Press Release

CureVac Announces Phase I/IIa Clinical Study Data of its mRNA Cancer Immunotherapy in Prostate Cancer Published in the Journal for ImmunoTherapy of Cancer

- Promising first-time immunogenicity data with a mRNA therapeutic from a Phase IIa study in Prostate cancer
- Peer-reviewed data indicate that CureVac’s mRNA cancer immunotherapy was well tolerated and immunogenic
- CureVac currently conducting randomized, placebo-controlled Phase IIb study in patients with metastatic castration-resistant prostate cancer

TÜBINGEN, Germany, July 7, 2015 – CureVac, a clinical-stage biopharmaceutical company pioneering the field of mRNA-based technology, today announced that a Phase I/IIa study of the company’s mRNA cancer immunotherapy (CV9103) in advanced castration-resistant prostate cancer was published in the peer-reviewed Journal for ImmunoTherapy of Cancer. CV9103 is a self-adjuvanted, sequence-optimized, chemically unmodified mRNA immunotherapy targeting four antigens: prostate-specific antigen (PSA), prostate-specific membrane antigen (PSMA), prostate stem cell antigen (PSCA), and six-transmembrane epithelial antigen of the prostate 1 (STEAP1).

The research article, titled “Self-adjuvanted mRNA vaccination in advanced prostate cancer patients: a first-in-man phase I/IIa study,” describes CureVac’s clinical study of CV9103 in 44 patients with advanced castration-resistant prostate cancer. The related data signify the first Phase IIa clinical study in which an mRNA therapy has demonstrated antigen-specific immune responses in the majority of patients. Based on the favorable data, CureVac is currently conducting a randomized, placebo-controlled Phase IIb study in 197 prostate cancer patients with the follower vaccine CV9104 targeting six antigens.

Ingmar Hoerr, CEO of CureVac, commented, “We are very pleased that the results of this Phase I/IIa clinical study of our RNActive® technology were published in such an esteemed peer-reviewed journal as it validates our leadership position in mRNA therapeutics and highlights the continued advancement of our clinical pipeline. Prostate cancer remains our most advanced program, with the Phase IIb clinical trial progressing as planned, but CureVac also possesses a deep and diverse mRNA-driven pipeline spanning six clinical trials with more than 300 individuals treated so far and about 15 programs targeting multiple treatment opportunities and disease indications.”

As described in the article, the Phase I part of the study was designed to investigate the safety and recommended dosage of CV9103, with 12 patients up to five intradermal injections of 256 (n = 3), 640 (n = 3), or 1280 μg (n = 6) mRNA. In the Phase IIa part, 32 patients were enrolled to receive the recommended dose of 1280 μg mRNA defined in Phase I. The primary endpoint of the study was safety and tolerability, and the secondary endpoint was induction of antigen specific immune responses monitored at baseline and at weeks 5, 9 and 17.

Data indicated that CV9103 was well tolerated, with the majority of related adverse events being of mild to moderate intensity. The most frequent treatment-related side effects were...
injection site erythema and injection site reaction in 27 (61%) and 21 (48%) patients, respectively. A quantitative analysis of ELISpot, ICS, and tetramer staining assays revealed that CV9103 was able to induce both CD4 and CD8 T cell responses. Of the 33 evaluable patients treated at 1280 μg, a cellular immune response could be detected in 25 (76%). Importantly immune responses against all four antigens could be induced indicating the versatility of the platform.

Arnulf Stenzl, Medical Director of the Department of Urology, University of Tübingen Medical School, and senior author of the paper, stated, “The data generated by this Phase I/IIa clinical study demonstrate that CV9103 mRNA was well tolerated and immunogenic. Furthermore a trend towards longer survival time was also observed in immune responders that was strongest in patients responding to multiple antigens CV9103. Based on these results, it is evident that this mRNA technology warrants further clinical investigation.”

Just recently, CureVac published promising data of its RNArt® technology platform in Molecular Therapy that demonstrated for the first time that sequence-optimized, chemically unmodified mRNAs raised relevant protein levels in non-human primates, indicating that mRNA achieves meaningful biological effects in large animals with body weight close to humans.

The full research article in Journal for ImmunoTherapy of Cancer may be accessed via the following URL: http://www.immunotherapycancer.org/content/3/1/26

About CureVac

CureVac, a German clinical stage biopharmaceutical company founded in 2000, is pioneering the field of mRNA-based technology for medical purposes, in which unmodified mRNA is specifically optimized and formulated. CureVac has been developing novel mRNA-based cancer immunotherapies and prophylactic vaccines against infectious diseases – both under the brand RNAActive®. Moreover, CureVac's technology RNArt® is designed as molecular therapy to trigger the body's own production of therapeutic proteins without stimulating the immune system. The technology RNAntibody® is being developed to express therapeutic levels of RNA encoded antibodies.

CureVac's mRNA products are currently the subject of seven active clinical studies in patients and healthy volunteers, including a Phase IIb trial in prostate cancer. In 2006, the company successfully established the first GMP facility worldwide for the manufacturing of mRNA.

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