ReiThera Announces its GRAd-COV2 COVID-19 Vaccine Candidate is Well Tolerated and Induces Clear Immune Responses in Healthy Subjects Aged 18-55 Years

Phase 1 Trial to Advance into Elderly Subjects Aged 65-85 Years

ROME, Italy, November 24th, 2020 – ReiThera Srl, a biotech company dedicated to the technology development, GMP manufacturing and clinical translation of genetic vaccines and medicinal products for advanced therapies, today provides an update on the ongoing Phase 1 study of its vaccine candidate (GRAd-COV2) against the novel coronavirus (SARS-CoV-2). The study has been designed and is run jointly with the Lazzaro Spallanzani National Institute for Infectious Diseases (INMI) in Rome (Italy) and received financial support from the Italian Ministry of Scientific Research and the Lazio Region (Rome).

The Company reports that the trial is advancing on schedule and that dosing and initial evaluation on the first cohort of healthy volunteers (aged 18-55 years) have been completed. Preliminary results from this cohort, which was divided into three study arms of 15 subjects, have shown that GRAd-COV2 was well-tolerated and generated spike-binding antibodies and T-cell responses at all three doses tested.

The trial is now advancing to investigate GRAd-COV2 in the second set of three cohorts of healthy, elderly subjects (aged 65-85 years). Results from the trial are expected to enable the selection of a vaccine dose for further investigation in a Phase 2/3 trial.

"We are making great progress with the Phase 1 trial of GRAd-COV2 and have completed the first part of the study as planned. The initial findings have shown that the vaccine candidate is well tolerated and immunogenic against SARS-CoV-2 in younger subjects, enabling the study to advance into the next phase in elderly subjects," **said ReiThera's Chief Executive Officer, Antonella Folgori**. *"Enrolment of elderly volunteers is also proceeding well, and we look forward to reporting initial results from the overall study around year end along with our plans for larger international studies."*

Dr Folgori added: *"We are grateful to our trial partners at the Lazzaro Spallanzani in Rome and the GB Rossi University Hospital in Verona, and also to the volunteers who have come forward in great numbers to participate in the study. It truly is a collaborative effort with a shared goal."*

ReiThera produced the vaccine material for this trial using its in-house GMP manufacturing expertise and capabilities in Italy. In parallel, the Company is working with LEUKOCARE in Germany to develop a thermostable formulation of the GRAd-COV2 vaccine and with Univercells in Belgium to develop a bespoke manufacturing process to enable rapid, large-scale production of the vaccine.

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About GRAd-COV2

GRAd-COV2, the candidate vaccine against SARS-CoV-2 recently developed by ReiThera, is based on a novel and proprietary replication-defective simian (gorilla) adenoviral vector (called GRAd) encoding the full-length coronavirus spike protein (GRAd-COV2). The spike protein enables the coronavirus to enter human cells.

Simian adenoviral (SAd) vectors have been extensively used as delivery agents for genetic vaccine candidates against multiple infectious diseases, including Ebola and RSV (Respiratory Syncytial Virus), in different populations, including elderly and infants enrolled in early and late stage clinical trials to date. Preclinical and clinical evidence have demonstrated that ReiThera's vaccine technology is safe and induces robust cellular and humoral immune responses.

ReiThera's novel GRAd vector belongs to species C adenovirus that are considered the most potent vaccine carriers and has low seroprevalence in humans. This means that GRAd vaccine immunogenicity is not hampered by pre-existing anti-human adenovirus antibodies.

About the Phase 1 trial of GRAd-COV2

The Phase 1 clinical trial underway is evaluating the safety and immunogenicity of GRAd-COV2 in 90 healthy volunteers divided equally into two age cohorts: 18-55 years and 65-85 years. Each cohort is divided into three study arms of 15 volunteers who receive one of three escalating doses of GRAd-COV2. Participants will be monitored over a 24-week period.

The study is being conducted in Italy at the Lazzaro Spallanzani National Institute for Infectious Diseases (INMI) in Rome and at the GB Rossi University Hospital in Verona, with funding provided by the Italian Ministry of Scientific Research and the Lazio Region (Rome).

The primary objective of the study is to evaluate the safety and tolerability of GRAd-COV2, and to select a vaccine dose for further investigation in a Phase 2/3 trial. The secondary objective is to evaluate the vaccine's ability to induce immune responses (antibodies and T cells) against the novel SARS-CoV-2 coronavirus in volunteers.

A larger international Phase 2/3 trial is planned to commence in the coming months, pending positive interim safety and immunogenicity results of the Phase 1 trial.

About ReiThera Srl

ReiThera Srl is a biotech company dedicated to the technology development, GMP manufacturing and clinical translation of genetic vaccines and medicinal products for advanced therapies. The company's management and scientific teams have developed a highly innovative technological platform based on simian adeno-vectored vaccines against several infectious diseases, such as RSV and Ebola.

ReiThera is led by an experienced management team that has worked together for many years in previous successful enterprises, including Okairos (acquired by GSK), and has a long-standing expertise in scalable processes for viral vector manufacturing, supported by a cGMP facility inclusive of filling suite and quality control laboratories. ReiThera is also part of a pan-European consortium focused on the development and large-scale manufacture of an adeno-viral vector vaccine against COVID-19.

ReiThera has its headquarters, R&D laboratories and GMP facilities in Rome, Italy.

For further information see: www.reithera.com

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