COVID-19 – Italian Medicine Agency approved a phase 1 clinical study on ReiThera vaccine in Italy

On July 24, the Italian Medicine Agency (AIFA) approved a phase 1 clinical study in Italy on the vaccine produced by ReiThera, an Italian biopharmaceutical company.

This is *a first-in-human*, open-label, dose escalation, phase 1A/1B clinical trial to assess the safety and immunogenicity of the candidate GRAd-COV2 vaccine in healthy volunteers aged 18-55 years and elderly volunteers aged 65-85 years. The vaccine will be administered intramuscularly once in time.

A total of 90 healthy volunteers are expected to be included in two cohorts with three arms each (i.e. 15 participants per arm in six arms). Each of the study arm will assess a unique dose of the candidate GRAd-COV2 in a particular population, either adults or elderlies. To minimize the risk of severe adverse event in frail subjects', enrolment of Elderlies-cohort will start after that 4-week safety results in Adults-Cohort will be available.

The study protocol has been positively evaluated by the Italian National Institute of Health (Istituto Superiore di Sanità – ISS) and obtained the approval from the National Ethical Committee for COVID.

The study is endorsed by the Ministry of Education, University and Research and by the Lazio Regional Government.

The study centres will be the National Institute for Infectious Disease "L. Spallanzani" in Rome and the Centro Ricerche Cliniche in Verona.