ReiThera's COVID-19 Vaccine Candidate Enters Phase 1 Clinical Study with First Healthy Volunteer Dosed in Italy

- **GRAd-COV2 encodes the full-length spike protein of the SARS-CoV-2 coronavirus**
- **90 healthy volunteers in two age cohorts (18-55 and 65-85 years) to be enrolled in two clinical sites in Italy**
- **The Phase 1 trial is being conducted by the Lazzaro Spallanzani National Institute for Infectious Diseases under the sponsorship of ReiThera**
- **The Phase 1 trial and the manufacture of clinical material needed for the study is funded by the Italian Ministry of Scientific Research and the Lazio Region (Rome)**
- **International Phase 2/3 trial in countries with high rates of coronavirus infection planned to start late 2020, pending initial Phase 1 outcome**

ROME, Italy, August 24, 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 announces that the first healthy volunteer has been dosed in a Phase 1 study of the Company's vaccine candidate (GRAd-COV2) against the novel coronavirus (SARS-CoV-2). The Phase 1 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.

ReiThera's vaccine candidate GRAd-COV2 encodes the full-length spike protein of the SARS-CoV-2 coronavirus. The vaccine technology is based on a novel, proprietary replication-defective gorilla adenoviral (GRAd) vector, which both induced a strong humoral and cellular immune response in preclinical studies and demonstrated a good safety profile. GRAd-COV2 is expected to induce strong immune responses based on low pre-existing immunity to the vector in humans.

Vaccines based on similar simian adenoviral vectors, such as Chimpanzee adenoviral vectors (ChAd), have been evaluated in Phase 1 and 2 clinical trials in other infectious diseases and proved to be safe and immunogenic with a single-dose vaccine.

The Phase 1 clinical trial 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 will be divided into three study arms of 15 volunteers which will be administered one of three escalating doses of GRAd-COV2. Participants will be monitored over a 24-week period.

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. Interim safety and immunogenicity analysis are expected by mid Q4 2020 which will guide dose selection for Phase 2/3 studies.

A larger international Phase 2/3 trial in countries where SARS-CoV-2 is still very active is planned to commence by the end of 2020, pending positive interim safety and immunogenicity results of the Phase 1 trial.

The Phase 1 trial of GRAd-COV2 is being funded by the Italian Ministry of Scientific Research and the Lazio Region. The study is being run jointly by ReiThera and Lazzaro Spallanzani INMI using initial vaccine material manufactured at ReiThera's cGMP facility in Rome.

In parallel, ReiThera is working with LEUKOCARE in Germany to develop a thermostable GRAd-COV2 vaccine formulation and with Univercells in Belgium to develop a bespoke manufacturing process to enable rapid, large-scale production of the vaccine.

"*This study is the first important step in the clinical development of our novel GRAd-COV2 vaccine against COVID-19,*" **said ReiThera's Chief Technology Officer, Stefano Colloca**. "*We are proud to undertake this trial in Italy where the impact of COVID-19 has been felt particularly hard. The cutting-edge science behind our approach is backed by many years of pioneering research on adenoviral vector technologies with pre-clinical and clinical data generated with a single-dose vaccine in other serious infectious diseases demonstrating potent humoral and cellular immune responses. This feature makes our technology platform suitable for an outbreak situation such as COVID-19 and has clear advantages in terms of manufacturing and compliance.*"

"The launch of this Phase 1 trial demonstrates ReiThera's expertise and what can be done when stakeholders come together towards a common goal," **said ReiThera's Chief Executive Officer, Antonella Folgori**. *"We are grateful to Lazzaro Spallanzani INMI for their ongoing collaboration and to the Italian Ministry of Scientific Research and the Lazio Region for funding the trial and initial manufacturing of the GRAd-COV2 vaccine candidate. We look forward to providing important updates about the safety and immunogenicity of our vaccine candidate over the coming months, and potentially advancing into international Phase 2/3 trial later in the year."*

###

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, with more than 5,000 individuals 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 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

Media Contacts:
ReiThera Srl
Antonella Folgori, Chief Executive Officer
media@reithera.com

Citigate Dewe Rogerson – International Press
Sylvie Berrebi, Mark Swallow PhD
+44 (0) 7714306525 / +44 (0) 7903737703
reithera@citigatedewerogerson.com

GPG Associati – Italian Press
Maria Alessio Ruffo
Maria.alessio@gpg-associati.it
Cell +39 3357450537