Website address:
https://www.gesundheitsindustrie-bw.de/en/article/press-release/ind-approval-for-curevac

Healthcare industry BW

IND Approval for CureVac

CureVac Receives IND Approval from the FDA to start its Phase I/IIa mRNA Vaccine Clinical Trial in Prostate Cancer.

CureVac GmbH announced last week that it has received approval for its Investigational New Drug (IND) application with the US Food and Drug Administration (FDA) to begin a Phase I/IIa clinical study with CV9103, a RNActive® - derived mRNA (messenger RNA) vaccine. This mRNA vaccine will be tested in patients with hormone-refractory metastatic prostate cancer.

CV9103 is the most advanced candidate in CureVac's vaccine pipeline of RNActive®-derived molecules for active immunotherapy of cancer. The vaccine is comprised of modified long chain mRNA molecules coding for four different antigens expressed by prostate cancer cells. The Phase I/IIa trial is designed to assess the safety, tolerability and biological activity of the vaccine. CureVac expects to start the treatment of the first patient in March 2009. First results from the Phase I/IIa trial are expected by H1 2010.

Thomas Lander, M.D., Managing Director and Chief Medical Officer of CureVac, commented: "Only shortly after receiving the approval of clinical development in the EU a few weeks ago, we are now looking forward to also starting the first Phase I/IIa trial in the US. CV9103 is the first mRNA-based vaccine to enter clinical trials in prostate cancer. This IND approval is a significant milestone in our goal of establishing a novel immunotherapy for the treatment of cancer."
"Without doubt, the North American market is strategically and commercially a very important area also for us. We are very pleased to work with Johannes Vieweg and his team from the Urology Clinic, Gainesville, University of Florida. Johannes and his group are among the most experienced teams in active immunotherapy," added Thomas Lander.

Source: CureVac GmbH - 05.01.2009

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