Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

**Title of Trial:** A Phase I clinical trial to assess safety of the Influenza Vaccine (whole virion, Inactivated) A/H1N1 (Pandemic) in Adults

**Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov):**
CTRI/2010/091/000082 (http://www.ctri.in/)

**Authors/sponsors:** Prasad Kulkarni/ Serum Institute of India Ltd

**Study Design (including the phase of clinical trial):** Phase I double-blind randomized active-controlled clinical trial

**Vaccine subtype:** H1N1 pandemic Virus: A/California/7/2009 (H1N1)v virus

**Manufacturer:** Serum Institute of India

**Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector):** Inactivated whole virion vaccine

**Adjuvant:** Aluminium hydroxide

**Delivery system/site:** Intramuscular injection

**Doses (antigen and adjuvant, number of doses, intervals between administrations):**
10µg and 15µg of viral protein per dose, Single dose on day 0.

**Study population Number of subjects involved:** 50 Age range: 18-49 yrs
**Health status:** Healthy volunteers

**Special inclusion/exclusion criteria:**

**Subject inclusion criteria**
Normal healthy adults of 18-49 years of age, willing to give consent and willing to comply with study protocol, Free of obvious health problems and agreeing for birth control measures.

**Subject exclusion criteria**
known allergy to eggs or other components of the vaccine, pregnancy, lactation, participation in other clinical trial, Chronic administration of immunosuppressants, Acute febrile illness or acute infectious disease, history of a bleeding disorder, Major congenital defects or serious chronic illness, History of H1N1 infection or influenzae vaccination, Receipt of licensed vaccine, sera and/or any blood products, Positive serology for HIV, HCV or HBsAg, History of alcoholism and/or IV drug abuse, history of GBS, Acute or chronic, disease of any system
Clinical Endpoints Assessed

Safety assessments: Vitals, solicited local and systemic reactions within 7 days, adverse events and SAEs in 42 days.

Immunogenicity assessments: None

Results
Safety:
Reactogenicity:
IIV (15 mcg): Pain (24 %), headache (8%), bodyache (8%), nausea (4%), fatigue (12%), myalgia (12%), chills (8%) and malaise (12%),

IIV (10 mcg): Pain (36 %), headache (24%), bodyache (12%), diarrhoea (4%), fatigue (8%), myalgia (24%) and malaise (4%),

SAEs: One case of Dog bite and one case of gall stone. Both resolved without sequelae and were not causally related.

Immunogenicity: Not done

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

Date envisaged for availability of results, if not yet available: 28 April 2010

Planned time schedule for next phase of development: Phase II/III