Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

Title of Trial: CS02: Randomised double blind, placebo controlled, Phase 1 dose-escalation study of two doses in healthy adults
Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov):
Authors/sponsors: O.Kiselev /Green Hills Biothechnology
Study Design (including the phase of clinical trial): Randomised, double blind, placebo-controlled phase I,

Vaccine subtype: H5N1 Virus: GHB04L1 Manufacturer: Henogen SA, Belgium

Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector): Replication deficient attenuated intranasal delNS1 vaccine produced in Vero cells. Vaccine approach is based on deletion of NS1 pathogenicity factor inhibiting innate immune response. Due to NS1 deletion vaccine virus can be produced to high titers in Vero cells, but similar to virus like particle vaccine is replication deficient in vivo, so that virus shedding is not observed and the virus is not pathogenic.

Adjuvant: None
Delivery system/site: Intranasal
Doses (antigen and adjuvant, number of doses, intervals between administrations): two applications, $10^{5.8}, 10^{7.5}$ TCID$_{50}$

Study population: Adult Number of subjects involved: 36 Age range: 18-50 Health status: Healthy volunteers Special inclusion/exclusion criteria:

Clinical Endpoints Assessed
End of the study 24 June 2009, report is avaible at the end of July

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

Results
Safety:
Reactogenicity:
AEs:
SAEs:

Immunogenicity

HI or NT:
GMTs :
GMT Ratios (post:pre):
Per cent responding (4 fold increase):
Per cent responders at specified titer:
SRH:
Per cent with titre (in mm$^2$)

Current status of the clinical trial (completed, ongoing, in preparation): ongoing
Date envisaged for availability of results, if not yet available:

Planned time schedule for next phase of development: