**5026** **Poster Discussion Session (Board #18), Sat, 8:00 AM-12:00 PM and 12:00 PM-1:00 PM**

# An exploratory analysis of bone scan lesion area (BSLA), circulating tumor cell (CTC) change, pain reduction, and overall survival (OS) in patients (pts) with castration-resistant prostate cancer (CRPC) treated with cabozantinib (cabo): Updated results of a phase II nonrandomized expansion (NRE) cohort.

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**Background:** The results of 144 pts with metastatic CRPC treated in a phase II NRE cohort with daily cabo 100 mg and 40 mg starting doses have been previously reported. Substantial rates of bone scan improvement, reductions in CTC counts and pain relief were observed. To better understand the implication of these effects, the association with OS was explored. **Methods:** Relevant baseline variables (LDH, BSLA, visceral disease, pain, hemoglobin, CTCs) and post-treatment changes at week 6: ≥30% reduction in BSLA using computer-aided assessment, CTC conversion (>5 vs. 4 or less/7.5 ml of blood), and pain intensity (7 day averaged worst pain score; BPI scale; using an IVR system) were associated with OS in 144 CRPC pts with bone metastasis who progressed within 6 months of docetaxel (D) treatment (≥225 mg/m$^2$) in either bone or soft tissue. Median OS was compared between responders and non-responders for each of the above outcomes categories using a Cox proportional hazard model. The findings were examined further after adjusting for significant baseline covariates selected from a stepwise Cox regression model. **Results:** See Table. **Conclusions:** Recognizing the limitations of associating response with survival, this retrospective analysis of decreases in BSLA, CTC conversions and reductions in pain intensity support further study in ongoing phase III trials. Clinical trial information: NCT00940225.

**Baseline characteristics, N=144.**

| | | | | |
|---|---|---|---|---|
| **Median age** | 66 | Sites of disease, % | | |
| **Prior therapies, %** | | Bone | 100 | |
| **≥2 prior lines therapy including docetaxel** | 73 | Visceral | 31 | |
| **Cabazitaxel** | 24 | Moderate to severe pain (BPI≥4), % | 47 | |
| **Abiraterone** | 43 | Median CTC count | 37 | |
| **Progression <1 mo from last taxane dose, %** | 36 | CTC count ≥5, % | 80 | |
| **Results** | | | | |
| **Median overall survival, mos** | | 10.8 (CI, 9.1-13.0) | | |
| | Univariate analysis | | Analysis adjusted for covariates | |
| **Response categories** | HR (95% CI) | P | HR (95% CI) | P |
| **Bone scan response** | 0.62 (0.38-1.00) | 0.054 | 0.47 (0.28-0.79) | 0.005 |
| **CTC conversion** | 0.40 (0.21-0.78) | 0.007 | 0.42 (0.19-0.92) | 0.031 |
| **Pain** | 0.65 (0.34-1.24) | 0.186 | 0.51 (0.24-1.11) | 0.090 |