TABLE 126 Breast cancer adverse events

Adverse event	Study									
	CSR Stopeck		Rosen 2004[109]		Lipton 2000[103,22]		Kohno 2005[102] (only grade 4 hypocalcaemia)		Body 2004[72]	
Intervention	D	Z	Z	P	P	PL	Z	PL	I*	PL
Time (years)	1.31	1.32	1.08	1.08	1.65	1.48	114	113	1.5	1.33
Number analysis	1013	1020	378	388	367	386	1	1	287	277
Adverse event,* n *(%)										
ONJ	20 (2.0)	14 (1.4)								
Renal toxicity	2 (0.2)	15 (1.5)	29 (7.7)	23 (5.9)			0	1 (0.9)	15 (5.2)	13 (4.7)
Hypercalcaemia	2 (0.2)	11 (1.1)			21 (5.7)	49 (12.7)	3 (2.6)	10 (8.8)		
Hypocalcaemia	6 (0.6)	4 (0.4)			3 (0.8)	3 (0.8)	1 (0.9)	1 (0.9)	27 (9.4)	14 (5.1)
Skin infection	9 (0.9)	5 (0.5)								
Abdominal pain	19 (1.9)	16 (1.6)					19 (16.7)	8 (7.1)	6 (2.1)	2 (0.7)
Alopecia			67 (17.7)	57 (14.7)			15 (13.2)	22 (19.5)		
Anaemia	34 (3.4)	39 (3.9)	96 (25.4)	91 (23.5)						
Arthralgia			90 (23.8)	76 (19.6)			24 (21.1)	18 (15.9)		
Asthenia	12 (1.2)	16 (1.6)	77 (20.4)	64 (16.5)						
Bone pain	11 (1.1)	14 (1.4)	228 (60.3)	223 (57.5)			36 (31.6)	51 (45.1)		
Constipation			92 (24.3)	100 (25.8)			33 (28.9)	37 (32.7)		
Cough			87 (23.0)	77 (19.8)						
Dehydration	13 (1.3)	26 (2.5)								
Diarrhoea	19 (1.9)	16 (1.6)	89 (23.5)	94 (24.2)			29 (25.4)	29 (25.7)		
Dizziness							17 (14.9)	25 (22.1)		
Dyspepsia									20 (7.0)	13 (4.7)

Diel 2004[140] Jackson 2005[150] (renal) Pecherstorfer 2006[154] (extension)		Paterson 1993[76]		Kirstensen 1999[75]	Carteni 2006[165] (pooled)		Coleman 2011[139] (AZURE abstract)		[a]Houston 2010[148]	
I**	PL	C	PL	C	NT	Z†	Z	NT	Z	I*
1.51 (0.87)	1.09 (1.37)	1.17	1.21	1.53	1.5	1.08	3	3	98	91
154 (46)	158 (16)	85	88	49	51	177	1665	1675	NR	NR
							11 (0.7)	0		
6 (3.9)	7 (4.4)					1 (0.6)	2 (0.1)	1 (0.1)	2 (2.0)	2 (2.2)
		28 (32.0)	52 (59.1)	5 (10.2)	5 (9.8)					
				13 (26.5)	2 (3.9)	28 (15.8)				
							10 (0.6)	8 (0.5)		
						8 (4.5)				
						32 (18.1)				
		4 (4.7)	5 (5.7)							
		5 (5.9)	2 (2.3)							

continued

TABLE 126 Breast cancer adverse events (*continued*)

Adverse event	Study									
	CSR Stopeck		Rosen 2004[109]		Lipton 2000[103,22]		Kohno 2005[102] (only grade 4 hypocalcaemia)		Body 2004[72]	
Dyspnoea	67 (6.6)	47 (4.6)	98 (25.9)	94 (24.2)			21 (18.4)	15 (13.3)		
Fatigue	18 (1.8)	5 (0.5)	152 (40.2)	159 (41.0)	147 (40.1)	107 (27.7)	51 (44.7)	36 (31.9)		
Flu-like symptoms										
Gastrointestinal symptoms										
General physical health deterioration	22 (2.2)	16 (1.6)								
Headache	16 (1.6)	9 (0.9)	70 (18.5)	94 (24.2)			34 (29.8)	32 (28.3)		
Hepatic failure	32 (3.2)	20 (2.0)								
Metastases to liver	23 (2.3)	32 (3.1)								
Myalgia			106 (28.0)	95 (24.5)						
Nausea	26 (2.6)	26 (2.5)	180 (47.6)	179 (46.1)			57 (50.0)	60 (53.1)	10 (3.5)	4 (1.4)
Neutropenia	18 (1.8)	25 (2.5)					18 (15.8)	19 (16.8)		
Oedema peripheral			58 (15.3)	73 (18.8)						
Oesophagitis									6 (2.1)	2 (0.7)
Pleural effusion	31 (3.1	32 (3.1)								
Pulmonary embolism	11 (1.1)	21 (2.1)								
Pyrexia	22 (2.2)	20 (2.9)	118 (31.2)	103 (26.5)	51 (13.9)	19 (4.9)	63 (55.3)	37 (32.7)		
Respiratory failure	24 (2.4)	20 (2.0)								
Thrombocytopenia	14 (1.4)	15 (1.5)								
Vomiting	40 (3.9)	36 (3.5)	119 (31.5)	120 (30.9)			37 (32.5)	44 (38.9)		

C*, 1.6 g daily; D, denosumab 120 mg 4-weekly; I*, ibandronic acid 50 mg orally; I**, ibandronic acid 6 mg intravenously; NR, not reported; NT, no treatment; PL, placebo; Z, zoledronic acid 4 mg 4-weekly; Z†, 4 mg and 3 mg combined.

a Observational study.

Diel 2004[140] Jackson 2005[150] (renal) Pecherstorfer 2006[154] (extension)		Paterson 1993[76]	Kirstensen 1999[75]	Carteni 2006[165] (pooled)	Coleman 2011[139] (AZURE abstract)		[a]Houston 2010[148]	
10 (6.5)	3 (1.9)						4 (4.1)	0
		2 (2.4)	1 (1.1)				12 (12.2)	12 (13.2)
6 (13.0)	1 (6.3)	1 (1.2)	0	7 (4.0)				
		18 (21.2)	19 (20.5)	9 (5.1)				
					8 (0.5)	10 (0.6)		
				67 (37.9)	4 (0.2)	3 (0.2)		
		7 (8.2)	10 (11.4)	10 (5.6)				