CureVac Presents Promising Data at SITC from Phase 1 Study of Oncology Candidate CV8102 Showing Systemic Immune Response

- *Immune profiling of clinical trial participants in Phase 1 dose-escalation study shows immune response in both injected and non-injected lesions*
- *Expansion part of Phase 1 study fully recruited; results expected in the second half of 2022*

TÜBINGEN, Germany/ BOSTON, USA – November 10, 2021 – CureVac N.V. (Nasdaq: CVAC), a global biopharmaceutical company developing a new class of transformative medicines based on messenger ribonucleic acid ("mRNA"), today announced promising data from the completed dose-escalation part of the Phase 1 clinical trial of CV8102, the company's lead oncology candidate. The data support the hypothesis that local injection of the RNA immuno-modulator into a single tumor lesion is able to induce a systemic response leading to immune attack against both injected and non-injected tumors. Extensive analysis of immune cell activation shows efficient stimulation of the immune system characterized by the induction of interferon alpha and interferon gamma signaling pathways. Serial tumor biopsies from individual patients demonstrated increased infiltration of tumor-fighting T cells in the microenvironment of injected as well as non-injected tumors. The study focuses on patients with advanced cutaneous melanoma, adenoid cystic carcinoma and squamous cell carcinoma of the skin or head and neck, treated with CV8102 alone and in combination with anti-PD-1 antibodies. The data are being presented at the Society for Immunotherapy of Cancer (SITC) Conference, held in Washington, D.C., and virtually from November 10–14, 2021.

"The preliminary data from the Phase 1 dose escalation part of this study allow a much deeper understanding of the promising biologic effects of CV8102 observed in several patients," said Dr. Klaus Edvardsen, Chief Development Officer at CureVac. "CV8102 is designed to mimic a viral infection of the injected tumor. This potentially leads to a broad activation of tumor-specific T cells, which can kill tumor cells at the injected but also at distant sites. We expect that the data will be supplemented by upcoming results of the expansion study, which will provide further insight into which patients are more likely to experience a clinical response to CV8102."

An expansion part of the Phase 1 study, initiated in February and fully recruited in October 2021, aims to confirm the safety, tolerability and efficacy of CV8102 at the recommended 600µg dose in patients with advanced melanoma. The study involves 40 trial participants, with 10 in the single-agent cohort and 30 in the combination cohort. Data from the expansion part of the study is expected in the second half of 2022.

The dose-escalation part of the study included a total of 58 patients, 33 of which were treated in the in the single-agent cohort and 25 in the combination cohort. Data presented in September at the European Society for Medical Oncology (ESMO) conference found that as of the cutoff date of June 21, 2021, in the single-agent CV8102 dose-escalation cohort, one patient with a complete response and two patients with a partial response were observed. In addition, 12 patients experienced stable disease. In the PD-1 combination dose-escalation cohort, one PD-1 refractory melanoma patient experienced a partial response while three patients experienced stable disease.

About CV8102 and the Phase 1 Clinical Trial

CV8102 is a single-stranded non-coding RNA optimized to maximize activation of cellular receptors that normally detect viral pathogens entering the cells, such as toll-like receptors 7 and 8 (TLR7/8), and retinoic acid inducible gene I (RIG-I), mimicking a viral infection of the tumor. CV8102 is designed to recruit and activate antigen-presenting cells at the site of injection to present tumor antigens released from tumor cells to T cells in the draining lymph node. This potentially leads to activation of tumor-specific T cells, which can kill tumor cells at the injected site, but also at distant non-injected tumor lesions or metastases.

The Phase 1, open-label, dose escalation and expansion study of CV8102 is fully recruited and includes patients with advanced melanoma, cutaneous squamous cell carcinoma, squamous cell carcinoma of head and neck or adenoid cystic carcinoma. The primary objective of the study is to assess safety and tolerability of CV8102.The dose escalation part tests escalating doses of single-agent CV8102 and CV8102 in combination with licensed anti-PD-1 antibodies in the range of 25-900µg. The expansion part of the study focuses on patients with advanced melanoma treated with a recommended dose of 600µg.

About CureVac

CureVac is a global biopharmaceutical company in the field of messenger RNA (mRNA) technology, with more than 20 years of expertise in developing and optimizing the 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 had its initial public offering on the New York Nasdaq in August 2020. It is headquartered in Tübingen, Germany, and employs more than 700 people at its sites in Tübingen, Frankfurt, and Boston, USA. 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.