35 patients has already been achieved. The company also plans to assess Cavatak in a phase I/II multi-dose intravenous STORM (Systemic Treatment Of Resistant Malignancies) clinical trial to be conducted at three prestigious cancer centres in the UK.