P052 A retrospective analysis of the safety and activity of Lutetium-177-PSMA radionuclide treatment in heavily-pretreated men with metastatic castration-resistant prostate cancer

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Introduction & Objectives: Despite significant progress in the last decade, metastatic castration-resistant prostate cancer (mCRPC) continues to be a lethal disease. Lutetium-177-PSMA (Lu-PSMA), a radio-labelled small molecule, binds with high affinity to prostate-specific membrane antigen (PSMA), enabling beta particle therapy targeted to metastatic lesions. In a recent prospective single-arm phase II trial, a PSA decrease of ≥50% was observed in almost 60% of patients receiving Lu-PSMA. At the Sheba medical center, Lu-PSMA has been given off-trial as an advanced treatment line since the beginning of 2017 to men who have exhausted all approved lines for which they were deemed fit, with less stringent criteria of baseline blood counts than in the prospective trial.
Our study aimed to retrospectively analyze the safety and activity of Lu-PSMA in heavily-pretreated men with mCRPC.

Materials & Methods: The electronic medical records of all patients treated with Lu-PSMA were reviewed and clinical data was extracted. Our clinical endpoints were 'subjective clinical benefit', defined as symptomatic improvement, and 'PSA response', defined as a PSA decrease≥ 50%. Descriptive statistics were performed using Excel.

Results: Forty eight patients received Lu-PSMA; median age was 75 years (range 57-92). Thirty seven of them (77%) received Lu-PSMA as a forth treatment line or beyond. The number of treatment cycles ranged from 1 to 4; the mean administered radioactivity was 6 GBq per cycle. The treatment was generally tolerable; side effects included weakness/fatigue (n=11, 23%), thrombocytopenia exacerbation (n=6, 13%), anemia exacerbation (n=5, 10%) and anorexia/nausea (n=3, 6%). Clinical benefit was observed in 27 patients (56%); of 43 men who had at least one PSA measurement following treatment, PSA response was observed in 21 patients (48%), and PSA decrease of any magnitude was observed in 30 patients (70%).

Conclusions: Our results indicate that Lu-PSMA is tolerable and active in the 'real-life' setting of heavily-pretreated men with mCRPC, in keeping with published prospective data.