

# Medicago and GSK announce the approval by Health Canada of COVIFENZ®<sup>®</sup>, an adjuvanted plant-based COVID-19 vaccine

**GSK** PUBLISHED FEB 24, 2022  
BY [GSK](#)

For media and investors only

- A vaccine manufactured in plants and developed in Canada

Medicago, a biopharmaceutical company headquartered in Quebec City, and GlaxoSmithKline (GSK) today announced that Health Canada has granted approval for COVIFENZ®<sup>®</sup>, COVID-19 vaccine, (plant-based virus-like particles [VLP], recombinant, adjuvanted). This vaccine is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 to 64 years of age.

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 at Medicago. “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.

Roger Connor, President of GSK Vaccines, added,

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. 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 (the Marketing Authorization Holder) to supply the COVID-19 vaccine. Medicago is committed to fulfilling this order as soon as possible.

As one of our government's top priority 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 the Honourable François-Philippe Champagne, Minister of Innovation, Science and Industry.

Health Canada based its decision on scientific data shared by Medicago as part of their 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. 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.

said Yosuke Kimura, Chief Scientific Officer at Medicago.

COVIFENZ® uses Coronavirus-Like Particle (CoVLP) technology with the vaccine composed of recombinant spike (S) glycoprotein expressed as virus-like particles (VLPs) co-administered with GSK's pandemic adjuvant. The vaccination regimen calls for two doses given intramuscularly 21 days apart (3.75 micrograms of CoVLP antigen in combination with GSK pandemic adjuvant in the same injection). The vaccine is stored at 2 °C to 8 °C. COVIFENZ® antigen will be manufactured in Canada and in North Carolina (US).

COVIFENZ® is not currently approved or authorized for the prevention of COVID-19 or any other indication anywhere other than Canada.

Medicago's COVIFENZ®, COVID-19 vaccine (plant-based virus-like particles [VLP], recombinant, adjuvanted), approved by Health Canada, is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 to 64 years of age.

Medicago is on a mission to help improve global public health using the power of plants. Founded in 1999 with the belief that innovative approaches and rigorous research would bring new solutions in healthcare, Medicago is a pioneer in plant-based therapeutics. We are proudly rooted in Quebec, with manufacturing capacity in both Canada and the US. Our passionate and curious team of over 500 scientific experts and employees are dedicated to using our technology to provide rapid responses to emerging global health challenges, and to advancing therapeutics against life-threatening diseases worldwide. Medicago is an affiliated company of Mitsubishi Tanabe Pharma Corporation. For more information: [www.medicago.com](http://www.medicago.com)

#### About Mitsubishi Tanabe Pharma Corporation

Mitsubishi Tanabe Pharma Corporation (MTPC) Group, the majority parent company of Medicago, is one of the large Japanese pharmaceutical companies, with its headquarters in Osaka, Japan. It positions vaccines as one of its key R&D areas under its Medium-Term Management Plan 21-25 and is also working to develop new modalities of vaccines. MTPC Group will further contribute to the prevention of infectious diseases which is one of the world's important social issues, by delivering a new option of plant-based VLP vaccine as a new type of vaccine. For further information please visit <https://www.mt-pharma.co.jp/e/>.

#### About GSK and its commitment to tackling COVID-19

GSK is a science-led global healthcare company. For further information please visit [www.gsk.com/about-us](http://www.gsk.com/about-us).

GSK is collaborating with companies and research groups across the world working on promising COVID-19 vaccine candidates through the use of our innovative vaccine adjuvant technology. The use of an adjuvant is of particular importance in a pandemic situation since it may reduce the amount of vaccine protein required per dose, allowing more vaccine doses to be produced and therefore contributing to

protecting more people.

Cautionary statement regarding forward-looking statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described in the Company's Annual Report on Form 20-F for 2020, GSK's 2021 Q4 Results and any impacts of the COVID-19 pandemic.

*Press release distributed by Wire Association on behalf of GSK, on Feb 24, 2022. For more information subscribe and [follow us](#).*

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