Vaccitech Universal flu vaccine passes Phase 2b clinical development milestones

Vaccitech initiates Phase 2b clinical studies for its MVA-NP+M1 universal flu vaccine (VTP-100) in Belgium and completes recruitment in Australia

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Vaccitech Ltd. announces that it has administered its pandemic universal influenza A vaccine MVA-NP+M1 (VTP-100) to the first participants in a Flu 010 study – a Phase 2b, randomised, double-blind, placebo controlled, influenza challenge study being conducted in Antwerp, Belgium.

In this trial, approved by both the U.S. Food and Drug Administration and Belgium Regulatory Authority, 155 participants in total will randomly receive either VTP-100 or placebo and 134 of those vaccinated will be challenged with the A/Belgium/4217/2015 (H3N2) influenza virus strain. The study will be conducted on an inpatient basis at the SGS Life Sciences quarantine facilities to assess the protective capabilities of VTP-100 as a standalone influenza vaccine for future use in pandemic or pre-pandemic situations. Results of the study are expected in early 2020. Vaccitech, through its wholly-owned subsidiary Vaccitech Australia Limited Pty, has also completed the vaccination of the planned 2,200 participants in the first year of the Flu 009 study, a double-blind, randomised, placebo-controlled phase 2b field trial in Australia. The trial has rapidly enrolled the planned target group in less than two months. Flu 009 will test the additive protective efficacy that VTP-100 may provide against influenza-like illness when administered as an adjunct to current licenced quadrivalent influenza seasonal vaccines (QIV). Nine clinical sites across Australia, under the leadership of Clinical Network Services Pty Ltd, recruited outpatients who had already received the standard of care QIV earlier in the influenza season, which typically peaks between July and October in the Southern Hemisphere. Influenza has been particularly prevalent in Australia so far this year, with a record number of viral infections confirmed to date.

Vaccitech will assess, by rates of laboratory confirmed influenza illness, whether VTP-100 + QIV offers improved efficacy over QIV given alone, and therefore represents a novel and needed add-on to underperforming seasonal influenza vaccination options. Depending on the interim results of the Flu 009 study, expected early 2020, Vaccitech will continue the trial for a second season in Australia and recruit up to 6,000 participants overall.

The influenza challenge study is co-funded by the Biomedical Advanced Research and Development Authority, a component of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services, under contract number HHSO100201900013C as part of BARDA's strategy for pandemic preparedness.

"We would like to thank BARDA and our clinical partners in Australia and Belgium who have played a critical role in progressing the clinical development of our universal influenza A vaccine. These two studies are designed to provide compelling evidence on the role that T-cells may play in protecting against influenza. We expect positive data to support the positioning of VTP-100 as a vaccine that can reduce the burden of influenza, both as a pre-pandemic intervention and as an add-on to a seasonal vaccine, especially in high risk individuals," remarked Tom Evans MD, Vaccitech's Chief Executive Officer.

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Notes to editors:

About Vaccitech's Platform and Influenza Programme

Vaccitech's VTP-100 vaccine candidate aims to prevent pandemic and seasonal influenza by eliciting broader and more durable immune protection against all "A strains" of the virus, which cannot be achieved by traditional vaccination. The vaccine consists of MVA, a replication deficient pox viral vector that has been safely tested in thousands of patients, to generate a strong immune reaction against Matrix 1 (M1) and Nucleoprotein (NP) influenza antigens. The antigens are highly conserved between influenza A viral subtypes and their intramuscular delivery in Vaccitech's MVA vector construct induces a potent cell-mediated immune response intended to reduce the likelihood of developing clinical illness from influenza. The trial is the latest in a series of studies Vaccitech has conducted to advance the medical product.

About Vaccitech and Vaccitech Australia Limited Pty

Vaccitech Ltd is a spin-out company of the University of Oxford that develops vaccines to target the biggest health risks to humanity. The company holds the rights to proprietary technology refined through over twenty years of research performed at the University's Jenner Institute, among the world's most prestigious vaccine research centre. Vaccitech is developing a vaccine platform that can elicit an unprecedented CD8+ T cell response against clinically relevant antigenic targets. The platform is applied in numerous infectious diseases and oncology programs and funded by partners that include Google Ventures and Sequoia China. Vaccitech Australia Pty is a wholly-owned subsidiary of Vaccitech Limited and is the sponsor of the FLU009 study in Australia, where it holds exclusive commercialisation rights.

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