

Title

Confirmation of Biosimilarity in a Pharmacokinetic/Pharmacodynamic Study in Healthy Volunteers for an Analytically Highly Similar Pegfilgrastim

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SUPPLEMENTARY TABLES

Demographic Data for Subjects in Study Apo-Peg-02, Overall N= 66 (Safety Analysis Set)

Parameter	Statistics	Total (N= 66)
Age [years]	Mean (\pm SD)	40.05 (\pm 8.770)
	Median	41
	Minimum - Maximum	20 - 55
Gender, n, (%)	Male	49 (74.24)
	Female	17 (25.76)
Race, n, (%)	White	39 (59.09)
	Black or African American	7 (10.61)
	Asian	6 (9.09)
	Other: Multi-Racial	7 (10.61)
	Other: Aboriginal	7 (10.61)
Ethnicity, n, (%)	Hispanic or Latino	23 (34.85)
	Not Hispanic or Latino	43 (65.15)
Body Height [cm]	Mean (\pm SD)	172.67 (\pm 8.128)
	Median	173.25
	Minimum - Maximum	150.5 - 188
Body Weight [kg]	Mean (\pm SD)	77.86 (\pm 9.630)
	Median	77.8
	Minimum - Maximum	61 - 96.6
BMI [kg/m^2]	Mean (\pm SD)	26.09 (\pm 2.421)
	Median	26.4
	Minimum - Maximum	19.7 - 29.6

Most Common Adverse Events with ≥ 5% Incidence

		Period 1			Period 2			Post-Trial
System Organ Class	AE Preferred Term	Proposed Pegfilgrastim Biosimilar (N= 33) n (%)	Pegfilgrastim Reference Product (N= 33) n (%)	Total (N= 66) n (%)	Proposed Pegfilgrastim Biosimilar (N= 27) n (%)	Pegfilgrastim Reference Product (N= 30) n (%)	Total (N= 57) n (%)	Total (N= 57)
Any AE		33 (100.0)	33 (100.0)	66 (100.0)	27 (100.0)	30 (100.0)	57 (100.0)	1 (1.75)
Cardiac Disorders	Palpitations	3 (9.09)	2 (6.06)	5 (7.58)		1 (3.33)	1 (1.75)	
Gastrointestinal Disorders	Nausea	3 (9.09)	4 (12.12)	7 (10.61)	1 (3.70)	6 (20.00)	7 (12.28)	
General Disorders And Administration Site Conditions	Asthenia	3 (9.09)	1 (3.03)	4 (6.06)				
	Chest Discomfort	2 (6.06)	2 (6.06)	4 (6.06)	1 (3.70)		1 (1.75)	
	Chest Pain	2 (6.06)	2 (6.06)	4 (6.06)	3 (11.11)	1 (3.33)	4 (7.02)	
	Feeling Hot	3 (9.09)	4 (12.12)	7 (10.61)	3 (11.11)	1 (3.33)	4 (7.02)	
	Non-Cardiac Chest Pain	3 (9.09)	2 (6.06)	5 (7.58)		1 (3.33)	1 (1.75)	
Investigations	Blood Pressure Diastolic Increased	2 (6.06)	1 (3.03)	3 (4.55)	2 (7.41)	2 (6.67)	4 (7.02)	
	Blood Pressure Increased	3 (9.09)	1 (3.03)	4 (6.06)	2 (7.41)	1 (3.33)	3 (5.26)	
	Blood Pressure Systolic Decreased	4 (12.12)	4 (12.12)	8 (12.12)	2 (7.41)	2 (6.67)	4 (7.02)	
	Blood Pressure Systolic Increased	1 (3.03)	2 (6.06)	3 (4.55)	3 (11.11)	6 (20.00)	9 (15.79)	
	Body Temperature Increased	3 (9.09)	1 (3.03)	4 (6.06)	1 (3.70)		1 (1.75)	
	Heart Rate Increased	2 (6.06)	3 (9.09)	5 (7.58)	1 (3.70)		1 (1.75)	
	Neutrophil Count Decreased	5 (15.15)		5 (7.58)		2 (6.67)	2 (3.51)	
	White Blood Cell Count Decreased	19 (57.58)	16 (48.48)	35 (53.03)	14 (51.85)	14 (46.67)	28 (49.12)	
	White Blood Cell Count Increased	33 (100.0)	33 (100.0)	66 (100.0)	27 (100.0)	30 (100.0)	57 (100.0)	
Musculoskeletal And Connective Tissue Disorders	Bone Pain	29 (87.88)	25 (75.76)	54 (81.82)	18 (66.67)	22 (73.33)	40 (70.18)	

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	Musculo-skeletal Stiffness	1 (3.03)	4 (12.12)	5 (7.58)				
	Myalgia	3 (9.09)	4 (12.12)	7 (10.61)	1 (3.70)	1 (3.33)	2 (3.51)	
	Pain In Extremity	2 (6.06)	2 (6.06)	4 (6.06)				
Nervous System Disorders	Dizziness	3 (9.09)	5 (15.15)	8 (12.12)	1 (3.70)	3 (10.00)	4 (7.02)	
	Headache	19 (57.58)	19 (57.58)	38 (57.58)	10 (37.04)	17 (56.67)	27 (47.37)	
Respiratory, Thoracic And Mediastinal Disorders	Cough	3 (9.09)	4 (12.12)	7 (10.61)	1 (3.70)		1 (1.75)	
	Oropharyngeal Pain	2 (6.06)	3 (9.09)	5 (7.58)	1 (3.70)	4 (13.33)	5 (8.77)	
Skin And Subcutaneous Tissue Disorders	Hyperhidrosis	2 (6.06)	2 (6.06)	4 (6.06)		1 (3.33)	1 (1.75)	