

Table 8.12.6c Best overall response per RECIST 1.1 based on independent central review (PFS-Full analysis set)

	Lu-PSMA-617+ BSC/BSoC (N=385)		BSC/BSoC only (N=196)
Best Overall Response (BOR), n (%)			
Complete Response (CR)	18 (4.7)		0
Partial Response (PR)	77 (20.0)		2 (1.0)
Stable Disease (SD)	68 (17.7)		30 (15.3)
Non-CR/Non-PD	121 (31.4)		48 (24.5)
Progressive Disease (PD)	39 (10.1)		39 (19.9)
Unknown	62 (16.1)		77 (39.3)
Overall Response Rate (ORR: CR+PR), n (%) [95% CI]	95 (24.7) [20.4, 29.3]		2 (1.0) [0.1, 3.6]
Odds Ratio [95% CI] ^a		31.64 [7.71, 129.94]	
Two-sided p-value ^a		<.001	
Disease Control Rate (DCR: CR+PR+SD+Non-CR/Non-PD>6 weeks), n (%) [95% CI]	284 (73.8) [69.1, 78.1]		80 (40.8) [33.9, 48.0]
Odds Ratio [95% CI] ^a		4.41 [3.01, 6.46]	
Two-sided p-value ^a		<.001	

^a Odds Ratio of Lu-PSMA-617+BSC/BSoC vs. BSC/BSoC based on logistic regression model stratifying for the randomization stratification factors, LDH (\leq 260 IU/L vs. > 260 IU/L); presence of liver metastases (yes vs. no); ECOG score (0 or 1 vs. 2); and inclusion of NAAD in best supportive/standard of care at time of randomization (yes vs no). IRT data for stratification are used. P-value based on Wald's Chi-Square test.

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Data Cutoff Date: 27JAN2021