

Table 8.10.1a Analysis of radiographic progression-free survival based on independent central review using stratified log-rank test and cox regression model - Actual event rPFS analysis (PFS-Full analysis set)

	Lu-PSMA-617+ BSC/BSoC (N=385)	BSC/BSoC only (N=196)
Radiographic Progression-free Survival (rPFS), n (%)		
Events	294 (76.4)	146 (74.5)
Radiographic progressions	171 (44.4)	63 (32.1)
Deaths	123 (31.9)	83 (42.3)
Censored	91 (23.6)	50 (25.5)
Ongoing without event	90 (23.4)	24 (12.2)
Adequate assessment not available ^a	1 (0.3)	26 (13.3)
Kaplan-Meier estimates (months)		
25th percentile [99.2% CI]	4.2 [2.8, 5.3]	2.2 [2.0, 2.5]
Median rPFS [99.2% CI]	8.9 [8.3, 11.1]	4.6 [3.4, 6.8]
75th percentile [99.2% CI]	15.0 [13.8, 17.7]	10.6 [7.7, 15.0]
rPFS rates (%)		
3 months (SE) [99.2% CI]	80.4 (2.03) [74.4, 85.2]	63.5 (3.73) [52.7, 72.4]
6 months (SE) [99.2% CI]	66.1 (2.43) [59.2, 72.1]	43.6 (3.92) [33.1, 53.7]
12 months (SE) [99.2% CI]	35.8 (2.54) [29.1, 42.5]	22.8 (3.43) [14.4, 32.4]
Hazard Ratio (Stratified Cox PH model) ^{b,c}		
99.2% CI		0.55 [0.42, 0.73]
Stratified Log-rank Test one-sided p-value ^c		
		<.001
Follow-up time (months) ^d		
Median [95% CI]	17.0 [16.9, 17.2]	19.6 [14.4, NE]
Minimum-Maximum	0.0 - 22.6	0.0 - 20.9

^a Patients censored without adequate post-baseline evaluations or adequate baseline assessment.^b Hazard Ratio of Lu-PSMA-617+BSC/BSoC vs. BSC/BSoC.^c Both Cox PH model and Log-rank test are stratified for 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.^d Follow-up time = (Date of event or censoring - randomization date + 1)/30.4375 (months) censoring for death or radiographic progression.

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