

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*

TÜBINGEN, Germany/ BOSTON, USA – August 18, 2022 – 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.

About CV0501

CV0501 is CureVac's first COVID-19 vaccine candidate applying chemically modified mRNA from the COVID-19 vaccine program developed in collaboration with GSK. It is based on CureVac's advanced second-generation mRNA backbone. CV0501 encodes for the prefusion stabilized full-length spike protein of the SARS-CoV-2 Omicron variant and is formulated within lipid nanoparticles (LNPs). As for all vaccines candidates applying the second-generation mRNA backbone, CV0501 was designed with specifically optimized non-coding regions to exhibit improved mRNA translation for increased and extended protein expression compared to the first-generation mRNA backbone. A clinical study testing the use of an unmodified mRNA candidate, CV2CoV, in SARS-CoV-2 is currently being conducted in the U.S.

About CureVac

CureVac (Nasdaq: CVAC) is a global biopharmaceutical company in the field of messenger RNA (mRNA) technology, with more than 20 years of expertise in developing, optimizing, and manufacturing this versatile biological molecule for medical purposes. The principle of CureVac's proprietary technology is the use of optimized mRNA as a data carrier to instruct the human body to produce its own proteins capable of fighting a broad range of diseases. In July 2020, CureVac entered in a collaboration with GSK to jointly develop new products in prophylactic vaccines for infectious diseases based on CureVac's second-generation mRNA technology. This collaboration was later extended to the development of second-generation COVID-19 vaccine candidates, and modified mRNA vaccine technologies. Based on its proprietary technology, CureVac has built a deep clinical pipeline across the areas of prophylactic vaccines, cancer therapies, antibody therapies, and the treatment of rare diseases. CureVac N.V. has its headquarters in Tübingen, Germany, and has more than 1,000 employees across its sites in Germany, the Netherlands, Belgium, Switzerland and the U.S. Further information can be found at www.curevac.com.

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Forward-Looking Statements CureVac

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For further information, please reference the company’s reports and documents filed with the U.S. Securities and Exchange Commission (SEC). You may get these documents by visiting EDGAR on the SEC website at www.sec.gov.