

Table 8.12.8b Subgroup characteristics – Baseline eGFR level and renal impairment based on medical history (FAS Safety Set)

Patients with renal impairment based on Medical history		Lu-PSMA-617 +BSC/BSoC (N=529)	BSC/BSoC only (N=205)	Overall (N=734)
Baseline eGFR level				
Yes	n	11	2	13
	Normal eGFR (≥ 90 mL/min)	1 (9.1)	0	1 (7.7)
	Mild impairment (eGFR= 60-<90 mL/min)	2 (18.2)	1 (50.0)	3 (23.1)
	Moderate impairment (eGFR 30-<60 mL/min)	7 (63.6)	1 (50.0)	8 (61.5)
	Severe impairment (eGFR <30 mL/min)	1 (9.1)	0	1 (7.7)
No	n	518	203	721
	Normal eGFR (≥ 90 mL/min)	228 (44.0)	78 (38.4)	306 (42.4)
	Mild impairment (eGFR= 60-<90 mL/min)	227 (43.8)	94 (46.3)	321 (44.5)
	Moderate impairment (eGFR 30-<60 mL/min)	62 (12.0)	30 (14.8)	92 (12.8)
	Severe impairment (eGFR <30 mL/min)	1 (0.2)	1 (0.5)	2 (0.3)

Renal impairment is determined through search of selected PTs in Medical History. Patients with at least one event are classified as 'Yes', otherwise as 'No', regardless of the events or timing of events.

eGFR categories are defined as follows: normal (eGFR ≥ 90 mL/min), mild (eGFR= 60-<90 mL/min), moderate (eGFR= 30-<60 mL/min) and severe (eGFR <30 mL/min).

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