ODM-201 is an androgen receptor (AR) inhibitor with high nonclinical and clinical efficacy. Bone scan index (BSI) is an imaging biomarker that reflects the percent of skeletal mass affected by tumor.

**Methods**

We retrospectively studied a consecutive series of 47 metastatic CRPC (mCRPC) patients (pts), who received ODM-201 in ARADES trial for BSI analysis. A data cut-off of April 4, 2014 was used for analyses. Total of 36/134 mCRPC pts (median age 68, range 55-82) with baseline and 12-week bone metastases were randomly selected to this evaluation. BSI data was obtained by using the automated quantification software EXINI bone® (EXINI Diagnostics AB, Lund, Sweden). Cox proportional-hazards regression models and Kaplan-Meier estimates of the survival function were used to investigate the association between changes in BSI and PSA from baseline to 12 weeks follow-up and progression data.

**Results**

Using Pearson correlation, BSI change from baseline correlated with RECIST target lesion response (r=0.50; p=0.0418), and CTC change from baseline (r=0.66; p<0.0001). BSI % change correlated with PSA %change (r=0.76; p<0.0001), RECIST target lesion response (r=0.51; p=0.0384), CTC % change (r=0.62; p=0.0011), and CTC conversion rate (r=0.67; p=0.0001). Pts with small (<20%) increase in BSI during 12 weeks had significantly longer time to PSA progression (median 72 vs 25 weeks, hazard ratio [HR] 0.21, 95% CI [0.05, 0.83]; p=0.0268) in the chemo-/CYP17I-naïve population, and significantly longer radiographic progression-free survival (rPFS) (median 50 vs 14 weeks, [HR] 0.35, 95% CI [0.17, 0.74]; p=0.0060), and time to radiologic progression in bone (median NR vs. 23, HR=0.20 95% CI [0.07, 0.58], p=0.0027), when analyzing all subgroups together.

In an analysis including all subgroups, pts with baseline BSI>1 had significantly longer median time to radiologic progression in bone than pts with baseline BSI<1 (median not reached vs. 35 weeks, [HR] 0.25, 95% CI [0.09, 0.66]; p=0.0056).

**Conclusions**

The baseline BSI was related to radiologic progression-free time in bone in pts with mCRPC, and on-treatment increase in BSI was associated with time to PSA progression, rPFS and progression of disease in bone. BSI for quantification of bone metastases could be a valuable complement to the traditional methods for evaluation of treatment response in mCRPC pts.