

ASX Announcement

IMUGENE AND CITY OF HOPE ANNOUNCE FIRST PATIENT DOSED IN PHASE 1 TRIAL TO TEST CANCER-KILLING ONCOLYTIC VIRUS AGAINST SOLID TUMORS

- City of Hope is first in world to test oncolytic virus, CF33-hNIS, in people with metastatic solid tumors.

SYDNEY, Australia, 18th May 2022 and LOS ANGELES, U.S., 17th May 2022: Imugene Limited (ASX:IMU), a clinical stage immuno-oncology company, and [City of Hope](#), one of the largest cancer research and treatment organizations in the United States, today announced that the first patient was dosed in a Phase 1 clinical trial evaluating the safety of novel cancer-killing virus CF33-hNIS VAXINIA when used in people with advanced solid tumors. The City of Hope-developed oncolytic virus has been shown to shrink colon, lung, breast, ovarian and pancreatic cancer tumors in preclinical laboratory and animal models¹.

“Our previous research demonstrated that oncolytic viruses can stimulate the immune system to respond to and kill cancer, as well as stimulate the immune system to be more responsive to other immunotherapies, including checkpoint inhibitors,” said Daneng Li, M.D., principal investigator and assistant professor of City of Hope’s Department of Medical Oncology & Therapeutics Research. “Now is the time to further enhance the power of immunotherapy, and we believe CF33-hNIS has the potential to improve outcomes for our patients in their battle with cancer.”

Oncolytic virus therapy is made possible once viruses found in nature are genetically modified to infect, replicate in and kill cancer cells, while sparing healthy cells. While immune checkpoint inhibitors have been effective in certain cancers, patients often relapse and eventually stop responding to or develop resistance to this type of treatment. Early research shows oncolytic viruses can prime a person’s immune system and increase the level of PD-L1 in tumors, making immunotherapy more effective against cancer².

The multicenter Phase 1 trial will start by delivering a low dose of CF33-hNIS to cancer patients with metastatic or advanced solid tumors who have had at least two prior lines of standard of care treatment. The investigational treatment will be delivered either as an injection directly into tumors or intravenously.

Once patients in the single therapy group have been treated with the lowest doses of CF33-hNIS and acceptable safety has been demonstrated, certain new study participants will receive the experimental oncolytic virus in combination with the immunotherapy pembrolizumab, an engineered antibody that improves the immune system's ability to fight cancer-causing cells. The study aims to recruit 100 patients across approximately 10 trial sites in the United States and Australia.

City of Hope exclusively licensed patent rights covering CF33 to Imugene Limited, a company developing novel therapies that activate the immune system against cancer. Imugene has given CF33-hNIS the name VAXINIA.

“Interestingly, the same characteristics that eventually make cancer cells resistant to chemotherapy or radiation treatment actually enhance the success of oncolytic viruses, such as CF33-hNIS,” said Yuman Fong, M.D., the Sangiacomo Family Chair in Surgical Oncology at City of Hope and the key developer of the genetically modified virus. “We are hoping to harness the promise of viraology and immunotherapy for the treatment of a wide variety of deadly cancers.”

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 approximately 24 months and is funded from existing budgets and resources.

The U.S. component of the Phase 1 trial is conducted under the U.S. Food and Drug Administration (FDA) investigational new drug (IND) process following FDA IND clearance in December 2021. Site activation and patient recruitment is proceeding.

The first clinical institution in the U.S. to receive ethics approval is City of Hope, a world-renowned cancer research and treatment organization in Los Angeles. Additional clinical sites will be opened across the U.S. in 2022.

Imugene M.D. and CEO Leslie Chong said, “The dosing of the first patient in our VAXINIA study is a significant milestone for Imugene and clinicians faced with the challenge of treatment for metastatic advanced solid tumors. Professor Yuman Fong and the City of Hope team have provided outstanding research. In addition to the positive preclinical results, we’re incredibly eager to unlock the potential of VAXINIA and the oncolytic virotherapy platform.”

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2. Shyambabu Chaurasiya, Annie Yang, Seonah Kang, Jianming Lu, Sang-In Kim, Anthony K. Park, Venkatesh Sivanandam, Zhifang Zhang, Yanghee Woo, Susanne G. Warner & Yuman Fong (2020) Oncolytic poxvirus CF33-hNIS-ΔF14.5 favorably modulates tumor immune microenvironment and works synergistically with anti-PD-L1 antibody in a triple-negative breast cancer model, *Oncolmmunology*, 9:1, DOI: [10.1080/2162402X.2020.1729300](https://doi.org/10.1080/2162402X.2020.1729300)

About Daneng Li, M.D.

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

Li earned his undergraduate degree from The Ohio State University in Columbus, Ohio, where he graduated 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 completed a hematology/oncology fellowship at Memorial Sloan-Kettering Cancer Center in New York City.

Board certified in internal medicine and medical oncology, Li serves on several national committees focused on his specialty tumor types. He has authored many publications in 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's mission is to deliver the cures of tomorrow to the people who need them today. Founded in 1913, [City of Hope](#) has grown into one of the largest cancer research and treatment organizations in the U.S. and one of the leading research centers for diabetes and other life-threatening illnesses. As an independent, National Cancer Institute-designated comprehensive cancer center, City of Hope brings a uniquely integrated model to patients, spanning cancer care, research and development, academics and training, and innovation initiatives. Research and technology developed at City of Hope has been the basis for [numerous breakthrough cancer medicines](#), as well as human synthetic insulin and monoclonal antibodies. A leader in [bone marrow transplantation](#) and immunotherapy, such as [CAR T](#)

cell therapy, City of Hope's personalized treatment protocols help advance cancer care throughout the world.

With a goal of expanding access to the latest discoveries and leading-edge care to more patients, families and communities, City of Hope's growing national system includes its main Los Angeles campus, a network of clinical care locations across Southern California, a new cancer center in Orange County, California, scheduled to open in 2022, and Cancer Treatment Centers of America. City of Hope's affiliated family of organizations includes Translational Genomics Research Institute and AccessHope™. For more information about City of Hope, follow us on Facebook, Twitter, YouTube, Instagram and LinkedIn.

*Release authorised by the Managing Director and Chief Executive Officer
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