Supplementary Online Content

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This supplementary material has been provided by the authors to give readers additional information about their work.

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eMethods

Additional Information on Study Procedures

Plasma adrenocorticotropic hormone (ACTH) was collected at 4 degrees Celsius and analyzed locally. Urine was collected with a record of 24-hour urine volume on day 1 of cycle 1 (with collection starting 24 hours before initiation of treatment), day 1 of cycles 3, 6, and every 6 cycles until cycle 36, and at the end of the main study. Frozen aliquots were sent in batches to a central laboratory where urinary steroids were analyzed using gas chromatography-mass spectrometry as described previously[1] in a clinically-accredited laboratory (Alta Bioscience, Birmingham, UK). Serum insulin and glucose were measured on day 1 of cycles 1, 2, 3, 6, 12, and 18, and at the end of the main study. Dual-energy x-ray absorptiometry scans to assess bone mineral density, total body fat and lean body mass were performed up to 28 days prior to cycle 1, at cycles 3, 6, and 12, and at the end of the main study. Serum PSA was measured on day 1 of cycles 1-6 and every three cycles thereafter. Radiographic disease progression was assessed by CT and bone scans performed up to 28 days prior to cycle 1 and every 12 weeks on treatment, or earlier if clinically indicated. To assess health-related quality of life, patients completed the EuroQol five dimensions (EQ-5D-5L) questionnaire[2] and the Functional Assessment of Cancer Therapy - Prostate Cancer (FACT-P) questionnaire[3] on day 1 of cycles 1, 6, and 18 and at the end of the main study.

Information on Urinary Steroid Analysis

For evaluation of the effect on steroid biosynthesis, we evaluated changes between day 1 of cycles 1 and 3 of: urinary metabolites of steroids upstream of CYP17A1, deoxycorticosterone (sum of tetrahydro-11-deoxycorticosterone and 5α-tetrahydro-11-deoxycorticosterone) and corticosterone (sum of tetrahydrocorticosterone, 5α-tetrahydrocorticosterone, tetrahydro-11-dehydrocorticosterone, and 5α-tetrahydro-11-dehydrocorticosterone); and urinary metabolites of downstream steroids, namely the major androgen metabolite androsterone, the adrenal androgen precursor dehydroepiandrosterone (DHEA), and

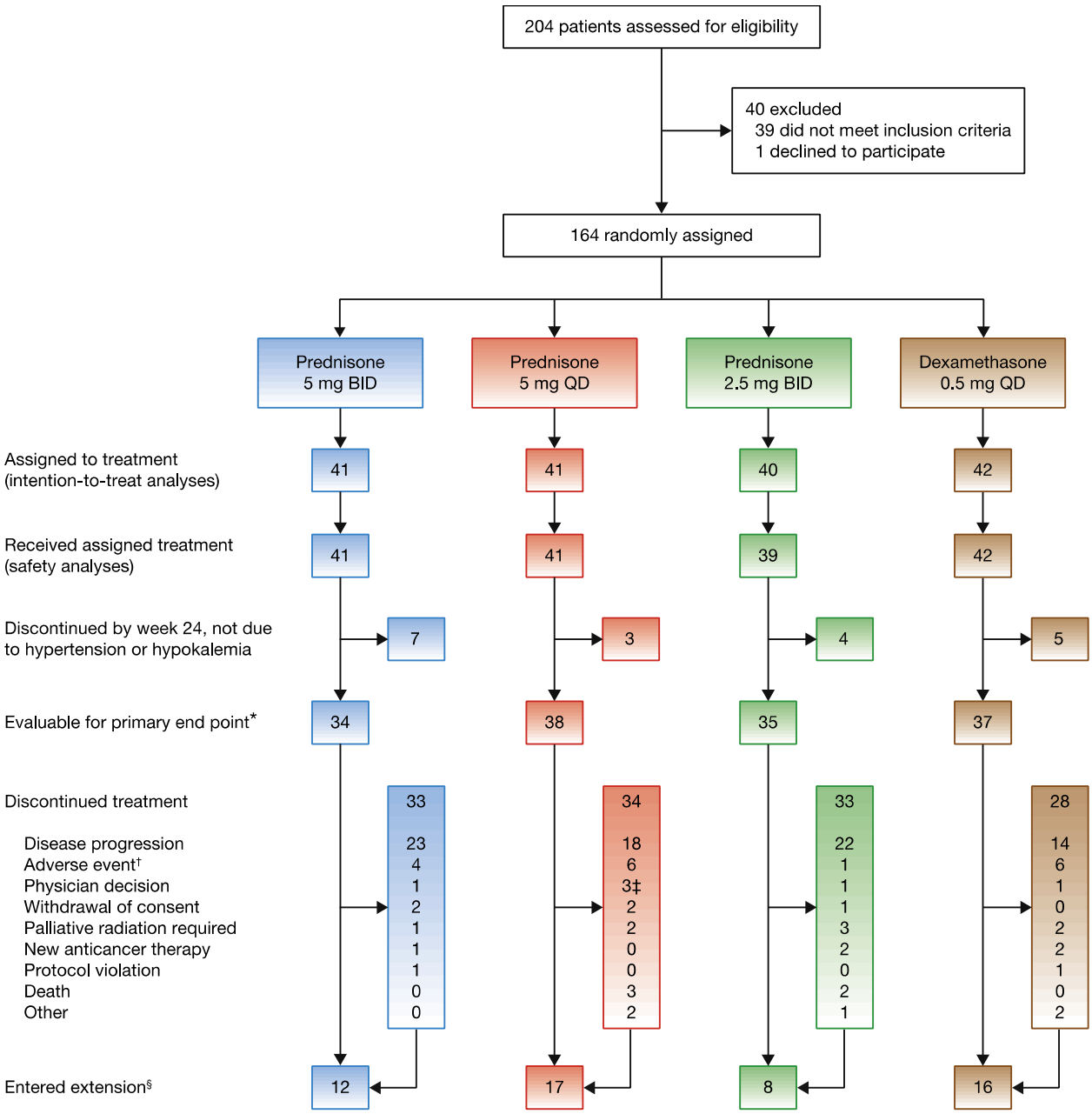
the sum of androgen precursors (dehydroepiandrosterone, 16α-hydroxy-DHEA, pregnenetriol, and pregnenediol).

eReferences

1. Attard G, Reid AH, Yap TA, et al. Phase I clinical trial of a selective inhibitor of CYP17, abiraterone acetate, confirms that castration-resistant prostate cancer commonly remains hormone driven. *J Clin Oncol.* 2008;26(28):4563-4571.
2. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res.* 2011;20(10):1727-1736.
3. Esper P, Mo F, Chodak G, Sinner M, Cella D, Pienta KJ. Measuring quality of life in men with prostate cancer using the functional assessment of cancer therapy-prostate instrument. *Urology.* 1997;50(6):920-928.

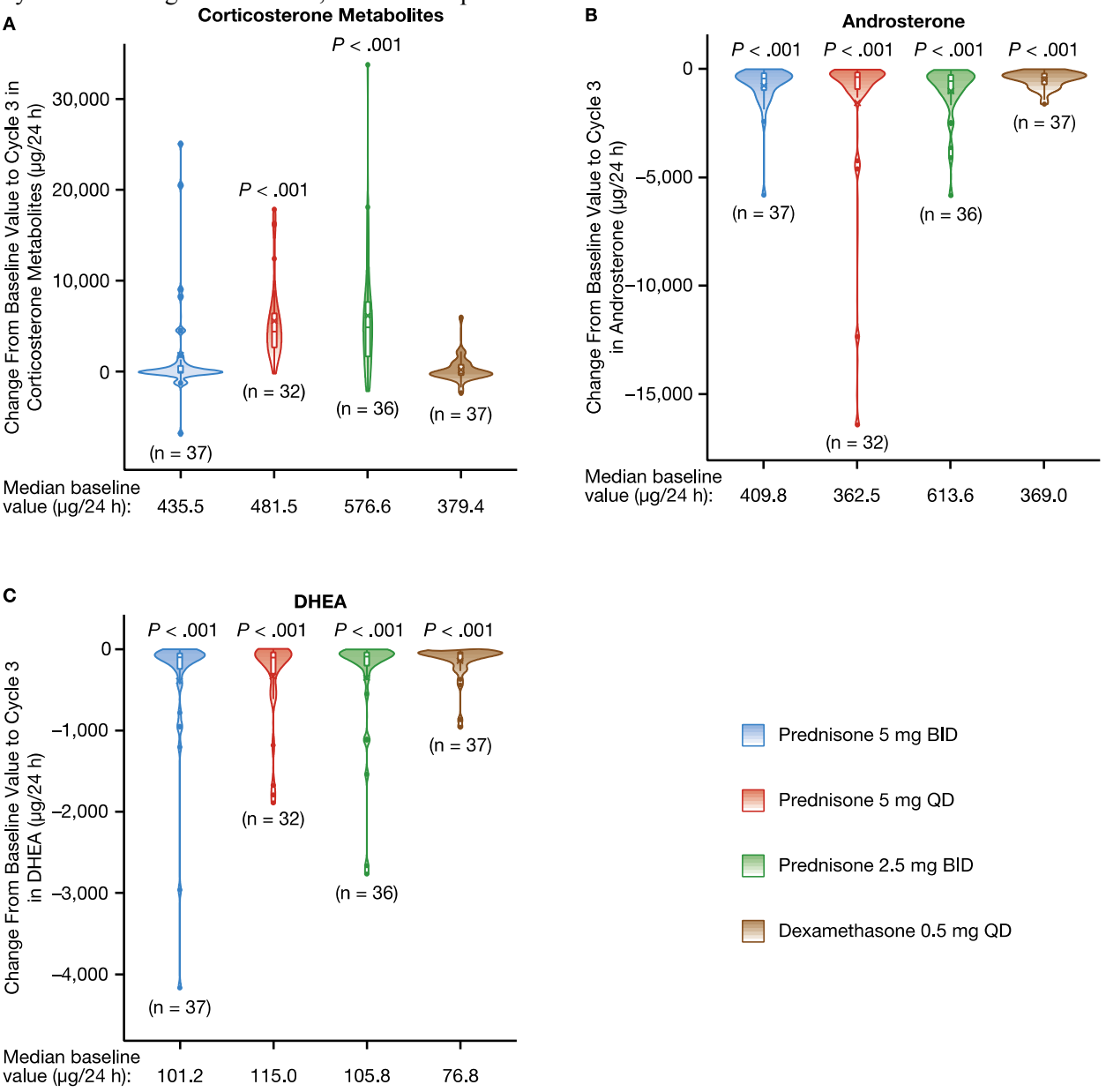
eFigure 1. Patient Disposition

*Patients completing the 24 weeks of treatment or discontinuing the 24 weeks early and experiencing either hypertension (CTCAE Grade ≥2) or hypokalemia. †Includes adverse event requiring treatment with diuretics, adverse event of grade 3 or 4 hypokalemia, adverse event with sustained toxicity greater than NCI-CTCAE (v4.0) grade 1, or other adverse event. ‡Includes 1 patient whose study treatment regimen was permanently changed by investigator. §Patients who required diuretic treatment or a change in glucocorticoid dose, or who experienced grade 3 or 4 hypokalemia, could join the extension protocol at improvement to grade ≤1 and in the absence of disease progression; patients who completed the main study also could join the extension protocol.



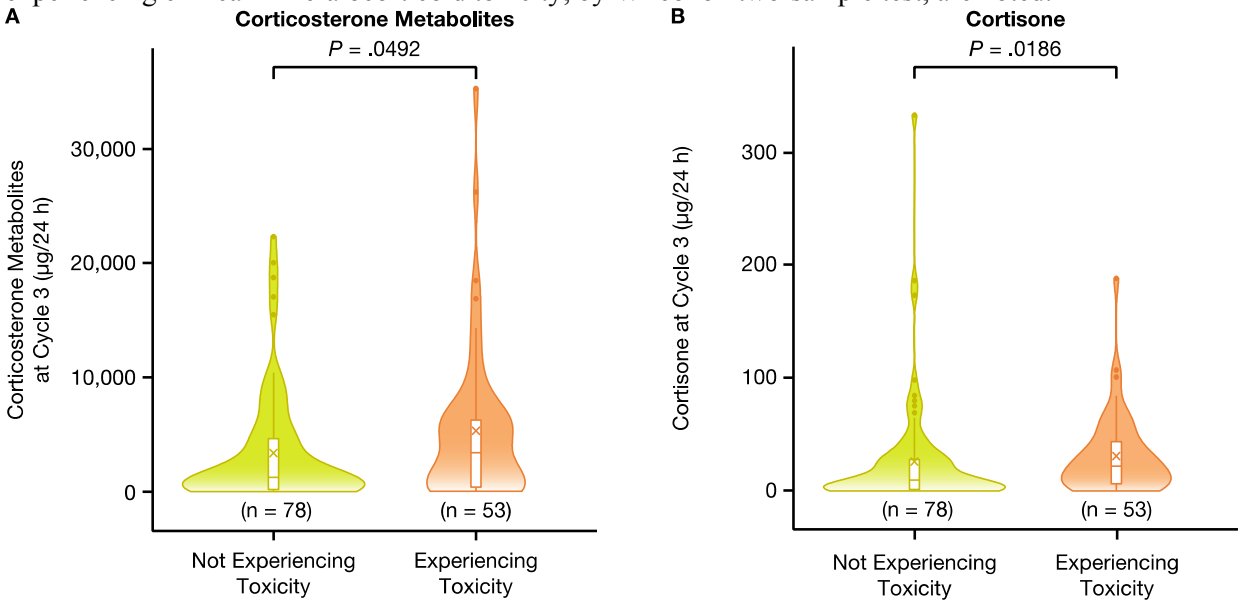
eFigure 2. Changes from baseline to cycle 3 by treatment group for urinary corticosterone metabolites (A), the major androgen metabolite androsterone (B), and DHEA (C); and values at cycle 3 for the urinary metabolites of corticosterone (D) and cortisone (E) among patients experiencing or not experiencing clinical mineralocorticoid excess toxicity (grade ≥2 hypertension or grade ≥1 hypokalemia) in the first 24 weeks

DHEA, dehydroepiandrosterone. Violin plots represent the four treatment regimen arms. Boxes represent median (horizontal bar), mean (X) and quartiles (Q1 and Q3), and whiskers indicate quartiles ± 1.5 × (Q3-Q1). Minimum and maximum values are the lowest and highest dots. Significant changes from baseline, by Wilcoxon Signed Rank test, are noted in panels A-C.

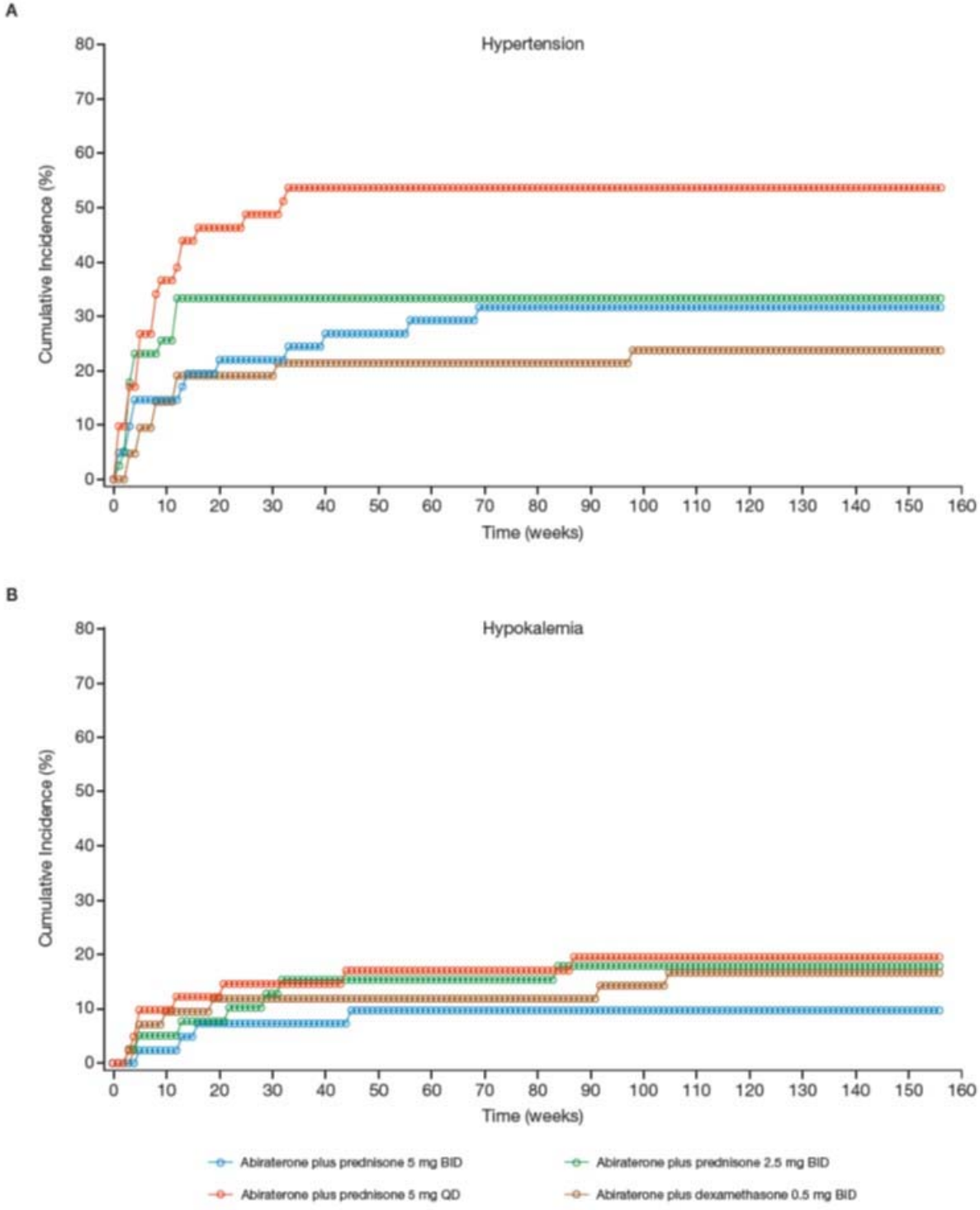


eFigure 3. Values at cycle 3 for the urinary metabolites of corticosterone (A) and cortisone (B) among patients experiencing or not experiencing clinical mineralocorticoid excess toxicity (grade ≥2 hypertension or grade ≥1 hypokalemia) in the first 24 weeks

Violin plots represent the four treatment regimen arms. Boxes represent median (horizontal bar), mean (X) and quartiles (Q1 and Q3), and whiskers indicate quartiles ± 1.5 × (Q3-Q1). Minimum and maximum values are the lowest and highest dots. Significant differences between patients experiencing or nor experiencing clinical mineralocorticoid toxicity, by Wilcoxon two-sample test, are noted.

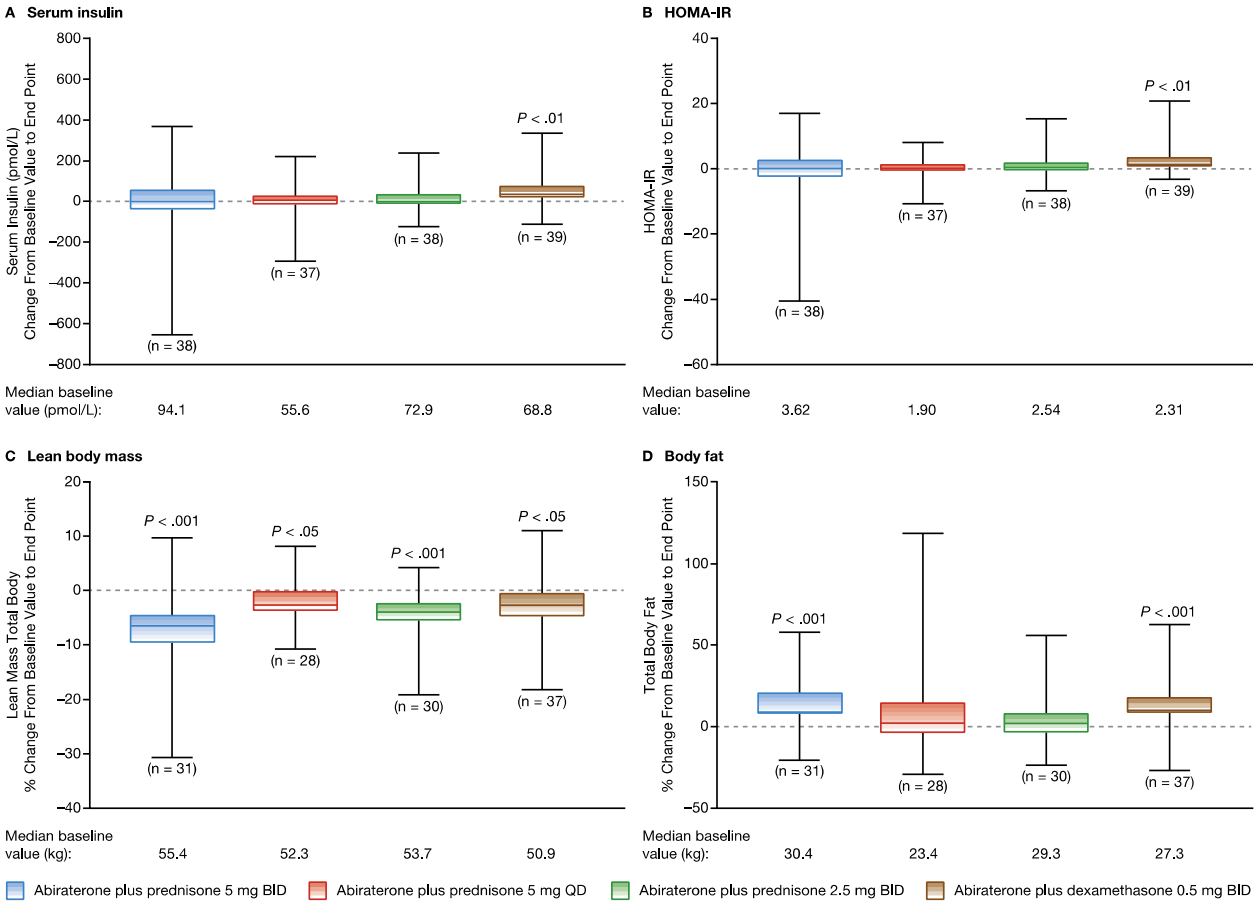


eFigure 4. Cumulative incidences for adverse events of hypokalemia or hypertension.
Note: this figure includes adverse events at any time during the main study treatment period; the primary study endpoint in Table 1 included only the first 24 weeks (6 cycles).

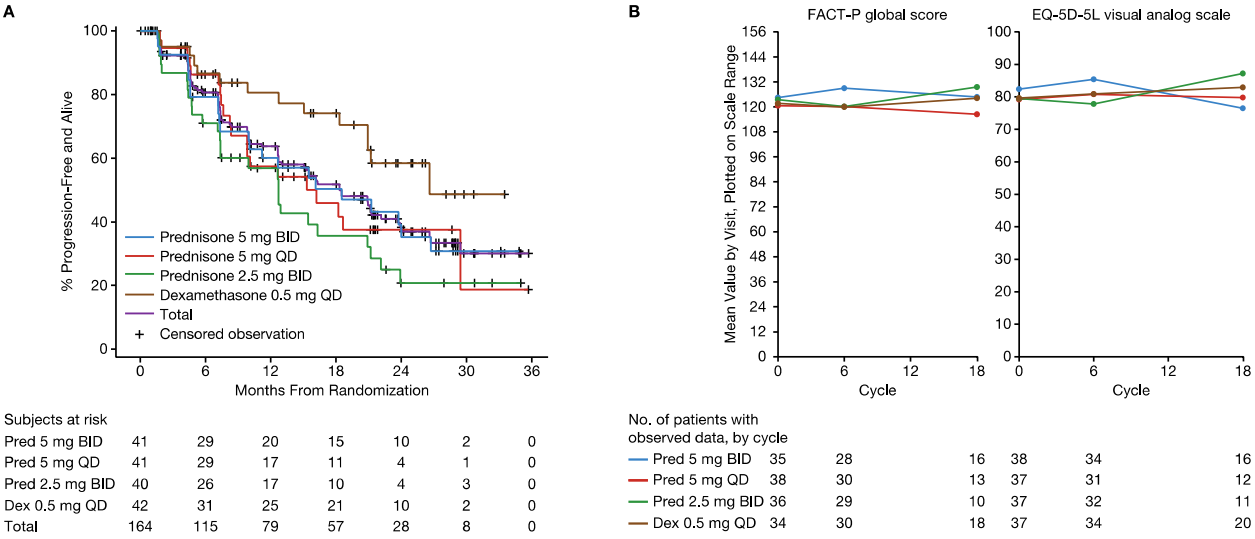


eFigure 5. Change from baseline in fasting serum insulin (A) and HOMA-IR (B), and percentage change from baseline in total lean body mass (C) and total body fat (D) at end of main study (up to 39 cycles).

HOMA-IR, homeostatic model assessment–insulin resistance; LOCF, last observation carried forward. Boxes represent median (horizontal bar) with 95% CIs, and whiskers indicate minimum and maximum values. Significant changes from baseline, by Wilcoxon Signed Rank test, are noted in each panel.



eFigure 6. Clinical benefit: Kaplan-Meier plot of radiographic progression-free survival during the main study for intention-to-treat population, divided by treatment group (A); and patient-reported quality of life as measured by EQ-5D-5L and FACT-P (B)



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eTable 2. Full list of urinary steroid metabolites analyzed by gas chromatography-mass spectrometry

Androsterone
Etiocholanolone
Dehydroepiandrosterone
11-oxoetiocholanolone
17 alpha-hydroxyprogesterone
11 beta-hydroxy androsterone
11 beta-hydroxyetiocholanolone
3 alpha 5 alpha 17 alpha-hydroxyprogesterone
16-alpha hydroxydehydroepiandrosterone
Pregnanediol
Pregnanetriol
5-Pregnenediol
Tetrahydro-11-deoxy-cortisol
Tetrahydroxycorticosterone
5 alpha tetrahydrodeoxycorticosterone
Pregnanetriolone
Tetrahydrocortisone
5-Pregnen-3-beta, 17-alpha, 20-alpha-triol
Tetrahydroaldosterone
Tetrahydrocorticosterone
5 alpha tetrahydrocorticosterone
5 alpha tetrahydroaldosterone
beta-Tetrahydrocortisol
5 alpha Tetrahydrocortisol
alpha-cortolone
3 alpha, 5-beta-tetrahydro-aldosterone
beta-cortol
beta-cortolone
alpha-cortol
Cortisone
Cortisol
6-beta hydroxycortisol

eTable 3. Baseline characteristics

	Abiraterone acetate with			
	Prednisone 5 mg BID (n=41)	Prednisone 5 mg QD (n=41)	Prednisone 2.5 mg BID (n=40)	Dexamethasone 5 mg QD (n=42)
Age (years) Median (range)	68.0 (50-88)	69.0 (54-88)	70.0 (67-72)	71.0 (54-90)
Body-mass index (kg/m^2) Mean (SD)	27.8 (4.5)	26.4 (3.3)	28.4 (3.9)	27.0 (3.8)
Gleason score at diagnosis				
≤ 7	19 (51.4%)	9 (23.7%)	17 (43.6%)	21 (52.5%)
8-10	18 (48.6%)	29 (76.3%)	22 (56.4%)	19 (47.5%)
Missing	4	3	1	2
Metastasis stage at diagnosis				
M0	22 (66.7%)	11 (37.9%)	13 (50.0%)	26 (81.3%)
M1	11 (33.3%)	18 (62.1%)	13 (50.0%)	6 (18.8%)
Missing	8	12	14	10
Time from diagnosis of prostate cancer to randomization (months)				
Mean (SD)	66.0 (56.1)	69.2 (53.9)	59.6 (38.4)	101.4 (65.0)
Missing	0	0	1	0
Time from start of systemic therapy to randomization (months)				
Mean (SD)	57.9 (43.7)	55.3 (40.5)	48.0 (30.2)	82.1 (61.2)
Missing	0	0	0	0
ECOG performance status at baseline				
0	37 (90.2%)	41 (100.0%)	34 (87.2%)	38 (90.5%)
1	4 (9.8%)	0	5 (12.8%)	4 (9.5%)
Missing	0	0	1	0
PSA at baseline (µg/L)				
Median (range)	55.3 (1.6-792.7)	49.3 (1.5-1537.0)	50.3 (2.2-893.7)	38.5 (0.7-712.0)
Missing	0	0	2	0
Measurable disease at baseline				
Measurable disease*	20 (90.9%)	18 (60.0%)	11 (61.1%)	16 (64.0%)
Missing	19	11	22	17
Metastatic sites at baseline				
Bone	33 (80.5%)	32 (78.0%)	34 (87.2%)	33 (80.5%)
Nodes	19 (46.3%)	25 (61.0%)	16 (41.0%)	21 (51.2%)
Lung†	0	1 (2.4%)	0	2 (4.9%)
Liver†	0	1 (2.4%)	0	1 (2.4%)
Missing	0	0	1	1
Bone lesions at baseline				
None	8 (20.0%)	10 (25.0%)	6 (15.8%)	9 (21.4%)
1-4	8 (20.0%)	11 (27.5%)	9 (23.7%)	15 (35.7%)

5-10	9 (22.5%)	4 (10.0%)	8 (21.1%)	5 (11.9%)
> 10	15 (37.5%)	15 (37.5%)	15 (39.5%)	13 (31.0%)
Missing	1	1	2	0
Blood pressure at baseline‡				
Stage <1§	30 (73.2%)	22 (53.7%)	28 (71.8%)	28 (66.7%)
Stage 1‖	9 (22.0%)	18 (43.9%)	9 (23.1%)	13 (31.0%)
Stage 2 or higher¶	2 (4.9%)	1 (2.4%)	2 (5.1%)	1 (2.4%)
Missing	0	0	1	0
Baseline medications				
Any antihypertensive	23 (56.1%)	16 (39.0%)	21 (52.5%)	23 (54.8%)
Potassium supplementation	0	0	0	0
Any lipid-modifying agent	14 (34.1%)	11 (26.8%)	10 (25.0%)	14 (33.3%)
Any bisphosphonate	2 (4.9%)	0	1 (2.5%)	2 (4.8%)
Denosumab	0	2 (4.9%)	2 (5.0%)	2 (4.8%)
Chemistry tests, mean (SD)				
Potassium (mmol/L)	4.32 (0.417)	4.26 (0.432)	4.29 (0.359)	4.39 (0.499)
Lactate dehydrogenase (U/L)	373.8 (371.5)	256.8 (89.7)	328.1 (266.5)	289.7 (171.1)
Alkaline phosphatase (IU/L)	194.0 (169.8)	167.0 (128.4)	194.5 (137.1)	171.3 (161.4)
Albumin (g/L)	42.18 (4.60)	41.80 (4.26)	43.63 (3.33)	43.00 (3.90)
Insulin (pmol/L)	125.3 (128.9)	73.2 (62.9)	95.6 (75.4)	72.3 (40.2)
HOMA-IR	5.26 (7.30)	2.54 (2.23)	3.60 (3.52)	2.61 (1.55)

ECOG=Eastern Cooperative Oncology Group; PSA=prostate specific antigen. Data are n (%), mean (SD), or median (range). *Per RECIST guidelines v1.1, measurable disease was defined as at least one target lesion with longest diameter ≥10 mm by computed tomography scan. †The initial study protocol excluded patients with lung or liver metastases; after 61 of 164 patients were enrolled, a protocol amendment included patients with lung or liver metastases. ‡Baseline blood pressure was the lowest of 3 consecutive measurements at the baseline visit. §Systolic blood pressure <140 mmHg and diastolic blood pressure <90 mmHg. ‖Systolic blood pressure 140-159 mmHg and/or diastolic blood pressure 90-99 mmHg. ¶Systolic blood pressure ≥160 mmHg and/or diastolic blood pressure ≥100 mmHg

eTable 4. Changes from baseline to cycle 3 by treatment group for plasma ACTH and key urinary steroid metabolites

	Abiraterone with			
	Prednisone 5 mg BID (n=41)	Prednisone 5 mg QD (n=41)	Prednisone 2.5 mg BID (n=39)	Dexamethasone 0.5 mg QD (n=42)
Plasma adrenocorticotropic hormone				
Absolute change (pmol/L)				
Median	-1.07	8.95	3.97	-1.82
IQR	-3.08 to 0.30	4.39 to 12.63	0.42 to 9.24	-3.39 to -0.10
P	.1602	<.0001	.0001	.0155
Percentage change (%)				
Median	-27	189	101	-39
IQR	-71 to 26	115 to 338	6 to 194	-63 to -4
P	.2667	<.0001	<.0001	.0527
Urinary deoxycorticosterone metabolites				
Absolute change (µg/24h)				
Median	11.4	75.9	100.5	5.1
IQR	-1.9 to 60.9	46.7 to 176.2	36.9 to 158.6	-6.2 to 20.9
P	.0007	<.0001	<.0001	.0708
Percentage change (%)				
Median	149	862	716	35
IQR	-15 to 324	351 to 1491	402 to 1391	-39 to 337
P	<.0001	<.0001	<.0001	.0074
Urinary corticosterone metabolites				
Absolute change (µg/24h)				
Median	17.8	4452.6	4913.5	-180.1
IQR	-99.1 to 646.2	2610.2 to 6573.0	1650.6 to 7787.9	-355.6 to 798.2
P	.1906	<.0001	<.0001	.7958
Percentage change (%)				
Median	13	984	1016	-42
IQR	-37 to 130	622 to 1851	471 to 1846	-79 to 135
P	.084	<.0001	<.0001	.7505
Urinary androsterone				
Absolute change (µg/24h)				
Median	-429.2	-367.3	-548.0	-364.8
IQR	-961.5 to -190.7	-922.7 to -147.9	-1105.0 to -272.8	-703.1 to -200.1
P	<.0001	<.0001	<.0001	<.0001
Percentage change (%)				
Median	-100	-99	-99	-100
IQR	-100 to -99	-100 to -98	-100 to -98	-100 to -99
P	<.0001	<.0001	<.0001	<.0001
Urinary dehydroepiandrosterone				
Absolute change (µg/24h)				
Median	-100.6	-103.5	-92.6	-58.0
IQR	-242.1 to -51.3	-346.3 to -39.3	-205.3 to -38.5	-151.0 to -38.2
P	<.0001	<.0001	<.0001	<.0001
Percentage change (%)				
Median	-97	-94	-90	-96

IQR	-99 to -93	-98 to -89	-97 to -82	-98 to -88
P	<.0001	<.0001	<.0001	<.0001
Urinary androgen precursors				
Absolute change (μg/24h)				
Median	-330.8	-37.0	-48.9	-262.1
IQR	-555.5 to -165.8	-189.2 to 68.0	-319.9 to 210.3	-369.0 to -89.5
P	<.0001	.1823	.3371	<.0001
Percentage change (%)				
Median	-81	-11	-14	-88
IQR	-89 to -63	-50 to 42	-53 to 39	-93 to -56
P	<.0001	.6608	.8899	<.0001

eTable 5. Urinary steroid metabolites with *P*<0.1 for the comparison of values at cycle 3 day 1 between patients with or without clinical mineralocorticoid excess toxicity in the first 24 weeks

Urinary Steroid Metabolite at Cycle 3 Day 1	*P* for Patients With vs Without Toxicity in First 24 Weeks*
16a-hydroxy-DHEA	0.0710
17-hydroxy-pregnanolone	0.0575
3a, 5a-17-hydroxy-pregnanolone	0.0204
5a-tetrahydro-11-dehydro-corticosterone	0.0706
5a-tetrahydro-corticosterone	0.0481
Corticosterone metabolites	0.0492
Cortisol	0.0148
Cortisone	0.0186
Pregnanetriol	0.0536
Pregnanetriolone	0.0775
Pregnenetriol	0.0710
Tetrahydro-11-dehydro-corticosterone	0.0554
Tetrahydro-11-deoxycorticosterone	0.0831
Tetrahydro-corticosterone	0.0395
Tetrahydrocortisol	0.0701
Tetrahydrocortisone	0.0287
a-cortol	0.0699
a-cortolone	0.0660
ß-cortolone	0.0671

**P* by Wilcoxon two-sample test with no correction for multiple testing.

eTable 6. Adverse events of hypokalemia by treatment group and severity

	Abiraterone with			
	Prednisone 5 mg BID (n=41)	Prednisone 5 mg QD (n=41)	Prednisone 2.5 mg BID (n=39)	Dexamethasone 0.5 mg QD (n=42)
Any grade	4 (9.8%)	8 (19.5%)	7 (17.9%)	7 (16.7%)
Grade 1 (mild)	2 (4.9%)	4 (9.8%)*	4 (10.3%)	5 (11.9%)
Grade 2 (moderate)	2 (4.9%)	2 (4.9%)*	3 (7.7%)	2 (4.8%)
Grade 3 (severe)	0	3 (7.3%)	0	0
Grade 4 (life-threatening)	0	0	0	0
Grade 5 (fatal)	0	0	0	0

One patient in the prednisone 5 mg QD group experienced both grade 1 and grade 2 hypokalemia.

eTable 7. Adverse events of special interest during the main study (up to 39 cycles)

	Abiraterone with							
	Prednisone 5 mg BID (n=41)		Prednisone 5 mg QD (n=41)		Prednisone 2.5 mg BID (n=39)		Dexamethasone 0.5 mg QD (n=42)	
Any adverse event	40 (97.6%)		37 (90.2%)		38 (97.4%)		42 (100.0%)	
Any grade 3-4 adverse event	11 (26.8%)		17 (41.5%)		13 (33.3%)		18 (42.9%)	
Any serious adverse event	9 (22.0%)		9 (22.0%)		11 (28.2%)		15 (35.7%)	
Adverse event leading to death	1 (2.4%)		1 (2.4%)		3 (7.7%)		2 (4.8%)	
Adverse events of interest†	All grades	Grade 3-4	All grades	Grade 3-4	All grades	Grade 3-4	All grades	Grade 3-4
Hypertension	12 (29.3%)	3 (7.3%)	22 (53.7%)	9 (22.0%)	13 (33.3%)	5 (12.8%)	9 (21.4%)	3 (7.1%)
Edema peripheral	8 (19.5%)	0	4 (9.8%)	0	3 (7.7%)	0	8 (19.0%)	0
Hypokalemia	4 (9.8%)	0	8 (19.5%)	3 (7.3%)	7 (17.9%)	0	7 (16.7%)	0
Weight increased	4 (9.8%)	1 (2.4%)	2 (4.9%)	0	1 (2.6%)	0	6 (14.3%)	0
ALT increased	3 (7.3%)	1 (2.4%)	2 (4.9%)	1 (2.4%)	3 (7.7%)	0	5 (11.9%)	1 (2.4%)
Blood bilirubin increased	3 (7.3%)	0	0	0	1 (2.6%)	0	0	0
Fatigue	2 (4.9%)	0	6 (14.6%)	0	4 (10.3%)	0	6 (14.3%)	0
Osteopenia	2 (4.9%)	0	3 (7.3%)	0	0	0	1 (2.4%)	0
AST increased	1 (2.4%)	0	2 (4.9%)	1 (2.4%)	3 (7.7%)	0	4 (9.5%)	0
Blood alkaline phosphatase increased	1 (2.4%)	0	1 (2.4%)	1 (2.4%)	1 (2.6%)	0	3 (7.1%)	0
Osteoporosis	1 (2.4%)	0	1 (2.4%)	0	1 (2.6%)	0	3 (7.1%)	0
Atrial flutter	0	0	1 (2.4%)	1 (2.4%)	0	0	0	0
Left ventricular failure	0	0	1 (2.4%)	0	0	0	0	0
Atrioventricular block first degree	0	0	0	0	1 (2.6%)	0	0	0
Atrioventricular block second degree	0	0	0	0	1 (2.6%)	0	0	0
Cardiac failure	0	0	0	0	1 (2.6%)	1 (2.6%)	0	0

Ventricular arrhythmia	0	0	0	0	1 (2.6%)	0	0	0
Hyperbilirubinemia	0	0	0	0	1 (2.6%)	0	0	0
Supraventricular tachyarrhythmia	0	0	0	0	0	0	1 (2.4%)	1 (2.4%)
Hyperglycemia	0	0	0	0	0	0	2 (4.8%)	0

ALT=alanine aminotransferase; AST=aspartate aminotransferase; BID=twice daily; QD=once daily. * Events that were reported at any grade for at least 5% of patients in any group (listed in descending order for the prednisone 5 mg BID group). † Adverse event of interest based on phase 2 and phase 3 studies of abiraterone acetate plus prednisone; all reported adverse events of interest are listed in descending order for the prednisone 5 mg BID group.

eTable 8. Changes from baseline in bone mineral density - total body and arms

	Abiraterone with			
	Prednisone 5 mg BID (n=41)	Prednisone 5 mg QD (n=41)	Prednisone 2.5 mg BID (n=39)	Dexamethasone 0.5 mg QD (n=42)
Total body				
Baseline				
N	32	33	31	37
Mean (SD)	1.20 (0.14)	1.14 (0.16)	1.22 (0.17)	1.12 (0.14)
Median	1.19	1.13	1.21	1.09
95% CI	(1.15, 1.25)	(1.09, 1.20)	(1.15, 1.28)	(1.07, 1.17)
Min, Max	(1.01; 1.70)	(0.82; 1.58)	(0.95; 1.63)	(0.88; 1.49)
Cycle 12, day 1 – % Change from Baseline				
N	23	20	14	27
Mean (SD)	-0.96 (9.19)	0.83 (6.04)	0.50 (3.03)	-1.46 (4.36)
Median	-0.09	-0.31	0.20	-0.65
95% CI	(-4.93, 3.01)	(-1.99, 3.66)	(-1.25, 2.24)	(-3.18, 0.27)
Min, Max	(-33.31; 11.78)	(-10.08; 15.55)	(-4.87; 6.35)	(-15.54; 5.89)
p-value	0.9531	0.8983	0.5830	0.1677
End of main study – % Change from Baseline				
N	32	33	31	37
Mean (SD)	-1.23 (8.82)	0.08 (5.66)	-0.12 (5.57)	-2.01 (4.30)
Median	-0.44	0.66	0.52	-1.26
95% CI	(-4.41, 1.95)	(-1.21, 2.80)	(-2.16, 1.93)	(-3.44, -0.57)
Min, Max	(-33.31; 15.59)	(-10.08; 15.55)	(-21.42; 9.18)	(-16.30; 5.09)
p-value	0.6184	0.4888	0.6184	0.0153
Arms				
Baseline				
N	32	33	30	37
Mean (SD)	1.27 (0.41)	1.24 (0.40)	1.38 (0.35)	1.33 (0.38)
Median	1.23	1.21	1.49	1.41
95% CI	(1.12, 1.42	(1.10, 1.38)	(1.25, 1.50)	(1.21, 1.46)
Min, Max	(0.68; 2.17)	(0.57; 1.93)	(0.68; 2.06)	(0.68; 2.22)
p-value				
Cycle 12, day 1 – % Change from Baseline				
N	21	22	14	26
Mean (SD)	3.30 (19.65)	0.49 (14.24)	-1.81 (15.57)	-2.40 (9.69)
Median	0.19	0.34	-0.15	-0.85
95% CI	(-5.64, 12.24)	(-5.83, 6.81)	(-10.80, 7.18)	(-6.32, 1.51)
Min, Max	(-49.97; 53.73)	(-51.71; 32.19)	(-49.15; 25.43)	(-34.00; 20.85)
p-value	0.5789	0.6486	0.8077	0.1459
End of main study – % Change from Baseline				
N	32	33	30	37
Mean (SD)	0.83 (18.75)	-2.05 (14.90)	-2.96 (18.50)	-4.91 (17.09)
Median	0.26	-0.47	-0.16	-0.42

	Abiraterone with			
	Prednisone 5 mg BID (n=41)	Prednisone 5 mg QD (n=41)	Prednisone 2.5 mg BID (n=39)	Dexamethasone 0.5 mg QD (n=42)
95% CI	(-5.93, 7.59)	(-7.34, 3.23)	(-9.87, 3.95)	(-10.61, 0.79)
Min, Max	(-50.23; 53.73)	(-52.66; 32.19)	(-51.42; 31.60)	(-54.84; 23.53)
p-value	0.7982	0.5695	0.6659	0.1909

eTable 9. Number of patients with any PSA response and confirmed PSA response during the main study (up to 39 cycles)

	Abiraterone with			
	Prednisone 5 mg BID (N=41)	Prednisone 5 mg QD (N=41)	Prednisone 2.5 mg BID (N=40)	Dexamethasone 0.5 mg QD (N=42)
Any PSA response				
n (%)	26 (63.4%)	32 (78.0%)	24 (60.0%)	37 (88.1%)
95% CI	(48.1, 76.4)	(63.3, 88.0)	(44.6, 73.7)	(75.0, 94.8)
Confirmed PSA response*				
n (%)	25 (61.0%)	30 (73.2%)	21 (52.5%)	34 (81.0%)
95% CI	(45.7, 74.3)	(58.1, 84.3)	(37.5, 67.1)	(66.7, 90.0)

PSA=prostate specific antigen. *Patients with a second documented reduction of ≥50% from baseline ≥4 weeks after the first reduction.