**PRESS RELEASE – FOR IMMEDIATE RELEASE**

**THE PHASE I/II CLINICAL STUDY OF THE FIRST EUROPEAN DNA VACCINE AGAINST COVID-19 HAS STARTED TODAY IN ITALY**

*March 1, 2021* - The first healthy volunteers received the initial dose of the DNA vaccine against COVID-19 (COVID-*e*Vax) designed by Takis and developed in collaboration with Rottapharm Biotech in Italy: it is the first DNA vaccine to reach the clinical stage in Europe.

Phase 1 will involve 80 healthy volunteers divided into 4 groups with different doses administered with or without booster, while Phase 2 will reach up to 240 subjects on the most promising doses.

The DNA vaccine represents an innovation compared to other technological platforms already available, such as those with messenger RNA or viral vectors. "DNA allows us to avoid the cold chain in storage and transport," said Luigi Aurisicchio, CEO and Scientific Director of Takis. "Due to its characteristics, the production of the antigen is prolonged over time and the vaccine could work well already in the first cycle. Furthermore, if necessary, the administration can be repeated several times for a more solid immune response, also thanks to the use of the electroporation technique developed by another Italian company, IGEA, which facilitates the entry of DNA into muscle cells and it also acts as an adjuvant, thus stimulating immunological processes ".

A vaccine therefore developed entirely in Italy and which also makes use of a prestigious consortium of Italian clinical centers for Phase 1 and Phase 2 of the clinical trial. In fact, the National Cancer Institute IRCCS Pascale Foundation in Naples, the National Institute of Infectious Diseases Lazzaro Spallanzani in Rome and the San Gerardo Hospital in Monza in collaboration with the University of Milan-Bicocca are participating in the study. The three clinical centers are involved in all study activities, but each has greater responsibility for one of the three main aspects of the trial.

The San Gerardo Hospital in Monza is responsible for the treatment of the first subjects in each dose and therefore for the verification of the preliminary results: the first administration took place today in the Phase 1 Research Center directed by Prof. Marina Cazzaniga, medical oncology scientist at the University of Milan-Bicocca. "The vaccine promotes the production of a very specific portion of the "Spike" protein, which the virus uses to bind to human cells" underlines Prof. Paolo Bonfanti, Director of the Infectious Diseases Unit of ASST Monza and associate professor of Infectious Diseases at the University of Milano-Bicocca “and against which, therefore, the body will trigger the immune response”.

Pascale Institute in Naples plays a decisive role in expanding the number of subjects for each dose, in order to consolidate the results. "Among other things" explains Prof. Paolo Ascierto, Director of the Unit of Melanoma, Oncological Immunotherapy and Innovative Therapies of the Pascale Institute in Naples, "the DNA vaccine can be easily and quickly modified to take into account the variants of the virus that are becoming prevalent or that may appear in the future ”.

Finally, the Spallanzani Institute in Rome is responsible for all laboratory tests that document the immune response and therefore the potential efficacy. In fact, the vaccine performed very well in laboratory tests, evoking a strong humoral and cellular immune response, which will now be confirmed in humans.

"With COVID-eVax we are demonstrating the ability of Italian Research in generating innovative solutions against the pandemic and we have asked for the collaboration of important Italian development centers" concludes Aurisicchio "We have found in Rottapharm Biotech a partner for the initial investment and support in clinical development, but financial intervention by Italian and European institutions is now required on a technology that could prove useful not only against COVID-19, but also on a series of other therapeutic indications, starting with cancer vaccines " .

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**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