Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

**Title of Trial**: Evaluation of adjuvanted and unadjuvanted H1N1 vaccine in the phase II clinical trial

**Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov)**: NCT00952276

**Authors/sponsors**: Dr M. Denis, Sanofi Pasteur

**Study Design**: Phase II, Randomized, double-blind trial

**Vaccine**:
- **Manufacturer**: Sanofi Pasteur
- **Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector)**: H1N1 inactivated split virion from the strain A/California/07/2009
- **Adjuvant**: AF03 or None
- **Delivery system/site**: Intramuscular injection

**Doses (antigen and adjuvant)**: 3.5 µg or 7.5 µg or 15 µg per dose. Two doses at day: 0 and 21

**Study population**: 450 subjects of 18-60 and >60 years old

**Age range**: Healthy volunteers

**Specific inclusion/exclusion criteria**:
- **Inclusion Criteria**:
  - Healthy adults aged 18 years or older on the day of inclusion
  - Informed consent has been signed and dated
  - Able to attend all scheduled visits and comply with all trial procedures
  - For a woman of child-bearing potential, use of an effective method of contraception or abstinence from at least 4 weeks prior to the first vaccination, until at least 4 weeks after last vaccination.

- **Exclusion Criteria**:
  - Known pregnancy or positive urine pregnancy test
  - Currently breastfeeding a child
  - Participation in another clinical trial investigating a vaccine, drug, medical device, or a medical procedure in the 4 weeks preceding the first trial vaccination
  - Planned participation in another clinical trial during the present trial period
  - Receipt of any vaccine in the 4 weeks preceding the trial vaccination, except for the inactivated seasonal influenza vaccine, within two weeks preceding trial vaccination
  - Planned receipt of any vaccine prior to the Day 42 blood sample
  - Receipt of blood or blood-derived products in the past 3 months which might interfere with the assessment of immune response
  - Known or suspected congenital or acquired immunodeficiency, immunosuppressive therapy such as anti-cancer chemotherapy or radiation therapy within the preceding 6 months, or long-term systemic corticosteroid therapy (prednisone or equivalent for more than 2 consecutive weeks within the past 3 months)
  - Self-reported seropositivity for Human Immunodeficiency Virus (HIV), Hepatitis B antigen, or Hepatitis C
• Known systemic hypersensitivity to any of the vaccine components, or history of a life-threatening reaction to the vaccine(s) used in the trial or to a vaccine containing any of the same substances
  • Self reported thrombocytopenia contraindicating intramuscular (IM) vaccination
  • Bleeding disorder or receipt of anticoagulants in the 3 weeks preceding inclusion contraindicating IM vaccination
  • Deprived of freedom by an administrative or court order, or in an emergency setting, or hospitalized involuntarily
  • Current alcohol abuse or drug addiction that may interfere with the subject's ability to comply with trial procedures
  • Chronic illness that in the opinion of the Investigator, is at a stage where it might interfere with trial conduct or completion
  • Employees of the Investigator or study center, with direct involvement in the proposed study or other studies under the direction of that Investigator or study center, as well as family members of the employees or the Investigator
  • Previous participation in a swine-origin A/H1N1 pandemic flu trial except if performed in 1976
  • Any confirmed case of influenza (including swine-origin A/H1N1 Influenza) since March 2009
  • Febrile illness (temperature ≥ 100.4°F [≥ 38.0°C]) or moderate or severe acute illness/infection (according to Investigator judgment) on the day of vaccination
  • Personal or family history of Guillain-Barré syndrome
  • Active neoplastic disease or a history of any hematologic malignancy
  • Known seizure/epilepsy history and/or taking anti-seizure medication
  • Receipt of psychiatric drugs. Subjects receiving a single antidepressant drug and stable for at least 3 months prior to enrollment, without decompensating symptoms will be allowed to enroll in the study
  • Any Grade 1, 2, or 3 liver function values (Alanine aminotransferase (ALT), Aspartate aminotransferase (AST), and Alkaline phosphatase) observed in blood sample taken at Screening
  • Any Grade 2 or Grade 3 laboratory abnormalities in blood sample taken at Screening
  • Receipt of any monovalent 2009 pandemic H1N1 vaccine.

Clinical Endpoints Assessed:

Safety assessments:

Immunogenicity assessments:

Results:

Safety:

Immunogenicity

GMTs:

GMT Ratios (post:pre):

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

Per cent responders at specified titre:

<table>
<thead>
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<th>Group</th>
<th>18-60y 1dose</th>
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<th>18-60y 2dose</th>
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(3.8µg+AF03) (15µg no Adj)
Others assays:

Status of trial (ongoing/completed): Completed in 2009