IMUGENE
Developing Cancer Immunotherapies

ASX Announcement

Bile Tract Cancer Patient maintains Complete Response in MAST Study for Over Two Years

- Patient hits major milestone in CF33 MAST VAXINIA study with complete response (CR) for over two years
- The Cohort review committee has cleared the first cohort of three patients in Bile Tract Cancer Expansion of the VAXINIA trial, with patients continuing to be enrolled
- VAXINIA has received both FDA Fast Track Designation and Orphan Designation Status
- CF33 VAXINIA method of composition and method of use protection patent extension granted to 2040 (previously to 2037) in the major US oncology market

SYDNEY, Australia, 5 November 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).

A bile tract cancer patient in Imugene's Phase 1 MAST trial remains a complete response, now surpassing more than two years in remission. Additionally, Imugene confirms its Bile Tract Cancer Expansion part of the trial has now cleared its first cohort, after the first three patients were evaluated for safety and experienced no dose limiting toxicities (DLTs). It is now open for full enrolment of up to 10 patients.

Imugene received FDA Fast Track Designation in November 2023 for the VAXINIA MAST clinical program and its treatment of Bile Tract Cancer, allowing for closer cooperation with the FDA to expedite the program and the subsequent approval process, including potential for accelerated approval and priority review. In September 2024, the Company received Orphan Drug Designation from the FDA for VAXINIA's treatment of Bile Tract Cancer, providing a range of incentives in addition to seven years market exclusivity upon FDA approval.

Recently, Imugene was also pleased to receive a patent extension to 2040 from the US Patent and Trademark Office (USPTO) for patent application number 16/324,541 which protects its oncolytic virotherapy CF33, including VAXINIA (CF33-hNIS) and CHECKVacc (CF33-hNIS-antiPDL1).

The patent is titled "CHIMERIC POXVIRUS COMPOSITION AND USES THEREOF".

Imugene's CEO, Leslie Chong, stated: "Imugene receiving this patent extension to 2040 from the US patent office is a significant milestone for the CF33 family of oncolytic viruses. The US is the core healthcare market, and we are delighted to strengthen the patent life."

"We're also very pleased to see the two-year milestone reached for the Bile Tract Cancer patient who has maintained a complete response in our MAST study. Most importantly this is an outstanding result for the patient given the limited treatment options available, but also demonstrates the excellent potential of the CF33 oncolytic virus for this and other cancer types. We continue to enroll into the bile tract cancer expansion of the MAST trial."

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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.