

2019年10月2日

各 位

季節性インフルエンザの予防をめざした植物由来 VLP ワクチン
(MT-2271) の承認申請受理 (カナダ) のお知らせ

田辺三菱製薬株式会社（本社：大阪市、代表取締役社長：三津家 正之）は、連結子会社であるメディカゴ社（本社：カナダ ケベック市、代表取締役：ブルース クラーク）が、季節性インフルエンザ予防の植物由来 VLP ワクチン（MT-2271）について、カナダ当局に承認申請し、このたび申請が受理されたことを発表しましたので、お知らせします。

- Medicago 社リリース（2019年10月1日付）

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.

なお、MT-2271 はメディカゴ社がカナダに続き、米国での申請準備を進めています。

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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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