Results of a Phase I/II Clinical Trial of BPX-101, a Novel Drug-Activated Dendritic Cell Vaccine for Metastatic Castration Resistant Prostate Cancer (mCRPC)

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Background: Despite recent advances in the treatment of mCRPC, the median survival continues to hover between ~50% and 90% within the first 12 weeks of therapy. Both subjects experienced post-docetaxel leukopenia (90% decline), and occult visceral metastases experienced a RECIST CR with docetaxel.

Methods: BPX-101 is a novel drug-activated dendritic cell vaccine containing a synthetic lipid of the mannose receptor, with a recombinant form of PSMA, and pre-activated with AP1903 and LPS. The results of a Phase I/II clinical trial of BPX-101 in patients with mCRPC are reported.

Results: A Phase I/II clinical trial of BPX-101, plus Activating Agent, AP1903, in Patients with Metastatic Castration Resistant Prostate Cancer (mCRPC)

We report clinical results from a Phase I/II, non-randomized, multiple-dose, 3+3 dose-escalation study of BPX-101, a drug-activated dendritic cell vaccine, plus Activating Agent, AP1903, in patients with mCRPC. BPX-101 can be reliably manufactured and safely administered, followed by AP1903 at non-toxic doses. Subjects continued up to 5 additional vaccination doses per patient. Patients in Cohort 4 are not eligible for maintenance doses, but will continue on study until progression.

Conclusion: Data from multiple subjects suggest a potential synergy between BPX-101 and docetaxel, with rapid and durable responses and prolonged disease control. This clinical trial provides the basis for further evaluation of BPX-101 and AP1903 in patients with mCRPC.

Clinical Outcomes & Safety

We report results of a Phase I/II clinical trial of BPX-101, a drug-activated dendritic cell vaccine, plus Activating Agent, AP1903, in Patients with Metastatic Castration Resistant Prostate Cancer (mCRPC).

In Cohort 1 and Cohort 2, 1 mL of BPX-101 was administered at each treatment visit as 5 doses during the induction phase. AP1903 (0.4 mg/kg) was infused 24 hours after each BPX-101 dose. Radiologic evaluation was performed every 12 weeks. Recently, a fourth cohort was enrolled, with subjects treated on a less frequent dosing schedule. AP1903 (0.4 mg/kg) was infused 24 hours after the initial dose of BPX-101, and subjects received AP1903 at 8-week intervals thereafter.

BPX-101 was generally well-tolerated at doses up to 1 mL (46% decline), and 1070 ng/mL to 104 ng/mL (90% decline)). One post-docetaxel subject experienced a single acute grade 2 cytokine reaction during infusion of AP1903. BPX-101 and AP1903 were administered at 1 mL (7 weeks).

In the 1 year time point, a third, high dose subject experienced a complete response (CR) per RECIST criteria by 8 weeks. This subject went off protocol prior to the end of induction due to progression.

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