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)[†] %	Standard Therapy (N = 263)[‡] %	p-Value
PRIMARY ENDPOINT			
Complete Response			
Overall[‡]	63	43	<0.001
OTHER PRESPECIFIED ENDPOINTS			
Complete Response			
Acute phase[§]	83	68	<0.001
Delayed phase[‖]	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	49 128	39	NS*
Delayed phase	53 138	40	NS*
No Significant Nausea			
Overall	71 185	64	NS**
Delayed phase	73 190	65	NS**

2003 Emend® Label (Ex. 2016)

Table 2

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

ENDPOINTS	Aprepitant Regimen (N= 261)[†] %	Standard Therapy (N= 263)[‡] %	p-Value
PRIMARY ENDPOINT			
Complete Response			
Overall[‡]	63	43	< 0.001
OTHER PRESPECIFIED (SECONDARY AND EXPLORATORY) ENDPOINTS			
Complete Response			
Acute phase[§]	83	68	< 0.001
Delayed phase[‖]	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

TABLE 2
Percentages of Patients who Reached Secondary and Exploratory Efficacy Endpoints, by Study Phase and Treatment Group

	Overall (Days 1–5)		Acute (Day 1)		Delayed (Days 2–5)	
Treatment group	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[c]	74
Complete protection	56[b]	41	80[b]	65	61[b]	44
Total control	44[b]	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
Eric Roeland, MD
5/11/26 ____pgs
reporter: maria sharp

Azurity Pharmaceuticals, Inc. - EXHIBIT 1066
Azurity Pharmaceuticals, Inc. v. Helsinn Healthcare S.A.
IPR2025-00945