

Table 8.12.6d Analysis of time to first symptomatic skeletal with on-treatment death as event using Cox regression model (PFS-Full analysis set)

	Lu-PSMA-617+ BSC/BSoC (N=385)	BSC/BSoC only (N=196)
Time to first symptomatic skeletal event (SSE), n (%)		
Events (SSE or Death)	103 (26.8)	55 (28.1)
SSEs	60 (15.6)	34 (17.3)
Deaths ^a	43 (11.2)	21 (10.7)
Censored	282 (73.2)	141 (71.9)
Kaplan-Meier estimates (months)		
25th percentile [95% CI]	8.8 [7.0, 10.5]	2.5 [2.0, 3.5]
Median time to first SSE [95% CI]	19.1 [18.2, NE]	10.5 [4.1, NE]
75th percentile [95% CI]	NE [NE, NE]	NE [NE, NE]
First SSE rates (%)		
3 months (SE) [95% CI]	91.1 (1.47) [87.8, 93.6]	70.2 (3.97) [61.7, 77.2]
6 months (SE) [95% CI]	83.0 (2.03) [78.6, 86.6]	54.8 (5.51) [43.4, 64.8]
12 months (SE) [95% CI]	67.1 (3.00) [60.8, 72.5]	46.2 (7.37) [31.5, 59.8]
Hazard Ratio (Stratified Cox PH model) ^{b c}		0.32
95% CI		[0.22, 0.46]
Stratified Log-rank Test two-sided p-value		<.001
Follow-up time (months) ^d		
Median [95% CI]	9.5 [8.8, 11.3]	2.7 [2.3, 3.1]
Minimum-Maximum	0.0 - 22.6	0.0 - 19.8

^a Deaths are on-treatment deaths, deaths that occurred during randomized treatment or within 30 days of randomized treatment discontinuation or within 12 weeks of randomization for those not treated.

^b Hazard Ratio of Lu-PSMA-617+BSC/BSoC vs. BSC/BSoC.

^c Cox PH model is 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 censoring for death or SSE.

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