

CureVac Announces Positive Data on Joint COVID-19 and Flu mRNA Vaccine Development Programs

- Promising COVID-19 and flu modified mRNA vaccine candidates identified based on positive preliminary data from ongoing Phase 1 studies
- All candidates use CureVac’s advanced second-generation mRNA backbone optimized to achieve improved mRNA translation and strong immune responses at low doses
- The preliminary results provide strong evidence of technology for CureVac’s mRNA platform; CureVac and partner GSK plan to advance modified mRNA COVID-19 and flu candidates to the next stages of clinical development
- COVID-19: monovalent modified mRNA vaccine candidate CV0501, encoding Omicron variant BA.1, successfully boosted antibody titers against BA.1 and the wild type variants and was generally well tolerated across all tested dose groups
- Flu: monovalent modified mRNA vaccine candidate Flu-SV-mRNA successfully boosted antibody titers against matching flu strain; even at lowest dose, titers were at least in line with a licensed comparator; Flu-SV-mRNA was well tolerated across all tested dose groups
- CureVac to host a webcast and conference call on January 6, 2023 at 3:00 p.m. CET / 9:00 a.m. EST. Access via the Investor Relations section of the [CureVac homepage](#)

TÜBINGEN, Germany/ BOSTON, USA – January 6, 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 preliminary data from ongoing Phase 1 clinical programs in COVID-19 and seasonal flu, assessing both modified and unmodified mRNA technology. The tested vaccine candidates are being developed in collaboration with GSK. The preliminary results generated by this broad technology approach showed that vaccine candidates using a modified second-generation mRNA backbone produced promising immunogenicity and reactogenicity profiles in both indications. Based on these preliminary data, development of modified mRNA COVID-19 and flu vaccine candidates will be advanced to the next stage of clinical testing in 2023.

“The positive results from this preliminary data analysis strongly validate the power of our proprietary mRNA-technology platform, opening the door to new opportunities in the development of effective prophylactic vaccines and also for advancement of our robust oncology strategy,” said Franz-Werner Haas, Chief Executive Officer of CureVac. “In 2022, we strengthened our proprietary technology platform and extended our robust product development efforts while expanding our organizational bandwidth. With this foundation, CureVac will turn the page and enter 2023 as a competitive player in the development of mRNA therapies.”

“The data derived from CureVac’s mRNA technology platform and second-generation mRNA backbone implemented in the current clinical compounds demonstrate the potential of our portfolio not just in COVID-19 and influenza, but across the spectrum of RNA therapies” said Igor Splawski, Chief Scientific Officer of CureVac. “This includes oncology, where CureVac’s second-generation mRNA backbone is applied.”

Each clinical program assessed vaccine candidates based on CureVac's advanced second-generation mRNA backbone, featuring modified and unmodified mRNA. While the COVID-19 program tested two monovalent candidates, the flu program included an unmodified multivalent and a modified monovalent vaccine candidate. Preliminary data from the modified, monovalent mRNA vaccine candidates CV0501 for COVID-19 and Flu-SV-mRNA for flu are being disclosed today, with final Phase 1 data to be published in due course.

COVID-19 Program

The second-generation mRNA backbone using modified mRNA was selected as the preferred technology for further clinical development in the COVID-19 program. The available preliminary data for CV0501 are based on cohort sizes of up to 30 subjects. Safety data cover the fully recruited dose groups of 12, 25, 50, 100 and 200µg in the younger adult age group (age 18-64) and 12, 25 and 50µg in the older adult age group (age ≥65). CV0501 was shown to be generally well tolerated. Immunogenicity data available for younger adults showed 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 8.1. The data read-out for older adults is currently being finalized.

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

The second-generation mRNA backbone using modified mRNA was selected as the preferred technology for further clinical development in the seasonal flu vaccine program. In the Phase 1 study of the monovalent Flu-SV-mRNA, expressing an H1N1 hemagglutinin antigen (subtype of influenza A), five doses ranging from 2 to 54µg with up to 24 subjects per dose cohort were evaluated in younger adults (age 18-45). In this age group, preliminary safety and reactogenicity data showed that the monovalent Flu-SV-mRNA candidate was generally well tolerated with no safety concerns observed to date across all tested dose levels. Immunogenicity of the monovalent Flu-SV-mRNA was assessed in parallel with a licensed seasonal flu vaccine comparator. Adjusted geometric mean hemagglutinin inhibition antibody titers elicited by Flu-SV-mRNA increased up to approximately 3.3 times those elicited by the licensed flu vaccine comparator in younger adults. The data read-out for older adults is currently being finalized.

Interim data support the progression of the modified second-generation mRNA technology for the development of a multivalent mRNA flu vaccine. The vaccine candidate for future clinical development is expected to target all four strains recommended by the WHO. A Phase 1/2 study for multivalent vaccine candidates is expected to start around mid-2023.

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.

CureVac will host a webcast and conference call on Friday, January 6, 2023 at 3:00 p.m. CET / 9:00 a.m. EST. The live conference call dial-in details and webcast link can be accessed via the Investor Relations section of the CureVac homepage at <https://www.curevac.com/en/newsroom/events/>

Corresponding presentation slides will be posted shortly before the start of the webcast. A replay will be made available at this website after the event.

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 ≥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. Data provided in this press release represent cleaned data prior to database lock.

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 www.sec.gov.