

2003 Emend® Label (Ex. 1016)

Table 2

Percent of Patients Responding by Treatment Group and Phase for Study 2 — Cycle 1

ENDPOINTS	Aprepitant Regimen (N = 261) ^a	Standard Therapy (N = 263) ^a	p-Value
PRIMARY ENDPOINT			
Complete Response	63	43	<0.001
Overall ^b			
OTHER PRESPECIFIED (SECONDARY AND EXPLORATORY) ENDPOINTS			
Complete Response			
Acute phase ^c	83	68	<0.001
Delayed phase ^c	68	47	<0.001
Complete Protection			
Overall	56	41	<0.001
Acute phase	80	65	<0.001
Delayed phase	61	44	<0.001
No Emesis			
Overall	66	44	<0.001
Acute phase	84	69	<0.001
Delayed phase	72	48	<0.001
No Nausea			
Overall	49	39	0.021
Delayed phase	53	40	0.004
No Significant Nausea			
Overall	71	64	<0.050
Delayed phase	73	65	<0.050

2008 Emend® Label (Ex. 1030)

Table 2

Percent of Patients Receiving Highly Emetogenic Chemotherapy Responding by Treatment Group and Phase for Study 2 — Cycle 1

ENDPOINTS	Aprepitant Regimen (N = 261) ^a	Standard Therapy (N = 263) ^a	p-Value
PRIMARY ENDPOINT			
Complete Response	63	43	<0.001
Overall ^b			
OTHER PRESPECIFIED ENDPOINTS			
Complete Response			
Acute phase ^c	83	68	<0.001
Delayed phase ^c	68	47	<0.001
Complete Protection			
Overall	56	41	<0.001
Acute phase	80	65	<0.001
Delayed phase	61	44	<0.001
No Emesis			
Overall	66	44	<0.001
Acute phase	84	69	<0.001
Delayed phase	72	48	<0.001
No Nausea			
Overall	49	39	NS ^d
Delayed phase	53	40	NS ^d
No Significant Nausea			
Overall	71	64	NS ^d
Delayed phase	73	65	NS ^d

TABLE 2

Percentages of Patients who Reached Secondary and Exploratory Efficacy Endpoints, by Study Phase and Treatment Group

Treatment group	Overall (Days 1-5)		Acute (Day 1)		Delayed (Days 2-5)	
	Aprepitant regimen (n = 260 patients) ^a	Standard therapy (n = 263 patients) ^a	Aprepitant regimen (n = 261 patients) ^a	Standard therapy (n = 263 patients) ^a	Aprepitant regimen (n = 260 patients) ^a	Standard therapy (n = 263 patients) ^a
No emesis	66 ^b	44	84 ^b	69	72 ^b	48
No rescue	82 ^b	73	96 ^b	90	83 ^b	74
Complete protection	56 ^b	41	80 ^b	65	61 ^b	44
Total control	44 ^c	32	64	57	50 ^b	34
No nausea	49 ^c	39	n/p	n/p	53 ^b	40
No significant nausea	71	64	n/p	n/p	73	65

n/p: Analysis not performed; complete protection: no emesis, no rescue therapy, and nausea visual analog scale (VAS) score <25 mm; total control: no emesis, no rescue therapy, and nausea VAS score <5 mm.

^a Because not every patient provided complete efficacy data, very slight variability (1 to 4 patients) occurred in the total numbers of patients across analyses for individual endpoints.

^b p < 0.01 compared with standard therapy.

^c p < 0.05 compared with standard therapy.

Poli-Bigelli reference (Ex. 1039)

EXHIBIT 1066

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