# 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 January 2023

**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 m	lark whether the registrant files or wi	ill 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	X

On January 30, 2023, CureVac N.V. (the "Company") issued a press release announcing positive extended preliminary data in older adults from ongoing Phase 1 clinical programs in COVID-19 and seasonal flu.

The information included in this Form 6-K (including Exhibit 99.1 and 99.2, but excluding the statements of the Company's Chief Executive Officer contained in Exhibit 99.1 hereto) is hereby incorporated by reference into the Company's Registration Statement on Form F-3 (File No. 333-259613).

#### 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: January 30, 2023

EXHIBIT NO.	DESCRIPTION
<u>99.1</u>	CureVac N.V. Press Release dated January 30, 2023.
<u>99.2</u>	Presentation entitled "Extended Preliminary Phase 1 Data from Joint COVID-19 and FlumRNA Vaccine Development Programs".



#### CureVac Announces Positive Data in Older Adults from COVID-19 and Flu mRNA Vaccine Development Programs

- Continued technology platform validation with extended preliminary data from older adults in ongoing Phase 1 studies in COVID-19 and flu
- COVID-19: monovalent modified mRNA construct CV0501 successfully boosted antibody titers against BA.1 and ancestral variants in adults age ≥65
- Flu: monovalent modified mRNA construct Flu-SV-mRNA elicited antibodies approximately 2.3 times those of licensed vaccine comparator in adults aged 60-80
- Reaffirming plan to advance modified mRNA COVID-19 and flu candidates to the next stages of clinical development in collaboration with GSK in 2023

**TÜBINGEN, Germany/ BOSTON, USA – January 30, 2023** – CureVac N.V. (Nasdaq: CVAC), a global biopharmaceutical company developing a new class of transformative medicines based on messenger ribonucleic acid ("mRNA"), today announced positive extended preliminary data from ongoing Phase 1 clinical programs in COVID-19 and seasonal flu conducted in collaboration with GSK. The newly reported data focus on older adult age groups in both indications. Detailed data can be reviewed in the associated presentation. The data further support the decision to advance updated versions of the modified mRNA COVID-19 and flu vaccine constructs to the next stage of clinical testing in 2023.

"The exciting preliminary data seen among older adults for our COVID-19 and flu programs significantly add to the validation of our technology platform into this highly relevant and at-risk population," said Franz-Werner Haas, Chief Executive Officer of CureVac. "The strong immune responses we observed in both indications further support our commitment to advancing to the next stage of product development in 2023."

#### **COVID-19 Program**

Newly reported immunogenicity data from CV0501 in older adults (age  $\geq$ 65) are based on the fully recruited dose groups of 12, 25 and 50µg, consisting of 10 subjects per dose. They show relevant titers of neutralizing antibodies beginning at the lowest tested dose. On day 29 at the 12µg dose level, CV0501 generated a ratio of post-boost to pre-boost serum neutralizing titers against BA.1 of 13.3.

While CV0501 encodes the Omicron BA.1 variant, a Phase 2 clinical study, expected to start later in 2023, will assess monovalent and/or bivalent vaccine candidates designed to target clinically relevant variants.

#### **Seasonal Flu Program**

A single dose of Flu-SV-mRNA (dose level undisclosed) was assessed for safety and reactogenicity in older adults (age 60-80) and was observed to be safe and well tolerated with no grade 3 adverse events in the 32 subjects who were administered the mRNA construct. Immunogenicity of Flu-SV-mRNA was assessed in parallel with a licensed seasonal flu vaccine comparator. Adjusted geometric mean hemagglutinin inhibition antibody titers elicited by Flu-SVmRNA in older adults were approximately 2.3 times those elicited by the licensed vaccine comparator. In the same age group, the percentage of subjects achieving seroconversion<sup>1</sup>) was 89.7% for Flu-SV-mRNA and 56.2% for the licensed flu vaccine comparator. The vaccine candidate for future clinical development is expected to target all four flu virus strains currently recommended by the WHO for influenza vaccines. A Phase 1/2 study for multivalent vaccine candidates is expected to start around mid-2023.

Previously discussed preliminary results in younger adults for the COVID-19 and flu programs can be reviewed via the conference call and webcast materials archived on January 6, 2023, on the Events section on the CureVac homepage.

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 in addition to unmodified mRNA.

#### About CV0501

CV0501 is the 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 the prefusion stabilized full-length spike protein of the SARS-CoV-2 Omicron variant BA.1 and is formulated with lipid nanoparticles (LNPs). As for all vaccine candidates applying the second-generation mRNA backbone, CV0501 was designed with specifically optimized non-coding regions aiming to deliver improved mRNA translation for increased and extended protein expression compared to the first-generation mRNA backbone. The ongoing Phase 1 dose-escalation study is assessing the safety, reactogenicity and immunogenicity of CV0501 as a booster vaccination in the dose range of 12 to a potential maximum of 200µg in the predefined age groups of 18-64 years and  $\geq$ 65 years. It is expected to also test additional cohorts at a 3 and 6µg dose level. The study is being conducted in the U.S., Australia, and the Philippines and is expected to enroll up to 180 healthy participants. Data provided in this press release represent preliminary data prior to database lock. Neutralizing antibodies were evaluated using a pseudo-typed neutralization assay.

#### About FLU-SV-mRNA

FLU-SV-mRNA is the first flu vaccine candidate applying modified mRNA from the infectious disease mRNA vaccine program developed in collaboration with GSK. It is based on CureVac's advanced second-generation mRNA backbone. The monovalent candidate encodes for the hemagglutinin (HA) protein from the A/Wisconsin/588/2019 (H1N1)pdm09-like virus based on the recommendations of the World Health Organization (WHO) for the Northern Hemisphere 2021-22 season. The ongoing Phase 1 dose-escalation study is assessing the safety, reactogenicity and immunogenicity of the monovalent candidate as a booster vaccination in up to five dose levels in the range of 2 to 54µg in the predefined age groups of 18-45 years and 60-80 years. It includes a licensed flu vaccine as an active comparator. The study is being conducted in Canada, Spain and Belgium and is fully enrolled with 198 healthy participants. The extended data provided in this press release represent cleaned data prior to database lock.

<sup>&</sup>lt;sup>1)</sup> Defined as the percentage of participants who either have a HI pre-dose antibody titer < 1:10 and a post-dose titer  $\ge$  1:40 or a pre-dose HI antibody titer  $\ge$  1:10 and at least a 4-fold increase in post-dose titer.

#### 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

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 N.V. and/or its wholly owned subsidiaries CureVac SE, CureVac Manufacturing GmbH, CureVac Inc., CureVac Swiss AG, CureVac Corporate Services GmbH, CureVac RNA Printer GmbH, CureVac Belgium SA and CureVac Netherlands B.V. (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 <u>www.sec.gov.</u>

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# Forward-Looking Statements



The information set forth herein does not purport to be complete or to contain all of the information you may desire. Statements contained herein are made as of the date of this document unless stated otherwise, and neither the delivery of this document at any time, nor any sale of securities, shall under any circumstances create an implication that the information contained herein is correct as of any time after such date or that information will be updated or revised to reflect information that subsequently becomes available or changes occurring after the date hereof.

This presentation of CureVac N.V. (the "company") 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 company's opinions, expectations, beliefs, plans, objectives, assumptions or projections of the company regarding future events or future results, in contrast with statements that reflect historical facts. Examples include discussion of 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 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 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

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.

CureVac | Extended Preliminary Phase 1 Data

#### (UREVAC) Comprehensive Second-Generation Clinical Development in Infectious Diseases



CureVac | Extended Preliminary Phase 1 Data

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# CV0501: BA.1 neutralizing antibodies (GMT) per dose level on days 15 and 29<sup>2)</sup>

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## CV0501: Wild Type neutralizing antibodies (GMT) per dose level on days 15 and 29<sup>2)</sup>





Older adults (60-80 years)<sup>2)</sup>



# Flu-SV-mRNA is well tolerated at single tested dose in older adults Preliminary data prior to database lock RureVac | Extended Preliminary Phase 1 Data Preliminary data prior to database lock RureVac | Extended Preliminary Phase 1 Data

CureVac | Extended Preliminary Phase 1 Data

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## Ratio post- to pre-boost titers<sup>2</sup>:

Older adults (60-80 years), ratio of serum HI GMT induced by Flu-SV-mRNA



# >> Antibody increase after booster in older adults more than double compared to licensed comparator

CureVac | Extended Preliminary Phase 1 Data

1) Preliminary data prior to database lock 2) Randomization ratio of 2:1 deviated from the ratio of 1:1 as per protocol 3) Undisclosed dose level

GMT: Geometric mean titers QIV: Quadrivalent influenza vaccine (licensed flu comparator vaccine), 2021-22 northern hemisphere strain composition. FDA/EMA approved.



# Serum HI GMT per dose on day 212)







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Extended preliminary clinical data in older adults continue to provide **strong validation** of CureVac's proprietary technology platform in prophylactic vaccines



COVID-19 and flu in 2023 according to state-of-the-art formats and tailored toward **public health needs** 

CureVac and GSK reaffirm continued clinical development in



**Fundamental transformation** of the company has enabled broadening of technology platform and product development pipeline in prophylactic vaccines



Manufacturing considered **a key success factor** for the scalable supply of clinical trials and commercial efforts – to be supported by **large-scale GMPIV plant** 



Second-generation mRNA backbone to also **drive forward oncology area** with two clinical trials anticipated to start in 2023



CureVac | Extended Preliminary Phase 1 Data

