IMUGENE
Developing Cancer Immunotherapies

ASX Announcement

Phase 1 CF33-hNIS (VAXINIA) Study Update

Positive Early Signals

- **CF33-hNIS administered alone, or in combination with pembrolizumab and either dosed intravenously (IV) or intratumourally (IT)**
- **38 heavily pre-treated patients dosed to date with CF33-hNIS virus**
- **All treatments to date have been determined to be safe and tolerable**
- **1 Complete Response (CR)* in biliary tract cancer treated at a mid-dose; patient has been in remission for over 430 days**
- **2 Partial Response (PRs)* in melanoma in a mid-dose level**
- **In the IT cohorts, 47% of injected lesions had a reduction in tumour burden, 3 lesions were completely eradicated; In IV cohorts, 53% of patients achieved stable disease as their best response, among the efficacy evaluable patients**
- **7 patients with gastrointestinal cancers who received CF33-hNIS alone during dose escalation achieved a disease control rate (CR, PR or SD) of 86% presented this week at the American Society of Clinical Oncology - Gastrointestinal Cancer Symposium (ASCO-GI)**

Sydney, Australia, 17 January 2024: Imugene Limited (ASX: IMU), a clinical stage immuno-oncology company, is pleased to provide a clinical trial update of its Phase 1 MAST (Metastatic Advanced Solid Tumours) trial evaluating the safety and efficacy of novel cancer-killing virus CF33-hNIS (VAXINIA).

- As of 12 January 2024, 38 patients have been dosed with VAXINIA during the continuing dose escalation phase, comprised of 19 patients dosed intratumourally and 19 patients dosed intravenously as either monotherapy or in combination with pembrolizumab.
- 31 patients were evaluable for efficacy (received at least their first scan at day 42). In the IT cohorts (14 patients), 7 of 15 (47%) injected lesions had a reduction in

tumour burden, 3 lesions were completely eradicated. 3 patients (21%) had an objective response: 1 complete response by iRECIST in a patient with cholangiocarcinoma (a type of biliary tract cancer); and 2 partial responses in patients with melanoma (skin cancer) by RECIST. In IV cohorts (17 patients), 53% of patients achieved stable disease as their best response.

- Patients who received prior checkpoint blockade therapy derived clinical benefit with and without pembrolizumab.
- Trial expansion is planned for 10-20 patients with biliary tract cancers.
- Early results presented this week at the annual ASCO-GI Symposium in San Francisco, California, show that 7 patients with gastrointestinal cancers who received CF33-hNIS alone including 3 colorectal, 2 biliary tract, 1 pancreatic and 1 liver cancer showed positive treatment effects, with a disease control rate (all CR, PR and SD) of 86%. Importantly, in these patients, changes in tumour burden correlated with systemic immunological changes known to promote anti-tumour immunity. The poster "Oncolytic Virus CF33-hNIS Monotherapy for the Treatment of Gastrointestinal Malignancies" will be presented on 18 January 2024 during Session A: Cancers of the Esophagus and Stomach and Other GI Cancers from 11:45 AM-1:15 PM.

Imugene MD & CEO Leslie Chong said: “This latest data reinforces the early positive responses we’ve seen in gastrointestinal cancers and in particular for cholangiocarcinoma (bile duct cancer). It provides an excellent platform to investigate the impact of VAXINIA at higher dose levels as we also expand the trial to additional patients with hard-to-treat biliary tract cancers. It is a proud moment for us to be able to present these results at ASCO-GI, and promote the potential of VAXINIA and CF33 more broadly.”

Notably, 1 patient with biliary tract cancer, treated IT with mid-dose level displayed pseudoprogression (see below) with a 49% increase in tumour burden after 2 cycles of therapy. However, by the 4th cycle they achieved a Complete Response (iCR) with no known recurrence in over 430 days. A second patient with bile duct cancer, who

previously progressed on prior drug therapies, achieved Stable Disease (SD) for > 4 months upon receiving IV-administered CF33-hNIS.

About Biliary Tract Cancers

Bile duct cancers are difficult to treat and typically respond modestly to immunotherapy drugs. Pseudoprogression is a phenomenon in which the cancer initially appears to be growing, largely due to the cancer cells being infected by the virus then followed by infiltration of cancer fighting immune cells. However, it is usually followed by a decrease in tumour burden when the therapy takes effect. This phenomenon can benefit patients receiving immunotherapy but often leads to premature discontinuation of treatment owing to the false impression the cancer is growing.

About the MAST Trial

The multicenter Phase 1 MAST trial commenced by delivering a low dose of VAXINIA to patients with metastatic or advanced solid tumours who have had at least two prior lines of standard of care treatment. The City of Hope-developed oncolytic virus has been shown to shrink colon, lung, breast, ovarian and pancreatic cancer tumours in preclinical laboratory and animal models[1]. Overall, the study aims to recruit cancer patients across approximately 10 trial sites in the United States and Australia.

The clinical trial is titled "A Phase I, Dose Escalation Safety and Tolerability Study of VAXINIA (CF33- hNIS), Administered Intratumourally or Intravenously as a Monotherapy or in Combination with Pembrolizumab in Adult Patients with Metastatic or Advanced Solid Tumours (MAST)." The trial commenced in May 2022 and is anticipated to run for approximately 24 months while being funded from existing budgets and resources.

Full study details can also be found on clinicaltrials.gov under study ID: NCT05346484.

*iRECIST and RECIST: (immune) Response evaluation criteria in solid tumours
*PFU: Plaque Forming Unit

References

[1] Warner SG, Kim SI, Chaurasiya S, O'Leary MP, Lu J, Sivanandam V, Woo Y, Chen NG, Fong Y. A Novel Chimeric Poxvirus Encoding hNIS Is Tumor-Tropic, Imageable, and Synergistic with Radioiodine to Sustain Colon Cancer Regression. Mol Ther Oncolytics. 2019 Apr 11;13:82-92. doi: 10.1016/j.omto.2019.04.001. PMID: 31061881; PMCID: PMC6495072.

For more information please contact:

Leslie Chong
Managing Director and Chief Executive Officer
info@imugene.com

Investor Enquiries
shareholderenquiries@imugene.com

Media Enquiries
Matt Wright
matt@nwrcommunications.com.au

Connect with us on LinkedIn @Imugene Limited
Follow us on Twitter @TeamImugene
Watch us on YouTube @ImugeneLimited
Join us on InvestorHub; investorhub.imugene.com

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 pipeline includes an off-the-shelf (allogeneic) cell therapy CAR T drug azer-cel (azercabtagene zapreleucel) which targets CD19 to treat blood cancers. Our pipeline also 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 Imugene Limited.