A randomized trial of abiraterone acetate (AA) administered with 1 of 4 glucocorticoid (GC) regimens in metastatic castration-resistant prostate cancer (mCRPC) patients (pts).

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Background: AA is approved for mCRPC, coadministered with prednisone (P) (5 mg BID) to prevent adverse events (AEs) associated with mineralocorticoid excess (ME). Lower GC doses had not previously been formally evaluated in combination with AA. **Methods**: This was an open-label, multicenter, phase 2 trial (NCT01867710) of asymptomatic chemotherapy-naïve mCRPC pts randomized 1:1:1:1 to AA (1000 mg QD) plus P 5 mg BID or P 5 mg QD or P 2.5 mg BID or dexamethasone (DEX) 0.5 mg QD. Pts who had previously received GC or ketoconazole were

excluded. The primary end point was no ME (% of pts experiencing neither hypokalemia nor hypertension during the first 24 weeks of treatment).Secondary end points included additional safety, as well as response rate in the first 24 weeks, defined as a decline in prostate-specific antigen (PSA) ≥ 50% confirmed after 4 weeks. **Results:** 164 pts were randomized; 133 (81.6%) completed 24 weeks' treatment. Median age: 70 years. Table 1 shows the rates of ME, hypertension, hypokalemia and PSA response. Changes in HbA1c values were minimal and observed in 16 (10.7%) pts. **Conclusions**: These data suggest that P 5 mg BID, which is approved in combination with AA, and DEX 0.5 mg QD, are effective in preventing ME-associated AEs, and that P 2.5 mg BID and P 5 mg QD can be safely used with appropriate monitoring. The suggestion of a higher PSA response rate with DEX 0.5 mg QD arm warrants further validation. Clinical trial information: NCT01867710

	P 5 mg BID	P 5 mg QD	P 2.5 mg BID	DEX 0.5 mg QD
	n = 41	n = 41	n = 40	n = 42
No ME[a], n/N (%)	27/34 (79.4)	17/37 (45.9)	22/35 (62.9)	28/37 (75.7)
Hypokalemia[a], n/N (%)				
Overall	3/41 (7.3)	6/41 (14.6)	3/39 (7.7)	4/42 (9.5)
Grade 3	0	2/41 (4.9)	0	0
Hypertension[a], n/N (%)				
Overall	6/41 (14.6)	15/41 (36.6)	12/39 (30.8)	5/42 (11.9)
Grade 3	3/41 (7.3)	6/41 (14.6)	5/39 (12.8)	1/42 (2.4)
≥ 50% PSA response at Week 12, n/N (%)	20/35 (57.1)	24/34 (70.6)	17/37 (45.9)	31/39 (79.5)
No change in HbA1c, n/N (%)[b]	28/38 (73.7)	34/36 (94.4)	37/37 (100)	35/39 (89.7)

N = Evaluable pts. [a]According to the National Cancer Institute Common Terminology Criteria for Adverse Events V4.0. No grade 4 occurred. [b]Change at end point versus baseline.