

Patient-reported outcomes (PROs) From TITAN: A phase 3, randomized, double-blind study of apalutamide (APA) versus placebo (PBO) added to androgen deprivation therapy (ADT) in patients (pts) with metastatic castration-sensitive prostate cancer (mCSPC)

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Introduction & Objectives: Compared with PBO, addition of APA to ADT significantly improved radiographic progression-free survival (rPFS [HR, 0.48; 95% CI, 0.39-0.60; $p < 0.0001$]), and overall survival (OS [HR, 0.67; 95% CI, 0.51-0.89; $p = 0.0053$]) in pts with mCSPC (TITAN Study; Chi KN et al. NEJM 2019). In this analysis, we evaluated pain, fatigue, and overall health-related quality of life (HRQoL) of pts in TITAN.

Materials & Methods: mCSPC pts (N = 1052) were randomized 1:1 to APA (240 mg QD; n = 525) or PBO (n = 527). All pts received ADT. Pts were stratified by Gleason score at diagnosis (≤ 7 vs > 7), region (North America vs European Union vs other countries), and prior docetaxel use (yes vs no). PROs were assessed using the Brief Pain Inventory-Short Form (BPI-SF), Brief Fatigue Inventory (BFI), Functional Assessment of Cancer Therapy-Prostate (FACT-P), and EuroQol Group EQ-5D-5L. BPI and BFI were completed for 7 consecutive days (D) (D -6 plus D1 of each cycle [C] visit), then at Months 4, 8, and 12 in follow-up. FACT-P and EQ-5D-5L were completed C1 through C7, then every other C through end of treatment (tmt), and at Months 4, 8, and 12 in follow-up. Analyses included descriptive statistics and mean change from baseline using mixed model of repeated measures.

Results: Pts were relatively asymptomatic at baseline: On 0-10 severity scales, median pain scores were 1.14 (APA) and 1.00 (PBO), and median fatigue scores were 1.29 (APA) and 1.43 (PBO). Pt experience of pain and fatigue (both intensity and interference) was similar between groups for the duration of tmt. For the majority of pts in both arms, pain and fatigue remained stable or improved during tmt, with greater improvements observed in pts with higher baseline severity scores. FACT-P total score and EQ-5D-5L data showed similar maintenance of overall HRQoL in both arms. Similar tolerability was experienced between groups based on the FACT-P single-item side effects bother question.

Conclusions: The addition of APA to ADT maintained overall HRQoL while significantly improving OS and rPFS in mCSPC pts.