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Canada Approves Medicago's Vaccine

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Health Canada has approved Covifenz, a tobacco plant-based coronavirus vaccination developed

by GlaxoSmithKline and Medicago, a biopharmaceutical company backed by Philip Morris International.

"The approval of our Covid-19 vaccine is a significant milestone for Canada in the fight against the pandemic. We appreciate Health Canada's timely review," said Takashi Nagao, president and CEO of Medicago, in a statement. "We're also grateful for the government of Canada's support in the development of this new vaccine, and we are manufacturing doses to start fulfilling its order."



"This first approval is an important milestone in our approach of pairing GSK's well-established pandemic adjuvant with promising antigens to develop protein-based, refrigerator-stable Covid-19 vaccines to help protect people against Covid-19 disease," said Roger Connor, president of GSK Vaccines. "We look forward to working with Medicago to make the vaccine available in Canada and to progress further regulatory submissions."

The government of Canada has a contract with Medicago to supply the Covid-19 vaccine.

"As one of our government's top priorities has been to reverse the 40-year decline faced by Canada's biomanufacturing sector, we are pleased to see Medicago's vaccine approval. It is a great milestone for Canada's biotechnology sector and for homegrown innovation. We will continue to support companies that want to produce vaccines in Canada and join the growing national biomanufacturing sector," said François-Philippe Champagne, minister of innovation, science and industry.

Health Canada based its decision on scientific data shared by Medicago as part of its rolling submission that began in April 2021 under an Interim Order and concluded with the filing of a New Drug Submission-CV.

"Today is a great day for Medicago as Covifenz becomes its first approved vaccine," said Yosuke Kimura, chief scientific officer at Medicago. "I'd like to thank the clinical investigators involved in our trials as well as Medicago's passionate and curious team of over 500 scientific experts and employees. Today only reinforces our commitment to using our technology to provide rapid responses to emerging global health challenges and to advancing therapeutics against life-threatening diseases worldwide."

Covifenz uses coronavirus-like particle technology with the vaccine composed of recombinant spike (S) glycoprotein expressed as virus-like particles co-administered with GSK's pandemic adjuvant. The vaccination regimen calls for two doses given intramuscularly 21 days apart (3.75 micrograms of coronavirus-like particle antigen in combination with GSK pandemic adjuvant in the same injection). The vaccine is stored at 2 degrees Celsius to 8 degrees Celsius. The Covifenz antigen will be manufactured in Canada and in North Carolina, USA.