

News Release

December 17, 2021

MT -2766, the world's first plant-based COVID -19 vaccine candidate Application for approval was submitted in Canada.

Mitsubishi Tanabe Pharma Corporation (Head Office: Osaka, Japan; President & Representative Director: Hiroaki Ueno; hereinafter, "MTPC") announced today that its affiliated company, Medicago Inc. (Head Office: Quebec, Canada; President: Takashi Nagao) has submitted an application for approval in Canada for a plant-based Virus-Like Particle (VLP) vaccine (project code: MT-2766) being developed to prevent COVID-19. MT-2766 is administered with GlaxoSmithKline (Head Office: London, UK) pandemic adjuvant.

MT-2766 has been reviewed under the rolling submission* in Canada since this April. Its Phase 3 data has been submitted in Canada as the final part of the application dossier based on the positive results from the Phase 3 part of the Phase 2/3 clinical study announced on December 7. Medicago is seeking review and approval for MT-2766 for indication in healthy adults, aged 18 years and above. If approved in Canada, it will be the world's first plant-based VLP vaccine for human use or for COVID-19. In addition, it can be stored and distributed in a refrigerator (2 to 8°C).

In Japan, a phase 1/2 clinical study has been ongoing since this October, and MTPC aims to apply for approval next spring by adding the results of the clinical study in Japan to the data used for the application in Canada. We plan to submit applications to WHO, the US, and the UK in the future. In addition, a study to confirm the antibody response of MT-2766 against Omicron variant is scheduled to be conducted in the future. And a booster study for people previously vaccinated with MT-2766, mRNA vaccine, or adenovirus vector vaccine is being considered to conduct as soon as possible. A pediatric study is also planned.

MTPC Group positions vaccines as one of its key R&D areas alongside the central nervous system and immuno-inflammation disease 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 issue, by delivering a new option of plant-based VLP vaccine as a new 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 (December 16, 2021)

[\[Medicago submits Phase 3 data to Health Canada for its plant-based COVID-19 vaccine candidate\]](#)

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