

# Protocol: VORINOSTAT FINAL REPORT

## Section 13 Table 4.1.4.1.3

### Dose Limiting Toxicity(Preferred Terms) by Dosage - Safety Set

		Number of Patients with DLT N(%) at respective dose of Vorinostat (mg/m2/day) (N=50)										
SOC (Meddra 20.1)	Preferred Term (Meddra 20.1)	130	180	230	280	330	380	430	480	530	580	714
Blood and lymphatic system disorders	Anaemia		1 (2.0)								1 (2.0)	
	Leukopenia			3 (6.0)	2 (4.0)	2 (4.0)	1 (2.0)	1 (2.0)			1 (2.0)	
	Thrombocytopenia		4 (8.0)	5 (10.0)	11 (22.0)	6 (12.0)	3 (6.0)	3 (6.0)	3 (6.0)	4 (8.0)	3 (6.0)	1 (2.0)
Gastrointestinal disorders	Abdominal pain				1 (2.0)							
	Abdominal pain upper	1 (2.0)	1 (2.0)									
	Nausea	1 (2.0)	1 (2.0)	1 (2.0)	1 (2.0)							
	Vomiting			1 (2.0)	1 (2.0)							
General disorders and administration site conditions	Fatigue	1 (2.0)	1 (2.0)	1 (2.0)	1 (2.0)			1 (2.0)	1 (2.0)		1 (2.0)	
Infections and infestations	Febrile infection				1 (2.0)						1 (2.0)	
Investigations	Alanine aminotransferase increased		1 (2.0)	2 (4.0)								
	Blood sodium decreased		1 (2.0)									
	Platelet count decreased		2 (4.0)	3 (6.0)	2 (4.0)		1 (2.0)	1 (2.0)				
	Weight decreased			1 (2.0)							1 (2.0)	
	White blood cell count decreased		1 (2.0)									
Metabolism and nutrition disorders	Decreased appetite	1 (2.0)	1 (2.0)	1 (2.0)								
	Hypermagnesaemia				1 (2.0)	1 (2.0)		1 (2.0)				
	Hypokalaemia			1 (2.0)								
	Hyponatraemia		1 (2.0)			1 (2.0)		1 (2.0)				

\*: Percentage was calculated on non-missing values only

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SOC (Meddra 20.1)	Preferred Term (Meddra 20.1)	130	180	230	280	330	380	430	480	530	580	714
Psychiatric disorders	Aggression		1 (2.0)									
	Apathy		1 (2.0)									
Social circumstances	Loss of personal independence in daily activities							1 (2.0)				

\*: Percentage was calculated on non-missing values only