Correlation of Serum Cytokines With Clinical Responses in Patients Treated with BPX-101, A Drug-Activated Vaccine for Metastatic Prostate Cancer (mRPC)

D.M. Spencer1, N. Laptev2, J.M. Levitt1, M. Seethammaragi3, G. Sonpavde2, J.D. McMannis1, Y. Bai1, J.M.C. Bull1, K.M. Slawin4,5

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Abstract

Background: We report the correlation of clinical and immune monitoring results for subjects randomized in Phase 1 trials of BPX-101, an activatable cell vaccine for mRPC.

Methods: Thirty-two participating patients were enrolled in a 3+3 dose escalation trial evaluating BPX-101 and activating agent AP1903. BPX-101 was administered intradermally every 4 weeks for 12 doses during the phase 1 dose, and every 6 months for maintenance. BM1501mg was administered 24 hours after each BPX101 dose. BM1501 was administered in a fixed 4-week schedule during the induction phase and continued over the 12 month maintenance phase. Clinical endpoints were measured a month after each BPX101 dose, and BM1501 dose.

Results: Planned enrollment of 12 subjects is complete, including each of 4 dose levels at 2.5 × 107, 5 × 107, 1 × 108 and 2 × 108. A pattern of scripting levels of serum cytokines one week after each dose, returning to baseline for the following week, was observed for each subject. IL-2, IFN-γ, TNF-α, and GM-CSF were measured. A level of GM-CSF was associated with a rise to IL-2 and IFN-γ, and maintenance of IL-2 and IFN-γ. A PI after one year serum study period cytokines spiked up to average after each vaccination. The results are consistent with the response of the vaccine, generating BCPX-101. After the first two boosters, levels flatten back to baseline after the full three boosters. In a second, high dose group (2 × 108), while maintaining a 4 x fold increase in cytokine levels, the maintenance dose of BM1501 induced a 6 x increase in IFN-γ, TNF-α, and IL-2. PG and MAP were spiked, including a 6 x increase in ACE for the subject at 2 × 108 cytokine levels were not associated with the cytokine elevation.

Conclusions: BPX-101 induces a spiking pattern of cytokine elevations after each dose in patients who successfully achieved disease reduction, even dramatic spikel in cytokine levels levels seen.

Introduction

Toxic cancer vaccines have recently modified the market, where they represent a novel modality to treat and prevent cancer. However, their implementation as a standard or viable approach to cancer treatment is hindered by concerns of toxicity or efficacy of short term disease progression. To enhance manageable and sustainable potent cancer antigen vaccination in cancer patients, we are developing a new generation of highly potent cancer vaccines by manipulating the current and broad-based repertoire of dendritic cells (DCs) in vivo.

BPX-101 is a therapeutic DC vaccine for the treatment of even non.

Interventions: To generate DCs with the promise of the anterior cancer antigen MUC 1, an analogous tetramer, DCVaccTM is an application of chemical induction of dendritic cell maturation, a technology that enables the use of specific cell type dependent cytokines. DCVaccTM is a unique platform that enables the creation of DCs with specific DCVaccTM technologies for multiple specific cell types. DCVaccTM is designed to generate DCs with specific DCVaccTM technologies for multiple specific cell types.

Clinical Trial Design

“A Phase (1), Non-randomized, Multiple-Accord, Dose-Exposure Study of the Safety, Pharmacokinetics, Pharmacodynamics and Efficacy of Thera

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