CureVac and the University Medical Center Mainz Start Phase 3 Clinical Trial for COVID-19 Vaccine Candidate, CVnCoV, in Healthcare Workers

- Study to assess safety and immunogenicity of CVnCoV in high-risk population group
- Study builds on observational epidemiological study

TÜBINGEN, Germany/ BOSTON, USA – December 21, 2020 – CureVac N.V. (Nasdaq: CVAC), a global clinical-stage biopharmaceutical company developing a new class of transformative medicines based on messenger ribonucleic acid (mRNA), announced today that the first participant in a clinical Phase 3 study with its COVID-19 vaccine, CVnCoV, in healthcare workers at the University Medical Center Mainz will be vaccinated on December 22, 2020. The study aims to evaluate the safety and immunogenicity of CVnCoV administered as a two-dose schedule of 12 µg. The trial follows an epidemiological, non-interventional study conducted with healthcare workers from the University Hospital in Mainz.

“With this clinical study in healthcare workers, we aim to investigate the difference our vaccine candidate can make in this specific group of individuals who are at particularly high risk of potential infection due to viral exposure,” said Dr. Lidia Oostvogels, Head of Infectious Diseases of CureVac. “Based on this trial, we hope to gain additional insights for effective prevention of COVID-19 in this vulnerable population.”

The randomized, observer blind, placebo-controlled clinical Phase 3 study will include more than 2,500 subjects, 18 years of age and older, who will be randomized into this study out of the non-interventional trial. It complements the recent initiation of CureVacs global pivotal Phase 2b/3 trial, HERALD, for CVnCoV in more than 35,000 participants.

The Phase 3 study builds on a non-interventional study on COVID-19 at the University Hospital Mainz involving 3,600 hospital employees, including medicine and dentistry students in their 5th semester or higher. The study has been ongoing for several months and investigates the distribution (epidemiology) of COVID-19 in a collective of employees of a University Hospital. It focuses on the rate at which SARS-CoV-2-specific antibodies arise and can be detected in hospital employees as well as the frequency of virologically confirmed COVID-19 cases in this cohort of hospital employees.

About CVnCoV
CureVac began development of its mRNA-based COVID-19 vaccine candidate in January 2020. The compound is an optimized, non-chemically modified mRNA, encoding the prefusion stabilized full-length spike protein of the SARS-CoV-2 virus. Phase 1 and 2a clinical trials of CVnCoV began in June and September 2020, respectively. Phase 1 interim data reported in November 2020 showed that CVnCoV was generally well tolerated across all tested doses and induced strong antibody responses in addition to first indication of T cell activation. The quality of immune response was comparable to recovered COVID-19 patients, closely mimicking the immune response after natural COVID-19
infection. The data support CureVac’s decision to advance a 12µg dose in its pivotal Phase 2b/3 study. Clinical trial material is provided by the company’s substantial production capacities for mRNA vaccines at its headquarters in Tübingen, supported by the current expansion of manufacturing capacities in Europe to allow for broad-scale manufacturing of CVnCoV for potential commercial supply preparedness.

About CureVac
CureVac is a global clinical-stage biopharmaceutical company in the field of messenger RNA (mRNA) technology, with more than 20 years of expertise in developing and optimizing the versatile biological molecule for medical purposes. The principle of CureVac's proprietary technology is the use of non-chemically modified mRNA as a data carrier to instruct the human body to produce its own proteins capable of fighting a broad range of diseases. Based on its proprietary technology, the company has built a deep clinical pipeline across the areas of prophylactic vaccines, cancer therapies, antibody therapies, and the treatment of rare diseases. CureVac had its initial public offering on the New York Nasdaq in August 2020. It is headquartered in Tübingen, Germany, and employs more than 500 people at its sites in Tübingen, Frankfurt, and Boston, USA. Further information can be found at www.curevac.com.

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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.