Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

Title of Trial: Safety and immunogenicity of CSL H5N1 vaccine in elderly
Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov):
Authors/sponsors: Dr T Nolan / CSL Ltd, Australia
Study Design (including the phase of clinical trial): The Phase II prospective, double-blind, randomized trial

Vaccine subtype: H5N1 Virus: A/Vietnam/1194/2004 Manufacturer: CSL Ltd, Australia
Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector): Inactivated split vaccine
Adjuvant: AlPO4
Delivery system/site: IM
Doses (antigen and adjuvant, number of doses, intervals between administrations): Two doses on the 0 and 21 days, 30µg and 45µg of viral protein per dose

Study population Number of subjects involved: 196 Age range: 65 years
Health status: Healthy volunteers
Special inclusion/exclusion criteria:

Clinical Endpoints Assessed
Safety assessments:
Immunogenicity assessments: after the first and second doses with additional evaluation of antibody status 6 months after the second vaccination

imunoassay type
HI (type of RBC used):
NT (type of neutralization assay):
SRH

Results
Safety:
Reactogenicity after vaccination with vaccines containing 30µg of viral proteins
AEs: No AE 32%
Solicited local 43%
Solicited systemic 36%
SAEs: No EAEs
Elderly reported less frequent AEs relative to younger adults and children

Immunogenicity

HI and NT:

Per cent responding (4 fold increase):
NT≥4 fold increase after two doses in elderly =
44% (45µg+ Alum)
48% (30µg+ Alum)

Per cent responders at specified titer (seroconversion):
NT≥40 after two doses in elderly =
46% (45µg+ Alum)
49% (30µg+ Alum)

**GMT Ratios (post:pre):**
Fold increase in NT after two doses in elderly =
3.6 (45µg+ Alum)
4.2 (30µg+ Alum)

**SRH:**
Per cent with titre (in mm²): None

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

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

Planned time schedule for next phase of development: