



Viralytics is at an exciting point in the company's development and is in the process of making a very important transition; from a company conducting Australian based Phase I safety studies, to a company conducting international Phase II studies. This positions the company well for our future growth and development

## CLINICAL DEVELOPMENT

### Phase II International melanoma trial – Investigational New Drug application update (IND)

The Company expects to lodge its IND application in November 2010 and commence its Phase II trial as soon as possible following the IND applications allowance. Subject to review by the FDA, the trial will be a 54 patient trial, with each patient receiving 10 injections of CAVATAK over a six month period. At each of the 10 visits the patients will receive an injection of CAVATAK into multiple lesions.

This strategy is a significant change of treatment from the earlier Phase I safety studies where the Company was only permitted to inject a single dose of CAVATAK into a single tumour.

This Phase II trial is designed to study not only the direct killing of the tumour by CAVATAK but also to measure any prolonged immune response triggered by CAVATAK using the patient's own immune defence against the cancer.

The trial is expected to be conducted in the USA, Europe and Australia. The Company has had a very positive initial response from international melanoma investigators expressing interest in joining the trial. The number of investigational sites are still to be determined. The final number will be chosen with the aim of having a 12-18 month recruitment period.



### Phase I Intravenous melanoma, breast and prostate cancer trial

This trial being run at two sites in Australia requires 3 patients to complete recruitment. While patient recruitment on this trial has been slow, we have had 3 patients join this trial in the last 2 months.

If this recruitment rate is maintained, the trial will be completed in the near future. This trial is a very important safety

trial for the Company as the trial lays the groundwork to expand into Phase II trials in many cancer indications.

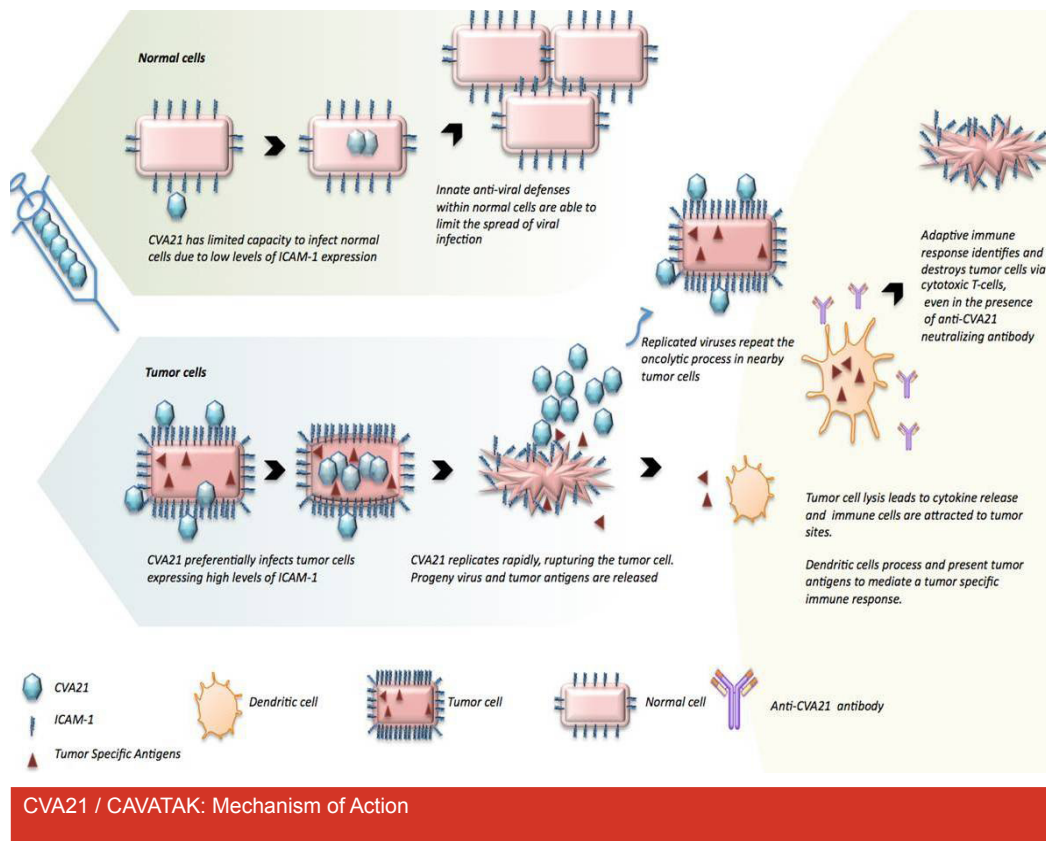
The Company is currently looking at a number of possible Phase II indications – there is more about this in the section FUTURE DIRECTIONS on page 3 of this update.

### Phase I Head and Neck trial

Patient recruitment for this 9 patient trial has been slow despite having 4 recruiting hospitals. Only 3 patients have been recruited to this trial so far. Once the Company has completed preparation

and lodgement of its Phase II Melanoma IND application, the Company will review and amend this trial if necessary to ensure patient recruitment is improved.





## SHAREHOLDER COMMUNICATIONS

### New Website

As your Company moves into international Phase II trials, effective communication with shareholders becomes more important.

Electronic communication is a very responsive and price effective way to communicate. We understand that this is not possible for some investors but we encourage shareholders to provide your company with your email address. If you wish to receive electronic newsletters and media releases from the Company please send your email address to [investorrelations@viralytics.com](mailto:investorrelations@viralytics.com) or simply log onto our website and sign up for electronic communications.

We also wish to advise that the Company is updating its web site and in early November a new look website will be up and running. We believe this will be a far more

informative site with features such as an animation of how our product works. We have found tools such as this enable shareholders and investors to better understand our technology than long descriptive

explanations. I look forward to shareholder and investor feedback on the website and suggestions on how we can further improve our communications.

## FUTURE DIRECTIONS

### Increasing shareholder returns

It is imperative if the true value of CAVATAK is to be realised that we advance the product into Phase II development.



The Company has spent the last 12 - 18 months compiling the necessary regulatory documents needed to advance to a Phase II trial under an IND. The Company has also spent the past 18 months producing for the first time, our product CAVATAK, at an independent specialist manufacturer to a standard required for international Phase II trials.

The work the Company has undertaken in this period also provides the core framework that needs to be completed if the Company decides to advance other cancer indications into clinical development.

Our short term clinical trial program is clearly focused on the areas listed below:

### Melanoma

Our first Phase II trial program will be in Melanoma patients, injecting CAVATAK directly into accessible tumours.

It is expected that our second Phase II trial will also be in Melanoma patients, where CAVATAK will be delivered intravenously. This second method of delivery increases substantially the number of patients we can potentially treat.

### Other cancer indications

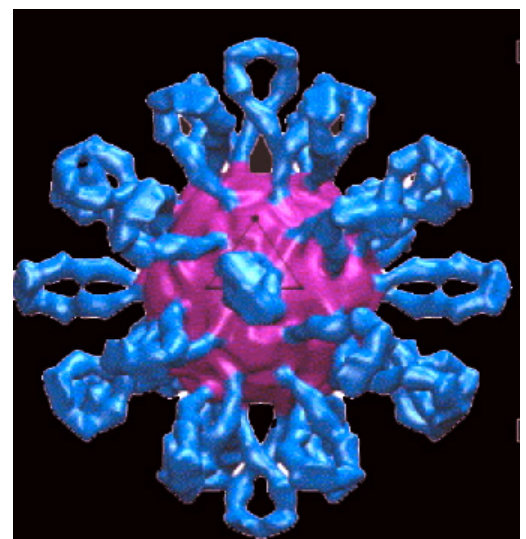
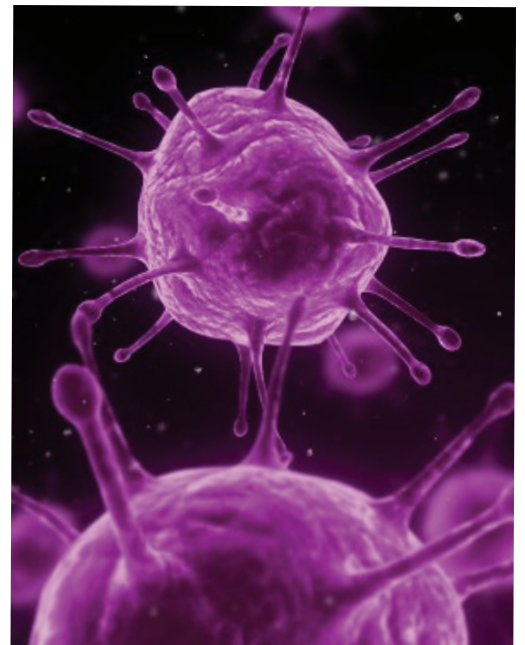
The Company believes that the quickest way to commercial success is to prove the activity of CAVATAK in cancer indications that currently have very poor treatment outcomes. In markets such as these, new products can be quickly taken to market compared to new products in cancer indications where there are long term survival periods.

For this reason, future pre-clinical and clinical work will be directed towards indications such as:

- Primary Brain cancer
- Pancreatic cancer
- Bladder cancer
- Lung cancer
- Multiple Myeloma

CAVATAK has the potential to treat many cancer indications. One of the most important decisions the Company has to make is to decide which indications to take to Phase II Clinical trials. Very few companies have the resources to investigate activities in multiple cancer indications at the same time.

Viralytic's must remain clearly focused on what it believes it can achieve with the resources it has available.



CAVATAK™ ICAM-1  
Xiao et al., Structure. 2005 Jul. 13:1019-33



### **Collaboration and grant funding**

Viralytics currently has in place a primary Brain cancer collaboration with North American Neurosurgeon Dr Guha and we are currently in discussion with a European party for a second collaboration in a new cancer indication.

Viralytics will also be actively looking for overseas grant opportunities. There are many possibilities in this area. Normally these grants require the associated clinical work to be carried out in the jurisdiction of the granting body.

Viralytics has not previously been able to apply for such grants as these trials require product that meets international GMP Phase II standards. An allowed IND will mean these product specifications have been met.

### **COMMERCIALISATION**

Recognition of the field of Virotherapy continues to grow around the world. There are increasing numbers of scientific papers being presented in this area.

There is a growing body of clinical data on the potential benefit of Virotherapy and as always sophisticated money is flowing into the field based on the growth in the science and clinical trial data.

Your Company's aim is to provide a solid body of evidence showing that CAVATAK is not only more effective

than current treatments for various cancer indications but also provides a better patient quality of life.

Commercialisation opportunities will naturally flow from this as well as the growth in the recognition of Virotherapy. Evidence of this was shown by a recent licensing agreement between a Virotherapy company who had completed Phase II liver cancer trials and a medium sized European pharmaceutical company for the European rights to their Virotherapy product.



Please visit the company website for more comprehensive details  
[www.viralytics.com](http://www.viralytics.com)

