



PRESS RELEASE

## **THE ITALIAN DRUG AGENCY AUTHORIZES THE PHASE I / II CLINICAL TRIAL OF COVID-eVax, THE ITALIAN VACCINE AGAINST COVID-19 BASED ON DNA TECHNOLOGY.**

*February 3, 2021* - Takis and Rottapharm Biotech announce the authorization of the clinical trial by the Italian Medicines Agency (AIFA) of COVID-eVax, the vaccine against COVID-19 designed by Takis and developed in collaboration with Rottapharm Biotech. The Phase I and II clinical trial can now start in February and will provide the first results on safety and immunogenicity about 3 months after the start of the trial.

Unlike other platforms already approved by the European Medicines Agency (EMA) such as mRNA and Adenoviral vectors, COVID-eVax is based on a DNA fragment injected into the muscle that promotes the production of a specific portion of the "Spike" protein, stimulating a strong immune reaction against the virus. The efficiency of the process is increased by the "electroporation" technique, which favors the passage of DNA inside the cells in a simple, rapid way and without side effects thanks to light and short electrical stimuli. Takis has been collaborating for years with another Italian company, IGEA, whose "electroporator" is already available throughout Europe. The three companies together are collaborating in the creation of an even more widespread system.

"The preclinical results have demonstrated the safety of the vaccine and its efficacy in inducing a powerful antibody and cellular immune response against the virus" stated Emanuele Marra, Director of the Infectious Diseases Department, and Giuseppe Roscilli, Director of the Generation and production of Monoclonal Antibodies at Takis. The phase I and II clinical study will be carried out at the National Cancer Institute IRCCS Pascale in Naples, the National Institute for Infectious Diseases Spallanzani in Rome and the San Gerardo Hospital in Monza in collaboration with the University of Milan-Bicocca.

"The authorization of AIFA represents the first important step in the development of DNA technology against COVID-19 but also for other diseases" said Luigi Aurisicchio, CEO and Scientific Director of Takis. "Among the important advantages, DNA is cheap, does not need complex formulations, can be produced on a large scale and does not need the cold chain. But above all, vaccination can be repeated over time to increase and maintain the immune response and its flexibility allows it to be easily adapted against the new variants of the virus that are emerging, should they become resistant to current vaccine therapies and therapeutic antibodies".

According to Lucio Rovati, President and Scientific Director of Rottapharm Biotech, "COVID-eVax is a vaccine that was born in Italy, is being developed in Italy with all Italian technologies, will be tested in Italy and, in case of success of clinical studies, will be produced in Italy thanks to a solid and highly competent consortium that is already working on the possible industrialization phase."

"The development of a synthetic DNA vaccine represents a further weapon for mass immunization and for the final victory over COVID-19", said Paolo Ascierio, Director of the Melanoma, Oncological Immunotherapy and Innovative Therapies Unit of the Institute Pascale of Naples and coordinator of the clinical study, together with Dr. Marina Cazzaniga and Prof. Paolo Bonfanti of the Milan-Bicocca University and Dr. Simone Lanini of the Spallanzani Institute in Rome.



"COVID-eVax was born from the passion and expertise of an Italian Biotech and a team with great experience in the development of innovative drugs, but also from an important courageous investment. However, to make this vaccine and its promising technology available to everyone, the intervention of Public institutions will be necessary to capitalize on what we have learned from this pandemic," concluded Rovati.

**For more info:**

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## **Takis**

Takis is a biotech company created by a group of scientists formerly from Merck Research Laboratories (MRL). 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 info, visit [www.takisbiotech.it](http://www.takisbiotech.it)

## **Rottapharm Biotech**

Rottapharm Biotech is a research company dedicated to the discovery and development of innovative drugs. The 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 characterization, pharmacokinetics, toxicology and pharmaceutical techniques 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 info, visit [www.rottapharmbiotech.com](http://www.rottapharmbiotech.com)