

Healthcare industry BW

CureVac Receives Regulatory Approval from German and Belgian Authorities to Initiate Phase I Clinical Trial of its SARS-CoV-2 Vaccine Candidate

CureVac AG, a clinical-stage biopharmaceutical company developing a new class of transformative medicines based on optimized mRNA, today announced that the German Health Authority Paul-Ehrlich-Institute (PEI) and the Belgian Federal Agency for Medicines and Health Products (FAMHP) have approved the Phase 1 clinical trial for its vaccine program to prevent SARS-CoV-2 infection. The trial will be conducted in Germany and Belgium. First subjects will be vaccinated at the Institute for Tropical Medicine in Tübingen and the Ghent University Hospital (Belgium), the Tropical Institute of the University Hospital Munich, LMU (Germany), and the Hannover Medical School (Germany).

- *Trial will start promptly and will be conducted in Germany and Belgium*
- *Dose escalation phase to assess range of 2 µg to 8 µg*
- *Clinical supply from CureVac's GMP-certified large scale mRNA production facility in Tübingen*

CureVac's mRNA vaccine candidate utilizes nucleotides without chemical modifications in the mRNA and is designed to provide a strong and balanced activation of the immune system. The mRNA encodes the full-length spike protein of SARS-CoV-2 and is formulated with lipid nanoparticles (LNP).

The vaccine project began in early 2020 and initially focused on characterization of several potential candidates that then led to the selection of the final candidate, termed CVnCoV. This thorough selection process was based on humoral and cellular immunogenicity data, a balanced immune-response as well as speed and capability for large scale manufacturing.

The Phase 1 dose escalation clinical trial will include 168 healthy subjects between the ages of 18 to 60 and will target a dose range of 2 µg to 8 µg. Aim is to determine the optimal dose as well as to evaluate the safety and immune profile of the vaccine in humans.

"We are encouraged that we received green light from the regulatory authorities to start the clinical development of our COVID-19 candidate. During the last few months our team has put a lot of efforts into the preclinical validation of several vaccine candidates to select an optimal construct. We are confident that our early optimization work will provide a safe and effective low dose vaccine. In parallel, we are already producing large quantities of this trial medication under GMP

conditions,” says acting CEO of CureVac, Dr. Franz-Werner Haas.

Dr. Mariola Fotin-Mleczek, CureVac Chief Technology Officer, adds: “We are convinced that we are on the right track with our SARS-CoV-2 vaccine candidate. The data we generated in various animal models indicated that the vaccine candidate induces high virus neutralizing antibody titers compared to sera from patients who recovered from COVID-19 disease. Immune response induced by our vaccine candidate was well balanced and included the generation of spike protein specific T cell responses. We now look forward to confirm these results in humans.”

CureVac has received financial support for its COVID-19 vaccine development from the Coalition for Epidemic Preparedness Innovations (CEPI).

About CureVac’s mRNA technology platform

CureVac’s mRNA technology platform has shown potential in the development and production of mRNA based vaccines and therapeutics. CureVac’s RNAoptimizer platform aims to optimize the properties of mRNA medicines based on its three core pillars: protein design, mRNA optimization and mRNA delivery. The technology can be tailored to induce varying degrees of immune responses against specific protein antigens of choice, potentially providing potent prophylactic vaccines for the prevention of infectious diseases, such as Rabies, as well as immunotherapies for the treatment of cancer. The technology can also be adapted to avoid immune activation for purposes of protein therapy and antibodies, thereby providing potential new therapeutic modalities for patients suffering from a vast range of diseases.

About CureVac AG

CureVac is a leading clinical stage biotechnology company in the field of messenger RNA (mRNA) technology with 20 years of expertise in developing and optimizing this versatile molecule for medical purposes. The principle of CureVac's proprietary technology is the use of mRNA as a data carrier to instruct the human body to produce its own proteins capable of fighting a wide range of diseases. The company applies its technologies for the development of cancer therapies, antibody therapies, the treatment of rare diseases, and prophylactic vaccines. CureVac has received significant investments, amongst others from dievini Hopp BioTech holding and the Bill & Melinda Gates Foundation. On June 15, the German Federal Ministry of Economics and Energy announced its commitment to invest 300 million Euros in CureVac through the Kreditanstalt für Wiederaufbau (KfW). CureVac has also entered into collaborations with multinational corporations and organizations, including Boehringer Ingelheim, Eli Lilly & Co, Genmab, CRISPR Therapeutics, the Bill & Melinda Gates Foundation, CEPI and others. CureVac is headquartered in Tübingen, Germany with sites in Frankfurt and Boston, USA.

For more information, please visit www.curevac.com or follow us on Twitter at [@CureVacAG](https://twitter.com/CureVacAG).



CureVac as a pioneer of mRNA technology

What is behind the novel COVID-19 vaccine?

All eyes are on vaccines against the coronavirus. The Tübingen-based company CureVac is doing pioneering work in this field, and intends to initiate clinical testing of its lead vaccine candidate in June. At the same time, Curevac is manufacturing the material for this vaccine candidate. But that's not all: the novel mRNA technology also has the potential to revolutionise the treatment of cancer and metabolic diseases. What makes the method so special?

Press release

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Further information

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German Federal Government invests 300 Million Euros in CureVac

The German Federal Minister for Economic Affairs and Energy, Peter Altmaier, and Dietmar Hopp, SAP co-founder and co-founder of the investment company dievini Hopp BioTech holding GmbH & Co. KG, announced today that the Federal Republic of Germany will invest 300 million Euros in the biopharmaceutical company CureVac AG, a pioneer in the preclinical and clinical development of mRNA-based drugs.