Press Release

CureVac Provides Clinical Update at 35th Annual J.P. Morgan Healthcare Conference

SAN FRANCISCO/TÜBINGEN (Germany), January 11, 2017 – CureVac, a clinical-stage biopharmaceutical company pioneering the field of mRNA-based technology, today presented an update of its clinical progress at the 35th Annual J.P. Morgan Healthcare Conference in San Francisco.

Interim Results of Phase I First-in-Human Clinical Trial with CV7201, an RNA Active® Rabies Vaccine

CureVac’s first-in-human phase I clinical trial with an mRNA-based rabies vaccine was designed to evaluate CV7201 in healthy volunteers without pre-existing immunity against the rabies virus. CV7201 encodes for the G protein of the rabies virus. To date, the vaccine appears well tolerated and no safety concerns were identified. In one cohort of 21 subjects vaccinated at the lowest dose of 80 µg with a needle-free device, virus neutralizing antibodies (VNTs) were detected in all subjects and in 17 (81%) exceeded the threshold considered protective by the WHO (0,5 IU/ml). The complete data set will be published after completion of a long-term safety valuation.

Regarding CV7201, CureVac is developing an optimized vaccine, which shows good efficacy when injected intramuscularly with a conventional needle. The company is planning to bring this vaccine into clinical testing in 2017.

Topline Result of Phase IIb Clinical Trial with CV9104, an RNA Active® Prostate Cancer Vaccine

CureVac’s double-blinded and placebo controlled phase IIb clinical trial with CV9104 was designed to evaluate the investigational mRNA-based cancer vaccine in patients with asymptomatic or minimally symptomatic metastatic castrate resistant prostate cancer. CV9104 is composed of six protamine-formulated mRNAs, encoding individually for self-antigens that are overexpressed in prostate cancer patients.

CV9104 failed to meet the primary endpoint of improving overall survival. Progression-free survival was similar in both arms of the clinical trial. No safety concerns were identified confirming the favorable safety results of previous trials with RNA Active® cancer vaccines. CureVac is continuing to evaluate the data and plans to present the full set of data at an upcoming medical conference.

Clinical Results to Point Way Forward to Medical Innovation

Ingmar Hoerr, Ph.D., co-founder and CEO of CureVac, stated: “We received encouraging data from the first ever clinical trial of a prophylactic RNA Active® mRNA vaccine in immune-naïve healthy volunteers indicating our vaccine is able to
effectively prime immune responses against a viral antigen. These results affirm the prior preclinical proof of concept data for our vaccine format and pave the way for us to advance more potent prophylactic vaccine formulations into the clinic. Regarding our CV9104 program, we now recognize that this therapeutic vaccine fails to induce a survival benefit as a monotherapy in patients with metastatic prostate cancer receiving standard of care therapies. However, we see the path forward for our RNAActive® cancer immunotherapy in combination with checkpoint inhibitors.”

Dr. Hoerr continued, “Having administered our RNA technologies to more than 450 human subjects and having conducted eight different clinical studies, we are confident that it can be administered safely, and based on data generated in our clinical program in rabies, we now have clear evidence that our RNAActive® technology induces effective immune responses in humans. As the pioneer in the mRNA field, we look forward to advancing our mRNA development and applying uniquely designed mRNA-based drugs in oncology, prophylactic vaccines and molecular therapies as CureVac strives to have the first mRNA-based product on the market for people suffering from high and unmet medical needs.”

About CV7201 Phase I Clinical Trial in Rabies
The study is designed to evaluate the safety and immunogenicity of CV7201 according to (1) dose level (2) route of injection and (3) injection schedule. Rabies-specific binding and neutralizing titers will be evaluated across different injection routes using an injection schedule of 0-7-28 and 0-28-56. The trial started in 2013 and is still ongoing. To date, more than 100 subjects have been enrolled in Germany and safety follow-up is ongoing.
More details can be found here.

About CV9104 Phase IIb Clinical Trial in Prostate Cancer
The phase IIb with CV9104 was a double-blind, placebo controlled trial with 197 chemo-naïve, asymptomatic or minimally symptomatic patients with metastatic, castrate-resistant prostate cancer randomized to CV9104 or placebo. The trial which was conducted in eight European countries started in 2012 and recruitment was completed in December 2013.
The primary endpoint of the study was overall survival and key secondary endpoints were progression-free survival and change of quality of life.
More details can be found here.

About CureVac AG
Founded in 2000 as a spin-off from the University of Tübingen in Germany, CureVac is a technology leader in the development of drugs that are based on the molecule Messenger RNA (mRNA). The fully integrated biopharmaceutical Company has more than 17 years of expertise in handling and optimizing this versatile molecule for medical purposes and has the most advanced product pipeline and IP portfolio in the industry.
The basic principle of CureVac's proprietary technology is the use of mRNA as a data carrier to instruct the human body to produce its own proteins capable of fighting a wide range of diseases.
Since its inception, strongly backed by SAP founder Dietmar Hopp’s dievini CureVac has received approximately $370 million (€355 million) in equity investments including an investment of the Bill & Melinda Gates Foundation of $ 52million in 2015. CureVac has entered into various collaborations with multinational corporations and organizations, including agreements with Boehringer Ingelheim, Sanofi Pasteur, the Bill & Melinda Gates Foundation and IAVI.

In 2006, CureVac successfully established the first GMP facility worldwide for the manufacturing of mRNA. In 2016 CureVac started the establishment of an industrial scale production.

For more information, please visit www.curevac.com.

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