

MEDIA RELEASE – FOR RELEASE ON WEDNESDAY, JULY 8, 2020 at 7:30 A.M.

Protecting cancer patients from COVID-19: world-first clinical trial tests a novel immune-boosting strategy

In the race to find new ways to prevent and treat COVID-19, Canadian researchers have launched an innovative clinical trial focussed on strengthening the immune system for one of the most vulnerable populations – cancer patients.

The trial involves IMM-101, a preparation of safe, heat-killed bacteria that broadly stimulates the innate, or “first-response,” arm of the immune system. The researchers hope that boosting cancer patients’ immune systems with IMM-101 will protect them from developing severe COVID-19 and other dangerous lung infections.

Researchers from The Ottawa Hospital came up with the idea for the trial and worked with the Canadian Cancer Trials Group (CCTG) at Queen’s University to design and run it in centres across the country. Funding and in-kind support, valued at \$2.8 million, is being provided by the Canadian Cancer Society, BioCanRx, the Ontario Institute for Cancer Research, The Ottawa Hospital Foundation, The Ottawa Hospital Academic Medical Organization, ATGen Canada/NKMax, and Immodulon Therapeutics, the manufacturer of IMM-101.

“An effective vaccine that provides specific protection against COVID-19 could take another year or more to develop, test, and implement,” says Dr. Rebecca Auer, study lead, surgical oncologist and Director of Cancer Research at The Ottawa Hospital and associate professor at the University of Ottawa. “In the meantime, there is an urgent need to protect people with cancer from severe COVID-19 infection, and we think this immune stimulator, IMM-101, may be able to do this.”

“We know the immune systems of cancer patients are compromised both by their disease and the treatments they receive placing them at much higher risk of severe complications from COVID-19,” says Dr. Chris O’Callaghan, CCTG Senior Investigator, who will be overseeing this important national trial. “These patients are unable to practice social isolation due to the need to regularly attend hospital to receive critically important cancer treatment.”

The trial, called [CCTG IC.8](#), has been approved by Health Canada and is expected to open at cancer centres across Canada this summer. People who are interested in participating should speak with their cancer specialist.

Additional Quotes

“COVID-19 has led to a quickly changing environment. Just as many businesses and organizations have had to adapt, some cancer researchers are also pivoting their work to address the unique challenges brought on by this pandemic,” says **Andrea Seale, CEO, Canadian Cancer Society**. “Thanks to the quick-thinking and innovation of Drs. Auer and O’Callaghan and with the support of Canadian Cancer Society donors, we are now able to conduct the world’s first clinical trial to prevent severe COVID-19 infections in people with cancer and help them live longer, healthier lives.”

“This trial could support an important change to the standard of care for cancer patients by administration of IMM-101 prior to starting cancer treatment,” says **Dr. John Bell, Scientific Director of**

BioCanRx. “Accelerating to the clinic, biotherapeutics that can enhance the quality of life of those living with cancer, is central to the BioCanRx mission.”

“There is a clear and urgent medical need for safe and effective ways to prevent SARS-CoV-2 infection and severe COVID-19 disease, especially for cancer patient populations,” says **Dr. Thomas-Oliver Kleen, Chief Scientific Officer at Immodulon.** “Immodulon is excited about this phase III trial and hopes that IMM-101 will provide increased protection against COVID-19 in these vulnerable patients.”

“OICR is excited to be collaborating on such a landmark clinical trial supporting cancer patients in this unprecedented time,” says **Dr. Laszlo Radvanyi, President & Scientific Director of the Ontario Institute for Cancer Research.** “IMM-101 may be an effective approach to protect our vulnerable patients not only against COVID-19, but also to boost their immune system to fight cancer.”

“Natural killer (NK) cells are the first line of anti-viral defense and, as such, a robust innate immune system and, in particular NK cell activity, is essential for protection against viruses such as SARS-CoV-2,” says **Dr. Katia Betito, President of ATGen Canada/NK Max.** “The possibility of boosting the immune system in high-risk patients such as those with cancer with a product like IMM-101 would be a major step in protecting this vulnerable population. We are excited to see whether our NK Vue test can provide a much-needed tool for the evaluation and follow-up of these patients.”

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About the Canadian Cancer Trials Group

Celebrating its 40th year, the Canadian Cancer Trials Group (CCTG) is a cancer clinical trials research cooperative that runs phase I-III trials to test anti-cancer and supportive therapies in over 80 institutions across Canada and Internationally. From their operations centre at Queen’s University, they have led and participated in over 500 trials in over 40 countries aimed at improving survival and quality of life for all people with cancer. CCTG is a national program of the Canadian Cancer Society who provide core funding for the Group.

About The Ottawa Hospital

The Ottawa Hospital is one of Canada’s top learning and research hospitals, where excellent care is inspired by research and driven by compassion. As the third-largest employer in Ottawa, our support staff, researchers, nurses, physicians, and volunteers never stop seeking solutions to the most complex health-care challenges. Our multi-campus hospital, affiliated with the University of Ottawa, attracts some of the most influential scientific minds from around the world. Backed by generous support from the community, we are committed to providing the world-class, compassionate care we would want for our loved ones. www.ohri.ca.

About the Canadian Cancer Society

The Canadian Cancer Society is the only national charity that supports Canadians with all cancers in communities across the country. No other organization does what we do; we are the voice for Canadians who care about cancer. We fund groundbreaking research, provide a support system for all those affected by cancer and shape health policies to prevent cancer and support those living with the disease. Help us make a difference. Call 1-888-939-3333 or visit cancer.ca today.

About BioCanRx

BioCanRx, Canada's Immunotherapy Network, is a network of scientists, clinicians, cancer stakeholders, academic institutions, NGOs and industry partners working together to accelerate the development of leading-edge immune oncology therapies for the benefit of patients. Our vision is to cure patients and enhance the quality of life of those living with cancer. BioCanRx invests in leading edge immune oncology research translating world-class technologies from the lab into early phase clinical trials. BioCanRx provides researchers with access to funding, expertise, training and manufacturing facilities and is a leader in the translation, manufacture and adoption of cancer immunotherapies. The network is committed to training and developing the talent needed for a thriving health biotechnology sector in Canada. BioCanRx receives funding from the federal government's Networks of Centres of Excellence, and support from industry, the provinces and charities. The network is hosted by the Ottawa Hospital Research Institute.

About Immodulon Therapeutics

Immodulon Therapeutics Ltd. (London, UK) is a privately-owned clinical-stage immuno-oncology company primarily focused on the development of safe, effective and novel treatments for cancer. Its lead drug candidate, IMM-101, has shown promise in early clinical trials, demonstrating potential for the platform. It contains heat-killed whole cell *Mycobacterium obuense* which activates dendritic cells and other cells of the innate immune system by several mechanisms, including via Toll-like receptors. Its mechanism of action should not only make this product applicable to a range of cancers but, in combination with immune checkpoint inhibitors and other standard-of care treatments, it is expected to enhance their efficacy without increasing the safety burden for the patient. For more information about Immodulon, please visit www.immodulon.com.

About the Ontario Institute for Cancer Research (OICR)

OICR is a collaborative, not-for-profit research institute funded by the Government of Ontario. We conduct and enable high-impact translational cancer research to accelerate the development of discoveries for patients around the world while maximizing the economic benefit of this research for the people of Ontario. For more information visit www.oicr.on.ca.

About ATGen Canada/NKMax

ATGen Canada/NKMax is the Canadian division of NKMax Co Ltd (Korea), a public biotechnology company dedicated to restoring and enhancing overall immune integrity. NK Vue, NKMax's proprietary blood test for the measurement of immune function, is the first commercially available test that quantifies natural killer cell activity in a small volume of stimulated whole blood. NKMax also develops

its proprietary natural killer cell expansion and activation technology as a treatment for a number of cancers and other disorders, and is currently conducting clinical trials in the US and Korea.

About The Ottawa Hospital Academic Medical Organization

The Ottawa Hospital Academic Medical Organization (TOHAMO) is the governance organization that represents the 825 academic physicians who practice at The Ottawa Hospital and the University of Ottawa. The TOHAMO Board oversees the allocation of \$2.270M in innovation funds annually through a competitive grants process, supported by the Innovation Fund of the Alternative Funding Plan for the Academic Health Sciences Centres of Ontario.