

## ASX Announcement

### **New Dose Escalation in Phase I Clinical Trial of Oncolytic Virotherapy CHECKvacc**

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**Sydney, Australia, 7 July 2023:** Imugene Limited (ASX:IMU), a clinical stage immuno-oncology company, is pleased to announce City of Hope®, a world-renowned independent cancer research and treatment center near Los Angeles, has confirmed the Phase I clinical trial of its oncolytic virotherapy candidate, CHECKvacc (HOV3, CF33-hNIS-anti-PDL1), will proceed to the fourth dose cohort.

The Protocol Management Team agreed CHECKvacc to be safe with no dose-limiting toxicities (DLTs) and no serious adverse reactions observed after review of all safety and tolerability data for the first 3 cohorts dosed with CHECKvacc as monotherapy. City of Hope will proceed with opening the fourth CHECKvacc Phase 1 cohort.

The first-in-human, Phase 1, single-centre, dose escalation study of CHECKvacc is recruiting patients with triple negative breast cancer (TNBC). The purpose of the study is to evaluate the safety and initial evidence of efficacy of intra-tumoural administration of CF33-hNIS-antiPDL1 against metastatic TNBC. The current trial design will involve a dose escalation, followed by an expansion to 12 patients at the final dose, which will be the recommended phase 2 dose (RP2D). The trial is anticipated to run for 24 months and is funded from existing budgets and resources.

The clinical trial is titled “A Phase I Study of Intratumoral Administration of CF33-hNIS-antiPDL1 in Patients with Advanced or Metastatic Triple Negative Breast Cancer”. The Principal Investigator leading the trial is Dr Jamie Rand MD, PhD.

Imugene MD & CEO Leslie Chong said “We are pleased with the results that we have seen so far with no observed toxicity with early encouraging results in oncolytic virus infection and replication in the TNBC tumours. We look forward to continuing this study and reporting to the market of its progress.”



CF33-hNIS-antiPDL1 is an immune checkpoint inhibitor armed chimeric vaccinia poxvirus from the lab of CF33 inventor Professor Yuman Fong, Chair of Sangiacomo Family Chair in Surgical Oncology at City of Hope, and a noted expert in the oncolytic virus field.

Oncolytic viruses (OVs) are designed to both selectively kill tumour cells and activate the immune system against cancer cells, with the potential to improve clinical response and survival.

Full study details can also be found on [clinicaltrials.gov](https://clinicaltrials.gov) under study ID: NCT05081492.

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### **About Triple-Negative Breast Cancer**

Triple-negative breast cancer (TNBC) is an aggressive subtype of breast cancer (affecting about 20% of all breast cancer patients), characterized by the lack of expression of estrogen receptor (ER), progesterone receptor (PgR), and human epidermal growth factor receptor 2 (HER2), with a dismal median survival of 12 months. There is no effective targeted therapy in patients with metastatic TNBC with the exception of tumours with germline BRCA mutation, which highlights TNBC as an area of unmet need.



Moreover, TNBC rapidly develops resistance to chemotherapy, and thus advances in chemotherapy alone are unlikely to improve prognosis. Therefore, novel therapies are desperately needed to improve the clinical outcome of TNBC.

### **About CHECKvacc**

CF33-hNIS-antiPDL1 (CHECKvacc) is a novel chimeric orthopoxvirus with robust anti-cancer activity including TNBC xenografts. Cells infected with CF33-hNIS-antiPDL1 were shown to express functional hNIS and anti-PD-L1 proteins. hNIS gene transfer allows tracking of virus by non-invasive imaging as well as radioiodine therapy. City of Hope's preliminary animal studies demonstrated that tumour cells infected with CF33-hNIS-anti-PD-L1 successfully secrete functional hNIS and immune checkpoint inhibitor anti-PD-L1. CF33-hNIS-antiPDL1 is safe and well-tolerated, detects and effectively kills TNBC at doses several magnitudes lower than other oncolytic viruses currently under clinical testing.

Extensive studies of CF33-hNIS-antiPDL1 have been performed on TNBC cancer cells in tissue culture. As few as 1 viral particle per 1000 tumour cells can kill all cell lines tested by 2 weeks. In very susceptible cell lines, complete cancer cell killing can occur within 1 week. Such effective cancer cell killing has also been observed for pancreatic cancer cells, stomach cancer cells, lung cancer cells, ovarian cancer cells and brain cancer cells in tissue culture.

Extensive testing in mice with TNBC as well as other cancer have been undertaken. Administration of CF33-hNIS-antiPDL1 allows for visualization of viral distribution in animals by non-invasive imaging. Administration of CF33-hNIS-antiPDL1 recruits cancer killing lymphocytes to areas with cancer. These effects can be seen at doses producing few side-effects in mice.

### **About Imugene (ASX:IMU)**

Imugene is a clinical stage immuno-oncology company developing a range of new and novel immunotherapies that seek to activate the immune system of cancer patients to



treat and eradicate tumours. Our unique platform technologies seek to harness the body's immune system against tumours, potentially achieving a similar or greater effect than synthetically manufactured monoclonal antibody and other immunotherapies. Our product pipeline includes multiple immunotherapy B-cell vaccine candidates and an oncolytic virotherapy (CF33) aimed at treating a variety of cancers in combination with standard of care drugs and emerging immunotherapies such as CAR T's for solid tumours. We are supported by a leading team of international cancer experts with extensive experience in developing new cancer therapies with many approved for sale and marketing for global markets.

Our vision is to help transform and improve the treatment of cancer and the lives of the millions of patients who need effective treatments. This vision is backed by a growing body of clinical evidence and peer-reviewed research. Imugene is well funded and resourced, to deliver on its commercial and clinical milestones. Together with leading specialists and medical professionals, we believe Imugene's immuno-oncology therapies will become foundation treatments for cancer. Our goal is to ensure that Imugene and its shareholders are at the forefront of this rapidly growing global market.

*Release authorised by the Managing Director and Chief Executive Officer*