BONE-MARKER LEVELS AND POTENTIAL CORRELATION WITH OUTCOMES IN PATIENTS WITH BLADDER CANCER AND BONE METASTASIS: PRELIMINARY RESULTS OF TUGAMO TRIAL

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RATIONAL: Levels of serum bone-markers (BM) might be correlated with outcome in terms of skeletal related events (SRE), disease progression and death in patients (pts) with advanced bladder cancer and bone metastases treated with zoledronic acid 4 mg IV/every 3-4 weeks (ZA).

METHODS: Observational, prospective trial. All pts were not previously treated with bisphosphonates: Serum samples were measured at baseline and every 3 months (mo) for 24 mo. Bone specific alkaline phosphatase (BALP) was analyzed by ELISA (immunoenzymatic assay, IDS), carboxiterminal telopeptide of type I collagen (CTX) and aminoterminal propeptide of type I collagen (P1NP) by automatised assay (Elecsys, Roche). We present preliminary results of an exploratory analysis of BM changes at 6 mo follow up.

RESULTS: 34 pts were recruited. Median age was 66 years; stage at diagnosis was III-IV in 22% and 61% of pts respectively; median time from diagnosis to detection of bone metastasis: 14 mo; PS 2-3: 50%; 70% pts were previously treated with chemotherapy; analgesics drug use: 93%; previous SRE: 50%. 60% of pts had elevated baseline levels of CTX and P1NP and 48% of BALP. At the time of this analysis 6 pts had a follow up of 6 mo.: 6 (83%) had CTX and BALP normalization and 5 (100%), P1NP respectively.

CONCLUSIONS: In this population with advanced, heavily pre-treated, symptomatic disease, elevations of baseline BM levels are present. Preliminary data shows a normalization of BM levels in response to ZA. A longer follow up is needed to correlate these changes with pts outcomes.