CureVac Advances Cancer Vaccine Candidate CVGBM to Part B of Phase 1 Study in Patients with Resected Glioblastoma

- First patient administered in dose-confirmation Part B of Phase 1 study with mRNA-based, multiepitope cancer vaccine candidate CVGBM
- Part B expected to include up to 20 patients to generate extended data on safety, tolerability, and immunogenicity of CVGBM

TÜBINGEN, Germany/BOSTON, USA – August 15, 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 the start of the dose-confirmation Part B of its ongoing Phase 1 study in patients with resected glioblastoma. CVGBM is CureVac's first investigational cancer vaccine based on its proprietary second-generation mRNA backbone. It encodes a single fusion protein comprising eight epitopes with demonstrated immunogenicity in glioblastoma.

"After successful completion of the dose-escalation part A of this clinical study with CVGBM, the dose expansion part B is important to confirm that we have selected the appropriate dose based on safety and immunogenicity for further studies in patients suffering from glioblastoma," said Dr. Myriam Mendila, Chief Scientific Officer of CureVac. "Importantly, the review by the Data Safety Monitoring Board confirmed there have been no dose-limiting toxicities to date in Part A with the four doses tested, and have enabled us to move forward to this next part of the study."

The open-label study is evaluating the safety and tolerability of CVGBM in patients with newly diagnosed and surgically resected MGMT-unmethylated glioblastoma or astrocytoma with a molecular signature of glioblastoma. CVGBM is administered as a monotherapy after surgical resection and completion of radiotherapy with or without chemotherapy. The study consists of two parts, a dose-escalation part (Part A) and a dose-expansion part (Part B). Part A has successfully been completed and involved 16 patients, testing doses in the range of 12 to 100 µg. A review of the safety data from Part A by the Data Safety Monitoring Board (DSMB) confirmed no dose-limiting toxicities. A 100 µg dose was recommended for Part B of the study.

Initial data on the dose-escalation Part A will be presented in an oral presentation at the European Society for Medical Oncology Congress (ESMO) on September 13, 2024.

More information can be found at clinicaltrials.gov (NCT05938387).

About CVGBM

Based on CureVac's proprietary second-generation mRNA backbone, designed for improved mRNA translation and increased as well as extended protein expression, CVGBM encodes a single fusion protein comprising eight epitopes derived from tumor-associated antigens (TAA) with relevance in glioblastoma, including HLA class I epitopes presented on HLA A0201 and class II epitopes. The applied epitopes have been previously shown to induce immune responses in glioblastoma patients when administered as peptide vaccines with adjuvants. CVGBM applies unmodified mRNA and is formulated within lipid nanoparticles (LNPs). The Phase 1 proof-of-principle study of CVGBM is currently being conducted in Germany, Belgium and the Netherlands.

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 vaccine 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 CureVac

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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.