



ASX and Media Release

## Viralytics Annual Report and Full Year Financial Results

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**25 August 2016, Sydney, Australia:** Viralytics Limited (ASX: VLA, OTCQX: VRACY) has released its Annual Report including financial results for the year ended 30 June 2016.

### FINANCIAL RESULTS

Net cash used in operating activities for the Year	\$7.5 million
Cash position at the end of the Year	\$46.1 million
Reported loss	\$9.1 million

### OPERATIONAL HIGHLIGHTS

In 2016, Viralytics continued to build a compelling body of clinical data in support of its lead product candidate, CAVATAK™, as described in the following summary of the highlights of the year.

#### Phase 2 CALM Melanoma Clinical Trial and Extension Study (US)

- Latest data were presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in June 2016. An overall response rate of 28 percent and a durable response rate (lasting six months or more) of 21 percent were demonstrated in 57 patients with advanced melanoma who were treated with intralesional CAVATAK.
- Investigators also reported similar overall response rates in patients previously treated with immunotherapy (29 percent) or other therapies (27 percent).
- Anti-cancer activity was observed in non-injected distant cancers, including lung and liver metastases, suggesting CAVATAK's ability to trigger a systemic anti-tumour immune response.
- Analysis of tumour tissue biopsies taken after CAVATAK administration showed notable changes within the tumour that may be predictive of future tumour response, particularly when CAVATAK is used in combination with checkpoint inhibitors.

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### **Phase 1 STORM (Part A) Solid Tumour Intravenous Clinical Trial (UK)**

- The first stage (Part A) of the STORM trial with monotherapy CAVATAK completed recruitment at three leading cancer centres in the UK.
- Clinical data reported in June 2016 showing results from tumour tissue biopsies taken from patients with advanced melanoma, non-small cell lung cancer (NSCLC) and metastatic bladder cancer confirmed that multiple intravenous infusions of CAVATAK produced tumour-targeted viral replication.
- Infection of the tumour by CAVATAK can potentially strengthen anti-cancer activity, both locally and systemically, and suggest that CAVATAK may have a role in checkpoint inhibitor combination strategies.
- Intravenous administration of CAVATAK was generally well tolerated.

### **Phase 1b STORM (part B)/Keynote 200 Late Stage Lung and Bladder Cancer (US)**

- The second stage (Part B) of the STORM trial is a clinical collaboration with Merck & Co., Inc. (MSD outside the US and Canada).
- Trial is evaluating intravenous CAVATAK administered in combination with Merck's checkpoint inhibitor KEYTRUDA<sup>®1</sup> (pembrolizumab) in late-stage lung and bladder cancer patients.
- Preliminary data expected in the first half of 2017.

### **Phase 1 CANON Non-Muscle Invasive Bladder Cancer Trial (UK)**

- The CANON study, which has completed recruitment, is evaluating the safety and tolerability of CAVATAK administered alone, and in combination with a sub-therapeutic dose of the standard chemotherapy, mitomycin C, in patients with non-muscle invasive bladder cancer.
- Results presented in March 2016 demonstrated tumour-targeted viral (CAVATAK) replication and viral-induced cancer cell death in a number of patients.
- Potential anti-cancer activity shown when administering CAVATAK either as a single agent or in combination with mitomycin C.

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<sup>1</sup> KEYTRUDA is a trademark of Merck & Company Inc.

- Intravesicular administration (via catheter into the bladder) of CAVATAK was generally well tolerated.

### **Phase 1b MITCI Combination with YERVOY in Melanoma Clinical Trial (US)**

- The ongoing MITCI trial is evaluating intravesicular CAVATAK in combination with the checkpoint inhibitor YERVOY<sup>® 2</sup> (ipilimumab) in patients with late-stage melanoma at four sites in the US.
- Results reported in April 2016 included objective responses in four patients and stable disease in one patient out of the first six evaluable patients with advanced, metastatic disease.

### **Phase 1b CAPRA Combination with KEYTRUDA in Melanoma Clinical Trial (US)**

- The CAPRA trial is evaluating intravesicular CAVATAK in combination with the checkpoint inhibitor KEYTRUDA in patients with late-stage melanoma at sites including Rutgers Cancer Institute in New Jersey, USA.
- Initial findings will be reported later in 2016.

### **CORPORATE OUTLOOK**

- With \$46.1 million cash at 30 June 2016, Viralytics is well funded, the result of a successful capital raise of \$32 million from specialist healthcare investors completed in January 2016.
- The company is building a compelling data package through its broad range of current and future clinical trials, with the aim of positioning Viralytics to capitalize on the intense interest in the growing field of cancer immunotherapy. In this way, Viralytics intends to drive partnering discussions and increase shareholder value.

"Viralytics made excellent progress in the 2016 financial year, as we continued to advance CAVATAK as an important potential new agent in the blockbuster field of cancer immunotherapy", stated Dr Malcolm McColl, Managing Director and Chief Executive Officer of Viralytics. "Our growing body of impressive clinical data across a range of cancer indications has raised the company's profile in the international oncology community. The clinical data along with our solid cash balance strengthens our position for a successful commercial transaction involving CAVATAK in the future."

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<sup>2</sup> YERVOY<sup>®</sup> is a registered trademark of Bristol-Myers Squibb Company



**About Viralytics Ltd:**

Viralytics is developing oncolytic immunotherapy treatments for a range of cancers. The company's lead investigational product, CAVATAK™, is currently being studied in Phase 1 and 2 clinical trials for the treatment of melanoma, as well as prostate, bladder and lung cancers. CAVATAK is a proprietary formulation of the common cold Coxsackievirus Type A21 (CVA21) that preferentially binds to specific 'receptor' proteins highly expressed on multiple cancer types. 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 – a two-pronged mechanism of action known as oncolytic immunotherapy.

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. For more information, please visit [www.viralytics.com](http://www.viralytics.com).

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