

## ASX Announcement

### IMUGENE RECEIVES ETHICS APPROVAL TO START PHASE I CLINICAL TRIAL OF NEW CANCER ONCOLYTIC VIROTHERAPY VAXINIA IN USA

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**SYDNEY, Australia, 23 March 2022:** Imugene Limited (ASX:IMU), a clinical stage immuno-oncology company, today announced it has received Western Institutional Review Board (WIRB) approval to commence a Phase I clinical trial of its oncolytic virotherapy candidate, VAXINIA (CF33-hNIS, HOV2) in multiple solid tumours in patients.

The US component of the Phase I trial will be conducted under the Food and Drug Administration (FDA) investigational new drug (IND) process following FDA IND clearance in December 2021. Site activation and patient recruitment will proceed immediately.

The first hospital in the USA to receive ethics approval is the City of Hope®, a world-renowned independent cancer research and treatment center near Los Angeles. Additional clinical sites will be opened across the USA in 2022.

The clinical trial is titled “A Phase I, Dose Escalation Safety and Tolerability Study of VAXINIA (CF33- hNIS), Administered Intratumorally or Intravenously as a Monotherapy or in Combination with Pembrolizumab in Adult Patients with Metastatic or Advanced Solid Tumours (MAST)”. The trial is anticipated to run for 24 months and is funded from existing budgets and resources.

The Principal Investigator leading the trial at City of Hope is Dr Daneng Li MD, an assistant professor in the Department of Medical Oncology & Therapeutics Research at City of Hope, specializing in treating gastrointestinal cancers. Dr Li currently leads the liver tumours program and is also the co-director of the Neuroendocrine Tumour Program at City of Hope.

This is an open-label, dose-escalation, multi-centre phase I study evaluating the safety of CF33-hNIS (hNIS – human sodium iodide symporter) administered via two routes of administration, intratumoural (IT) or intravenous (IV), either as a monotherapy or in combination with pembrolizumab administered intravenously in patients with metastatic or advanced solid tumours.

The trial will involve a dose escalation, before the trial expands to up to 10 patients at the final monotherapy and combination dose. CF33-hNIS is a chimeric vaccinia poxvirus from the lab of

CF33 inventor Professor Yuman Fong, Chair of Sangiacomo Family Chair in Surgical Oncology at City of Hope, and a noted expert in the oncolytic virus field.

Oncolytic viruses (OVs) are designed to both selectively kill tumour cells and activate the immune system against cancer cells, with the potential to improve clinical response and survival.

Imugene MD & CEO Leslie Chong said, “The start of our USA VAXINIA study is a significant milestone for Imugene and clinicians treating Americans faced with the challenge of metastatic advanced solid tumours. Accomplishing this goal speaks to the perseverance and dedication of Imugene’s clinical and research team as we continue to build on our clinical and commercial potential.

“Following the outstanding work of Professor Yuman Fong and the City of Hope team, in addition to the positive pre-clinical results, we’re incredibly eager to unlock the potential of VAXINIA and the oncolytic virotherapy platform more broadly.”

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**About Dr Daneng Li**

Daneng Li, M.D., is an assistant professor in the Department of Medical Oncology & Therapeutics Research at City of Hope, specializing in treating gastrointestinal cancers. Dr Li currently leads the liver tumours program and is also the co-director of the Neuroendocrine Tumour Program at City of Hope.

Dr Li earned his undergraduate degree from The Ohio State University in Columbus, Ohio, graduating summa cum laude. He then went on to receive his medical doctorate from Weill Cornell Medical College in New York, before pursuing an internship and residency in internal medicine at New York-Presbyterian Hospital/Weill Cornell Medical Center. He then completed a hematology/oncology fellowship at Memorial Sloan-Kettering Cancer Center in New York City.

Board certified in internal medicine and medical oncology, Dr. Li serves on several national committees focused on his specialty tumour types. He has authored several publications in the peer reviewed literature, and has presented his work nationally.

### **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 product pipeline 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 City of Hope®**

City of Hope is an independent biomedical research and treatment center for cancer, diabetes and other life-threatening diseases. Founded in 1913, City of Hope is a leader in bone marrow transplantation and immunotherapy such as CAR T cell therapy. City of Hope's translational research and personalized treatment protocols advance care throughout the world. Human synthetic insulin, monoclonal antibodies, and numerous breakthrough cancer drugs are based on technology developed at the institution. Translational Genomics Research Institute (TGen) became a part of City of Hope in 2016. AccessHope™, a wholly owned subsidiary, was launched in 2019, dedicated to serving employers and their health care partners by providing access to City of Hope's exceptional cancer expertise. A National Cancer Institute-designated comprehensive cancer center and a founding member of the National Comprehensive Cancer Network, City of Hope is ranked among the nation's "Best Hospitals" in cancer by U.S. News & World Report. Its main campus is located near Los Angeles,

with additional locations throughout Southern California and in Arizona. For more information about City of Hope, follow us on Facebook, Twitter, YouTube or Instagram.

*Release authorised by the Managing Director and Chief Executive Officer  
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