Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

Title of Trial: Immunogenicity and Safety Study of GlaxoSmithKline (GSK) Biologicals' Influenza Vaccine(s) GSK3277510A and GSK3277509A in Adults 18 to 60 Years of Age

Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov): NCT02177734

Authors/sponsors: GlaxoSmithKline

Study Design: Randomized, Parallel Assignment, Double Blind

Vaccine: H7N9
   Manufacturer: GlaxoSmithKline
   Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector): Inactivated split
   Adjuvant: AS03
   Delivery system/site: IM

Doses (antigen and adjuvant):

Experimental: Formulation 1 Group
Subjects in this group will receive two doses of GSK3277510A H7N9 vaccine formulation 1 at a 21 day interval

Experimental: Formulation 2 Group
Subjects in this group will receive two doses of GSK3277510A H7N9 vaccine formulation 2 at a 21 day interval

Experimental: Formulation 3 Group
Subjects in this group will receive two doses of GSK3277510A H7N9 vaccine formulation 3 at a 21 day interval

Experimental: Formulation 4 Group
Subjects in this group will receive two doses of GSK3277510A H7N9 vaccine formulation 4 at a 21 day interval

Experimental: Formulation 5 Group
Subjects in this group will receive two doses of GSK3277509A H7N9 vaccine formulation 5 at a 21 day interval

Placebo Comparator: Placebo Group
Subjects in this group will receive two doses of placebo at a 21 day interval

Study population: 420 subject of 10-60 years old

Age range: Health status: Healthy

Specific inclusion criteria
•Male or female adults who are 18 to 60 years of age (inclusive) at the time of first study vaccination.
•Written informed consent obtained from subject.
•Subjects who the investigator believes can and will comply with the requirements of the protocol.
•Healthy subjects as established by medical history and physical examination.
•Access to a consistent means of telephone contact.
•For subjects who undergo a screening visit: Results of screening safety laboratory tests that figure in eligibility assessment must be within reference ranges before dosing.
• Female subjects of non-childbearing potential may be enrolled in the study.

• Female subjects of childbearing potential may be enrolled in the study, if they
  - have practiced adequate contraception for 30 days prior to vaccination, and
  - have a negative pregnancy test on the day of vaccination, and agree to continue to practice adequate
    contraception until 2 months after the last dose administered.

Clinical Endpoints Assessed:

Safety assessments:
• Humoral immune response in terms of vaccine-homologous hemagglutination inhibition (HI) antibody
  titers
• Occurrence of each solicited local symptom
• Occurrence of each solicited general symptom [ Time Frame: During a 7-day follow-up period (i.e., day of vaccination and 6 subsequent days) after each vaccination.]
• Occurrence of clinical safety laboratory abnormalities reported for samples [ Time Frame: At the Day 0, 7, 21, 28 and 42 visits. ]
• Occurrence of unsolicited adverse events (AEs) [ Time Frame: 21 days after each dose. ]
• Occurrence of Medically Attended Adverse Events (MAEs), potential Immune Mediated Diseases (pIMDs) and Serious Adverse Events (SAEs) [Active Phase

Immunogenicity assessments:
• Evaluation of adjuvant effect as assessed by vaccine-homologous hemagglutination inhibition (HI) antibody
• Humoral immune response in terms of vaccine-homologous hemagglutination inhibition (HI) antibody
  titers for plain antigen vaccine
• Humoral immune response in terms of vaccine-homologous (H7N9) HI antibody titers
• Humoral immune response in terms of vaccine-homologous (H7N9) neutralizing (MN) antibody titers. • Humoral immune response in terms of vaccine-homologous (H7N9) HI antibody titers by age stratum. [ Time Frame: GMTs, Seropositivity rates and SPR at Days 0, 21, 42 and Months 6 and 12. SCR and MGI at Days 21, 42 and Months 6 and 12.
• Humoral immune response in terms of vaccine homologous (H7N9) neutralizing (MN) antibody titers for
  each study group by age stratum (18–40 years; 41–60 years)

Results: Not yet available

Safety:

Immunogenicity

GMTs :

GMT Ratios (post:pre):

Per cent responding (4 fold or greater rise and definition for reporting):

Per cent responders at specified tite :

Others assays:

Status of trial (ongoing/completed): 2014-2017