For personal use only

ASX Announcement

IMUGENE LICENSES CD19 ONCOLYTIC VIRUS FROM CITY OF HOPE TO TURN CAR T THERAPY AGAINST SOLID TUMOURS

- Imugene enhances portfolio with novel CD19 expressing oncolytic virus from City of Hope, a Comprehensive Cancer Center in Los Angeles, California, to be developed in combination with CD19 CAR T cell therapy
- Worldwide exclusive licence to combine the oncolytic virus and cell therapy technology
- Long patent life
- Phase 1 clinical trial anticipated to commence in 2022
- Builds on Imugene's deep oncolytic virus expertise
- Four-year Sponsored Research Agreement with City of Hope to further develop the technology

Sydney, Australia, 18 May 2021: Imugene Ltd (ASX:IMU), an immuno-oncology company and City of Hope®, a world-renowned independent cancer research and treatment center near Los Angeles, today announced they have entered into a licensing agreement for the patents covering a novel combination immunotherapy. The therapy unleashes a CD19 expressing oncolytic virus to enable CD19 directed chimeric antigen receptor (CAR) T cell therapies to target solid tumours, which are currently otherwise difficult to treat with CAR T cell therapy alone.

The worldwide exclusive licence of the patents covering the cell therapy technology, which includes CF33-CD19, known as onCARlytics™, or an agent that tags cancer cells for CAR T cell destruction, was developed at City of Hope.

City of Hope scientists led by Saul Priceman, Ph.D., have combined two potent immunotherapies. Imugene's CD19 oncolytic virus and CD19 CAR T cell therapy — with the goal of targeting and eradicating solid tumours that are otherwise difficult to treat with CAR T cell therapy alone.

"Our research demonstrates that oncolytic viruses are a powerful and promising approach that can be combined strategically with CAR T cell therapy to effectively target solid tumours in patients," said Priceman, assistant professor in City of Hope's Department of Hematology & Hematopoietic Cell Transplantation." This therapeutic platform addresses two major challenges that make solid tumours so difficult to treat with immunotherapy. There are limited solid tumour targets that T cells can be redirected against with CARs. Solid tumours are surrounded by a brick wall -- a so-called immunosuppressive tumour microenvironment. When a CAR T cell attempts to enter the tumour, survive, and kill cancer cells, it can't effectively because of this barrier."

Imugene's MD & CEO, Ms Leslie Chong said "This platform opens up the entire field of use to cellular therapy for the CF33 OV. Supercharging CF33 with CD19 is a revolutionary new paradigm in combination therapy with any CD19 binding therapies to include bi-specifics, antibody drug conjugates and CAR T, cell therapy for solid tumours. The CAR T cell field currently only treats ~10% of all cancers such as blood or liquid tumours, whereas this technology has the potential to open up the solid tumour market."

City of Hope scientists genetically engineered an oncolytic virus to enter tumour cells and force the expression of CD19 on the cell surface. The scientists were then able to use CD19 directed CAR T cells to recognize and attack these solid tumours. The preclinical research was published recently and featured on the front cover of the prestigious journal Science Translational Medicine [1].

CD19 CAR T cell therapy is approved by the U.S. Food and Drug Administration to treat certain types of blood cancers, namely B cell lymphomas and acute lymphoblastic leukemia. This new research may expand the use of CD19 CAR T therapy with onCARlytics™ to the treatment of patients with potentially any solid tumour.

This discovery highlights a City of Hope research collaboration including Priceman, Anthony Park, Ph.D., postdoctoral research fellow in Priceman's Lab, Stephen Forman, M.D., professor of the Department of Hematology & Hematopoietic Cell Transplantation and director of City of Hope's T Cell Therapeutics Research Program, and Yuman Fong, M.D., professor and Sangiacomo Family Chair in Surgical Oncology at City of Hope. "Our City of Hope team designed this CF33 oncolytic virus to do what it does so well. It enters the cancer cell, uses the cell's own machinery to replicate itself, and engineer the cancer cells to express the well-known CAR T cell target, CD19," Fong said.

A separate four year Sponsored Research Agreement with City of Hope and the research team led by Dr.Priceman to further develop the technology has also been executed.

Under the terms of the licence agreement, Imugene acquires the exclusive world-wide rights to develop and commercialize the patents covering the CF33-CD19 for which it has agreed to pay City of Hope license fees comprising an upfront, annual maintenance fees which are creditable against future royalty payments, performance based consideration linked to the achievement of certain value-inflection development milestones and commercial outcomes, as well as net sales based on single digit royalty payments, and sublicensing fees.

All upfront cash payments under the licence agreement will be funded through Imugene's existing cash reserves.

This release has been authorised by the directors of Imugene Limited.

For more information please contact:

Imugene
Leslie Chong
Managing Director and Chief Executive Officer
T: +61 458 040 433
Follow us on Twitter @TeamImugene
Like us on Facebook @Imugene
Connect with us on LinkedIn @Imugene Limited

City of Hope
Letisia Marquez
Media Relations Manager
T; +1(626) 476-7593
lemarquez@coh.org
Follow us on Facebook, Twitter, YouTube or Instagram

[1] Effective combination immunotherapy using oncolytic viruses to deliver CAR targets to solid tumours.
Park AK, Fong Y, Kim SI, Yang J, Murad JP, Lu J, Jeang B, Chang WC, Chen NG, Thomas SH, Forman SJ, Priceman SJ.Sci Transl Med. 2020 Sep 2;12(559):eaaz1863. doi: 10.1126/scitranslmed.aaz1863.PMID: 32878978

For personal use only

OnCARlytics™

Researchers first created an oncolytic virus (CF33-CD19) in Fong's lab to get into tumour cells and start producing CD19. They did this successfully in triple-negative breast, pancreatic, prostate, ovarian, head and neck, and brain cancer cell lines. CF33-CD19 oncolytic virus was then combined with CD19 CAR T cells in vitro and in vivo mice studies. Researchers showed significant activity with mice being cured of their cancer with the CF33-CD19 and CAR T cell combination, as well as prolonged protective anti-tumour immunity. Solid tumours don't express CD19 on their cell surface, therefore introducing the CF33-CD19 allowed for CD19 to be present on the solid tumour cell surface, as well as helped to reverse the tumour's harsh microenvironment, making it receptive to receiving CAR T cell therapy. The first clinical trial is anticipated to start in 2022 and will evaluate the safety and efficacy of CF33-CD19 in combination with CAR T therapy in patients with solid tumours.

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.
Follow us on Twitter @TeamImugene
Like us on Facebook @Imugene
Connect with us on LinkedIn @Imugene Limited

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.

For personal use only