



PRESS RELEASE

DNA-BASED COVID-eVax VACCINE PROTECTS AGAINST SARS-CoV-2 IN PRECLINICAL MODELS AND IS EFFICACIOUS AGAINST VARIANTS

June 16, 2021 - Takis and Rottapharm Biotech announce the submission of the results obtained in preclinical models with the COVID-eVax vaccine, the characterization of the immune response and the levels of protection from SARS-CoV-2 infection to a leading scientific journal.

COVID-eVax is an innovative vaccine different from the others approved or under development and is the first in Europe based on the DNA platform, in synergy with the so-called "electroporation" technology, developed in collaboration with the IGEA company in Carpi, which thanks to short electrical stimuli mediates the passage of DNA inside the cells and activates the immune system. 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.

"The COVID-eVax vaccine is a "precision vaccine" because it produces only a specific portion of the "Spike" protein essential for the virus to enter our cells. The data obtained indicate a high level of safety and potential efficacy" stated Emanuele Marra, Director of the Infectious Diseases Department of Takis.

"The studies carried out show that the antibodies generated by the vaccine are able to neutralize SARS-CoV-2 and its most worrying variants to similar levels," comments Giuseppe Roscilli, Director of the generation and production of Monoclonal Antibodies, Takis.

The study is the result of an international collaboration, which sees among the protagonists the two Italian companies that are developing COVID-eVax (Takis and Rottapharm Biotech), important Italian academic institutions (Spallanzani Institute and Regina Elena Institute in Rome; INGM and San Raffaele Hospital in Milan) and foreign (University of Ulm - Germany; University of Tel Aviv - Israel; National Infection Service, Public Health England - United Kingdom).

"The data obtained in the hACE2 mouse model, which has the same receptor as humans and develops a similar disease, show protection from the virus and the absence of respiratory symptoms and clinical effects due to SARS-CoV2 infection," says Matteo Iannacone, Director of the Immune Response Dynamics Unit at the San Raffaele Hospital in Milan and Professor of General Pathology at the Vita-Salute San Raffaele University. "Thanks to competitive European funding, the results obtained in mice have been confirmed in the ferret, a widely used model for respiratory viruses and predictor of vaccine efficacy," says Fabio Palombo, Director of Cancer Vaccines at Takis. Antonella Conforti, Director at Evvixax, the veterinary spinoff of Takis, says: "We are also applying the technology in the veterinary field. In fact, SARS-CoV-2 is able to infect various animal species and it is important to prevent the emergence of new variants with vaccination, where possible."

Based on these results and many others, a phase I and II clinical trial began in March at Italian clinical centers: San Gerardo Hospital of Monza with the University of Milan-



Bicocca, the National Cancer Institute IRCCS Pascale of Naples, the National Institute on Spallanzani Infectious Diseases of Rome and the Clinical Research Center of Verona, in collaboration with the VisMederi laboratories in Siena.

"The clinical study is underway and we expect the first results on the safety and immunogenicity of the vaccine by the end of August" declares Lucio Rovati, President and Scientific Director of Rottapharm Biotech, "In the current scenario, COVID-eVax could represent an excellent tool in countries where there is currently no vaccine availability or as a booster of the immune response over time induced by other vaccine platforms."

"Never as in this historical moment have we understood how important Scientific Research is to fight the Pandemic and other diseases. In Italy we have excellent scientists with excellent ideas and skills that must be appropriately financed to make the country more competitive"- continues Iannacone.

"The COVID-eVax platform, which we have named X-eVax, where X stands for antigen "X", can be used for many other diseases, including cancer. By investing in this technological sector, in the future we will be able to generate new vaccines more quickly but also innovative gene therapies in oncology and other therapeutic sectors", concluded Luigi Aurisicchio, CEO and Scientific Director of Takis.

Link to the publication on BioRxiv:

<https://www.biorxiv.org/content/10.1101/2021.06.14.448343v1>

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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

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