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LONDON, UK (GlobalData), 10 March 2016 - A new tobacco-based seasonal influenza vaccine being developed by Mitsubishi Tanabe Pharma and currently in Phase III studies could potentially <u>rival traditional chicken egg-based vaccines</u>, as it aims to launch in the US for the 2018-19 flu season, according to an analyst with research and consulting firm GlobalData.

The technology involved in the new vaccine, which can be produced in four weeks, six times faster than egg-based methods, involves implanting influenza genetic material into tobacco leaves, a manufacturing process originally developed by Medicago, a Canadian company acquired by Mitsubishi Tanabe in 2013.

Achilleas Livieratos, Ph.D., GlobalData's Analyst covering Infectious Diseases, states that there are a number of serious limitations that come with the use of egg-based vaccines, leaving a substantial need for alternatives.

Livieratos says: "As well as taking six months to work, during which time minor genetic mutations can decrease vaccine efficacy, individuals with egg allergies cannot safely receive vaccines, leaving them vulnerable to infection.

"A number of vaccine giants including Sanofi, GlaxoSmithKline and MedImmune/AstraZeneca are also developing their vaccine portfolios. However, their current egg-based, quadrivalent, inactivated (split virus) seasonal influenza vaccines lack the manufacturing efficiency of tobacco plant-derived vaccines that can also generate virus-like particles (VLPs)."

The analyst adds that Novavax has already advanced its insect cell-based VLP seasonal influenza vaccine candidate into Phase III of clinical development, ahead of Mitsubishi Tanabe. However, important differences exist between plant-based and conventional cell culture-based production methods, as the former boasts reduced infrastructure cost and half the production

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time compared with the latter.

Livieratos continues: "Mitsubishi Tanabe's pipeline tobacco product is one of a number of VLP influenza vaccines set to take over from the traditional kind, as they represent an exciting emerging vaccine class that can generate effective and longer-lasting protection while also being amenable to a diverse array of production methods.

"Mitsubishi Tanabe will need to demonstrate strong safety data and yearly production consistency of its tobacco-based vaccine. If the company's product, or one like it, is approved, GlobalData expects a novel vaccine that boasts a rapid, plant-based manufacturing process to have a significant impact on the seasonal influenza vaccine landscape."