Title of Trial: A Phase I clinical trial to assess safety of the Pandemic influenza vaccine (Human, live attenuated) A (H1N1) 2009 of SIIL in Adults.

Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov): CTRI/2010/091/000008 (http://www.ctri.in/)

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

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

Vaccine subtype: H1N1 pandemic Virus: A/California/7/2009 (H1N1)v virus
Manufacturer: Serum Institute of India Ltd

Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector): Live attenuated vaccine
Adjuvant: None
Delivery system/site: Intranasal spray
Doses (antigen and adjuvant, number of doses, intervals between administrations): $10^{7.0}EID_{50}/0.5$ ml, Single dose of 0.5 ml 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, disorder, nasal pathology, Major congenital defects or serious chronic illness, History of H1N1 infection or influenzae vaccination, Receipt of licensed vaccine, sera and/or any blood products, intra-nasal medication, 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**: Mucosal immunity and viral replication.

**Results**

**Safety:**

**Reactogenicity:**

**LAIV vaccine:** nasal discomfort (8 %), sneezing (28 %), stuffy nose (8 %), runny nose (8%), Headache (20 %), Chills (8 %), fatigue (12 %), sore throat (16 %), cough (12 %), myalgia (8 %), arthralgia (8%), irritability (8%) and Nausea (8 %)

**Placebo:** nasal discomfort (8 %), sneezing (4 %), stuffy nose (4 %), runny nose (4%), Headache (8%), fatigue (4 %), sore throat (4 %), loss of appetite (4%) and diarrhoea (8 %)

**SAEs:** None.

**Immunogenicity:** sample under testing

**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