Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

Title of Trial: A phase I, national, open, monocentric, comparative clinical trial to evaluate the immunogenicity and reactogenicity of the Cantgrip pandemic vaccine (purified monovalent inactivated flu vaccine) and Purified trivalent inactivated flu seasonal vaccine for parenteral route in adults, prepared for 2009-2010 season

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

Authors/sponsors: Roxana Dimitriu/Cantacuzino, Romania

Study Design (including the phase of clinical trial): Phase I

Vaccine subtype: H1N1 pandemic 2009 Virus: 
Manufacturer: Cantacuzino, Romania
Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector): HINI pandemic 2009 inactivated split vaccine and trivalent seasonal inactivated ivaccine (TIV)
Adjuvant: 
Delivery system/site: Intramuscular

Doses (antigen and adjuvant, number of doses, intervals between administrations):
Two vaccination schedules: 1) single dose, 2) Two doses at day 0, 21

Study population
Number of subjects involved: 280 Age range: 18-60 years and 60 years
Health status: Health volunteers
Special inclusion/exclusion criteria:

Clinical Endpoints Assessed
Safety assessments:
Immunogenicity assessments:
  immunoassay type
  HI (type of RBC used):
  NT (type of neutralization assay):
SRH

Results
Safety:
Reactogenicity:
AEs:
Vaccine Age groups: 18-60 years 60 years
H1N1
Local reactions 74% 20%
Systemic reactions 70% 59%
TIV
Local reactions No data No data
Systemic reactions 24% 0%

SAEs: None

Immunogenicity
HI:
All three CHMP criteria of immunogenicity were fulfilled by H1N1 pandemic vaccine and seasonal trivalent vaccine or NT:

**GMTs:**

**GMT Ratios (post:pre):**

Fold increase in HI after one dose:
18-60y ≥60y
86.1 40.2

Per cent responding (4 fold increase):

HI≥4 fold increase after one dose:
18-60y ≥60y
64% 95%

Per cent responders at specified titer:

HI≥40 after one dose:
18-60y ≥60y
94% 98%

**SRH:**
Per cent with titre (in mm²)

Current status of the clinical trial (completed, ongoing, in preparation): Completed in 2009

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

Planned time schedule for next phase of development: