CureVac Initiates Rolling Submission With European Medicines Agency for COVID-19 Vaccine Candidate, CVnCoV

- Rolling submission with EMA initiated to accelerate time to potential marketing authorization of CVnCoV
- Submission of CVnCoV pre-clinical data package marks start of the rolling process

TÜBINGEN, Germany/ BOSTON, USA – February 12, 2021 – CureVac N.V. (Nasdaq: CVAC), a global biopharmaceutical company developing a new class of transformative medicines based on messenger ribonucleic acid (mRNA), today announced initiation of a rolling submission with the European Medicines Agency (EMA) for CVnCoV, the company’s mRNA-based COVID-19 vaccine candidate, currently in late-stage clinical testing. The process was initiated when the first data package consisting of CVnCoV pre-clinical data was submitted to EMA and passed the technical validation.

“We are confident in the potential of our mRNA technology to contribute to the fight against the global public health emergency that is COVID-19,” said Dr. Lidia Oostvogels, Vice President Area Head Infectious Diseases at CureVac. “Working together with the EMA to initiate a rolling regulatory process is a critical step in enabling potential access to our vaccine by the many people who still need protection from this deadly disease.”

The rolling submission represents a time-optimized route to provide and review all necessary data needed for a potential market authorization during a public health emergency. Over the course of the rolling submission process, EMA will assess CVnCoV’s compliance with standards for vaccine efficacy, safety, and pharmaceutical quality on the basis of individually submitted data packages as a prerequisite for a formal market authorization application.

CVnCoV is currently being investigated in a randomized, observer blind, placebo-controlled Phase 2b/3 clinical trial called HERALD in healthy adults at a dose of 12 µg at sites in Europe and Latin America.

About CVnCoV
CureVac began development of its mRNA-based COVID-19 vaccine candidate in January 2020. The vaccine is an optimized, non-chemically modified mRNA, encoding the prefusion stabilized full-length spike protein of the SARS-CoV-2 virus, and formulated within Lipid Nano Particles (LNPs). 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 into its current pivotal Phase 2b/3 study, the HERALD study, which started in December 2020. 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, allowing broad-scale manufacturing of CVnCoV for potential commercial supply preparedness.

About CureVac
CureVac is a global 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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Forward-Looking Statements
This press release contains statements that constitute “forward looking statements” as that term is defined in the United States Private Securities Litigation Reform Act of 1995, including statements that express the opinions, expectations, beliefs, plans, objectives, assumptions or projections of CureVac (the “company”) regarding future events or future results, in contrast with statements that reflect historical facts. Examples include discussion of the potential efficacy of the company’s vaccine and treatment candidates and the company’s strategies, financing plans, growth opportunities and market growth. In some cases, you can identify such forward-looking statements by terminology such as “anticipate,” “intend,” “believe,” “estimate,” “plan,” “seek,” “project,” or “expect,” “may,” “will,” “would,” “could,” “potential,” “intend,” or “should,” the negative of these terms or similar expressions. Forward-looking statements are based on management’s current beliefs and assumptions and on information currently available to the company. However, these forward-looking statements are not a guarantee of the company’s performance, and you should not place undue reliance on such statements. Forward-looking statements are subject to many risks, uncertainties and other variable circumstances, including negative
worldwide economic conditions and ongoing instability and volatility in the worldwide financial markets, ability to obtain funding, ability to conduct current and future preclinical studies and clinical trials, the timing, expense and uncertainty of regulatory approval, reliance on third parties and collaboration partners, ability to commercialize products, ability to manufacture any products, possible changes in current and proposed legislation, regulations and governmental policies, pressures from increasing competition and consolidation in the company’s industry, the effects of the COVID-19 pandemic on the company’s business and results of operations, ability to manage growth, reliance on key personnel, reliance on intellectual property protection, ability to provide for patient safety, and fluctuations of operating results due to the effect of exchange rates or other factors. Such risks and uncertainties may cause the statements to be inaccurate and readers are cautioned not to place undue reliance on such statements. Many of these risks are outside of the company’s control and could cause its actual results to differ materially from those it thought would occur. The forward-looking statements included in this press release are made only as of the date hereof. The company does not undertake, and specifically declines, any obligation to update any such statements or to publicly announce the results of any revisions to any such statements to reflect future events or developments, except as required by law.

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.