# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

# FORM 6-K

## REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 OF THE SECURITIES EXCHANGE ACT OF 1934

For the month of March, 2021

Commission File Number: 001-39446

# CureVac N.V.

(Exact Name of Registrant as Specified in Its Charter)

Friedrich-Miescher-Strasse 15, 72076 Tübingen, Germany +49 7071 9883 0

(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:						
	Form 20-F	$\boxtimes$	Form 40-F			
Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):						
	Yes		No	$\boxtimes$		
Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):						
	Yes		No	$\boxtimes$		
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On March 22, 2021, CureVac N.V. (the "Company") issued a press release announcing its plans to expand and further specify the protocols of the ongoing late-stage clinical trials of its COVID-19 vaccine candidate, CVnCoV.

The information in this Form 6-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act.

## **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CUREVAC N.V.

By: /s/ Franz-Werner Haas, LLD, LLM

Chief Executive Officer

Date: March 22, 2021

## EXHIBIT INDEX

EXHIBIT NO. DESCRIPTION

99.1 CureVac N.V. Press Release dated March 22, 2021.



# CureVac Expands CVnCoV Covid-19 Vaccine Candidate Clinical Trial Analyses to Include Phase 3 Variant Specification and Efficacy Secondary Endpoint to Phase 2a

- · Impact of new SARS-CoV-2 variants supports specification of select strains for anticipated case-driven interim analysis in pivotal Phase 2b/3 study
- · Progress in Phase 2a trial in older adults in Peru and Panama enables addition of secondary vaccine efficacy endpoint
- · CureVac reaffirms intention to apply for formal market authorization in Q2 2021

**TÜBINGEN, Germany/ BOSTON, USA – March 22, 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 plans to expand and further specify the protocols of its ongoing late-stage clinical trials with CVnCoV, its COVID-19 vaccine candidate.

CVnCoV efficacy is currently being evaluated in the pivotal HERALD Phase 2b/3 trial in Europe and Latin America. Rapid distribution of new virus variants in the countries where the study is conducted supports the need for further analysis specification for the anticipated case-driven interim analysis. This will allow to determine efficacy of the vaccine candidate for select variants. The company has ongoing discussions with the European Medicines Agency (EMA) to potentially include an amendment related to select virus strains in the study.

For its Phase 2a dose-confirmation trial in older adults in Peru and Panama, CureVac has submitted a protocol amendment to include a secondary objective for vaccine efficacy. The study initially aimed to evaluate safety, reactogenicity and immunogenicity of CVnCoV in adults. Expanded trial analysis is expected to allow for collection of relevant efficacy data which includes the important group of approximately 270 participants above the age of 60, treated with 12µg of CVnCoV.

"Our goal is to offer the public and especially the vulnerable older age groups the best possible protection against the virus and its variants with our vaccine candidate", said Ulrike Gnad-Vogt, Interim Chief Development Officer of CureVac. "The additional efficacy analysis in Phase 2a is intended to leverage the data we can collect from older adults, and will represent important complementary data to the statistically relevant efficacy data from our HERALD trial. At the same time we need to make sure that our efficacy data are meaningful in view of the emergence of new virus variants. We are therefore aiming to specify what type of virus we are dealing with in the HERALD trial."

CureVac expects data readouts from both clinical trials in the second quarter 2021. It also reaffirms its intention to file for formal marketing authorization within the second quarter 2021.

#### About CVnCoV

CureVac began development of its mRNA-based COVID-19 vaccine candidates in January 2020. The vaccine candidate chosen first for clinical development, CVnCoV, 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 Nanoparticles (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. In December 2020 CureVac initiated a pivotal Phase 2b/3, the HERALD study, with a 12µg dose of CVnCoV. In February 2021 CureVac initiated a rolling submission with the European Medicines Agency (EMA) for CVnCoV.

CureVac has entered into several strategic partnerships for the further development, production and commercialization of CVnCoV. The company signed a collaboration agreement with Bayer in January 2021 with regards to CureVac's current vaccine candidate CVnCoV. In February 2021 CureVac and the British pharmaceutical company GlaxoSmithKline (GSK) agreed to jointly develop next-generation multi-valent mRNA vaccines against COVID-19. The development of new vaccine candidates is strengthened by a partnership with the UK Government and its Vaccines Taskforce, which CureVac also entered in February 2021. GSK will also potentially contribute to this collaboration. Clinical trial and commercial 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 the Phase 2a Clinical Trial**

CureVac started its Phase 2a Clinical Trial with CVnCoV at the end of September 2020. The dose-confirmation study has been conducted in Peru and Panama and enrolled a total of 670 participants in two distinct groups: older adults ages 61 and above, and younger participants 18 to 60 years old. The participants received two vaccinations at intervals of 28 days with the aim to evaluate safety, reactogenicity and immunogenicity in healthy adults.

#### **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 600 people at its sites in Tübingen, Frankfurt, and Boston, USA. Further information can be found at <a href="https://www.curevac.com">www.curevac.com</a>.

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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. Forwardlooking 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. Forwardlooking 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 <a href="https://www.sec.gov">www.sec.gov</a>