A Message from the Managing Director

Viralytics' prominent profile at the recent annual meetings of the American Association for Cancer Research (AACR) and the American Society of Clinical Oncology (ASCO) demonstrates the excellent clinical progress we are making toward our goal of developing CAVATAK® as an important new agent in the blockbuster field of cancer immunotherapy. We are utilising this heightened interest in Viralytics to expand our clinical program and to advance our activities towards partnering or licensing CAVATAK at a key value point.

With more than 20,000 attendees at AACR and over 35,000 attendees at ASCO, these two conferences provided a wonderful opportunity for us to feature the latest CAVATAK clinical trial results. We were pleased that our MITCI trial, which is assessing CAVATAK and YERVOY® in melanoma patients, was chosen by both the AACR and ASCO organizers for podium and other high-profile presentations.

At the AACR meeting, the MITCI trial data were shared at a press conference and then presented to a full house at the plenary session on new agents in clinical development. The impressive results were very well received and considered a highlight of the conference. At the ASCO meeting, the MITCI data were featured as a main stage presentation focused on important clinical studies in the cancer immunotherapy field.

With the significant number of melanoma patients who have progressed following treatment with checkpoint therapies such as YERVOY and KEYTRUDA®, there is a high unmet need in this setting, and with ongoing positive results, we are developing plans for a Phase 3 pivotal registration study. We can now see a potential path to the US market.

Compelling early results from the CAPRA study assessing CAVATAK and KEYTRUDA in melanoma patients were presented in a poster at AACR. We are adding patients in both of these trials and will provide updates throughout the coming months. In addition, we plan to begin clinical trials in new indications such as colorectal cancer, and head and neck cancer. Closer to home, we are excited to be recruiting patients in Australia, with our STORM/KEYNOTE-200 trial opening sites in Melbourne and The Gold Coast, with others to follow.

Alongside our trial progress we continue to develop our team to support our clinical, manufacture and regulatory activities. We welcome Rae Saltzstein (featured in this newsletter) as Director CMC Operations and Mariana Nielsen as Associate Director Quality Affairs.

CAVATAK's potential as a valuable addition to the cancer immunotherapy field continues to grow. Its prominence at recent conferences has helped build interest from pharma companies, institutional investors, and oncologists. We plan to leverage this interest to drive partnering discussions and to ensure that we are able to capture the full commercial opportunity created by the innovative technology and our hard-working team.

With Kind Regards

Dr. Malcolm McColl
Managing Director and Chief Executive Officer

1 CAVATAK® is a novel investigational product in clinical development across multiple cancer indications.
2 YERVOY® is a trademark of the Bristol-Myers Squibb Company
3 KEYTRUDA® is a trademark of Merck & Company Inc.
CAVATAK Highlighted at Preeminent Global Oncology Conferences

In April CAVATAK was featured prominently at the American Association for Cancer Research Annual Meeting 2017, held in Washington DC, USA, including two podium presentations and one poster, as well as the conference press programme.

In June we attended the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago. Our poster on the MITCI trial was chosen for a main stage discussion session on promising new developmental agents in cancer immunotherapy. The latest data from the MITCI trial was presented and discussed and which, along with other trials, is set out in more detail below.

PHASE 1B MITCI CLINICAL TRIAL

The impressive results of the Phase 1b MITCI (Melanoma Intra-Tumoral CAVATAK and ipilimumab) trial were reported in a podium presentation at the AACR Meeting by lead study author Dr Brendan D. Curti of the Providence Cancer Center in Portland, Oregon. In the trial, treatment with a combination of CAVATAK and the checkpoint inhibitor YERVOY (ipilimumab) led to confirmed responses in half of patients with advanced melanoma, including some whose disease had progressed despite prior treatment with an immune checkpoint inhibitor. In addition, there were fewer than expected adverse events associated with the novel combination.

“In recent years, the number of treatment options for patients with advanced melanoma has increased with the development of immune checkpoint inhibitors such as ipilimumab,” said Dr. Curti. “However, not all patients respond to these immunotherapies and some who respond go on to have disease progression later.”

“It is very encouraging that the CAVATAK-YERVOY combination has yielded responses greater than six months for a number of patients, both those whose melanoma has progressed after immune checkpoint inhibitor therapy and those who have not yet been treated with immunotherapeutics. The low incidence and low grade of adverse events is also very encouraging.”

Based on these results, Dr Curti and colleagues at other sites in the US are enrolling up to 70 patients with advanced melanoma into the MITCI trial.

To read the MITCI clinical trial press release at AACR, please visit our website.

PHASE 1B CAPRA CLINICAL TRIAL

The promising results of the Phase 1b CAPRA (CAVATAK and Pembrolizumab in Advanced Melanoma) clinical trial were reported at the AACR Meeting by lead study author Dr Ann Silk of the Rutgers Cancer Institute of New Jersey. In the trial, patients with advanced melanoma are being treated with a combination of CAVATAK and the checkpoint inhibitor KEYTRUDA. Initial data indicate that CAVATAK in combination with KEYTRUDA has the potential to enhance activity of the checkpoint inhibitors while also reducing the number and severity of adverse events. In the trial, there was a best overall response rate (BORR) of 60 percent and stable disease in 27 percent of 15 evaluable patients. This BORR compares favourably with published trial data demonstrating a BORR of 33 percent in advanced melanoma patients who received KEYTRUDA alone. Moreover, in the sub-group of patients with the most advanced, metastatic disease, the BORR was 83 percent, or five of six patients. There were no Grade III or higher treatment-related adverse events.

“These results compare favourably with other combination studies, and I look forward to expanding the study up to 50 patients, including those who have failed prior checkpoint therapies,” said Dr Silk.

To read the CAPRA clinical trial press release, please visit our website.

PHASE 1B KEYNOTE-200 CLINICAL TRIAL

Progress in the Phase 1b KEYNOTE-200, or STORM (Systemic Treatment of Resistant Metastatic Disease) Part B clinical trial was described in a podium presentation at the April AACR Meeting by Dr Charles Rudin of Memorial Sloan Kettering Cancer Center in New York. It was also presented as a poster at the ASCO Meeting in June. In the trial, patients with advanced non-small cell lung cancer or metastatic bladder cancer are being treated with a combination of intravenously administered CAVATAK and the checkpoint inhibitor KEYTRUDA (pembrolizumab).

Enrolment in the combination dose escalation phase of the study is complete, and recruitment of the expansion cohort of 80 patients is underway. 17 subjects have been treated at the highest CAVATAK dose. This includes those who have not yet been treated with checkpoint inhibitors as well as those who have progressed after checkpoint inhibitor therapy.

According to Dr Rudin, “So far, the low rate and incidence of adverse events – even in heavily pretreated patients with advanced disease – is encouraging, and I am pleased we can now commence more rapid enrolment in the expansion phase.”

To read the latest KEYNOTE-200 clinical trial press release, please visit our website.

2017 Achievements

- Reported positive interim results CAPRA study
- Reported positive interim results MITCI study
- Identified potential path to market in melanoma in setting of high unmet need
- Completed dose escalation in KEYNOTE-200 study and underway with dose expansion
- Pre-clinical work to identify further target indications
- Further develop CAVATAK manufacture program
Dr Brendan Curti MD presenting MITCI data at AACR Press Conference – April 2017

MITCI Trial Presentation on main stage in session on promising new developmental agents at ASCO – June 2017

Professor Darren Shafren and Mark Grose from Viralytics at the KEYNOTE-200 Poster – ASCO 2017

Dr Brendan Curti MD presenting MITCI data at AACR Plenary Session – April 2017

Dr Robert Andtbacka MD presenting the MITCI Poster at ASCO – June 2017

Dr Ann Silk MD presenting CAPRA data at AACR – April 2017
CAVATAK’s promising performance in the MITCI trial gained recognition in several biotechnology publications and was chosen as a conference media highlight by the organizers of the recent AACR meeting in Washington DC. This news coverage further adds to Viralytics’ growing profile among our key audiences of pharma companies, oncologists and investors.

The coverage included an interview with Dr McColl in Endpoints News, which noted that the MITCI results place Viralytics on a stage with leading oncology companies and characterized the company as a “small biotech with big ambitions.” In addition, R and D Magazine and HemOnc Today quoted lead investigator Dr Brendan D. Curti, who explained that the combination of CAVATAK and YERVOY was much more clinically active than either agent given alone.

Links to these stories are available from the In the Media section of our website.

First Australian Patient Enrolled in KEYNOTE-200 Clinical Trial

We are happy to welcome Monash Health Clinical Trials Centre in Melbourne to our group of outstanding clinical trial centres taking part in the KEYNOTE-200 clinical trial assessing CAVATAK and KEYTRUDA in patients with advanced lung or metastatic bladder cancer. Monash recently enrolled the first Australian participant – a bladder cancer patient – in the study, which has enrolled patients internationally and is currently in an 80-patient expansion phase. It is especially gratifying to be able to include Monash and other Australian centres in efforts to advance the CAVATAK technology which was developed locally with support from the University of Newcastle and Hunter Medical Research Institute.

Meet Rae Saltzstein
Director of CMC Operations

We are pleased to add Ms. Rae Saltzstein to our management team as Director of CMC Operations. In this position, Rae will play a pivotal leadership role advising on the development and manufacturing of CAVATAK and working closely with our regulatory affairs team to develop the registration package for CAVATAK.

Rae brings over 20 years of highly relevant experience to Viralytics, focusing on the quality and manufacture (CMC) regulatory aspects of novel biologics, including viral-vector gene transfer therapeutics and viral vaccines, ranging from pre-IND through to late-stage clinical development. She has worked as an independent consultant serving clients such as gene therapy start-up companies and large non-profit vaccine organizations. Previously, she was Sr. Director of Quality at Celladon Corporation and Sr. Director of Quality and Regulatory Affairs at Targeted Genetics Corporation. Rae received her B.S. in microbiology from Oregon State University and holds the RAC credential from the Regulatory Affairs Professionals Society in the USA.

Certain statements made in this presentation are forward looking statements within the meaning of the safe harbour provisions of the United States Private Securities Litigation Reform Act of 1995. These forward looking statements are not historical facts but rather are based on Viralytics’ current expectations, estimates, assumptions and projections about the industry in which Viralytics operates. Material referred to in this document that use the words ‘estimate’, ‘project’, ‘intend’, ‘expect’, ‘plan’, ‘believe’, ‘guidance’ and similar expressions are intended to identify forward looking statements and should be considered an at-risk statement. These forward looking statements are not a guarantee of future performance and involve known and unknown risks and uncertainties, some of which are beyond the control of Viralytics in which are difficult to predict, which could cause the actual results, performance or achievements of Viralytics to be materially different from those which may be expressed or implied by these statements. These statements are based on our management’s current expectations and are subject to a number of uncertainties and risks that could change the results described in the forward looking statements. Risks and uncertainties include, but are not limited to, general industry conditions and competition, general economic factors, the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally, and challenges inherent in new product development. Investors should be aware that there are no assurances that results will not differ from those projected and Viralytics cautions shareholders and prospective shareholders not to place undue reliance on these forward-looking statements, which reflect the view of Viralytics only as of the date of this presentation. Viralytics is not under a duty to update any forward looking statement as a result of new information, future events or otherwise, except as required by law or by any appropriate regulating authority.

Please visit the company website for more comprehensive details: www.viralytics.com