ELECTRONIC SUPPLEMENTARY MATERIAL

Title: Comparison of a Novel Formulation of Abiraterone Acetate Versus the Originator Formulation in Healthy Male Subjects : Two Randomized, Open-Label, Crossover Studies

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Caption :
Study 101 Bioequivalence Analysis of Dose Proportionality for AAFP

Online Resource 1. Bioequivalence analysis of dose proportionality for AAFP 100 mg and 400 mg after dose normalization to 200 mg.

PK Paramet	Average (raw			ANOVA Model-Based Least-Square Mean (log scale)					
	AAFP 100 mg	AAFP 200 mg	Ratio (%)	AAFP 100 mg	AAFP 200 mg	Mean Differenc	(90% CI)	Geometric Mean Ratio	(90% CI of Ratio)
$AUC_{0-\infty}$	150.731	183.348	82.5	4.866	5.091	−0.225	(−0.370, −0.080)	0.799	(0.691 − 0.923)
AUC_{0-t}	136.876	169.801	81	4.76	5.004	−0.244	(−0.397, −0.091)	0.783	(0.673 − 0.913)
C_{max}	35.265	39.07	101.5	3.377	3.471	−0.094	(−0.318, 0.130)	0.910	(0.727 − 1.139)

	AAFP 400 mg	AAFP 200 mg	Ratio (%)	AAFP 400 mg	AAFP 200 mg	Mean Differenc	(90% CI)	Geometric Mean Ratio	(90% CI of Ratio)
$AUC_{0-\infty}$	165.276	183.344	95	5.034	5.091	−0.057	(−0.198, 0.084)	0.945	(0.821 − 1.087)*
AUC_{0-t}	156.727	169.988	98.1	4.969	5.004	−0.035	(−0.183, 0.113)	0.966	(0.832 − 1.120)*
C_{max}	34.158	39.106	98.4	3.399	3.471	−0.072	(−0.290, 0.146)	0.931	(0.748 − 1.157)

PK Parameters	Statistics	Power Model: $P = a \times Dose^b$	
		A	B
$AUC_{0-\infty}$	Parameter Estimates	0.4596	1.087
	95% CI - Lower Limit	0.1325	0.8537
	95% CI - Upper Limit	1.5935	1.3203
	p value	0.2154	<0.0001
AUC_{0-t}	Parameter Estimates	0.3540	1.1202
	95% CI - Lower Limit	0.0970	0.8772
	95% CI - Upper Limit	1.2923	1.3632
	p value	0.1137	<0.0001

C_{max}		0.1802	0.9670
	Parameter Estimates	0.1802	0.9670
	95% CI - Lower Limit	0.0415	0.6913
	95% CI - Upper Limit	0.7831	1.2427
	p value	0.0231	<0.0001

AAFP, abiraterone acetate fine particle; $AUC_{0-\infty}$, area under the plasma concentration–time curve from time 0 extrapolated to infinite time; AUC_{0-t}, area under the plasma concentration–time curve from time 0 to the time of the last quantifiable concentration; C_{max}, maximum concentration; CI, confidence interval.

* The 90% CI fell within the recommended 0.800–1.250 limits of bioequivalence when analyzed on log.