APPENDIX 4: SUMMARY OF RELEVANT PATIENT POPULATION AND BASELINE CHARACTERISTICS

STUDY NAME	AGE				T-SCORE				PREVALENT FRACTURES (FX)			PRIOR USE OF BISPHOSPHONATES		
	Age (Mean ± SD)		Years Since Menopause		Inclusion Criteria		Baseline Data (Mean ± SD)		Inclusion Criteria	Baseline Data (% prevalent Fx)		Inclusion Criteria	Baseline Data (% treatment-experienced)	
	Active	PL	Active	PL			Active	PL		Active	PL		Active	PL
DENOSUMAB														
FREEDOM [18,36]	72.3 (5.2)	72.3 (5.2)	NR	NR	T-score between -2.5 and -4 at LS or TH		At LS: -2.82 (0.70) At FN: -2.15 (0.72)	At LS: -2.84 (0.69) At FN: -2.17 (0.71)	≤ 2 moderate Fx allowed. No severe	23.8%	23.4%	Prohibited within 12 months	NR	
ZOLEDRONIC ACID														
HORIZON PFT [19,29,30,33,37,38]	73.1 (5.3)	73 (5.4)	NR	NR	• ≤ -2.5 – no Fx; • ≤ -1.5 with Fx; at FN only		73% of patients < -2.5	71% of patients < -2.5	Yes	62.3%	64.2%	Washout period required	14.6%	14.4%
RALOXIFENE														
MORE [20,24-26,28,31,39,40]*	66.4 (6.9)	66.6 (7)	18.6 (8.5)	18.7 (8.3)	• ≤ -2.5 – no Fx; • Low BMD with Fx;		At LS: -2.55 (1.09) At FN:	At LS: -2.58 (1.14) AT FN:	Yes	37.9%	36.4%	Prohibited within 6 months	NR	

STUDY NAME	AGE				T-SCORE			PREVALENT FRACTURES (FX)			PRIOR USE OF BISPHOSPHONATES	
	Age (Mean ± SD)		Years Since Menopause		Inclusion Criteria	Baseline Data (Mean ± SD)		Inclusion Criteria	Baseline Data (% prevalent Fx)		Inclusion Criteria	Baseline Data (% treatment-experienced)
	Active	PL	Active	PL		Active	PL		Active	PL		Active	PL
					• ≥ 2 Fx regardless of BMD; at FN or LS	-2.32 (0.55)	-2.33 (0.55)						
CORE (BMD sub-study)[5][†]	66.7 (6.9)	67.5 (7)	NR	NR		AT LS: -2.18 (1.03) At FN: -2.25 (0.43)	AT LS: -2.17 (0.95) At FN: -2.23 (0.43)		26%	27%			
Michalska[22]	65.6 (7.1)	64.5 (6.3)	19.5 (7.9)	16.0 (6.0)	<- 2.5 at LS or proximal femur	NR		NA	NR		Required	100%	
Silverman[23],[41]	66.4 (6.7)	66.5 (6.8)	19.5 (8.7)	19.5 (8.8)	• Between -2.5 and -4 at LS or FN (no Fx); • Vertebral Fx regardless of BMD	At: LS: -2.4 (1.2) At FN: -1.7 (0.9)	At LS: -2.4 (1.2) At FN: -1.8 (0.9)	Yes	56.3%	56.4%	Prohibited within 6 months	NR	

FN = femoral neck; Fx = fracture; LS = lumbar spine NA = not addressed; NR = not reported; PL = placebo; SD = standard deviation; TH = total hip.

* Baseline data from Delmas, which reported the four-year results of MORE [†] Subset of CORE, in which patients did not use other bone-active agents.