Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

**Title of Trial:** Clinical evaluation in the phase II of a novel recombinant influenza vaccine candidate

**Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov):** FLU-v 002

**Authors/sponsors:** Dr Wilson Caparrós-Wanderley, CSO

**Study Design:** A randomised double-blind, placebo controlled, Phase II trial in healthy volunteers to evaluate the safety, tolerability and protective efficacy of a single S/C dose of FLU-v against live influenza challenge

**Objectives:**
To confirm the safety and tolerability of FLU-v
To determine the protective efficacy of FLU-v against challenge with an H3N2 Influenza A strain.
To determine the cross reactivity ex vivo against heterologous strains of Influenza

**Vaccine:** Recombinant
  **Manufacturer:** SEEK, UK

  **Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector):** Admixture of 4 synthetic polypeptides relevant to regions of M1, M2 and NP

  **Adjuvant:** ISA-51 or none

  **Delivery system/site:** Subcutaneous injection

**Doses (antigen and adjuvant):** 500µg per dose, single dose

**Study population:** 28 adults

  **Age range:** Healthy volunteers

  **Specific inclusion/exclusion criteria:** Enrollment: Healthy Males (age 18-45) with HAI <10 to challenge strain

**Clinical Endpoints Assessed:**
  **Safety assessments:**

  **Immunogenicity assessments:** Challenge with Influenza H3N2 A/Wisconsin/67/2005, 105.25 TCID50

**Results:**
  **Safety:** FLU-v is safe and well tolerated.

  **Immunogenicity:** A single dose of FLU-v reduces viral count and symptoms following live challenge with Influenza A. FLU-v induces cellular immune responses that recognise serologically non-cross-reactive strains of influenza

**Status of trial (ongoing/completed):** Completed in 2011