

ASX Announcement

New PD1-Vaxx Phase 2 Colorectal Cancer Clinical Trial to Open in UK and Australia

- **New PD1-Vaxx Phase 2 colorectal (CRC) cancer clinical trial to commence in 2024**
- **Approximately 10 sites, 6 in Australia and 4 in the UK with approximately 44 patients to be enrolled in the study over about 18 months**
- **Investigator Sponsored Study (IST) clinical trial to be conducted by the Cancer Research UK Southampton Clinical Trials Unit at the University of Southampton in collaboration with Royal Surrey Hospital NHS Foundation Trust and The Australasian Gastro-Intestinal Trials Group (AGITG)**
- **Primary objective is to determine major pathological response rates, a measurement of tumour size, after treating with PD1-Vaxx before surgery to remove any residual tumour also known as neoadjuvant in operable CRC cancer patients.**

SYDNEY, Australia, 6 December 2023: Imugene Limited (ASX:IMU), a clinical stage immuno-oncology company, has signed a letter of intent with the University of Southampton in collaboration with Cancer Research UK Southampton Clinical Trials Unit at the Royal Surrey Hospital NHS Foundation Trust and The Australasian Gastro-Intestinal Trials Group (AGITG) to open a Phase 2 clinical trial, “Neo-POLEM”, in which PD1-Vaxx vaccine will be evaluated for patients diagnosed with operable CRC cancer.

The Chief Investigator is Dr Tony Dhillon based at the Royal Surrey Hospital NHS Foundation Trust in Surrey in collaboration with the University of Southampton, UK and Co-Chief Investigator Prof Timothy Price from the Queen Elizabeth Hospital in Adelaide, SA.

Dr Tony Dhillon said, “We are very excited to open this potentially groundbreaking trial using a vaccine to PD-1 in MSI High early colorectal cancer. Prof Tim Price, Imugene and I



have been working on the trial design and are thrilled to finally see sites set up in the UK and Australia. We are grateful to the University of Southampton Clinical trials Unit (CTU) who are running the trial and the Australasian Gastro-Intestinal Trials Group (AGTIG) who have been involved from the beginning”.

The title of the study is “A phase 2 trial of neoadjuvant PD-1 vaccine IMU-201 (PD1-Vaxx) in operable dMMR/MSI-H Colorectal Cancer” (see below for further explanation and definition). The primary objective of the study is to determine the pathological response rates and the secondary objectives are to assess the safety of PD1-Vaxx, evaluate biomarkers, and evaluate the objective response rates and overall survival.

Imugene MD & CEO, Ms Leslie Chong said, “We are excited to commence this important Phase 2 trial with PD1-Vaxx after being approached by the leading colorectal cancer oncologists from both Australia and the UK. The study costs are partially funded being Investigator Sponsored studies, and fall within current cash flow forecasts, she added.”

Colorectal cancer (CRC), also known as bowel cancer, is the third most common cancer, with a worldwide annual incidence of over 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. In 2018, there were 15,610 new cases of bowel cancer diagnosed in Australia (8,490 males and 7,120 females). In 2022, an estimated 15,713 new cases of bowel cancer were diagnosed in Australia (8,300 males and 7,413 females). It is estimated that a person has a 1 in 19 (or 5.2%) risk of being diagnosed with bowel cancer by the age of 85 (1 in 18 or 5.6% for males and 1 in 21 or 4.8% for females)¹.

Neoadjuvant (before surgery) chemotherapy and surgical resection of the colon or rectum is the standard of care treatment for locally advanced colorectal cancer. A subset of colorectal cancer is caused by a deficiency in “mismatch repair” (dMMR), a phenomenon known as microsatellite instability (MSI), which results in a higher mutation of the cancer cells and more rapid tumour growth. Because mismatch repair-deficient colorectal cancer is responsive to programmed death 1 (PD-1) blockade in the context of metastatic



disease, it is hypothesized that checkpoint blockade with PD1-Vaxx could be effective in patients with mismatch repair-deficient, locally advanced colorectal cancer.

¹ <https://www.canceraustralia.gov.au/cancer-types/bowel-cancer/statistics>

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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.

About the Southampton Clinical Trials Unit (SCTU)

The Southampton Clinical Trials Unit (SCTU) is a Cancer Research UK (CRUK) core-funded CTU with expertise in the design, conduct and analysis of interventional, multi-centre clinical trials. The SCTU is based within the University of Southampton with offices at the University Hospital Southampton NHS Foundation Trust Southampton General Hospital site. For more information, visit the SCTU website.

About The University of Southampton (UoS)

The University of Southampton drives original thinking, turns knowledge into action and impact, and creates solutions to the world's challenges. We are among the top 100 institutions globally (QS World University Rankings 2023). Our academics are leaders in their fields, forging links with high-profile international businesses and organisations, and inspiring a 22,000-strong community of exceptional students, from over 135 countries worldwide. Through our high-quality education, the University helps students on a journey of discovery to realise their potential and join our global network of over 200,000 alumni. www.southampton.ac.uk



About the AGITG

The Australasian Gastro-Intestinal Trials Group (AGITG) is a multi-disciplinary collaborative group that undertakes patient-centric research to advance medical care and practice in the treatment of gastro-intestinal cancer. Since 1991, the AGITG has led more than 70 GI cancer clinical trials, enrolling 8,800 patients across 129 hospitals in Australia and New Zealand, and 125 sites globally.

Release authorised by the Managing Director and Chief Executive Officer Imugene Limited.