



October 2, 2019

**Notification of acceptance of the New Drug Submission
for Scientific Review of VLP Seasonal Influenza Vaccines
(MT-2271) by Health Canada**

Mitsubishi Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; President & Representative Director; Masayuki Mitsuka; hereafter, "MTPC") announced today that its affiliated company, Medicago Inc. (Head Office: Quebec, Canada; President & Chief Executive Officer; Bruce D. Clark) has released that Health Canada had accepted New Drug Submission for a plant-based quadrivalent Virus-Like Particle (VLP) influenza recombinant vaccine for scientific review.

Medicago release (October 1, 2019)

Medicago's New Drug Submission accepted for scientific review by Health Canada: an important step for Medicago towards the commercialization of its innovative influenza vaccine.

Medicago is preparing to apply for VLP Seasonal Influenza Vaccines(MT-2271) in the United States, following its application in Canada.

- Health Canada= Health Authorities of Canada

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PRESS RELEASE

MEDICAGO'S NEW DRUG SUBMISSION ACCEPTED FOR SCIENTIFIC REVIEW BY HEALTH CANADA:

an important step for Medicago towards commercialization of its innovative influenza vaccine.

Quebec City, Oct 01, 2019: Medicago, a biotechnology company and global leader in the development and production of plant-derived vaccines with headquarters in Quebec City, announces today that Health Canada accepted for scientific review its New Drug Submission (NDS) for a plant-based Quadrivalent Virus-Like Particle (QVLP) influenza recombinant vaccine.

"This is an important step on the road to commercialization", said Dr. Bruce Clark, President & Chief Executive Officer of Medicago. "Approval of our application will enable us to offer an innovative influenza vaccine which is manufactured using the natural metabolic capability of plants. When approved, Medicago's QVLP vaccine can provide an alternative to current licensed vaccines to help in the prevention of seasonal influenza infections" he added. Pending the regulatory review, Medicago's new vaccine could become available before the next influenza season in Canada, in 2020.

Developed in Quebec City, Medicago's technology uses the ability of natural, non-transgenic plants, serving as "mini factories", to efficiently produce recombinant proteins to generate the virus-like particles (VLP) contained in its vaccine. The recombinant technology reduces the risk of virus mutation that could occur with certain other production systems and that may impact vaccine efficacy. The VLPs are designed to mimic the influenza virus in size and shape but are not infectious since they are lacking the genetic material to replicate. Medicago's influenza development program also includes pandemic and universal flu investigational vaccines.

According to the World Health Organization (WHO), each year, influenza epidemics cause 3 to 5 million cases of severe illness and about 290,000 to 650,000 deaths around the globe. In Canada, the authorities indicate that Influenza and pneumonia are ranked among the top 10 leading causes of death with approximately 12,200 hospitalizations and 3,500 deaths each year.

In 2018, Medicago launched the construction of a new \$245 million manufacturing complex in Quebec City that will include research and development as well as production facilities. This new production factory will complement the commercial production facility in Durham, North Carolina and expand annual production capacity up to 50 million doses of quadrivalent vaccines against seasonal influenza.

About Medicago

Medicago is a biopharmaceutical company with more than 450 employees in Canada and the United States. Medicago's mission is to improve global health outcomes by leveraging innovative plant-based technologies for rapid responses to emerging global health challenges.

For more information: www.medicago.com

Source : Medicago

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