

ASX Announcement

First Patient Dosed in Australia for PD1-Vaxx Neo-POLEM Phase II trial

- The Phase II 'Neo-POLEM' Investigator Sponsored Trial (IST) to investigate the potential of PD1-Vaxx to improve treatment outcomes in a specific kind of colorectal cancer (bowel cancer) has dosed the first patient at Queen Elizabeth Hospital in Adelaide.
- Neo-POLEM is a neoadjuvant trial in which patients will be dosed with PD1-Vaxx prior to surgery.
- 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, 27 June 2025: Imugene Limited (ASX: IMU), a clinical-stage immuno-oncology company, is pleased to announce the first patient dosed in 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: "Dosing the first patient in the Neo-POLEM study represents hopeful treatment options for those suffering from these subtypes of colorectal cancer. We are encouraged by the potential of PD1-Vaxx to activate the body's own immune system to fight cancer in this earliest stage of disease. Our focus remains firmly on improving outcomes for people living with this disease, and we're grateful to the patients and clinical teams in Australia and the UK who are making this progress possible."

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.

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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.