

## ASX Announcement

### First site activation in Australia for PD1-Vaxx Neo-POLEM Phase II trial

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- The Phase II 'Neo-POLEM' Investigator Sponsored Trial (IST) will investigate the potential of PD1-Vaxx to improve treatment outcomes in a specific kind of colorectal cancer (bowel cancer)
- The trial will recruit patients in both Australia and the United Kingdom.
- Colorectal cancer is the world's third most common cancer, with 80% of cases treatable at diagnosis.

**SYDNEY, Australia, 2 June 2025:** Imugene Limited (ASX: IMU), a clinical-stage immunoncology company, is pleased to announce the first site activation within Australia, as part of the investigator sponsored Phase II Neo-POLEM clinical trial.

Neo-POLEM is a Phase II study investigating the potential of PD1-Vaxx, a neoadjuvant PD-1 vaccine, to improve treatment outcomes for patients with mismatch repair-deficient / microsatellite instability high (dMMR/MSI-high) colorectal cancer. Approximately 15% of patients with colorectal cancer have the dMMR/MSI-high subtype.

The trial is an IST being conducted by Cancer Research UK Southampton Clinical Trials Unit in collaboration with Royal Surrey Hospital NHS Foundation Trust and the Australasian Gastro-Intestinal Trial Group (AGITG).

The primary objective of the study is to determine major pathological response rates, a measure of tumour size reduction post-treatment with PD1-Vaxx before surgery, with secondary objectives to assess the safety of PD1-Vaxx, evaluate biomarkers, and evaluate the objective response rates and overall survival.

This trial builds upon compelling early evidence that immunotherapy can deliver significant benefits in this patient population. The trial will recruit patients in both Australia and the United Kingdom.

Imugene's CEO and Managing Director Leslie Chong said: "We're very pleased to see this Neo-POLEM IST open and enrolling in Australia. PD1-Vaxx has the potential to offer a



durable immune response and improve treatment outcomes, and we look forward to further progress in both Australia and the UK.”

Colorectal cancer (CRC), also known as bowel cancer, is the third most common cancer, with a worldwide annual incidence of more than 1.2 million cases and a mortality rate of approximately 50%. About 80% of patients with colon cancer have localised and resectable disease at diagnosis. Approximately 15% of CRC is dMMR/MSI-high.

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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 novel cancer therapies that are currently marketed globally.

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.*