PROTOCOL SUMMARY

1. Protocol Title: A SAFETY AND FEASIBILITY STUDY OF ACTIVE IMMUNOTHERAPY IN PATIENTS WITH METASTATIC PROSTATE CARCINOMA USING AUTOLOGOUS DENDRITIC CELLS PULSED WITH ANTIGEN ENCODED IN AMPLIFIED AUTOLOGOUS TUMOR RNA

2. Purpose and Rationale: Because prostate cancer is incurable when locally advanced or metastatic and conventional therapies do not offer a clear survival benefit, new therapeutic approaches are warranted. This proposal is based upon the premise that a clinically effective cell-mediated immune response against spontaneously arising tumors can be elicited by activation of tumor-associated cytotoxic T cells (CTL). In particular, we propose to examine a novel immunization strategy to elicit CTL responses against a broad spectrum of tumor associated antigens encoded in messenger RNA (mRNA) amplified from autologous tumor tissue.

This protocol proposes a safety and feasibility trial in patients with metastatic prostate cancer (stages $D_1 - D_3$) investigating the induction of antitumor immunity by administration of **cultured autologous peripheral blood precursor derived dendritic cells (DC), pulsed with mRNA amplified from autologous primary or metastatic prostate tumor tissue, hereafter referred to as $DC_{TU\text{-}RNA}$.**

3. Specific Hypothesis To Be Tested: The feasibility and dose-limiting toxicity of administering escalating doses of $DC_{TU\text{-}RNA}$ will be defined. As a secondary endpoint, the ability of $DC_{TU\text{-}RNA}$ to induce tumor-specific immune responses will be evaluated. Finally, the anti-tumor effect based on PSA (biochemical) response criteria will be defined.