Background Treatment with abiraterone acetate + prednisone can improve outcomes in mCRPC patients with or without prior chemotherapy. Cohort D of phase 1b/2 study KEYNOTE-365 (NCT02861573) evaluated safety and efficacy of PD-1 inhibitor pembrolizumab + abiraterone acetate and prednisone in patients who had not received chemorapy for mCRPC.

Methods Patients were enrolled who had not received second-generation hormonal manipulation for mCRPC or failed/were intolerant to enzalutamide for mCRPC; had progressive disease ≤6 months before screening; and had ECOG PS 0/1. Patients received pembrolizumab 200 mg IV Q3W + abiraterone acetate 1000 mg orally QD and prednisone demonstrated antitumor activity in patients with chemotherapy-naive mCRPC. Safety was generally consistent with individual profiles of each agent. There was an increased incidence of grade 3–4 ALT/AST laboratory elevations.

Conclusions Pembrolizumab + abiraterone acetate and prednisone demonstrated antitumor activity in patients with chemotherapy-naive mCRPC. Safety was generally consistent with individual profiles of each agent. There was an increased incidence of grade 3–4 ALT/AST laboratory elevations.