IMUGENE
Developing Cancer Immunotherapies

ASX Announcement

First patient dosed in Phase 1 bile tract cancer trial

- The first patient in the trial has been dosed in Australia at St. Vincent's Hospital, Melbourne
- The trial is expected to enrol 10 patients with bile tract cancer (cholangiocarcinoma)
- Interim results from the Phase 1 MAST trial demonstrated positive responses in gastrointestinal cancers, and in particular a Complete Response (CR) in bile tract cancer
- The fifth cohort of both arms of the Phase 1 MAST monotherapy dose escalation trial have now cleared, with the sixth high dose cohort of each arm now open

Sydney, Australia, 10 July 2024: Imugene Limited (ASX:IMU), a clinical stage immune-oncology company, is pleased to announce that the first patient has been dosed in its trial for bile tract cancer (cholangiocarcinoma) patients.

This is an expansion of the MAST (Metastatic Advanced Solid Tumours) Phase 1 trial after early responses were observed in gastrointestinal cancers, and particularly cholangiocarcinoma, using Imugene's cancer-killing virus CF33 (VAXINIA).

The first patient in the trial was treated at St. Vincent's Hospital, with a total of 10 patients to be enrolled.

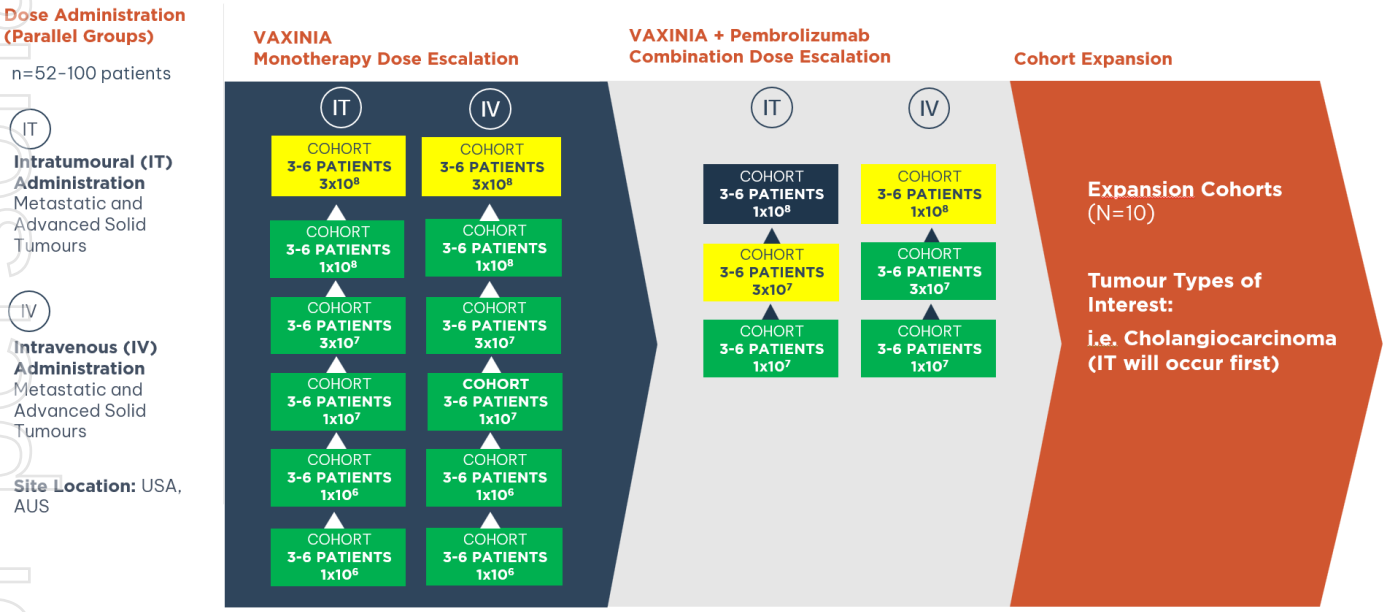
Imugene Managing Director & CEO Leslie Chong said: "Given the results we've seen to date we are eager to see the potential of VAXINIA in bile tract cancer. We look forward to now advancing to the higher doses in the trial to gather further key data and make a genuine difference to patients in need of innovative treatment options."

In November 2023, the FDA granted the VAXINIA MAST clinical program Fast Track Designation for the treatment of bile tract cancer, which allows Imugene closer cooperation with the FDA to expedite the program and potential approval process.

Bile tract cancer is a rare disease in which malignant cancer cells form in the bile ducts. It is difficult to treat and generally responds poorly to immunotherapy drugs.

One patient with bile tract cancer who had failed three prior lines of therapy received a mid-dose of IT-administered monotherapy VAXINIA achieved a complete response, meaning the disappearance of all signs of cancer in response to treatment, and the patient has been on the study for over 620 days. A second patient with cholangiocarcinoma, who has also progressed on prior drug therapies, achieved stable disease for more than four months upon receiving IV-administered VAXINIA.

The Cohort Review Committee has now cleared the fifth cohort for both arms, intratumoral (IT) and intravenous (IV), of the monotherapy dose escalation portion of the MAST trial, with no safety signals observed thus far. Consequently, the sixth cohort of each arm of the dose escalation trial are now open and enrolling.



**Further dose escalation to continue as long as no safety issues are observed*

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. With no safety signals identified to date, the trial has since progressed through the monotherapy dose escalation cohorts as well as the combination study, whereby VAXINIA is administered with well-known checkpoint inhibitor pembrolizumab. CF33 oncolytic virus, developed by City of Hope, has been shown to

shrink colon, lung, breast, ovarian and pancreatic cancer tumours in preclinical laboratory and animal models[1].

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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.

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.