IMUGENE
Developing Cancer Immunotherapies

ASX Announcement

Imugene images and tracks CHECKvacc replication in patients with triple-negative breast cancer

- **Data presented at American Association for Cancer Research (AACR) Annual Meeting 2023**

Sydney, Australia, 20 April 2023: Imugene Limited (ASX: IMU), a clinical stage immuno-oncology company, is pleased to announce positive imaging data on its oncolytic virotherapy candidate, CHECKvacc (CF33-hNIS-antiPDL1), which was presented at the AACR Annual Meeting 2023 in Orlando, Florida overnight.

Dr Jamie Rand, an Assistant Professor in the Division of Breast Surgery at the City of Hope's Department of Surgery, presented the abstract titled "hNIS imaging data from a first-in-human trial of the oncolytic virus CF33-hNIS-antiPD-L1 in patients with triple negative breast cancer".

The conclusions of the abstract were as follows:

- CF33-hNIS-antiPD-L1 is safe and well tolerated at dose levels 1 through 3.
- SPECT (single-photon emission computerized tomography) imaging after treatment with CF33-hNIS-antiPD-L1 administered by IT (intratumoral) injection in patients with mTNBC (metastatic triple-negative breast cancer) showed enhancement in 75% of injected lesions, suggesting local viral replication with resulting hNIS (human sodium iodide symporter) expression.
- This technique allows Imugene to track where the virus is replicating in real time during treatment.
- This is the first known report of successful hNIS-based imaging to track oncolytic poxvirus replication in humans.

- There was improved SPECT imaging enhancement in subcutaneous nodules, intramuscular nodules, and lymph nodes when compared to matted dermal metastasis.
- Further analysis will evaluate the correlation of SPECT imaging results with pathologic immune cell infiltrate, viral staining, and tumor response. Preliminary evaluation suggests increased CD8+ T-cell infiltration and increased PD-L1 expression following IT injection of CF33-hNIS-antiPD-L1.

The poster is available on Imugene's website: https://www.imugene.com/conference-presentations

Imugene MD & CEO Leslie Chong said: "While it was pleasing to see the primary objective of safety and tolerability of CHECKvacc confirmed, the imaging data presented showed several other positive outcomes resulting from our first-in-human trial. We'll complete further analysis of the data and look forward to the trial continuing, with a view to improving the prognosis of a cancer with limited options for its patients."

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.

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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 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 using SPECT. 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-PDL1. 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