Table 8.12.6a Best overall response per RECIST 1.1 based on independent central review (Response evaluable analysis set)

	Lu-PSMA-617+ BSC/BSoC (N=319)		BSC/BSoC only (N=120)
Best Overall Response (BOR), n (%)			
Complete Response (CR)	18 (5.6)		0
Partial Response (PR)	77 (24.1)		2 (1.7)
Stable Disease (SD)	68 (21.3)		30 (25.0)
Non-CR/Non-PD	121 (37.9)		48 (40.0)
Progressive Disease (PD)	33 (10.3)		35 (29.2)
Unknown	2 (0.6)		5 (4.2)
Overall Response Rate (ORR: CR+PR), n (%) [95% CI]	95 (29.8) [24.8, 35.1]		2 (1.7) [0.2, 5.9]
Odds Ratio [95% CI][a]		24.99 [6.05, 103.24]	
Two-sided p-value[a]		<.001	
Disease Control Rate (DCR: CR+PR+SD+Non-CR/Non-PD>6 weeks), n (%) [95% CI]	284 (89.0) [85.1, 92.2]		80 (66.7) [57.5, 75.0]
Odds Ratio [95% CI][a]		5.79 [3.18, 10.55]	
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 (<= 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