Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

**Title of Trial:** A Phase II/III clinical trial to assess safety and immunogenicity of the Influenza Vaccine (whole virion, Inactivated) A/H1N1 (Pandemic) Administered at two dose levels in Adults, Elderly and Pediatric Populations.

**Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov):**
CTRI/2010/091/000093 (http://www.ctri.in/)

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

**Study Design (including the phase of clinical trial):** Phase II/III 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, two doses on Day 0 and 21.

**Study population Number of subjects involved:** 330 **Age range:** 3yrs and above

**Health status:** Healthy children (≥ 3-17 yrs), adults (≥ 18-49 yrs) and Elderly (≥ 50 yrs)

**Special inclusion/exclusion criteria:**

**Subject inclusion criteria**
Normal healthy subjects of appropriate age (children 3-17 years; adult 18-49 years; elderly ≥ 50 years), 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, 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 in 42 days and SAEs in 90 days.

**Immunogenicity assessments:** Haemagglutination Inhibition (HI) on Day 0, 21 and 42.

**Results**

**Safety:** Awaited

**SAEs:** None

**Immunogenicity:** Awaited

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

**Date envisaged for availability of results, if not yet available:** 10 May 2010

**Planned time schedule for next phase of development:** Post licensure studies