Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

Title of Trial: Safety and Immunogenicity of a Recombinant M2e-flagellin Influenza Vaccine (STF2.4xM2e) in Healthy Adults
Clinical Trial registration site if applicable: ClinicalTrials.gov
Authors/sponsors: Alan Shaw, Vaxinnate Corp

Study Design (including the phase of clinical trial): Sixty subjects 18-49 years old were enrolled in a multicenter, double-blind, randomized, placebo-controlled trial to assess vaccine doses ranging from 0.3-10 µg. An additional 16 subjects were enrolled in a second open label study to evaluate doses of 0.03 and 0.1 µg. Vaccine/placebo was given intramuscularly (i.m.) at 0 and 28 days. Clinical and laboratory safety assessments took place 1 and 7 days after immunization. Immune responses to M2e and flagellin were assessed by ELISA at 7, 14 and 28 days after each dose. Seroconversion was defined as a serum IgG anti-M2e antibody value ≥ 0.174 µg/ml and a four-fold rise in titer.

Vaccine subtype: M2 protein
Manufacturer: Vaxinnate Corp, USA
Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector): recombinant
Adjuvant: Flagellin
Delivery system/site: IM
Doses (antigen and adjuvant, number of doses, intervals between administrations): 0.3-10 µg of M2 protein fused to Flagellin, 2 doses given at day 0 and 28

Study population: health adults
Number of subjects involved: 60
Age: 18-49
Health status: Health volunteers
Special inclusion/exclusion criteria: none

Clinical Endpoints Assessed

On day of vaccination, study subjects were observed in clinic for a minimum of 30 minutes post each vaccination and 4 hours (± 60 minutes) post-dose as directed by the study physician or designate. Solicitation of local and systemic reactogenicity events were captured via clinic visits and telephone contact as applicable using standardized grading. Reactogenicity assessment also included unsolicited complaints. All local and systemic reactogenicity reporting in the 7 days after both immunizations were supported with the use of a Memory Aid that was reviewed and interpreted by medical staff. Clinic visit on Days 1, 7 (± 2), 14 (± 2), 28 (± 2) and 180 (± 7) to assess adverse events and clinical labs.

Results:
Doses of 0.03 to 1 µg were safe and well tolerated in all subjects. Doses of 0.3 and 1.0 µg were immunogenic in 18 (75%) of 24 vaccinees after the first dose and 23 (96%) after the second dose. In the 1.0 µg group, the geometric mean M2e antibody concentration was 0.4 µg/ml after the first dose and 1.7 µg/ml after the booster dose. Immune response to flagellin was robust but did not appear to interfere with M2e antibody responses after the booster dose. Following the first injection of VAX102 at higher doses (3 and 10 µg) flu-like symptoms consistent with cytokine release were noted, with the presence of elevated levels of C-reactive protein. Geometric means of M2e antibody concentrations and seroconversion rates were not significantly different among the 1, 3, and 10 µg doses (p>0.05).

Current status of the clinical trial (completed, ongoing, in preparation): completed

Date envisaged for availability of results, if not yet available: available

Planned time schedule for next phase of development: currently evaluating 1 ug i.m. compared to 2 ug s.c. in 60 subjects as final dose selection study prior to clinical efficacy study