LONG-TERM EFFICACY AND SAFETY OF ENZALUTAMIDE MONOTHERAPY IN HORMONE-NAIVE PROSTATE CANCER: 2-YEAR FOLLOW-UP


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Aim: Androgen-deprivation therapy (ADT) is the first-choice treatment for advanced prostate cancer (PC). Enzalutamide (ENZ) is approved for the treatment of post-docetaxel metastatic castration-resistant PC. In previous analyses of a Phase 2 study in pts with hormone-naive PC (HNPC) eligible for ADT, ENZ monotherapy after 6 mos and 1 yr (49 wks) was associated with a high prostate-specific antigen (PSA) response rate regardless of presence of metastatic disease at baseline, and with stable bone mineral density (BMD) and quality of life (QoL) on treatment. Here we report long-term efficacy and safety in pts treated up to 2 yrs.

Methods: 67 patients with HNPC and noncastrate testosterone (≥230 ng/dL) were enrolled in this open-label single-arm study (NCT01302041) and received ENZ 160 mg/d until disease progression or unacceptable toxicity. The primary variable of PSA response (≥80% decline from baseline) was assessed at 6 mos, 1 yr, and 2 yrs. Additional endpoints included best overall objective tumour response, BMD, body composition, QoL and safety.

Results: 67 pts were treated. Median age was 73.0 yrs (range 48-86); 26 (38.8%) had metastatic disease at baseline, and 24 (35.8%) and 16 (23.9%) had prior prostatectomy and radiation, respectively. 4 pts discontinued during the second year of follow-up and 45 remained on ENZ at 2 yrs. PSA response rate in pts remaining on ENZ at 2 yrs was 100% (95% CI 92, 100). Of 26 pts with metastases at baseline, 13 (50%) had complete response and 4 (15.4%) partial response as best overall tumour response over 2 yrs. There were decreases in mean (SD) total body BMD of -0.39% (2.24) and lean body mass -5.27% (3.66) at 2 yrs. EORTC-QLQ C30 QoL data showed maintenance of global health status through 2 yrs, though there were clinically meaningful deteriorations (≥10 points) on the fatigue, and role functioning scales. Most common adverse events (AEs) were gynaecomastia, fatigue, nipple pain and hot flush.

Conclusions: ENZ monotherapy was associated with significant long-term PSA reductions and good tumour response in men with HNPC. This was achieved without adversely affecting total body BMD or global health status.

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