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Notification of Changes in the U.S. Development Plan of VLP Vaccine for Seasonal Influenza Prevention (MT-2271) and an Impairment Loss (Non-recurring Items)

Mitsubishi Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; President & Representative Director; Hiroaki Ueno; hereafter, "MTPC") announced today the change in development plan of Virus Like Particle (VLP) vaccine for the prevention of seasonal influenza (MT-2271) in the United States which has been developed by its affiliated company, Medicago Inc. (Head Office: Quebec, Canada; CEO; Bruce D. Clark)

The phase 3 clinical studies of MT-2271 were conducted in adults (18-64 years) and elderly populations (65 years and older). MT-2271 did not meet the pre-specified success criteria of the primary endpoint in the adult population, however results demonstrated significant vaccine efficacy compared to placebo in prevention of influenza infection. Furthermore, in the clinical study in elderly population, the results met the success criteria of the primary endpoint, non-inferiority to comparative licensed egg-derived vaccine in efficacy. There were no significant issues observed in the safety of MT-2271 in both phase 3 studies. Medicago has decided to re-evaluate its licensing strategy in the United States following the FDA's decision to request an additional clinical trial and does not plan to file an application for approval of MT-2271 in the United States at this time. Following this change, MTPC has decided to write off intangible assets (in-process research and development expenses), in the amount of approximately 24 billion Japanese Yen, as an impairment loss (non-recurring items) in the fiscal year ending in March 2020.

We note MT-2271 has been accepted for review by Health Canada. The details of the clinical studies will be announced by Medicago.

Since a level of efficacy has indeed been confirmed in the clinical studies compared with a placebo or a comparator (an egg-derived vaccine), Medicago will leverage the unique advantages of its plant-based VLP platform technology and continue to develop a Quadrivalent VLP vaccine to prevent seasonal influenza. To further improve the efficacy demonstrated in these studies, Medicago started to investigate the development of the product with an adjuvant* among new development initiatives.

Medicago has successfully produced a candidate VLP vaccine against coronavirus disease 2019 (COVID-19) as announced last month. MTPC will continue to support Medicago to contribute to the early development of vaccines to prevent COVID-19 infection and explore various possibilities of VLP vaccines.

*An adjuvant is a substance that is used concomitantly to enhance or support the effects of drugs and is expected to enhance immunogenicity when administered with vaccines.

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