

SUPPLEMENTARY MATERIAL

Biosimilar Pegfilgrastim-cbqv Demonstrates Similar Immunogenicity to Pegfilgrastim in Healthy Subjects Across Three Randomized Clinical Studies

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Table S1. Subject demographics (study CHS-1701-04)

Characteristic	Pegfil-cbqv (n = 151)	Pegfil (n = 152)
Age, mean (range)	35.2 (19–50)	33.4 (18–50)
Sex, n %		
Male	94 (62.3)	87 (57.2)
Female	57 (37.7)	65 (42.8)
Race		
White	93 (61.6)	99 (65.1)
Black or African American	57 (37.7)	48 (31.6)
Asian	0	3 (2.0)
American Indian or Alaska native	0	0
Native Hawaiian or Pacific Islander	0	0
Multiple	0	0
Other	1 (0.7)	2 (1.3)
Weight, mean (range), kg	77.1 (55.2–109.3)	76.6 (50.2–108.0)
BMI, mean (range), kg/m ²	26.3 (18.9–32.0)	26.5 (18.9–32.0)

BMI body mass index; Pegfil pegfilgrastim; Pegfil-cbqv pegfilgrastim-cbqv

Table S2. ADA data for subjects with measurable anti-G-CSF antibody titers (≥2)

Subject	Treatment Group	Visit	ADA Result	PEG Binding	G-CSF Binding	Anti-G-CSF Antibody Titers ^b
1 ^a	Pegfilgrastim-cbqv	P1D1 predose	Negative	—	—	—
		P1D13	Positive	Yes	Yes	64
		P1D27	Positive	Yes	Yes	16
		P1D41	Positive	No	Yes	4
		P2D1 predose	Positive	Yes	No	—
		P2D13	Negative	—	—	—
		P2D27	Negative	—	—	—
		P2D41/follow-up	Positive	Yes	No	—
2 ^a	Pegfilgrastim-cbqv	Additional Follow-up 1	Negative	—	—	—
		P1D1 predose	Negative	—	—	—
		P1D13	Positive	Yes	Yes	16
		P1D27	Positive	Yes	Yes	8
		P1D41	Positive	Yes	No	—
		P2D1 predose ^d	N/A	—	—	—
		P2D13	Positive	Yes	No	—
3	Pegfilgrastim	P2D27	Positive	Yes	No	—
		P2D41/follow-up	Positive ^c	Yes	No	—
		P1D1 predose	Negative	—	—	—
		P1D13	Positive	Yes	Yes	64
		P1D27	Positive	No	No	—
		P1D41	Negative	—	—	—
		P2D1 predose	Negative	—	—	—
		P2D13	Negative	—	—	—
		P2D27	Negative	—	—	—
		P2D41	Negative	—	—	—

ADA antidrug antibody; D day; G-CSF granulocyte colony-stimulating factor; LLPC lower limit of positive control; P period

^aADA endpoint subject.

^bTiter precision is 16.3–2000.0 ng/mL; 16.3 ng/mL of positive control showed titer in the range <2 to 4.

^cSubject was lost to follow-up before the first additional follow-up visit required for subjects who were ADA-positive at period 2 day 41 or Early Termination with an ADA-titer higher than at baseline (period 1 day 1 predose), based on the original ADA assay results.

Note: Period 1 day 41 could also be period 2 day 1 visit.

Table S3. Subject demographics (pooled analysis)

Characteristic	Pegfil-cbqv (n = 337)	Pegfil (n = 356)
Age, mean (range)	34.1 (18–50)	33.5 (18–50)
Sex, n %		
Male	217 (64.4)	225 (63.2)
Female	120 (35.6)	131 (36.8)
Race		
White	208 (61.7)	218 (61.2)
Black or African American	113 (33.5)	116 (32.6)
Asian	6 (1.8)	11 (3.1)
American Indian or Alaska native	1 (0.3)	1 (0.3)
Native Hawaiian or pacific islander	1 (0.3)	1 (0.3)
Multiple	4 (1.2)	4 (1.1)
Other	4 (1.2)	5 (1.4)
Weight, mean (range), kg	76.0 (50.0–112.7)	75.5 (50.0–112.7)
BMI, mean (range), kg/m ²	25.9 (18.8–32.0)	25.9 (18.8–32.0)

BMI body mass index; Pegfil pegfilgrastim; Pegfil-cbqv pegfilgrastim-cbqv