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

	Lu-PSMA-617+ BSC/BSoC (N=551)	BSC/BSoC only (N=280)
Time to first symptomatic skeletal event (SSE), n (%)		
Events (SSE or Death)	149 (27.0)	70 (25.0)
SSEs	88 (16.0)	41 (14.6)
Deaths[a]	61 (11.1)	29 (10.4)
Censored	402 (73.0)	210 (75.0)
Kaplan-Meier estimates (months)		
25th percentile [95% CI]	8.3 [7.0, 10.2]	2.5 [2.0, 3.1]
Median time to first SSE [95% CI]	22.6 [18.8, NE]	10.5 [5.4, NE]
75th percentile [95% CI]	NE [NE, NE]	NE [NE, NE]
First SSE rates (%)		
3 months (SE) [95% CI]	90.9 (1.25) [88.1, 93.0]	69.1 (3.56) [61.5, 75.4]
6 months (SE) [95% CI]	82.0 (1.73) [78.3, 85.1]	56.2 (4.66) [46.6, 64.7]
12 months (SE) [95% CI]	66.9 (2.49) [61.8, 71.6]	50.0 (5.95) [37.9, 60.9]
Hazard Ratio (Stratified Cox PH model)[b c]	0.35	
95% CI	[0.25, 0.47]	
Stratified Log-rank Test two-sided p-value	<.001	
Follow-up time (months)[d]		
Median [95% CI]	9.2 [8.8, 10.6]	2.5 [2.2, 2.8]
Minimum-Maximum	0.0 - 31.4	0.0 - 27.1

[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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