

ASX and Media Release

INVESTIGATIONAL NEW DRUG APPLICATION LODGED WITH THE FDA

3rd November 2010, Sydney: Viralytics Limited (ASX: VLA, OTC: VRACY) is pleased to announce that it has lodged an Investigational New Drug (IND) application for a Phase II Melanoma trial with the US Food and Drug Administration (FDA).

Subject to review by the FDA, the Phase II trial will be a 54 patient trial, with each patient receiving up to 10 injections of CAVATAK over a six month period. At each of the scheduled 10 visits the patients will receive an injection of CAVATAK into multiple lesions. The study will be referred to as the CALM study (**CAVATAK** in **L**ate stage **M**elanoma).

The dosing schedule in the Phase II CALM study is designed to maximise the direct killing of tumours by CAVATAK but also to generate potential anti-tumour immune responses initiated by patient's immune system against CAVATAK-infected tumour cells. The proposed treatment regimen represents a significant increase in dosing frequency from the initial Phase I melanoma safety studies, where the Company was only permitted to inject a single dose of CAVATAK into a single tumour.

The Phase II CALM study is expected to be conducted in the USA, Europe and Australia.

The IND application itself is a document of approximately 1200 pages – comprising sections discussing the mode of action of the technology, listing in detail the clinical trial data achieved to date and detailed descriptions of the preclinical toxicology studies undertaken. The document also contains in depth technical descriptions of the CAVATAK production process from the specialist US based manufacturing facility and the United Kingdom based vial filling facility to the extensive adventitious agent testing program on the product.

The lodgment of this application is a significant achievement for the Company. The IND application is a central body of work that is the core of future Phase II clinical trial applications and provides a central document for due diligence review by potential licensing partners.

During the FDA review of the IND application, Viralytics will be engaged in the appointment of an international clinical research organization to conduct the CALM study on our behalf including the recruitment of clinical sites.

Chief Science Officer, Professor Darren Shafren will outline the design of the Phase II CALM study in a presentation at the International Melanoma Conference on 4th November, 2010.

Enquiries

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