

## Vaccitech provides update for its Phase 2 Universal Influenza studies

25 November 2019 | News

**Vaccitech progresses clinical development of Universal Influenza A Vaccine (VTP-100) in Belgium and Australia and expects top-line data in early 2020**



Vaccitech Ltd, a clinical-stage T cell immunotherapy company developing products to treat and prevent cancer and infectious diseases, reports successful recruitment and vaccination for its Universal influenza A vaccine MVA-NP+M1 (VTP-100), across two Phase 2 clinical studies, FLU009 and FLU010. Final primary endpoint data from FLU010 is expected in early 2020. The Phase 2 studies are part of a dual development pathway for VTP-100 that will address both pandemic and seasonal influenza vaccine markets.

FLU010 is a randomised, double-blind, placebo controlled, influenza challenge study conducted in Antwerp, Belgium, and co-funded by BARDA for \$8.6M. There have been 145 participants vaccinated, of which 108 were challenged with the A/Belgium/4217/2015 (H3N2) influenza virus. Another group is scheduled to be challenged by the end of year. FLU010, approved by the FDA and the Belgian Regulatory Authority, FAMHP, is designed to assess the protective capabilities of VTP-100 as a standalone influenza vaccine. The study is powered to evaluate potential correlations of vaccine-induced protection from influenza. Top-line data will read out in early 2020.

Vaccitech's wholly-owned subsidiary, Vaccitech Australia Limited Pty, also confirms that FLU009 is on track to collect a high number of influenza A positive samples from 2149 participants. The 2019 season of influenza in Australia has produced an especially high number of influenza cases and is one of the longest seasons on record. FLU009 is a single-blind, randomised, placebo-controlled Phase 2 field trial in Australia.

The study will test, by examining laboratory confirmed influenza illness, the additive protective efficacy against influenza A viruses that VTP-100 provides to that of licenced seasonal influenza vaccines. An interim analysis of results, expected early 2020, will steer Vaccitech's decision on how many participants will be recruited for a second season. It is anticipated that 3,800 participants will be the maximum number, which would give a total of 6,000 over the two influenza seasons. Approximately a quarter of the participants will be aged 65 years and over – one of the most at-risk demographic groups for influenza-related morbidity and mortality.

Bill Enright, Vaccitech Chief Executive Officer, comments, "We are pleased by the progress of both our Phase 2 clinical trials for our universal influenza vaccine and are on track to announce top line data in early 2020. There remains a pressing need

to find an effective universal vaccine across all A virus strains that can be manufactured at speed and we believe that our VTP-100 product is a potential solution to this global health issue.”

The FLU010 clinical study has been funded in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. HHSO100201900013C.