Real-life Analysis of [177Lu]Lu-PSMA-617 on mCRPC Patients cohort treated in France

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Objective:

VISION study demonstrated that adding [177Lu]Lu-PSMA-617 to BSoC improved imaging-based progression-free survival and overall survival in patients with PSMA-positive mCRPC. French Health Authorities approved an early access "cohort" for [177Lu]Lu-PSMA-617 in this setting.

Methods:

PSMA positive mCRPC patients who had received at least 1 taxane-based chemotherapy and ≥1 ARPI were included. [177Lu]Lu-PSMA-617 (7.4 GBq) was given up to 6 cycles every 6 weeks. Patients' characteristics and safety data are reported for the whole population. Efficacy was assessed within a sub-population with a minimum of 6 months follow-up after 1st [177Lu]Lu-PSMA-617 injection. AE grading was not performed.

Results:

From 1/12/2021 to 31/10/2023, 1340 patients were included, and 696 patients were evaluated for efficacy. At data cut-off, 749 were still on treatment, 591 discontinued treatments including 259 due to disease progression (43.8%), AE (9.8%) or death (6.0%). 210 patients (35.5%) finished all 6 injections.

Patients baseline characteristics: median age 73.4 years; ECOG 0-1: 87.4%; median PSA level 63 ng/ml; metastatic sites: bone 93.4%, lymph node 60.9%, liver 9.3%; prior taxane regimen: 97.4% of which 56.6% had 2; previous ARPI treatment: 100% and 64.3% had 2 or more (median: 2). Concomitant treatment with ARPI was observed in 26.3%.

Regarding efficacy results, the median progression free survival at imaging was determined by investigators (Conventional or TEP imaging) with a median of 7.3 months. The median time to clinical symptoms progression was 7.7 months. 68.4% of patients had a reduction in PSA level at any time point.

Patients received a median of 4 cycles.

12.0 % (n= 159) of patients experienced >1 treatment-related AE(TRAE). Most AE were considered as anticipated (244/344). The most common class of reported TRAE was hematotoxicity (192/344 TRAE).

Conclusions:

In this real life cohort of mCRPC treated with [177Lu]Lu-PSMA-617 patients were heavily pretreated, received less concomitant ARPI treatment and higher incidence of 2 prior taxane regimens compared to VISION. Patient profile is evolving with patients in earlier lines after several months of experience. Safety profile of [177Lu]Lu-PSMA-617 remains favorable. The cohort is still ongoing, updated results will be presented at urology summit, including longer follow-up period and higher number of patients who completed treatment.

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