SUPPLEMENTARY DATA

Supplementary Table SI Adverse events.

Adverse events	n (%) by Group		Relative risk (95% CI)	P value
	rhG-CSF	Placebo		
Total number of participants	76	74		
Participants with AE	52 (68)	43 (58)		
Blood and lymphatic system disorders	4 (5)	l (l)	3.9 (0.4, 34.2)	0.22
Cardiac disorders	1(1)	NA^{Υ}	NA	
Gastrointestinal disorders	33 (43)	24 (32)	1.3 (0.9, 2.0)	0.17
General disorders and administration site conditions	10 (13)	13 (18)	0.7 (0.4, 1.6)	0.44
Hepatobiliary disorders	I (I.3)	NA	NA	
Immune system disorders	2 (3)	NA	NA	
Infections and infestations	16 (21)	10 (14)	1.6 (0.8, 3.2)	0.23
Injury, poisoning and procedural complications	2 (3)	3 (4)	0.6 (0.1, 3.7)	0.63
Significantly deranged serum parameters	8(11)	5 (7)	1.6 (0.5, 4.6)	0.42
Musculoskeletal and connective tissue disorders	20 (26)	6 (8.1)	3.2 (1.4, 7.5)	0.01
Nervous system disorders	21 (28)	14 (19)	1.5 (0.8, 2.6)	0.22
Pregnancy, puerperium and perinatal conditions	8(11)	4 (5)	2.0 (0.6, 6.1)	0.25
Psychiatric disorders	I (I)	NA	NA	
Renal and urinary disorders	l (l)	1(1)	1.0 (0.1, 15.5)	0.99
Reproductive system and breast disorders	19 (25)	I (I5)	1.7 (0.9, 3.3)	0.13
Respiratory, thoracic and mediastinal disorders	4 (5)	2 (3)	1.9 (0.4, 10.3)	0.44
Skin and subcutaneous tissue disorders	8(11)	2 (3)	3.9 (0.9, 17.8)	0.08
Vascular disorders	l (l)	l (l)	1.0 (0.1, 15.2)	0.98

Among these, serious adverse events in the rhG-CSF group comprised of two occurrences of gastrointestinal disorders, a diagnosis of lower respiratory tract infection and one occurrence of severe headache, whereas serious adverse events in the placebo group comprised of a diagnosis of pneumonia and a diagnosis of endometritis.

Please note that this table is a summary of all adverse events. Some participants had multiple system involvement and therefore numbers in each system class will not add up to the total number of participants with AE.

 $^{{}^\}Upsilon NA$ indicates there were no events in the group.