

News Release

February 24, 2022

COVID-19 vaccine, “COVIFENZ[®]” (MT-2766) has been approved in Canada.

Mitsubishi Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; President & Representative Director: Hiroaki Ueno; hereinafter, “MTPC”) announced today that its affiliated company, Medicago Inc. (Head Office: Quebec, Canada; President: Takashi Nagao) and GlaxoSmithKline plc (Head Office: London, UK, hereafter, “GSK”) jointly announced that Health Canada has granted full approval for COVIFENZ[®] (COVID-19 vaccine, plant-based virus-like particles [VLP], project code: MT-2766) on February 24. COVIFENZ[®] is administered with GSK’s pandemic adjuvant.

COVIFENZ[®] is a VLP vaccine indicated for the prevention of COVID-19, an infection with the SARS-CoV-2 virus, in adults aged 18 to 64 years and is manufactured by using plants. COVIFENZ[®] was reviewed under the rolling submission* in Canada since last April and data from the Phase 3 part of the Phase 2/3 clinical study were submitted as the final part of the application dossier in last December. The results of the Phase 3 part showed efficacy against Delta and Gamma variants of 75.3% and 88.6% respectively in an environment where variants were dominant during the Phase 3 period. In addition, no related serious adverse events were observed.

Medicago has a contract with the Government of Canada to supply the purchased doses of this vaccine. Medicago is committed to fulfilling this order as soon as possible. In Japan, a Phase 1/2 clinical study has been ongoing since last October, and MTPC aims to apply for approval in the second quarter of fiscal 2022 by adding the results of the clinical study in Japan to the data used for the application in Canada.

MTPC group positions vaccines as one of key R&D areas alongside the central nervous system and immune-inflammation disease areas, 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 issue, by delivering a new option of plant-based VLP vaccine as a novel type of vaccine.

*Rolling Submission (rolling submission, staged submission):

A system in which Health Canada reviews documents submitted in stages without waiting for submission of all data in order to shorten the time from application to approval.

Medicago release (February 24, 2022, local time)

[\[Medicago and GSK announce the approval by Health Canada of COVIFENZ®, an Adjuvanted Plant-Based COVID-19 Vaccine\]](#)

■ About COVIFENZ®

COVIFENZ® uses a VLP expressing a spike protein of coronavirus and is used in combination with GSK's pandemic adjuvant. VLP vaccine 3.75µg and adjuvant will be administered intramuscularly 2 times at 21-day intervals, and can be stored and distributed in a refrigerator (2-8°C).

■ About Medicago

Medicago is a Canadian biopharmaceutical company established in 1999 to specialize in research and development of new vaccines using VLP technology. It has a unique technology to extract and purify plants efficiently by generating VLP in their cells through recombinant technology. Mitsubishi Tanabe Pharma is committed to creating new drugs that address unmet medical needs and building a management base to provide these products globally. Aiming to further develop the vaccine business through the acquisition of new biologics technologies, we became a major shareholder in September 2013. We are currently engaged in the development of novel coronavirus and seasonal influenza vaccines, and through research and development and manufacturing of various vaccines using VLP technology, we are working to contribute to the health and prevention of infectious diseases for people around the world.

Mitsubishi Tanabe Pharma Corporation

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