



CureVac Commences Global Pivotal Phase 2b/3 Trial for COVID-19 Vaccine Candidate, CVnCoV

- *First individual enrolled in Phase 2b/3 study to assess efficacy and safety of CVnCoV at 12 µg*
- *Study expected to enroll more than 35,000 participants, focusing on Europe and Latin America*

TÜBINGEN, Germany/ BOSTON, USA – December 14, 2020 – CureVac N.V. (Nasdaq: CVAC), a clinical-stage biopharmaceutical company developing a new class of transformative medicines based on messenger ribonucleic acid (mRNA), announced today that it has enrolled the first participant in the pivotal Phase 2b/3 study of its mRNA vaccine candidate, CVnCoV, against COVID-19. The randomized, observer blind, placebo-controlled Phase 2b/3 trial called HERALD will assess the safety and efficacy of CVnCoV in adults at a dose of 12 µg. The study is expected to include more than 35,000 participants at sites in Europe and Latin America.

“With the start of the pivotal Phase 2b/3 study, we have reached another important milestone in the development of our vaccine candidate, CVnCoV,” said Dr. Franz-Werner Haas, CEO of CureVac. “The clinical safety and immunogenicity data achieved to date look promising and we are hopeful that this trial will continue to demonstrate the impact of mRNA technology and our vaccine to prevent COVID-19, and to help defeat this pandemic.”

The HERALD trial will start with an initial Phase 2b part, which is expected to seamlessly merge into a Phase 3 efficacy trial. Subjects 18 years of age or older will be enrolled at multiple sites and will receive a two-dose schedule of either SARS-CoV-2 or placebo.

Besides the primary safety objective, the study design includes two primary efficacy objectives: the demonstration of the efficacy of CVnCoV in preventing first episodes of confirmed cases of COVID-19 of any severity, as well as preventing moderate to severe confirmed cases of COVID-19 in participants who have never been infected with SARS-CoV-2.

Efficacy of CVnCoV will be assessed by an event-driven analysis based on a certain number of participants who present with laboratory confirmed symptomatic COVID-19 disease during the study. To ensure continued and close safety monitoring of the participants in the trial, data will be reviewed by an independent Data Safety Monitoring Board on a regular basis.

Following completion of the trial, subjects will continue to be monitored in a 1-year extension study. The extension study will collect additional data to evaluate long-term safety, persistence of antibodies to SARS-CoV-2 and the occurrence of COVID-19 cases to assess the duration of vaccine efficacy.

The study will be conducted in compliance with the requirements of the ethical principles that have their origin in the Declaration of Helsinki and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). A detailed outline of the study is available at

clinicaltrials.gov (Identifier: NCT04652102) and the full study protocol can be viewed on the CureVac website.

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 supported 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.