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Developing Cancer Immunotherapies

ASX Announcement

FDA Fast Track Designation for Bile Duct Cancer granted for CF33-hNIS (VAXINIA) MAST Clinical Program

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- **FDA's Fast Track Designation for CF33-hNIS (VAXINIA) offers closer cooperation with the FDA to expedite the MAST clinical program and subsequent potential approval process**
- **Fast Track provides eligibility for Accelerated Approval and Priority Review**
- **Imugene will utilise the Fast Track designation to work with the FDA on advancing this important drug program towards patients on an accelerated timeline**

Sydney, Australia, 28 November 2023: Imugene Limited (ASX: IMU), a clinical stage immuno-oncology company, is pleased to announce its MAST (Metastatic Advanced Solid Tumours) clinical program evaluating the safety and efficacy of novel cancer-killing virus CF33-hNIS (VAXINIA), has been granted Fast Track designation from the **US Food and Drug Administration (FDA).**

Imugene CEO and MD Ms Leslie Chong said, "The Fast Track process of drug development is designed to facilitate the development, and the review of drugs to treat serious conditions and fill an unmet medical need, with Fast Track status often leading to earlier drug approval and access by patients".

Benefits of Fast Track designation include:

- Increased frequency of meetings with the FDA to discuss the drug's development plan;
- Eligibility for Accelerated Approval and Priority Review, if relevant criteria are met; and

- Regular dialogue with the FDA known as a Rolling Review in support of a New Drug Application or Biologic License Application.

Imugene CMO Dr Paul Woodard said, "We are very encouraged to received Fast Track Designation by the FDA. We have received a high level of interest from clinicians in the emerging data from the difficult to treat bile duct cancer patient population".

FDA Fast Track was granted based on the promising data package from Imugene detailing Phase 1 efficacy and tolerability data in patients suffering with bile duct cancer. Bile duct cancer is a rare disease in which malignant (cancer) cells form in the bile ducts. Bile duct cancer is also called cholangiocarcinoma. Bile duct cancers are difficult to treat and typically respond poorly to immunotherapy drugs.

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 12 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 Intratumorally 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.

About Fast Track designation

FDA Fast Track designation is awarded to help important new therapies reach patients earlier. It is designed to facilitate the development and expedite the review of drug

candidates to treat serious conditions and fill an unmet medical need. Importantly, Imugene will now have access to more frequent meetings and communications with the FDA, potentially receiving Rolling Review of its Biologic License Application (once submitted) and may be eligible for Accelerated Approval and Priority Review, if relevant criteria are met, for VAXINIA in bile duct cancer.

More information on Fast Track designation is available on the US FDA's website[2]

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.

2 https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track

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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.