Website address:
https://www.gesundheitsindustrie-bw.de/en/article/press-release/curevac-starts-phase-1-clinical-study-modified-omicron-targeting-covid-19-vaccine-candidate

CureVac Starts Phase 1 Clinical Study of Modified, Omicron-Targeting COVID-19 Vaccine Candidate

Phase 1 dose-escalation study to be conducted at clinical sites in the U.S., the UK, Australia, and the Philippines. Milestone demonstrates CureVac's continued execution on comprehensive clinical program of second-generation vaccine candidates for infectious diseases.

CureVac N.V. (Nasdaq: CVAC), a global biopharmaceutical company developing a new class of transformative medicines based on messenger ribonucleic acid ("mRNA"), today announced the start of a Phase 1 study of the modified COVID-19 mRNA vaccine candidate CV0501, administered as a booster dose to previous COVID-19 vaccination. Developed in collaboration with GSK, CV0501 is based on CureVac's second-generation mRNA backbone and is designed to specifically protect against the Omicron variant.

"Licensed COVID-19 vaccines that encode for the original virus variant, continue to protect against severe disease and hospitalization, but they are increasingly challenged by immune evasion of new variants such as Omicron," said CureVac interim Chief Development Officer Dr. Ulrike Gnad-Vogt. "As we extend the clinical studies of our second-generation backbone into modified mRNA, targeting the Omicron variant will further explore the full potential of our improved second-generation design as a booster vaccination for a relevant variant."

The CV0501 study follows the start of a Phase 1 study in March 2022 that evaluates an unmodified second-generation COVID-19 vaccine candidate CV2CoV, encoding for the original virus variant. The comprehensive approach to evaluate both an unmodified and a modified, second-generation vaccine candidate against COVID-19 is expected to identify the best-performing candidate for later-stage clinical development. In line with this approach, data from both studies are expected to be reported as a combined data set.

The Phase 1 dose-escalation study will be conducted at clinical sites in the U.S., the UK, Australia, and the Philippines and is expected to enroll up to 180 healthy, COVID-19-vaccinated adults to evaluate the safety, reactogenicity and immunogenicity of a single booster dose of CV0501 in the dose range of 12µg to 50µg. Additional dose levels below 12µg and above 50µg may be evaluated if supported by safety and immunogenicity data at these dose levels.

COVID-19 studies are being conducted alongside CureVac and GSK's jointly developed influenza vaccine program, in which clinical evaluation of the unmodified seasonal influenza candidate CVSQIV and the modified candidate FLU SV mRNA have similarly been initiated.

The CureVac-GSK infectious disease collaboration was first announced in July 2020. It focuses on the development of new products based on CureVac's mRNA technology for different targets in the field of infectious diseases. The collaboration was extended in February 2021 to also include jointly developed vaccine candidates for COVID-19. In 2022, the companies broadened their development strategy to test modified mRNA technologies in addition to unmodified mRNA.

Press release

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Source: CureVac AG

Further information

- CureVac AG