Supplementary Material

For the original article: **Investigating the Pharmacokinetics, Injection Speed, and Usability of Subcutaneous Efgartigimod PH20 Administered With a Prefilled Syringe**

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Figure S1. Injection Speed Study: Volume Leakage and Backflow at the Injection Site. The boxes represent the 25th percentile (lower quartile), the median (the bar in the box), and the 75th percentile (upper quartile). The circles represent the mean, and the bars extending from the box mark the minimum and maximum values. Triangles outside of the whiskers indicate outlier values.

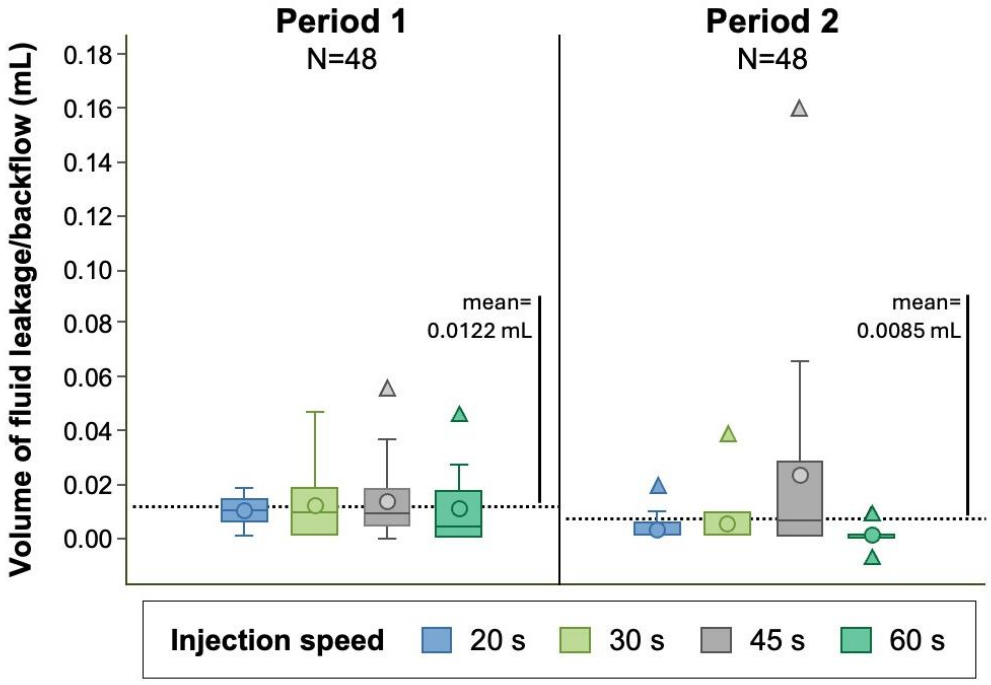

Table S1. Bioequivalence Study: Participant Demographics

	Overall (N=72)
Age, y	
Mean (SD)	36.0 (8.8)
Median (min, max)	35.0 (20, 55)
Sex at birth, n (%)	
Female	44 (61.1)
Male	28 (38.9)
Race, n (%)	
American Indian or Alaskan Native	3 (4.2)
Black or African American	9 (12.5)
White	58 (80.6)
White, Black, or African American	1 (1.4)
Black, African American, American Indian, or Alaska Native	1 (1.4)
Ethnicity, n (%)	
Hispanic or Latino	57 (79.2)
Not Hispanic or Latino	15 (20.8)
BMI, kg/m^2	
Mean (SD)	25.3 (2.8)
Median (min, max)	25.2 (18.5, 30.0)
Weight, kg	
Mean (SD)	71.6 (12.5)
Median (min, max)	69.6 (50.6, 96.8)

BMI, body mass index.

Table S2. Bioequivalence Study: Summary of Statistical Comparisons of Efgartigimod PK Parameters After a Single Injection of Efgartigimod PH20 SC 1000 mg Administered via PFS vs V+S

Parameter, unit	PFS (test)		V+S (reference)			
	n[a]	Geometric LSM	n	Geometric LSM	GMR, %	90% CI, %
C_{max}, µg/mL	70	34.7	72	31.6	109.7	103.4-116.4
AUC_{0-t}, µg × h/mL	70	5305.9	72	4911.2	108.0	103.7-112.5
AUC_{0-inf}, µg × h/mL	70	5389.0	72	4995.1	107.9	103.7-112.3

[a]One participant was excluded from this evaluation due early dropout from the study.

AUC_{0-inf}, area under the concentration-time curve from 0 to infinity; AUC_{0-t}, area under the concentration-time curve from 0 to last quantifiable concentration; C_{max}, maximum observed concentration; GMR, geometric least-squares mean ratio; LSM, least-squares mean; PFS, prefilled syringe; PK, pharmacokinetic; SC, subcutaneous; V+S, vial and syringe. Note that parameters were natural logarithmic transformed before analysis.

Table S3. Bioequivalence Study: Summary of Efgartigimod PK Parameters After a Single Injection of Efgartigimod PH20 SC 1000 mg Administered via PFS or V+S

Parameter, unit	PFS (n=70[a]; test)	V+S (n=72; reference)
C_{max}, µg/mL, mean (SD)	37.0 (12.7)	34.5 (14.3)
T_{max} (h), median (min, max)	48.0 (12.0, 119.3)	72.0 (12.0, 119.3)
$AUC_{0\text{-}168h}$, µg × h/mL, mean (SD)	4230.8 (1142.6)	3937.9 (1328.4)
$AUC_{0\text{-}t}$, µg × h/mL, mean (SD)	5526.6 (1374.5)	5157.3 (1563.5)
$AUC_{0\text{-}inf}$, µg × h/mL, mean (SD)	5610.4 (1383.4)	5238.9 (1571.6)
$t_{1/2}$, h, mean (SD)	81.9 (8.1)	84.6 (9.1)
CL/F, L/h, mean (SD)	0.1890 (0.0471)	0.2137 (0.0868)
V_z/F, L, mean (SD)	22.5 (6.9)	26.5 (12.9)

[a]One participant was excluded from this evaluation due early dropout from the study.

$AUC_{0\text{-}168h}$, area under the concentration-time curve from 0 to 168 hours; $AUC_{0\text{-}inf}$, area under the concentration-time curve from 0 to infinity; $AUC_{0\text{-}t}$, area under the concentration-time curve from 0 to last quantifiable concentration; CL/F, apparent clearance; C_{max}, maximum observed concentration; PFS, prefilled syringe; PK, pharmacokinetic; SC, subcutaneous; T_{max}, time to C_{max}; $t_{1/2}$, elimination half-life; V+S, vial and syringe; V_z/F, apparent volume of distribution.

Table S4. Injection Speed Study: Participant Demographics

Injection speed group	20 s (n=12)	30 s (n=12)	45 s (n=12)	60 s (n=12)	Overall (N=48)
Sex at birth, n (%)					
Female	8 (66.7)	7 (58.3)	3 (25.0)	8 (66.7)	26 (54.2)
Male	4 (33.3)	5 (41.7)	9 (75.0)	4 (33.3)	22 (45.8)
Race, n (%)					
White	10 (83.3)	9 (75.0)	11 (91.7)	11 (91.7)	41 (85.4)
Black or African American	1 (8.3)	1 (8.3)	1 (8.3)	1 (8.3)	4 (8.3)
Asian	0	0	0	0	0
American Indian or Alaska Native	1 (8.3)	0	0	0	1 (2.1)
Native Hawaiian or Other Pacific Islander	0	1 (8.3)	0	0	1 (2.1)
Other	0	1 (8.3)	0	0	1 (2.1)
Ethnicity, n (%)					
Hispanic or Latino	4 (33.3)	3 (25.0)	4 (33.3)	5 (41.7)	16 (33.3)
Not Hispanic or Latino	8 (66.7)	9 (75.0)	8 (66.7)	7 (58.3)	32 (66.7)
Age, y, mean (SD)	26.9 (7.8)	28.8 (5.7)	27.8 (8.8)	27.4 (6.7)	27.7 (7.1)
Weight, kg, mean (SD)	67.6 (9.6)	78.4 (11.8)	71.4 (11.9)	69.4 (12.7)	71.7 (11.9)
BMI, kg/m^2, mean (SD)	23.2 (3.0)	25.7 (2.5)	23.7 (3.0)	24.0 (3.2)	24.2 (3.0)

BMI, body mass index.

Table S5. Injection Speed Study: Overview of AEs

Safety Set[a]	20 s (n=24)		30 s (n=24)		45 s (n=24)		60 s (n=24)		Overall (N=48)	
	n (%)	m	n (%)	m	n (%)	m	n (%)	m	n (%)	m
≥1 AE	7 (29.2)	9	10 (41.7)	11	9 (37.5)	11	7 (29.2)	9	24 (50.0)	40
Participants with AE by severity										
Mild	7 (29.2)	9	9 (37.5)	10	8 (33.3)	10	7 (29.2)	9	22 (45.8)	38
Moderate	0	0	1 (4.2)	1	1 (4.2)	1	0	0	2 (4.2)	2
Severe, life-threatening, or death	0	0	0	0	0	0	0	0	0	0
Treatment-related AEs	7 (29.2)	8	9 (37.5)	10	7 (29.2)	7	7 (29.2)	9	21 (43.8)	34
Not treatment-related AEs	1 (4.2)	1	1 (4.2)	1	2 (8.3)	4	0	0	4 (8.3)	6
≥1 SAE	0	0	0	0	0	0	0	0	0	0
≥1 Infection	0	0	1 (4.2)	1	0	0	0	0	1 (2.1)	1
≥1 Injection-related reaction	1 (4.2)	1	2 (8.3)	2	1 (4.2)	1	0	0	3 (6.3)	4
≥1 ISR	5 (20.8)	5	7 (29.2)	8	6 (25.0)	6	7 (29.2)	8	17 (35.4)	27
Participants who discontinued due to AE	0	0	0	0	0	0	0	0	0	0

[a]The safety set was defined as all participants who received at least 1 dose of efgartigimod PH20 SC.

AE, adverse event; m, number of events; ISR, injection site reaction; SAE, serious adverse event.

Table S6. Injection Speed Study: Summary of ISRs

	20 s (n=12) n (%)		**30 s (n=12) n (%)**		**45 s (n=12) n (%)**		**60 s (n=12) n (%)**		**Overall (N=48) n (%)**	
Period	**1**	**2**	**1**	**2**	**1**	**2**	**1**	**2**	**1**	**2**
Erythema	11 (91.7)	11 (91.7)	12 (100.0)	8 (66.7)	11 (91.7)	12 (100.0)	11 (91.7)	10 (83.3)	**45 (93.8)**	**41 (85.4)**
Swelling	6 (50.0)	10 (83.3)	8 (66.7)	9 (75.0)	12 (100.0)	9 (75.0)	7 (58.3)	11 (91.7)	**33 (68.8)**	**39 (81.3)**
Induration	1 (8.3)	0	0	0	1 (8.3)	1 (8.3)	2 (16.7)	1 (8.3)	**4 (8.3)**	**2 (4.2)**
Total	12 (100.0)	12 (100.0)	12 (100.0)	10 (83.3)	12 (100.0)	12 (100.0)	11 (91.7)	12 (100.0)	**47 (97.9)**	**46 (95.8)**

ISR, injection site reaction.

Table S7. Human Factors Studies: Participant Demographics

	Participants with gMG (n=15)	Participants with CIDP (n=15)	Lay caregivers (n=15)
Sex, n (%)			
Female	11 (73.3)	7 (46.7)	10 (66.7)
Male	4 (26.7)	8 (53.3)	5 (33.3)
Age, mean (range)	57.1 (31-77)	43.1 (19-70)	52.1 (31-65)
Ethnicity, n (%)			
African American	3 (20.0)	5 (33.3)	4 (26.7)
Asian	2 (13.3)	0	1 (6.7)
Hispanic	1 (6.7)	1 (6.7)	2 (13.3)
White	9 (60.0)	9 (60.0)	8 (53.3)
Injection experience, n (%)			
Experienced	9 (60.0)	6 (40.0)	7 (46.7)
Naïve	6 (40.0)	9 (60.0)	8 (53.3)
Dexterity/hand impairment, n (%)			
Mild	4 (26.7)	2 (13.3)	0
Moderate	2 (13.3)	3 (20.0)	0
No impairment	9 (60.0)	10 (66.7)	15 (100.0)
Visual impairment, n (%)			
Yes	11 (73.3)	4 (26.7)	1 (6.7)
No	4 (26.7)	11 (73.3)	14 (93.3)
Cognitive impairment, n (%)			
Yes	6 (40.0)	9 (60.0)	0
No	9 (60.0)	6 (40.0)	15 (100.0)
English fluency, n (%)			
Yes	15 (100.0)	15 (100.0)	15 (100.0)
No	0	0	0

CIDP, chronic inflammatory demyelinating polyradiculoneuropathy; gMG, generalized myasthenia gravis

Table S8. Human Factors Studies: Knowledge Tasks

Question	Information participants were asked to locate and identify
In addition to what comes in the carton, what supplies, if any, would you need for your injection?	Gather safety needle Gather alcohol swab Gather sterile gauze and/or bandage Gather sharps disposal container
How many doses can you give with a single PFS?	The PFS is single use Do not reuse the PFS
Where should you store this product?	Store in refrigerator from 36 °F to 46 °F (2 °C to 8 °C)
What can you tell me about storage of the syringe related to the carton?	Keep PFS in original carton
What storage considerations should you take if children are in the household?	Keep out of reach of children
Are there any specific ways that you should not store this product? If yes, what are they?	Do not freeze PFS Do not store in direct sunlight
What should you do if the PFS has been frozen?	Do not use PFS that has been frozen
What should you do if the PFS has been left in direct sunlight?	Do not use PFS that has been left in direct sunlight
What, if anything, should you check on or about the syringe before using it?	Check expiration date on the PFS label Check the PFS for damage Check the appearance of the medication
What, if anything, should you do if the syringe is expired?	Do not use expired medication
What, if anything, should you do if the syringe shows signs of damage?	Do not use PFS if it appears damaged
What should the liquid medicine in the PFS look like?	The liquid should be clear to light yellow A little cloudiness is normal
What, if anything, should you do if the medicine does not look the way it should?	Do not use PFS if the medication is discolored or contains particles
What, if anything, should you do with the syringe after you have taken it out of the refrigerator and checked that it is okay to use?	Allow the PFS to warm to room temperature (sit for ≥30 min)
What can you tell me about warming the PFS any other way than left on the surface?	Do not warm the PFS in any other way
What, if anything, should you do if the PFS has been at room temperature for longer than 4 hours?	Do not leave PFS at room temperature for longer than 4 hours
When choosing an injection site, how does the last injection site play a role in that decision?	Rotate injection sites for each injection
What areas of the skin should you avoid or not inject into?	Do not inject into skin that is irritated, red, bruised, infected, or scarred Do not inject into a vein
What, if anything, should you do if you see blood at the injection site after you remove the needle from the skin?	Treat the injection site with gauze pad or adhesive bandage, if needed

PFS, prefilled syringe.