

ASX and Media Release

**CAVATAK™ Immunotherapy Combination
Demonstrates Superior Anti-cancer Activity
Presented at the European Society for Medical Oncology
(ESMO) 2014 Congress**

- *Preclinical studies show CAVATAK™ combined with checkpoint inhibitor agents provides significantly greater anti-tumour activity than checkpoint inhibitors alone*
- *Data suggest an anti-tumour immune response*
- *Results strengthen CAVATAK's potential role as combination therapy with checkpoint inhibitors, a major new class of anticancer immunotherapies*

30 September 2014, Sydney, Australia: Viralytics Limited (ASX:VLA, OTC:VRACY) overnight announced at the European Society for Medical Oncology (ESMO) 2014 Congress in Madrid that preclinical studies have generated further evidence of improved CAVATAK™ anti-cancer activity when used in combination with immune checkpoint inhibitors, a new class of cancer immunotherapies with blockbuster potential. CAVATAK™ is a proprietary formulation of a common cold virus that has been shown to preferentially infect and attack cancer cells.

The latest preclinical study assessed the activity of CAVATAK™ given in combination with either the mouse homologue of the CTLA-4 monoclonal antibody ipilimumab, or an anti-PD-1 monoclonal antibody. In both cases, the combination of the checkpoint inhibitor with CAVATAK produced superior efficacy outcomes in a two-phased mouse melanoma study, compared to the efficacy of either agent alone.

The results of these preclinical studies provide encouragement that the combination of these new immunotherapies with CAVATAK™ may provide significant clinical benefits to patients.

Ipilimumab and the anti-PD-1 monoclonal antibodies belong to a new class of cancer immunotherapy agents called immune checkpoint inhibitors. Ipilimumab was launched in 2011 for the treatment of late-stage melanoma and is marketed worldwide by Bristol-Myer Squibb under the trademark Yervoy®¹. In 2013, Yervoy® had sales of \$US 960 million.

The anti-PD1 monoclonal antibodies have activity across a broad range of cancer types, including melanoma, lung and bladder cancer. Merck achieved the first US approval for an anti-PD-1 therapy (pembrolizumab) in early September 2014.

¹ Yervoy® is a trademark of the Bristol-Myers Squibb company



Future sales of checkpoint inhibitor agents have been estimated to be as high as \$US 24 billion per annum in the next decade, according to a 2013 Citigroup report².

Dr Malcolm McColl, Chief Executive Officer of Viralytics said, "We are delighted to report this further evidence of enhanced activity when CAVATAK™ is administered with checkpoint inhibitors and believe that these preclinical data strongly support investigation in human clinical trials. Such agents are forecast to form the backbone of future cancer treatment. Further improved activity with CAVATAK provides a major commercial opportunity for Viralytics."

The poster focussing on the preclinical combination of CAVATAK™ and checkpoint inhibitors was presented by Dr Darren Shafren, Viralytics, Chief Scientific Officer, at the Immunotherapy of Cancer session at the ESMO 2014 Congress on Monday, 29th September.

The poster may be found on the Viralytics website at this site:

<http://www.viralytics.com/wp-content/uploads/2014/09/140929-CVA21-and-PD-1-or-CTLA-4-blockade-combination-Poster-ESMO.jpg>

The ESMO conference is the largest oncology conference held in Europe, with more than 16,000 attendees.

About Viralytics Ltd:

Viralytics is developing oncolytic immunotherapy treatments for a range of cancers. Viralytics' lead investigational product, CAVATAK™, is a proprietary formulation of the common cold Coxsackievirus Type A21 (CVA21). CVA21 binds to specific 'receptor' proteins highly expressed on multiple cancer types including, but not limited to: melanoma; prostate, lung, breast and bladder cancers; and multiple myeloma. CAVATAK™ acts to kill both local and metastatic cancer cells through cell lysis and the potential generation of an immune response against the cancer cells. Together this mechanism of action is known as oncolytic immunotherapy. CAVATAK™'s preferential targeting of cancer cells creates the potential for a more tolerable cancer treatment.

The company has completed enrolment in a single arm Phase 2 clinical trial of intratumourally administered CAVATAK™ in the treatment of Late-stage Melanoma (the CALM study), at multiple prestigious cancer clinics in the US. The study is being conducted in patients with late stage (IIIC and IV) malignant melanoma.

In addition, Viralytics is progressing a Phase 1/2 trial of CAVATAK™ delivered systemically (intravenously). This trial, referred to as the STORM (Systemic Treatment Of Resistant Malignancies) study, is enrolling patients with melanoma, prostate, lung or metastatic bladder cancers. The second stage of the STORM trial will include combination treatments with existing chemotherapies in one of the above cancer types. The STORM trial is being conducted at three UK cancer centres.

Based in Sydney Australia, the company is listed on the Australian Securities Exchange (ASX: VLA) while Viralytics' ADRs also trade under VRACY on the US OTCQX International market.

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² <https://www.citivelocity.com/citigps/OpArticleDetail.action?recordId=209>