



PRESS RELEASE

Takis and Rottapharm Biotech announce favourable preliminary results from the phase I clinical trial of COVID-eVax, a DNA-based vaccine candidate against COVID-19

September 7, 2021 – Italy – Takis and Rottapharm Biotech today announced preliminary results from the phase I clinical study conducted in Italy with COVID-eVax (the first DNA vaccine candidate against COVID-19 to reach the clinical development stage in Europe).

COVID-eVax was well tolerated and induced an immune response (humoral and/or cell-mediated response) with all tested doses (0.5 mg, 1 mg and 2 mg, administered as prime-boost regimen). The best response was observed in the group treated at the highest dose, with the induction of an immune response in up to 90% of the volunteers. Particularly relevant was the cell-mediated immune response (i.e. the immune response generated by T lymphocytes, which complements the response induced by antibodies and prevents the replication of the virus in infected human cells).

"The preliminary results are favourable," said Dr. Lucio Rovati, President and Chief Scientific Officer at Rottapharm Biotech. "We believe that the data generated in this study are a validation of the efficiency of the new technology platform of DNA vaccines, which is different from those already available, i.e. mRNA or viral vector vaccines, and potentially useful also in other therapeutic areas, such as oncology. "

However, Dr. Rovati added that it will be difficult to carry out the second part of the study (the phase II) as initially planned, due to the current high number of vaccinated people thanks to the vaccination campaigns. "We are thinking about possible alternatives: the immunogenicity profile of the vaccine, with a strong cellular immune response, is such that Covid-eVax should be tested as a third dose when the antibody response from available vaccines decreases, and in order to provide a strong boost to the immune system memory."

"We would like to express our sincere gratitude to the volunteers who participated in the study, for making themselves available to research: a great act of generosity, especially at this time when there are other vaccines available", underlines Dr. Luigi Aurisicchio, CEO and Scientific Director of Takis, hoping that the Green pass not yet granted to the volunteers will arrive in the next few days. "Special thanks also to the investigators who conducted the study, for the praiseworthy work done in the recent months: Prof. Marina Cazzaniga and Prof. Paolo Bonfanti of the San Gerardo Hospital in Monza together with the University of Milano-Bicocca for having enrolled the largest number of volunteers, Prof. Paolo Ascierio of the Pascale Institute in Naples for believing in this project since its inception, and Dr. Stefano Milleri of the Clinical Research Center in Verona for readily accepting to support the study when an acceleration was necessary; in addition thanks to Prof. Emanuele Montomoli for the exceptional openness and expertise in carrying out the immunological investigations at

the VisMederi laboratories." Dr. Aurisicchio concluded: "For the continuation of the clinical development, the funding that we have not been able to obtain so far would be necessary: after all, even the existing vaccines, despite being developed by large companies, have required important interventions by their own countries, as it is logical for vaccines against a global pandemic."

Contacts:

Takis

Dr. Luigi Aurisicchio (CEO/CSO)

aurisicchio@takisbiotech.it

Rottapharm Biotech

Dr. Federica Girolami (Business Development, Scientific Liaison and Drug Safety Director)

Tel. 346 4131428

federica.girolami@rottapharmbiotech.com

Takis

Takis is a biotechnology company created by a group of scientists formerly from Merck Research Laboratories (MRL) and it is located in Rome (Italy). The group has more than 15 years of experience and proven expertise in drug discovery in Oncology and is recognized for the design and implementation of a number of innovative technologies, including that of DNA gene therapy. One of Takis's core assets is its experience with electroporation, a technology that can be used for a variety of clinically useful applications, from vaccine development to somatic gene therapy. Takis' pipeline includes four cancer vaccine candidates based on this technology. Takis is also actively involved in the generation of humanized monoclonal antibodies for use in oncology and infectious diseases, including COVID-19.

For more information on the company, visit www.takisbiotech.it

Rottapharm Biotech

Rottapharm Biotech is a research company dedicated to the discovery and development of innovative drugs. It is located in Monza (Italy) The company expertise in research and development includes medicinal / computational chemistry for small molecules, a proprietary platform for the generation and selection of new monoclonal antibodies and the development of other biological drugs and advanced therapies, the validation of new molecular targets, the pharmacological, pharmacokinetic, toxicological and pharmaceutical characterization of new drug candidates; the design and conduct of innovative clinical trials. The company strategy is to develop its own pipeline independently and then seek partnerships with pharmaceutical companies, as well as investing in alliances on innovative projects of other biotech companies or university spin-offs.

For more information on the company, visit www.rottapharmbiotech.com