CureVac Announces Dosing of First Participant in a Phase 2 Study in Seasonal Influenza; Development in Collaboration with GSK

- Phase 2 study to assess updated formulations for improved immune responses of multivalent vaccine candidate against influenza B strain
- Study initiated following previously reported interim data from Phase 2 Part of combined Phase 1/2 study in seasonal influenza
- Composition of vaccine candidate changed to match all three WHO-recommended flu strains, following recommendation to exclude B/Yamagata lineage

TÜBINGEN, Germany/BOSTON, USA – May 28, 2024 – CureVac N.V. (Nasdaq: CVAC) ("CureVac"), a global biopharmaceutical company developing a new class of transformative medicines based on messenger ribonucleic acid ("mRNA"), today announced dosing of the first participant in a Phase 2 study of the multivalent seasonal influenza vaccine candidate developed in collaboration with GSK. The study will assess targeted optimizations for improved immune responses of the vaccine candidate against the relevant influenza B strain.

This new Phase 2 study in the joint CureVac/GSK seasonal influenza program has been initiated following interim data from the Phase 2 part of the ongoing combined Phase 1/2 study in seasonal influenza reported on April 4, 2024. The reported data showed that among younger and older adults, serum hemagglutinin inhibition (HAI) geometric mean titers elicited by the vaccine candidate against influenza A strains numerically exceeded those of the applied licensed comparator vaccines consistently across all tested dose levels. For influenza B strains, serum HAI geometric mean titers were lower than those elicited by the licensed comparator vaccines across tested age groups and dose levels.

For the now initiated Phase 2 study, the design of the multivalent vaccine candidate has been changed to address all three World Health Organization (WHO)-recommended influenza strains, following its recommendation from February 2024 to exclude the influenza B/Yamagata lineage and apply a trivalent vaccine format going forward. The three remaining influenza strains include two influenza A strains and one influenza B strain.

"The previously reported positive interim data of the Phase 2 part of the combined Phase 1/2 study in seasonal influenza confirmed that our technology platform elicits strong overall antibody titers at well-tolerated dose levels, underscoring the potential of our second-generation mRNA backbone in our collaborative seasonal influenza vaccine program," said Dr. Myriam Mendila, Chief Scientific Officer of CureVac. "Historically, it's been challenging to target influenza B strains with a potent vaccine strategy. We are making progress in adapting and optimizing our clinical approach to address this challenge and improve performance against the remaining B strain."

The Phase 2 study assesses the reactogenicity, safety, and immunogenicity of different dose levels of a modified, multivalent vaccine candidate, encoding antigens matched to all three WHO-recommended flu strains. The study will include 250 healthy younger adults aged 18 to 64 and 250 healthy older adults aged 65 to 85. In each age group, different dose levels will be tested in comparison to an age-appropriate, licensed comparator vaccine.

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 1,100 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, cash runway, 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, fluctuations of operating results due to the effect of exchange rates, delays in litigation proceedings, different judicial outcomes 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.