



ASX and Media Release

Viralytics Annual Report and Full Year Financial Results

18 August 2017, Sydney, Australia: Viralytics Limited (ASX: VLA, OTCQX: VRACY) has released its Annual Report, including financial results for the year ended 30 June 2017.

FINANCIAL RESULTS

Net cash used in operating activities for the Year	\$ 11.4 million
Cash position at the end of the Year	\$34.3 million
Reported loss	\$ 12.3 million

OPERATIONAL HIGHLIGHTS

In 2017, Viralytics continued to build a broad and substantial 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 1b MITCI Combination with YERVOY^{®1} in Melanoma Clinical Trial (US)

- The continuing Phase 1b MITCI trial is evaluating intralesional CAVATAK in combination with the checkpoint inhibitor YERVOY (ipilimumab) in patients with late-stage melanoma at four sites in the US.
- Results reported in June 2017 at the American Society of Clinical Oncology (ASCO) annual meeting included a best overall response rate (BORR) of 67 percent (8/12) in advanced melanoma patients naïve to prior checkpoint inhibitor therapy. The BORR for YERVOY as a monotherapy in late-stage patients has been reported at 11 percent.²
- In a subgroup of patients who previously received single-agent PD-1 blockade therapy, data showed a confirmed BORR of 33 percent (2/6) and a disease control rate (DCR) of 67 percent (4/6). In a further subset of patients who had progressed on both anti-PD-1 and anti-CTLA-4 therapies, a BORR of 14 percent (1/7) was observed, with a DCR of 57 percent (4/7).

¹ YERVOY[®] is a trademark of the Bristol-Myers Squibb Company

² Hodi et al. N Engl J Med. 2010; 363(8):711.

- An ongoing response rate of 38 percent (6/16) has been seen in non-injected liver and lung lesions, with a stable disease rate of 56 percent (9/16).
- There has been a low rate of adverse events, with no dose-limiting toxicities in the first 25 patients, and only two grade 3 ipilimumab-related adverse events.

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

- The ongoing Phase 1b CAPRA trial is evaluating intralesional CAVATAK in combination with the checkpoint inhibitor KEYTRUDA in patients with late-stage melanoma.
- Initial data reported at the AACR annual conference in April 2017 from the first 15 evaluable patients included a BORR of 60 percent and stable disease in 27 percent of patients.
- Partial responses have been seen in nine patients who have responded to the combination, with one subject having a partial response ongoing one year after the initiation of therapy and two complete responses in the target lesions.
- In the subgroup of patients with the most advanced disease, the BORR was 83 percent (5/6 patients.)
- No dose-limiting toxicities and no Grade 3 or higher treatment-related adverse events were reported.
- Study is expanding to up to 50 patients, including those who have failed prior checkpoint therapies.

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

- The ongoing Phase 1b KEYNOTE-200 (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^{®3} (pembrolizumab) in late-stage lung and bladder cancer patients.

³ KEYTRUDA is a trademark of Merck & Company Inc.

- Early data were presented at the American Association of Cancer Research (AACR) annual conference in April 2017, revealing strong enrolment and a low incidence of adverse events, even in subjects treated at the highest CAVATAK-KEYTRUDA dose.
- Recruitment is rapidly advancing in the 80-patient dose expansion phase of the study, including new clinical sites in Australia in addition to the existing US sites.

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

- The CANON study, which was completed in 2016, investigated the safety and tolerability of CAVATAK delivered as a single agent directly into the bladder through a catheter (intravesical administration), as well as in combination with a sub-therapeutic dose of the standard chemotherapy, mitomycin C, in patients with non-muscle invasive bladder cancer.
- Results released in October 2016 demonstrated tumour-targeted viral (CAVATAK) replication and viral-induced cancer cell death in multiple patients.
- Clinical activity was shown when administering CAVATAK either as a single agent or in combination with mitomycin C.
- A complete response was observed in one of the three patients in the highest-dose cohort of the monotherapy.
- Intravesicular administration (via catheter into the bladder) of CAVATAK was generally well tolerated, with no grade 2 or higher treatment-related adverse events.

CORPORATE OUTLOOK

- With \$34.3 million cash at 30 June 2017, Viralytics is well funded and has a strong shareholder register including 55 percent institutional representation.
- The company is focused on building a compelling clinical data package for CAVATAK and expanding its team and resources to support that effort – all with the goal of driving partnering discussions and increasing shareholder value.



“Viralytics made remarkable clinical progress in the 2017 financial year, moving us closer to the initiation of pivotal clinical trials, elevating our profile at major international oncology meetings, and demonstrating CAVATAK’s potential as an important new agent in the cancer immunotherapy field,” stated Dr Malcolm McColl, Managing Director and Chief Executive Officer of Viralytics. “This progress has fuelled growing interest from pharmaceutical companies, investors and oncologists, and advanced our efforts to realize the full clinical and commercial potential of CAVATAK.”

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.

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