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Efficacy and toxicity of [^{177}Lu]Lu-PSMA-617 for metastatic castration-resistant prostate cancer in a real-world setting: Results from the U.S. Expanded Access Program and comparisons with phase 3 VISION data.

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Background: ThePhase 3 VISION trial demonstrated that [^{177}Lu]Lu-PSMA-617 prolonged overall survival (OS) in metastatic-castration resistant prostate cancer (mCRPC) patients who progressed on taxane-based chemotherapy and androgen receptor-signaling inhibitors (ARSi). The expanded access program (EAP) (NCT04825652) was opened to provide access to [^{177}Lu]Lu-PSMA-617 for eligible patients until regulatory approval was obtained. The VISION trial required strict inclusion and exclusion criteria, which may not represent the patient population encountered in clinical practice. This study aimed to evaluate the efficacy and safety profile of [^{177}Lu]Lu-PSMA-617 in a real-world setting within the EAP and compare the results with those from the VISION trial. **Methods:** Patients enrolled in the EAP between May 2021 and March 2022 at four institutions in the United States with available toxicity and outcome data were included. Outcome measures included overall survival (OS), ≥50% PSA decline rates (PSA-RR), and incidences of toxicity according to Common Terminology Criteria for Adverse Events (CTCAE) v5.0. Differences in baseline characteristics, toxicity, and PSA-RR between the EAP and VISION were evaluated using a t-test of proportions. **Results:** 117 patients with mCRPC were eligible and included. Patients enrolled in the EAP were similarly pretreated with taxane-based chemotherapy regimens (>1 taxane: 47% vs 40%; p=0.16) and more heavily pretreated with ARSi (>1 ARSi: 70% vs 46%; p<0.001). EAP patients had similar levels of ≥3 grade anemia (18% vs 13%; p=0.15), thrombocytopenia (13% vs 8%; p=0.13), and neutropenia (3% vs 3%; p=0.85) and higher levels of ≥3 grade lymphopenia (34% vs 8%; p<0.001). Patients treated within the EAP experienced numerically shorter OS (median OS: 13.7 vs 15.3 months) and similar PSA-RR (40% vs 46%; p=0.29). Median follow-up was numerically shorter in the EAP compared with VISION (14.7 mo vs 20.3 mo). **Conclusions:** mCRPC patients treated with [^{177}Lu]Lu-PSMA-617 in a real-world setting were more heavily pretreated with ARSi, had a similar safety profile, and experienced numerically shorter OS and similar PSA-RR compared with VISION trial patients. A major limitation of this study is that we did not have access to individual patient data from the VISION trial, so we were not able to assess whether differences in OS between VISION and the EAP were statistically significant. Research Sponsor: None.