

CureVac Receives U.S. FDA IND Clearance to Initiate Phase 1 Clinical Trial for Novel mRNA-Based Precision Immunotherapy in Squamous Non-Small Cell Lung Cancer

- **Significant Regulatory Milestone:** U.S. FDA cleared IND application for CVHNLC, CureVac's investigational therapy targeting squamous non-small cell lung cancer
- **Proprietary Epitopes:** CVHNLC encodes novel tumor epitopes identified through proprietary whole genome-based discovery platform
- **Enhanced Combination Therapy:** CVHNLC to be tested in combination with pembrolizumab, aiming to amplify targeted anti-tumor immune responses
- **Clinical Progress:** Patient treatment anticipated to start in the second half of 2025
- **Pipeline Advancement:** IND clearance highlights CureVac's continued oncology pipeline growth, with more candidates planned to enter the clinic in 2026

TÜBINGEN, Germany/BOSTON, USA – April 7, 2025 – CureVac N.V. (Nasdaq: CVAC) ("CureVac"), a global biotech company developing a new class of transformative medicines based on messenger ribonucleic acid ("mRNA"), today announced that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for a Phase 1 clinical study of CVHNLC in patients with squamous non-small cell lung cancer (sqNSCLC). CVHNLC is CureVac's investigational mRNA-based precision immunotherapy consisting of two different mRNA constructs encoding eight tumor-associated antigens (TAAs) with prevalence across sqNSCLC patients. Encoded antigens include a novel class of TAAs that have not been previously tested in cancer immunotherapy trials.

The phase 1, dose-finding, open-label study will assess the safety and tolerability of CVHNLC plus pembrolizumab in patients with advanced sqNSCLC. The study comprises a dose-escalation part (Part A) of first-line maintenance treatment after either chemotherapy combined with pembrolizumab or pembrolizumab monotherapy. This is followed by an optional dose expansion part (Part B) in which CVHNLC is tested in combination with first-line chemotherapy and pembrolizumab.

"Immune checkpoint blockade has become a new standard of care for patients with metastatic squamous non-small cell lung cancer; however, overall prognosis still remains poor in advanced as well as in early settings of this disease, highlighting the urgent need for new therapeutic options," said Dr. Myriam Mendila, CureVac's Chief Scientific Officer. "Squamous non-small cell lung cancer exhibits a high prevalence of shared tumor antigens among patients, presenting a unique opportunity for developing targeted off-the-shelf mRNA immunotherapies. We believe by administering CVHNLC with checkpoint inhibition, we will trigger an amplified and targeted immune response, thereby increasing the efficacy against the cancer. Our goal is to take this combination also into earlier setting of the disease."

In Part A, patients with metastatic Stage IV sqNSCLC, who have received at least three cycles of pembrolizumab, either as monotherapy or in combination with chemotherapy, will be enrolled.

CVHNLC doses between 100µg and 400µg plus pembrolizumab maintenance therapy for up to 12 months or until disease progression or undue toxicity occurs, will be administered with dose escalation. Primary endpoints include incidence of dose-limiting toxicities and treatment-related and emergent adverse events; secondary endpoints include overall response rate, progression-free survival, duration of response, and disease control rate.

“CVHNLC is our second oncology program to enter the clinical stage, highlighting the continued progress we are making with our mRNA-based precision immunotherapies. Importantly, we have been able to design CVHNLC using both known, shared tumor antigens and novel proprietary antigens discovered using our differentiated in-house technology platform,” said Dr. Alexander Zehnder, Chief Executive Officer of CureVac. “We are leveraging this approach in the design of multiple novel cancer mRNA programs in our collaboration with MD Anderson Cancer Center, which we anticipate entering the clinic in the next 18-24 months.”

About CVHNLC

CVHNLC has been built on CureVac’s advanced second-generation mRNA backbone, featuring two different constructs utilizing unmodified mRNA formulated in lipid nanoparticles (LNPs). Its multi-epitope design encodes eight shared antigens, four of which are well-known with established relevance in solid tumors. The other four antigens are a novel class of TAAs uniquely derived from CureVac’s proprietary whole-genome discovery platform.

About Squamous Non-Small Cell Lung Cancer

In the U.S., there are approximately 225,000 new cases of lung cancer each year, 87% of which are NSCLC, according to the American Cancer Society. Squamous non-small cell lung cancer (sqNSCLC) represents approximately 20-30% of all NSCLC cases and is considered a more aggressive form, posing significant challenges in disease control and treatment. Patients with sqNSCLC often face a tougher prognosis compared to other types of NSCLC. In the early sqNSCLC setting after neoadjuvant treatment, there is a 30-40% relapse rate within two years, with median overall survival of 15-17 months in metastatic setting.

About CureVac

CureVac (Nasdaq: CVAC) is a pioneering multinational biotech company founded in 2000 to advance the field of messenger RNA (mRNA) technology for application in human medicine. In more than two decades of developing, optimizing, and manufacturing this versatile biological molecule for medical purposes, CureVac has introduced and refined key underlying technologies that were essential to the production of mRNA vaccines against COVID-19, and is currently laying the groundwork for application of mRNA in new therapeutic areas of major unmet need. CureVac is leveraging mRNA technology, combined with advanced omics and computational tools, to design and develop off-the-shelf and personalized cancer immunotherapy product candidates. It also develops programs in prophylactic vaccines and in treatments that enable the human body to produce its own therapeutic proteins. Headquartered in Tübingen, Germany,

CureVac also operates sites in the Netherlands, Belgium, Switzerland, and the U.S. Further information can be found at www.curevac.com.

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Forward-Looking Statements of 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 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 timing of programs entering the clinic. In some cases, you can identify such forward-looking statements by terminology such as “anticipate,” “intend,” “believe,” “estimate,” “plan,” “seek,” “project,” “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 (the "SEC"). You may get these documents by visiting EDGAR on the SEC website at www.sec.gov.