

## ASX Announcement

### Imugene receives Orphan Drug Designation for treatment of Bile Tract Cancer

---

- US FDA grants CF33-hNIS (VAXINIA) Orphan Drug Designation (ODD)
- ODD provides Imugene with a range of incentives and 7 years of market exclusivity
- Bile Tract Cancer is a rare solid cancer with high unmet clinical need
- Following positive results in its MAST trial, Imugene has initiated a Bile Tract Cancer Expansion Trial with a total of 10 patients to be enrolled

**SYDNEY, Australia, 18 September 2024:** Imugene Limited (ASX:IMU), a clinical-stage immuno- oncology company, is pleased to announce that it has received Orphan Drug Designation (ODD) from the United States Food and Drug Administration (FDA) for its novel oncolytic virotherapy CF33-hNIS (VAXINIA), for the treatment of cholangiocarcinoma, a rare and aggressive form of bile tract cancer.

The FDA grants Orphan Drug status to promote development of drugs for rare diseases that affect fewer than 200,000 people in the United States. This designation provides Imugene with a range of incentives, including tax credits, potential grant funding, waiver of certain administrative fees, and seven years of market exclusivity upon FDA approval.

Imugene's application was supported by preclinical and clinical data from its ongoing Phase 1 MAST (Metastatic Advanced Solid Tumours) trial, which is investigating the safety and efficacy of VAXINIA. Promising results have already been observed, including one patient with cholangiocarcinoma achieving a complete response and another achieving stable disease after treatment with VAXINIA.

The MAST trial, which involves delivering the oncolytic virus either as a monotherapy or in combination with checkpoint inhibitors, is currently in the dose-escalation phase. This has recently been expanded into a further cohort of 10 patients with bile tract cancers, including cholangiocarcinoma.



Imugene's Managing Director & CEO, Leslie Chong, commented: "Receiving Orphan Drug Designation from the FDA is a major milestone for us. It reflects the potential of VAXINIA to address the urgent need for new treatments for cholangiocarcinoma, a disease with limited therapeutic options. We are excited to continue advancing this program, which has already shown meaningful clinical responses in patients."

Cholangiocarcinoma is a rare malignancy arising from the bile ducts, which has a poor prognosis and is often resistant to conventional treatments, including chemotherapy and immunotherapy. Imugene's innovative oncolytic virotherapy, VAXINIA, is designed to selectively target and destroy cancer cells, while also stimulating an immune response against the tumour.

For more information please contact:

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

**General Investor Enquiries**  
shareholderenquiries@imugene.com

**U.S Investor Enquiries**  
Heather Armstrong  
harmstrong@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

## **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.*