March 17, 2021

Initiatives Against COVID-19 in Canada - Initiate Phase 3 Portion of Phase 2/3 Clinical Trials and Fast Track Designation Granted by FDA -

Mitsubishi Tanabe Pharma Corporation (Head Office: Osaka, Japan; President & Representative Director; Hiroaki Ueno) announced today that its affiliated company, Medicago Inc. (Head Office: Quebec, Canada; President; Takashi Nagao) and GlaxoSmithKline (Head Office: London, United Kingdom; hereafter, "GSK") jointly announced on March 16 local time that Canadian and US regulatory authorities approved the start of Phase 3 portion of Phase 2/3 clinical trials for its plant-derived virus-like particle (VLP) vaccine candidate (project code: MT-2766) for the prevention of COVID-19 which has been developing by Medicago. In addition, MT-2766 was granted Fast Track designation* by the U.S. Food and Drug Administration (FDA) on February 17 local time.

The summaries of the Phase 3 portion of Phase 2/3 clinical trials are as follows:

[Phase 3 Portion of Phase 2/3 Clinical Trials]

■Subjects: The trial will start in Canada and the United States and enroll up to 30,000 subjects composed of healthy adults, elderly and adults with comorbidity.

■Dosage and administration: Two doses of 3.75μg VLP vaccine candidate combined with GSK's adjuvant given 21 days apart.

■Endpoints: Placebo-controlled design that will evaluate the efficacy and safety.

Mitsubishi Tanabe Pharma Group will work to develop and deliver MT-2766 to society as soon as possible, contributing even further to the prevention of COVID-19, a pressing social issue.

Medicago release (March 16, 2021, local time)
Medicago and GSK start Phase 3 trial of adjuvanted COVID-19 vaccine candidate

*The Fast Track designation allows the FDA to expedite the development and review of new drugs and vaccines intended to treat or prevent serious conditions that have the potential to address unmet medical needs.

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