December 7, 2021

MT-2766, Adjuvanted COVID-19 Vaccine Candidate, Showed Positive Efficacy and Safety Results in Phase 3 Study Conducted in an Environment Dominated by the Variants

Mitsubishi Tanabe Pharma Corporation (Head Office: Osaka, Japan; President & Representative Director: Hiroaki Ueno; hereinafter, "MTPC") announced today that its affliated company, Medicago Inc. (Head Office: Quebec, Canada; President: Takashi Nagao) and GlaxoSmithKline plc (Head office: London, UK,hereafter, "GSK") jointly announced positive efficacy and safety results from the Phase 3 study for a plant-based virus-like particle (VLP) vaccine (project code: MT-2766) being developed to prevent COVID-19. MT-2766 is administered with GSK's pandemic adjuvant.

With MT-2766, Medicago has completed dosing in a global Phase3 study involving over 24,000 subjects and has completed an interim analysis of this study. A summary of the results are as follows.

[Summary]

- Countries: 6 countries in total (Canada, US, UK, Mexico, Argentina, and Brazil)
- Subjects: 24,000 subjects (≥ 18 years) were randomized to MT -2766 or placebo
- Dosage and administration: Two doses of 3.75 μg of antigen combined with GSK's pandemic adjuvant intramuscularly administered 21 days apart.
- Endpoints: Efficacy and safety

[Interim Analysis Results]

- Variants (except omicron) were mainly circulating during this study period, and all cases were caused by the variants.The vaccine efficacy against all variants was 71%.
  - The efficacy against delta and gamma variants was 75.3% and 88.6%, respectively.
  - There were no alpha, lambda, or mu variants in the vaccinated group, but 12 cases in the placebo group.
- The corresponding number for people with an initial seronegative status indicating no previous exposure to COVID-19 was 75.6%.

- No related serious adverse events were observed, the reactogenicity was generally mild to moderate and transient; symptoms lasting on average only 1 to 3 days. The frequency of mild fever was low (<10%), even after the second dose.

The Independent Data Monitoring Committee (IDMC)* has recommended that the ongoing Ph3 study should continue without modification. In Canada, the application will be filed promptly. Approval in Canada would be the first approval for MT-2766. In Japan, a phase 1/2 clinical study has been ongoing since October of this year, and MTPC aims to apply for approval next spring by adding the results of the clinical study in Japan to the results obtained during the global Phase 2/3. We plan to submit applications to WHO, the US, and the UK in the future.

MT-2766 uses plant-based VLP and, if approved, would be the first plant-based VLP vaccine for use in humans in the world. In addition, it can be stored and distributed in a refrigerator (2 to 8℃).

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.

Medicago release (December 7, 2021, 7am local time)
【Medicago and GSK announce positive Phase 3 efficacy and safety results for adjuvanted plant-based COVID-19 vaccine candidate】

*Independent Data Monitoring Committee (IDMC): A committee that periodically evaluates the progress of a clinical study, safety data, and important efficacy data, and recommends to sponsors to continue, modify, or stop a study.

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