ASX Announcement

Imugene presents new and first CHECKvacc data at the 2022 San Antonio Breast Cancer Symposium

Sydney, Australia, 9 December 2022: Imugene Limited (ASX:IMU), a clinical stage immuno-oncology company, announces new and first data from triple negative breast cancer (TNBC) patients in the Phase I CHECKVacc trial has been presented as a poster presentation at the 2022 San Antonio Breast Cancer Symposium (SABC 2022) on 9 December 2022 AEDT in San Antonio, Texas. Information is also available on the company's website.

The presentation, titled "Phase I study of intratumoral administration of CF33-hNIS-antiPD-L1 (CHECKvacc) in patients with metastatic triple negative breast cancer", was presented by Dr Yuan Yuan M.D., PhD, Cedars Sinai Medicine, Los Angeles and Dr Jamie Rand M.D., City of Hope, Los Angeles.

Imugene MD & CEO Leslie Chong said: "Phase 1 trials are generally designed to look for safety, tolerability and early response signals to determine the optimal dose for further development. I am encouraged that we are seeing positive signals with correlative biomarker and imaging data at such an early stage of our CHECKVacc Phase I trial."

CF33-hNIS-antiPD-L1 administered by intratumoral injection in patients with metatstatic TNBC is safe and well tolerated at the dose levels tested. Highlights and results include:

1. From October 2021 to June 2022, 6 patients were enrolled in this ongoing study and received at least 1 dose of CHECKvacc injection at dose level 1 (1 x 10^5 pfu) or dose level 2 (3 x 10^5 pfu).
2. No dose-limiting toxicities were observed. No treatment related adverse events were reported for 6 patients except 1 patient with injection site discoloration.
3. 99mTc SPECT imaging for virus tracking from virus induced replication of the human sodium iodide (hNIS) transgene shows enhancement in 4/6 (67%) patients in the first 2 dose levels. Enhancement was greater in patients with injection of nodal disease compared to dermal metastasis.
4. SPECT imaging of patient COH-004 (DL-2) on C1D8 showed significant enhancement of injected lymph node.
5. Baseline and on-treatment tumor biopsies of patient COH-004 using spatial immune profiling showed an increase in PD-L1 positive cells following treatment with CHECKVacc, demonstrating immune activation and tumor microenvironment changes in association with response to therapy.

Taken together, these data support further evaluation of CHECKVacc in TNBC.

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, one of the largest cancer research and treatment organizations in the United States, 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 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) [2], with a dismal median survival of 12 months. There is no effective targeted therapy in patients with metastatic TNBC with the exception of tumors 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 tumor 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 perform on TNBC cancer cells in tissue culture. As few as 1 viral particle per 1000 tumor 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

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