

# News Release

September 30, 2021

## **Start of a Japanese Clinical Study of MT-2766, Adjuvanted COVID-19 Vaccine Candidate**

Mitsubishi Tanabe Pharma Corporation (Head Office: Osaka, Japan; President & Representative Director; Hiroaki Ueno; hereafter, "MTPC") announced today the start of the phase 1/2 clinical study in Japan (hereafter, "this study") from October 2 for the plant-derived virus-like particle (VLP) vaccine candidate (project code: MT-2766 in combination with GlaxoSmithKline's (Head Office: London, United Kingdom) pandemic adjuvant) for the prevention of COVID-19 which is being developed by its affiliated company, Medicago Inc. (Head Office: Quebec, Canada; President; Takashi Nagao). MTPC aims to file an application for approval of MT -2766 in Japan by March 2022.

The summaries of this study are as follows:

- Subjects :145 Japanese male and female subjects aged 20 years or older.
- Method : Randomized, placebo-controlled study. Subjects will be assigned to 3 groups, normal dose group, lower dose group and placebo group, and will receive 2 doses at 21 days apart.
- Endpoints: Evaluate the safety and immunogenicity.

MT-2766 has completed dosing in the phase 3 portion of phase 2/3 study with approximately 24,000 subjects in Canada, the US, the UK, Brazil, Argentina and Mexico and its results are under analysis. The data of global clinical studies and this study will be used to support an early application for approval of MT-2766 in Japan.

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-derived VLP vaccine as a new type of vaccine.

\*For details of this study, please visit Japan Regulatory of Clinical Trials website (<https://jrct.niph.go.jp/>) and enter jRCT number (jRCT2051210093) from search page to view.

### About VLP Vaccines

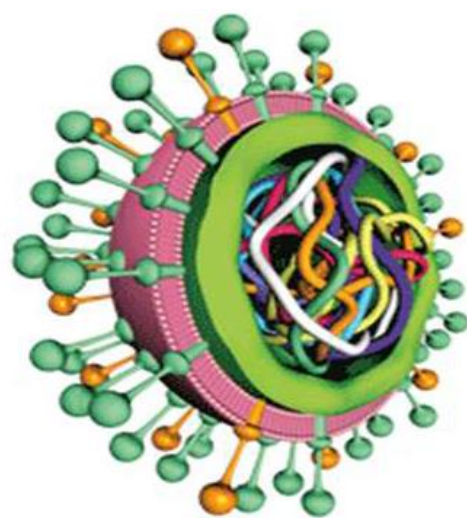
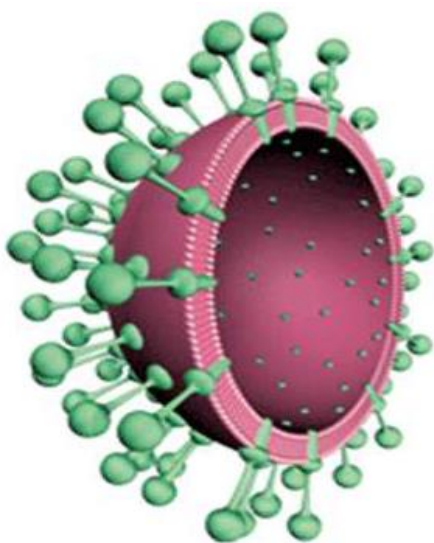
A novel vaccine using virus like particle manufacturing technology. VLP has an external structure similar to that of viruses, and are expected to induce a high immunogenicity. Since VLP does not have genetic materials, it does not proliferate in the body and is attracting attention as a promising vaccine technology with excellent safety. In addition, plant-derived VLP manufacturing technology is expected to enable mass production in a short period of time.

#### VLP

is a non-infectious and a more efficient way of presenting antigens to the immune system.

#### Common virus

with a surface antigens, lipid membrane, internal proteins and genetic materials.



## **About Medicago**

Medicago was established in 1999 as a Canadian biopharmaceutical company specializing in research and development of new vaccines using VLP technology. Medicago has unique technologies that enable the production of VLP in plant cells through genetic manipulation, and the efficient extraction and purification of VLP. Mitsubishi Tanabe Pharma, which is committed to creating new pharmaceuticals that meet unmet medical needs and building the management infrastructure to provide products to the global market, became a major shareholder in Medicago in September 2013 with the aim of further developing the vaccine business through the acquisition of new biologics technologies. Medicago is currently engaged in the development of COVID-19 and seasonal influenza vaccines and is working to contribute to the health of people around the world and the prevention of infectious diseases through the research, development, and manufacture of various vaccines utilizing its VLP technology.

## **Mitsubishi Tanabe Pharma Corporation**

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