

Meeting Abstract: 2014 Genitourinary Cancers Symposium

FREE ACCESS Prostate Cancer February 01, 2014



A phase II trial of prostate-specific membrane antigen antibody drug conjugate (PSMA ADC) in taxane-refractory metastatic castration-resistant prostate cancer (mCRPC).

A phase II trial of prostate-specific membrane antigen antibody

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Abstract

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Background: The abundant expression of prostate-specific membrane antigen (PSMA) on prostate cancer cells provides a rationale for antibody therapy. PSMA antibody drug conjugate (ADC) is a fully human antibody to PSMA linked to the microtubule disrupting agent monomethyl auristatin E (MMAE). It binds PSMA and is internalized and cleaved by

lysosomal enzymes releasing free MMAE causing cell cycle arrest and apoptosis. We enrolled 70 patients (pts) in a phase II trial of PSMA ADC in taxane-refractory metastatic castration-resistant prostate cancer (mCRPC). **Methods:** Pts with progressive mCRPC following taxane and ECOG PS 0 or 1 were eligible. PSMA ADC was administered Q3 week IV for up to eight cycles. Safety, tumor response by prostate-specific antigen (PSA), circulating tumor cells (CTC), imaging, biomarkers and clinical progression were assessed. Dosing was initiated at 2.5 mg/kg and adjustment

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A phase 2 trial of prostate-specific membrane antigen antibody drug conjugate (PSMA ADC) in taxane-refractory metastatic castration-resistant prostate cancer (mCRPC)

CSPC Exhibit 1209

Prostate-specific membrane antigen antibody drug conjugate (PSMA ADC): A phase I trial in metastatic castration-resistant prostate cancer (mCRPC) previously treated with a taxane.

A phase 2 study of prostate specific membrane antigen antibody drug conjugate (PSMA ADC) in patients (pts) with progressive metastatic castration-resistant prostate cancer (mCRPC) following abiraterone and/or enzalutamide (abi/enz).

for tolerability was allowed. **Results:** Thirty five pts began treatment at 2.5 mg/kg. Due to neutropenia, the remaining 35 pts began at 2.3 mg/kg. All pts received prior docetaxel and abiraterone and/or enzalutamide. Forty one percent also received cabazitaxel. Adverse events (AEs) were consistent with what was seen in phase I; most common significant AEs were neutropenia (grade 4, 6.7% and 11.4% at 2.3 and 2.5 mg/kg, respectively) and peripheral neuropathy (grade 3 or higher, 6.7% (2.3) and 5.7% (2.5)). Two pts at 2.5 mg/kg died of sepsis. 43% of pts at 2.3 and 37% of pts at 2.5 had declines in CTC from 5 or more to less than 5 cells/7.5 ml blood and 57.1% (2.3) and 74.1% (2.5) had 50% or more CTC declines; 26.1% (2.3) and 16.1% (2.5) had PSA declines of 30% or more thus far. PSA and CTC responses were associated with higher PSMA expression on CTC and lower neuroendocrine (NE) markers. The CTC conversion rate (5 or more to less than 5) was approximately 80% in pts with low NE markers. Prior cabazitaxel or abiraterone and/or

enzalutamide did not appear to affect response. Centralized assessments of images by RECIST of all pts are currently planned and will be presented. **Conclusions:** PSMA ADC at 2.3 mg/kg was generally well tolerated in pts with progressive mCRPC previously treated with taxane. Anti-tumor activity, CTC and PSA reductions were observed at 2.3 and 2.5 mg/kg. Updated safety, tumor response and radiographic assessments from the full cohorts of 2.3 and 2.5 mg/kg will be presented. Testing in taxane naïve pts is also ongoing. [Clinical trial information: NCT01695044.](#)

This is an ASCO Meeting Abstract from the 2014 Genitourinary Cancers Symposium. This abstract does not include a full text component.

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