Final Version

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

	Lu-PSMA-617+ BSC/BSoC (N=551)		BSC/BSoC only (N=280)
Best Overall Response (BOR), n (%)			
Complete Response (CR)	26 (4.7)		2 (0.7)
Partial Response (PR)	102 (18.5)		2 (0.7)
Stable Disease (SD)	101 (18.3)		36 (12.9)
Non-CR/Non-PD	173 (31.4)		59 (21.1)
Progressive Disease (PD)	57 (10.3)		43 (15.4)
Unknown	92 (16.7)		138 (49.3)
Overall Response Rate (ORR: CR+PR), n (%) [95% CI]	128 (23.2) [19.8, 27.0]		4 (1.4) [0.4, 3.6]
Odds Ratio [95% CI][a]		20.98 [7.67, 57.43]	
Two-sided p-value[a]		<.001	
Disease Control Rate (DCR: CR+PR+SD+Non-CR/Non-PD>6 weeks), n (%) [95% CI]	402 (73.0) [69.0, 76.6]		99 (35.4) [29.8, 41.3]
Odds Ratio [95% CI][a]		5.31 [3.85, 7.32]	
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.

Output ID: T-8-12-6b 2022-06-10 18:36
G:\APPDATA\SAS_BIOMETRY\PROD\PROJECTS\PSMA617\VISION\HA_REQUESTS\HEALTHCANADA_REQUEST_02\PRODUCTION\TLF\PGM\t-eff-or-ci.sas
Data Cutoff Date: 27JAN2021