On behalf of Astellas and Medivation, we are submitting this request for review of data for the NCCN Prostate Cancer Guideline Panel on Xtandi® (enzalutamide) from two multicenter, randomized, double-blind, double-dummy phase 2 clinical trials (TERRAIN and STRIVE) which compared enzalutamide to bicalutamide in men with castration-resistance prostate cancer (CRPC).1-3 The TERRAIN trial enrolled 375 men with metastatic CRPC and the STRIVE trial enrolled 396 men with either metastatic or non-metastatic CRPC.

Specific Changes: We are providing data from the TERRAIN and STRIVE trials which evaluated the use of enzalutamide compared to bicalutamide in men with CRPC as described above; data from these trials were presented in plenary sessions at the 30th Annual Congress of the European Association of Urology in Madrid, Spain (TERRAIN), and the American Urological Association Annual 2015 Meeting in New Orleans, LA, respectively (STRIVE and TERRAIN).1-3

FDA Clearance: Enzalutamide is currently approved for the treatment of patients with mCRPC.4

Rationale: Two multicenter, randomized, double-blind, double-dummy phase 2 clinical trials, TERRAIN and STRIVE, demonstrated significant increases in progression-free survival (PFS) for enzalutamide 160 mg/day compared to bicalutamide 50 mg/day in men with CRPC: in TERRAIN, a significant increase in PFS was observed, with a hazard ratio (HR) of 0.44 (95% CI, 0.34-0.57; \(P<0.0001\)), while in STRIVE, the overall HR was 0.24 (95% CI, 0.18-0.32; \(P<0.0001\)) (HR for the subset of metastatic CRPC patients was 0.24 [95% CI, 0.17-0.34; \(P<0.0001\)], and 0.24 [95% CI, 0.14-0.42] for the non-metastatic subset) with the most common enzalutamide adverse events in these trials being fatigue, back pain, hot flush, and hypertension.1-3

Additional details of the TERRAIN and STRIVE trials can be accessed here:

TERRAIN:

STRIVE:
Cited References


