

Phase I/IIa Study Of RNActive®-Derived Therapeutic Vaccine In  
Metastatic Hormone Refractory Prostate Cancer

Part 2: Scientific Abstract

## **SCIENTIFIC ABSTRACT**

Our long-term objective is to develop clinically effective vaccine strategy for the treatment of prostate cancer subjects by inducing immunity against four prostate specific antigens. These four prostate specific antigens are attractive candidates for specific immunotherapy as they are overexpressed mainly in prostate and prostate cancer cells but not in other tissues. We have performed preclinical studies demonstrating that CV9103 induces immune responses in relevant animal models and human cell culture experiments. Having evaluated the biological activity of CV9103 in preclinical models we will now pursue with the conduct of a phase I/II clinical trial designed to evaluate the safety of administering CV9103 to subjects with hormone-refractory metastatic prostate cancer HRPC. We hypothesize that administration of CV9103 to subjects with metastatic HRPC is safe and will lead to detectable levels of CV9103 antigen specific humoral and cellular immune responses detectable in the peripheral blood of prostate cancer subjects. Therefore, we propose to analyze the bioactivity of CV9103 by measuring the presence, magnitude and duration of antigen specific CD8 and CD4 T cell responses as well a antigen specific B cell responses from peripheral blood of study subjects prior enrolled. The proposed project will set the stage for scientifically valid phase II studies to assess the clinical efficacy of vaccinating prostate cancer subjects with CV9103.