Efficacy and Safety of Subcutaneous (SC) Efgartigimod PH20 in CIDP: ADHERE/ADHERE+ Trials

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Murray Lowe **Anissa Tse**	Employees of argenx at the time of the study
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Jeffrey T. Guptill **Erik Hofman** **Peter Ulrichts** **Benjamin Van Hoorick**	Employees of argenx
Tina Dysgaard **Yessar M. Hussain** **Gwendal Le Masson** **Jie Lin** **Mihaela-Adriana Simu** **Ting Chang** **Ryo Yamasaki**	Nothing to declare

Efgartigimod alfa with recombinant human hyaluronidase is not approved by Health Canada for the treatment of patients with CIDP as efficacy and safety have not been established

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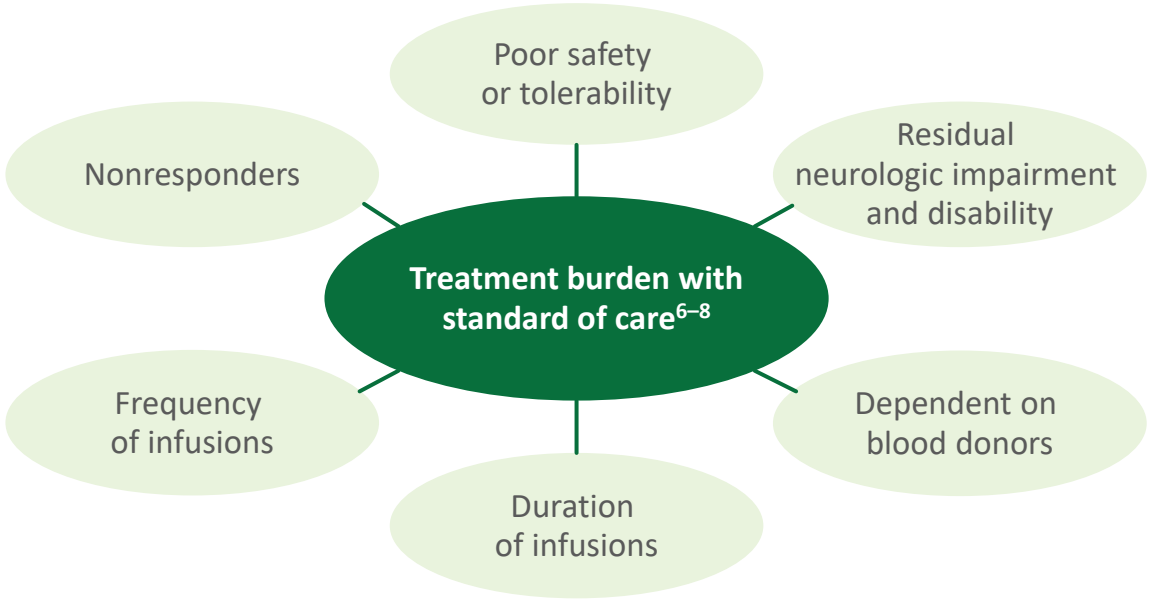
CIDP Is a Severe and Progressing Immune-Mediated Polyneuropathy[1–4]

- CIDP is an **autoimmune, inflammatory, demyelinating neuropathy** resulting in distal/proximal weakness and/or sensory deficits, with a high treatment burden[1,5]



- Evidence supports **a role for pathogenic IgGs** in the pathogenesis of CIDP, although in most patients a specific antibody is currently not detectable[2,9–11]
- **Efgartigimod** is a human IgG1 Fc fragment that outcompetes endogenous IgG, preventing recycling and promoting lysosomal degradation of IgG, leading to lower IgG levels **without impacting IgG production**[12–17]
- **Efgartigimod PH20 SC** is a coformulation of efgartigimod and recombinant human hyaluronidase PH20 (rHuPH20), which allows for **rapid (30–90s single injection)** SC administration[18,19]

Efgartigimod has been shown to **reduce IgG antibody levels** in healthy volunteers and patients with other autoimmune diseases[12,14–17]

CIDP, chronic inflammatory demyelinating polyneuropathy; IgG, immunoglobulin G; s, second; SC, subcutaneous.

1. Cox ZC, et al. *Clin Geriatr Med*. 2021. **2.** Querol L, et al. *Sci Rep.* 2017. **3.** Broers MC, et al. *Neuroepidemiology*. 2019. **4**. Nobile-Orazio E. *J Peripher Nerv Syst*. 2014. **5.** Van den Bergh PYK, et al. *Eur J Neurol*. 2021. **6.** Brun S, et al. *Immuno.* 2022. **7**. Bus SRM, et al. *J Neurol*. 2022. **8**. Gorson KC. *Ther Adv Neurol Disord*. 2012. **9.** Mathey EK, et al. *J Neurol Neurosurg Psychiatry*. 2015. **10.** Yan WX, et al. *Ann Neurol.* 2000. **11**. Manso C, et al. *J Clin Invest.* 2019. **12.** Ulrichts P, et al. *J Clin Invest*. 2018. **13.** Vaccaro C, et al. *Nat Biotech*. 2005. **14**. Howard JF Jr, et al. *Lancet Neurol*. 2021. **15**. Goebeler M, et al. *Br J Dermatol*. 2022. **16.** Broome CM, et al. *Lancet*. 2023. **17.** Howard JF Jr, et al. *Front Neurol*. 2024. **18**. Locke KW, et al. *Drug Deliv*. 2019. **19.** VYVGART HYTRULO. Prescribing information. argenx; 2023. https://www.argenx.com/product/vyvgart-hytrulo-prescribing-information.pdf. Accessed June 21, 2024.

Efgartigimod in CIDP: Study Designs of ADHERE and ADHERE+

99% Rollover

ADHERE

IDENTIFY PARTICIPANTS WITH ACTIVE DISEASE

SCREENING
≤4 weeks

- Probable or definite CIDP confirmed by adjudication panel of CIDP experts[1]

RUN-IN PERIOD
≤12 weeks

- Participants on treatment must suspend therapy (Ig or corticosteroids) and demonstrate evidence of clinically meaningful deterioration*
- Participants off treatment with active disease may skip the run-in and enter stage A

TREATMENT PERIOD

OPEN-LABEL: STAGE A
≤12 weeks

DOUBLE-BLINDED: STAGE B
≤48 weeks

QW 1000 mg efgartigimod PH20 SC

Responders

QW 1000 mg efgartigimod PH20 SC

R (1:1)

QW placebo PH20 SC

Until confirmed evidence of clinical improvement† for 2 consecutive visits

Until 88 events (relapses)‡

PRIMARY ENDPOINT
Percentage of participants with confirmed evidence of clinical improvement

PRIMARY ENDPOINT
Time to first aINCAT deterioration§ (relapse) compared with stage B baseline

ADHERE+

OPEN-LABEL EXTENSION

OLE TREATMENT
≤2 years

QW 1000 mg efgartigimod PH20 SC

ROLLOVER CRITERIA

- Completed Week 48 stage B (ADHERE)
- Deteriorated in stage B (ADHERE)
- Terminated ADHERE early (sufficient primary endpoint events)

PRIMARY ENDPOINT
Long-term safety and tolerability

aINCAT, adjusted INCAT; CIDP, chronic inflammatory demyelinating polyneuropathy; ECI, evidence of clinical improvement; ECMD, evidence of clinically meaningful deterioration; HR, hazard ratio; Ig, immunoglobulin; INCAT, Inflammatory Neuropathy Cause and Treatment; I-RODS, Inflammatory Rasch-Built Overall Disability Scale; OLE, open-label extension; PH20, recombinant human hyaluronidase PH20; QW, once weekly; R, randomization; SC, subcutaneous.

*ECMD was defined as an aINCAT increase of ≥1 points, an I-RODS decrease of ≥4 points (centile metric), or a grip strength decrease of ≥8 kPa. †ECI was defined as a clinical improvement on the parameters that the participant worsened in during run-in (≥4-point increase in I-RODS and/or ≥8-kPa increase in mean grip strength) or clinical improvement (≥1-point decrease) in INCAT. ECI was confirmed after these criteria were met after four injections and two consecutive visits. ‡The primary endpoint was assessed once 88 total relapses or events were achieved in stage B and was based on the HR for the time to first aINCAT deterioration (ie, relapse). §aINCAT deterioration was defined as a ≥1-point increase in aINCAT compared with stage B baseline, which was confirmed at a consecutive visit after the first 1-point increase in aINCAT or not confirmed for participants with ≥2-point increase in aINCAT compared with stage B baseline.

1. Van den Bergh PYK, et al. *Eur J Neurol.* 2010.

Baseline Characteristics Were Similar Between Stages A and B and Well-Balanced Between Treatment Groups in ADHERE

	ADHERE			ADHERE+
	Open-Label Stage A	Double-Blinded Stage B		
	Efgartigimod PH20 SC (N=322)	Efgartigimod PH20 SC (N=111)	Placebo SC (N=110)	Efgartigimod PH20 SC (N=228)
Age, y, mean (SD)*	54.0 (13.9)	54.5 (13.2)	51.3 (14.5)	53.2 (14.1)†
Sex, male, n (%)*	208 (64.6)	73 (65.8)	69 (62.7)	142 (62.3)†
Time since diagnosis, y, mean (SD)*	4.9 (6.1)	3.7 (4.4)	3.8 (4.7)	4.9 (5.6)†
Typical CIDP diagnosis, n (%)*	268 (83.2)	97 (87.4)	95 (86.4)	199 (87.3)†
Unstable active disease (CDAS: 5), n (%)*	197 (61.2)	74 (66.7)	76 (69.1)	151 (66.2)†
Prior treatment (within past 6 mo), n (%)*				
Corticosteroids	63 (19.6)	26 (23.4)	24 (21.8)	51 (22.4)†
Immunoglobulins (IVIg, SCIg)	165 (51.2)	49 (44.1)	47 (42.7)	104 (45.6)†
Off treatment‡	94 (29.2)	36 (32.4)	39 (35.5)	73 (32.0)†
aINCAT score, mean (SD)§,‖	4.6 (1.7)	3.1 (1.5)	3.3 (1.6)	4.5 (1.6)¶
I-RODS score, mean (SD)§,‖	40.1 (14.7)	53.6 (17.9)	51.2 (15.4)	41.2 (15.4)¶
Grip strength (dominant hand), kPa, mean (SD)§,**	39.0 (24.2)	54.9 (23.6)	58.0 (25.1)	39.0 (23.6)¶

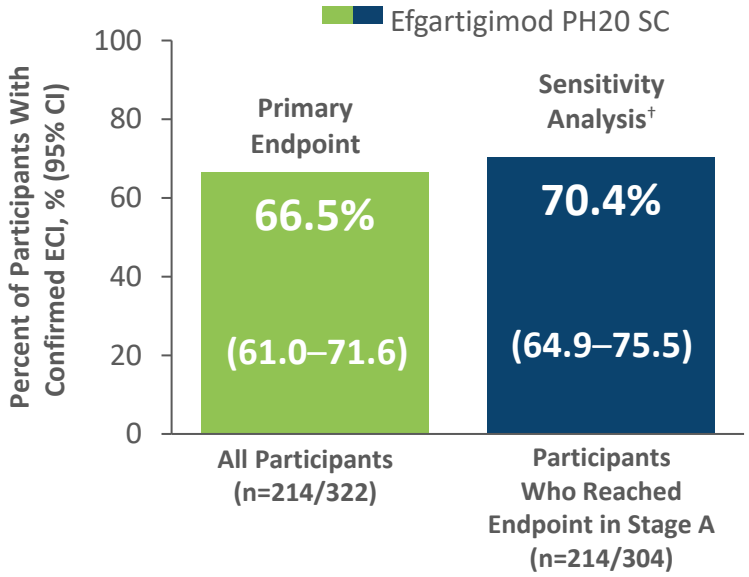
aINCAT, adjusted Inflammatory Neuropathy Cause and Treatment; CDAS, CIDP disease activity status; CIDP, chronic inflammatory demyelinating polyneuropathy; I-RODS, Inflammatory-Rasch-built Overall Disability Scale; IVIg, intravenous immunoglobulin; mo, month; PH20, recombinant human hyaluronidase PH20; SC, subcutaneous; SCIg, subcutaneous immunoglobulin; SD, standard deviation; y, year.

*Scores shown were assessed at screening in ADHERE. †Scores shown were assessed at baseline in ADHERE+. ‡Off treatment was defined as participants who had never received CIDP treatment (treatment naïve) or who had not received CIDP treatment (corticosteroids, IVIg, or SCIg) within 6 months of study entry. §Clinical assessments were performed at the beginning of each stage. ‖Lower scores represent improvement on adjusted INCAT while higher scores represent improvement for I-RODS. ¶Scores shown were assessed at stage A baseline. **Non-dominant scores were similar.

ADHERE+ data cut-off: June 15, 2023.

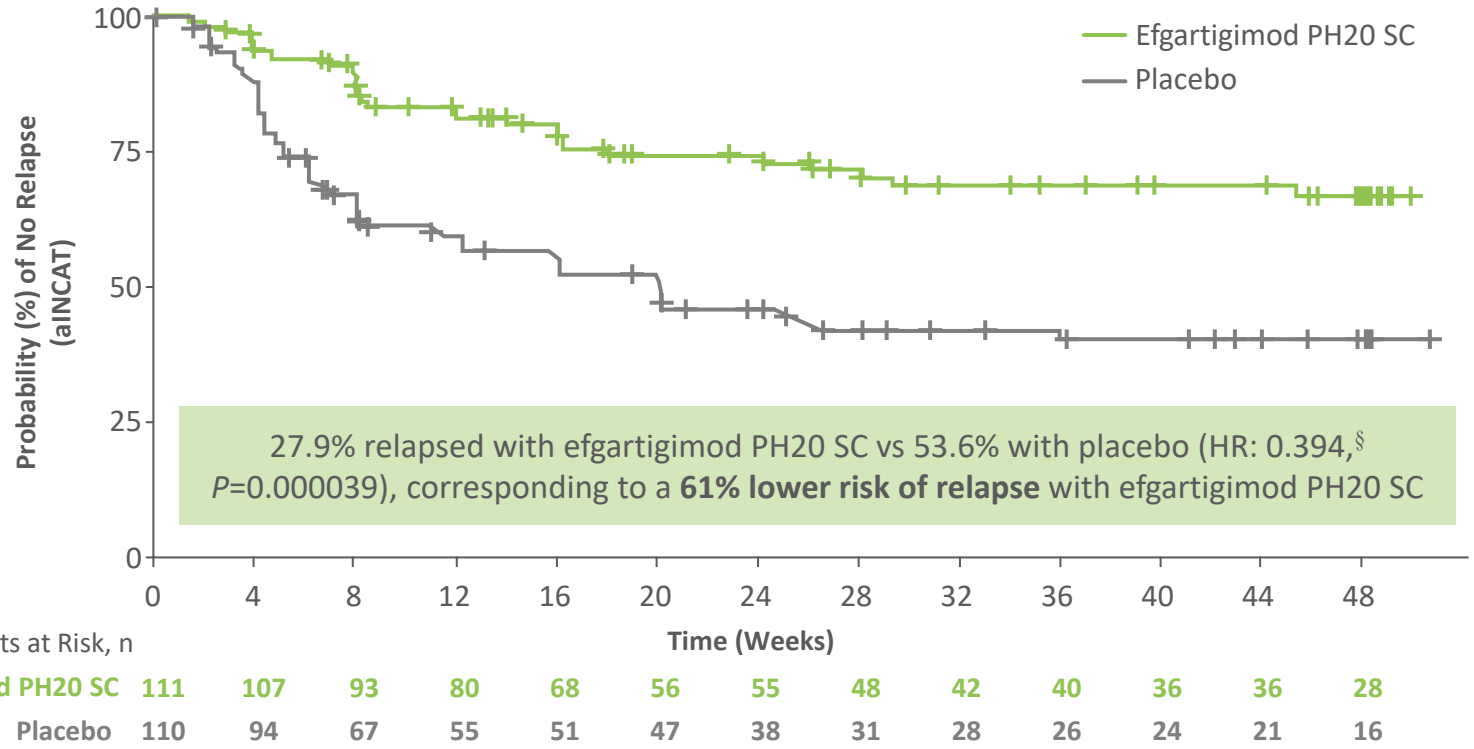
Confirmed Evidence of Clinical Improvement With Efgartigimod in 66.5% of Participants (Stage A) and 61% Reduced Relapse Risk Compared With Placebo (Stage B)

ADHERE Open-Label Stage A: Primary Endpoint
Percent of Participants With Confirmed ECI*



Across all prior CIDP medication subgroups in stage A, most participants responded to treatment with efgartigimod PH20 SC

ADHERE Double-Blinded Stage B: Primary Endpoint
Time-to-First aINCAT Deterioration‡ Compared With Stage B Baseline



27.9% relapsed with efgartigimod PH20 SC vs 53.6% with placebo (HR: 0.394,§ *P*=0.000039), corresponding to a **61% lower risk of relapse** with efgartigimod PH20 SC

Participants at Risk, n													
Efgartigimod PH20 SC	111	107	93	80	68	56	55	48	42	40	36	36	28
Placebo	110	94	67	55	51	47	38	31	28	26	24	21	16

aINCAT, adjusted Inflammatory Neuropathy Cause and Treatment; CI, confidence interval; CIDP, chronic inflammatory demyelinating polyneuropathy; ECI, evidence of clinical improvement; HR, hazard ratio; I-RODS, Inflammatory Rasch-built Overall Disability Scale; PH20, recombinant human hyaluronidase PH20; SC, subcutaneous.

*ECI was defined as a clinical improvement on the parameters that the participant worsened in during run-in (≥4-point increase in I-RODS and/or ≥8-kPa increase in mean grip strength) or clinical improvement (≥1-point decrease) in INCAT. ECI was confirmed after these criteria were met after four injections and two consecutive visits. †Prespecified sensitivity analysis excluded participants who were ongoing in stage A at the time of study completion (after the 88th event had occurred) and did not have the full opportunity to achieve a response. ‡The time-to-first aINCAT deterioration was defined as the number of days from first dose in stage B to the first occurrence of an increase of ≥1 points on the aINCAT score compared with stage B baseline. §The HR was obtained from a Cox proportional hazard model with treatment as a fixed effect, and the model was stratified by prior CIDP therapy and aINCAT score during stage A.

Consistent Improvements Observed With Efgartigimod Across All Secondary Endpoints, All Supportive of Primary Endpoints in ADHERE

	ADHERE Open-Label Stage A	ADHERE Double-Blinded Stage B	
	Efgartigimod PH20 SC (N=322)	Efgartigimod PH20 SC (N=111)	Placebo (N=110)
I-RODS[1] decrease of ≥4 points (disease worsening),[*] n (%)	–	40 (36.0)	57 (51.8)
HR (95% CI)[†] [Nominal *P* value]		0.537 (0.354–0.814) [0.0034]	
I-RODS increase of ≥4 points (disease improvement), n (%)	–	50 (45.0)	40 (36.4)
Odds ratio (95% CI)[‡] [Nominal *P* value]		1.441 (0.814–2.567) [0.2294]	
Change from baseline to last assessment[§]			
aINCAT[2] score,[‖] mean (SD)	–0.9 (1.7)	0.1 (1.1)	0.9 (2.0)
I-RODS score, mean (SD)	7.7 (15.5)	0.8 (12.3)	–7.0 (19.1)
Grip strength (dominant hand), kPa, mean (SD)	12.3 (18.7)	2.1 (13.3)	–8.2 (20.7)
EQ-5D-5L VAS,[§] mean (SE)	10.7 (1.3)	0.5 (1.8)	–10.2 (2.5)

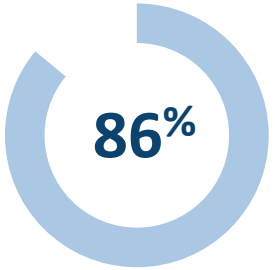
aINCAT, adjusted Inflammatory Neuropathy Cause and Treatment; CI, confidence interval; CIDP, chronic inflammatory demyelinating polyneuropathy; EQ-5D-5L, EuroQol-5 Dimension-5 Levels; HR, hazard ratio; I-RODS, Inflammatory Rasch-built Overall Disability Scale; PH20, recombinant human hyaluronidase PH20; PRO, patient-reported outcome; SC, subcutaneous; SD, standard deviation; SE, standard error; VAS, visual analog scale.

[*]I-RODS[1] is a PRO, a 24-item scale with each item representing a common daily activity that ranges from very difficult to do to very easy to do. Lower I-RODS score indicates worsening of disease. [†]The HR was obtained from a Cox proportional hazard model with treatment as a fixed effect, and the model was stratified by prior CIDP therapy and aINCAT score during stage A. [‡]The odds ratio was obtained from an exact logistic regression model with treatment as a fixed effect, and the model was stratified by prior CIDP therapy and aINCAT score during stage A. [§]For stage A, this was the change from stage A baseline to stage A last assessment, and for stage B, this was the change from stage B baseline to stage B last assessment. [‖]The INCAT disability score[2] is a 10-point scale that assesses activity limitations of arms and legs; both are scored separately from 0 to 5, with 0 representing no functional impairment and 5 representing inability to make any purposeful movement. For the aINCAT score, changes in the function of the upper limbs from 0 (normal) to 1 (minor symptoms) or vice versa were not recorded as deterioration or improvement, because these changes were not considered clinically significant. Higher aINCAT score indicates worsening of disease.

1. van Nes S I, et al. *Neurology*. 2011. **2.** Breiner A, et al. *Muscle Nerve*. 2014.

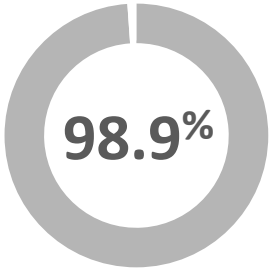
ADHERE+ Demonstrated High Participant Retention and Compliance, and Ease of Administration With Efgartigimod

of eligible participants **rolled over to ADHERE+**



of participants were still **ongoing at Interim Analysis I of ADHERE+**

(cut-off date: June 15, 2023)



of participants demonstrated **treatment compliance*** with efgartigimod PH20 SC

ADHERE+	Efgartigimod PH20 SC (N=228)
Self-administration training	
Participants receiving training, n (%)†	166 (72.8)
Participants considered capable to perform self-administration after one training, n (%)‡	56 (71.8)
Caregiver-supported administration training	
Caregivers receiving training, n (%)	12 (5.3)
Caregivers considered capable of performing administration at least once, n (%)	9 (75.0)
Mode of administration, n (%)	
Administration at scheduled visit on-site	888 (13.0)
Administration by home nurse or qualified person	940 (13.8)
Administration at the site by concierge service	2038 (29.9)
Self-administration	2530 (37.1)
Administration by caregiver	422 (6.2)

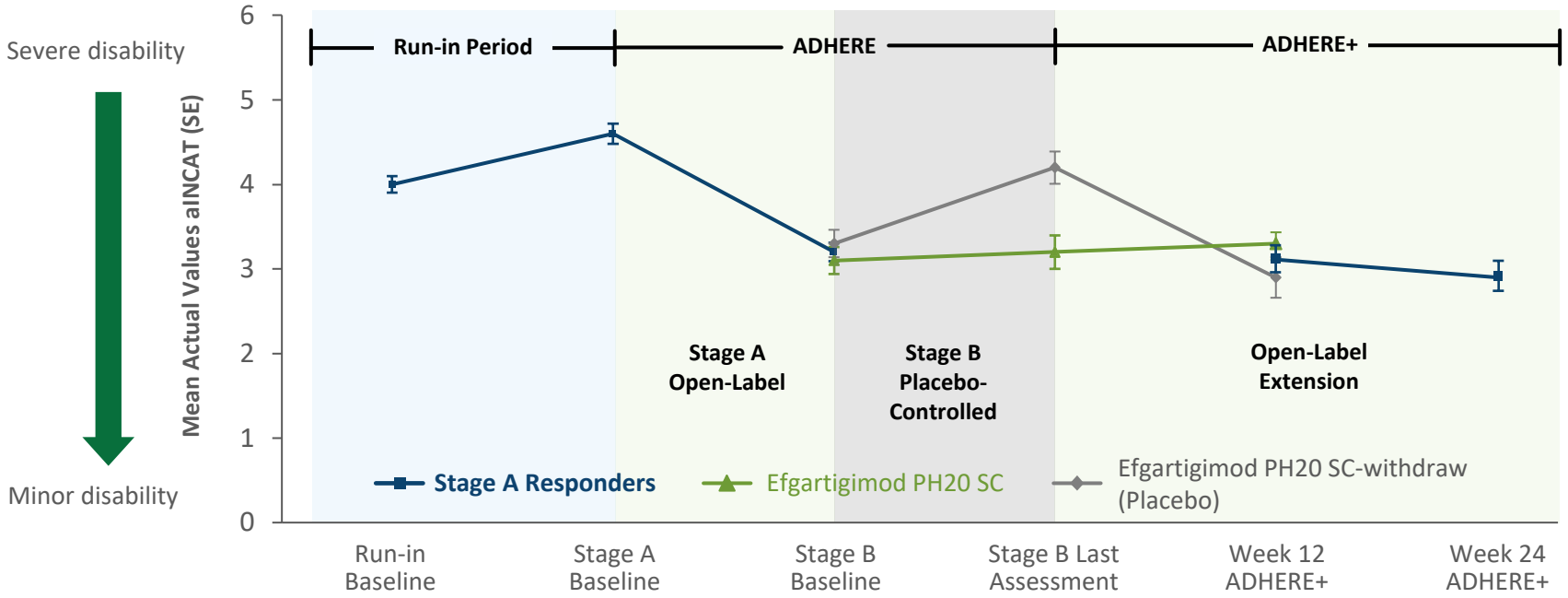
Min, minimum; max, maximum; PH20, recombinant human hyaluronidase PH20; SC, subcutaneous; SD, standard deviation.

*Treatment compliance was calculated as 100 × (number of doses actually received / number of doses expected). †All participants received mandatory self-administration training during stage A of ADHERE. ‡Analysis set population included participants considered capable of performing self-administration at least once (n=78/166).

ADHERE+ Interim Analysis I data cut-off: June 15, 2023.

Improvements in Functional Ability With Efgartigimod From Stage A Baseline Were Maintained Through ADHERE and up to Week 24 of ADHERE+

***Post Hoc* Analysis:* Longitudinal Mean aINCAT Scores† in ADHERE and ADHERE+**



Participants, n	Run-in Baseline	Stage A Baseline	Stage B Baseline	Stage B Last Assessment	Week 12 ADHERE+	Week 24 ADHERE+
Stage A Responders	191	191			106	86
Efgartigimod PH20 SC			97	97		
Efgartigimod PH20 SC-withdraw (Placebo)			94	93		

Post Hoc Analysis‡

- During randomized-withdrawal in stage B, **mean aINCAT scores deteriorated in participants receiving placebo,** whereas **active efgartigimod participants maintained the improvements** seen in stage A
- **Mean aINCAT scores** from run-in baseline of ADHERE to Week 24 of ADHERE+ **decreased** by **1.1 points (considered a clinically meaningful improvement)**[1] in stage A responders

aINCAT, adjusted Inflammatory Neuropathy Cause and Treatment; PH20, recombinant human hyaluronidase PH20; SC, subcutaneous; SE, standard error.

*Analysis set population included efgartigimod-responders in stage A with run-in baseline values. Mean treatment duration was 29.9 weeks. †The INCAT disability score[1] is a 10-point scale that assesses activity limitations of arms and legs; both are scored separately from 0–5, with 0 representing no functional impairment and 5 representing inability to make any purposeful movement. For the aINCAT score, changes in the function of the upper limbs from 0 (normal) to 1 (minor symptoms) or vice versa were not recorded as deterioration or improvement, because these changes were not considered clinically significant. Higher aINCAT score indicates worsening of functional ability. ‡Analysis set population included efgartigimod-responders in stage A who completed week 24 of ADHERE+ at the time of the Interim Analysis I of the ADHERE+ data cut-off (June 15, 2023).

1. Breiner A, et al. *Muscle Nerve*. 2014.

Efgartigimod Was Well Tolerated and Most TEAEs Were Mild or Moderate in Severity in ADHERE and ADHERE+

	ADHERE			ADHERE+
	Open-Label Stage A	Double-Blinded Stage B		
n (%) [event rate*]	Efgartigimod PH20 SC (N=322; PYFU=46.9)	Efgartigimod PH20 SC (N=111; PYFU=56.7)	Placebo SC (N=110; PYFU=42.1)	Efgartigimod PH20 SC (N=228; PYFU=137.4)
Any TEAE	204 (63.4) [13.4]	71 (64.0) [3.5]	62 (56.4) [5.1]	131 (57.5) [3.5]
Any SAE	21 (6.5) [0.5]	6 (5.4) [0.1]	6 (5.5) [0.2]	21 (9.2) [0.3]
Any injection site reactions	62 (19.3) [2.6]	16 (14.4) [0.4]	7 (6.4) [0.2]	22 (9.6) [0.3]
Discontinued due to TEAEs†	22 (6.8) [0.5]	3 (2.7) [0.05]	1 (0.9) [0.02]	9 (3.9) [0.09]
Deaths‡	2 (0.6) [0.04]	0	1 (0.9) [0.02]	1 (0.4) [0.007]
Most common TEAEs (≥5% of participants in any group)				
Injection site erythema	33 (10.2) [1.13]	6 (5.4) [0.11]	0	7 (3.1) [0.1]
CIDP§	17 (5.3) [0.41]	1 (0.9) [0.02]	1 (0.9) [0.02]	5 (2.2) [0.06]
Headache	16 (5.0) [0.6]	4 (3.6) [0.11]	2 (1.8) [0.05]	8 (3.5) [0.09]
Upper respiratory tract infection	11 (3.4) [0.26]	2 (1.8) [0.05]	11 (10.0) [0.26]	14 (6.1) [0.12]
COVID-19	7 (2.2) [0.17]	19 (17.1) [0.35]	14 (12.7) [0.33]	31 (13.6) [0.23]
Injection site bruising	4 (1.2) [0.11]	6 (5.4) [0.11]	1 (0.9) [0.02]	6 (2.6) [0.05]

AE, adverse event; CIDP, chronic inflammatory demyelinating polyneuropathy; COVID-19, coronavirus disease 2019; PH20, recombinant human hyaluronidase PH20; PYFU, participants years of follow-up; SAE, serious adverse event; SC, subcutaneous; TEAE, treatment-emergent adverse event.

*Event rates were calculated as the number of events divided by the PYFU. †TEAEs grouped under Preferred Terms leading to efgartigimod PH20 SC discontinuation were: cardiac arrest (n=1), injection site rash (n=1), COVID-19 (n=1), COVID-19 pneumonia (n=1), muscular weakness (n=1), CIDP (n=15), quadriparesis (n=1), and pruritus (n=1) in ADHERE stage A; COVID-19 pneumonia (n=1), prostate cancer (n=1), and transitional cell carcinoma (n=1) in ADHERE stage B efgartigimod PH20 SC; pneumonia (n=1) in ADHERE stage B placebo SC; lymphadenitis (n=1), eye movement disorder (n=1), asthenia (n=1), hepatic function abnormal (n=1), COVID-19 (n=1), CIDP (n=4), and cranial nerve disorder (n=1) in ADHERE+ efgartigimod PH20 SC. ‡Two deaths (cardiac arrest and deterioration of CIDP) in stage A were considered not related to efgartigimod PH20 SC by the investigator; one death (pneumonia) in the placebo arm of stage B was considered treatment related by the investigator; one death (CIDP deterioration) in ADHERE+ was considered related to efgartigimod PH20 SC by the investigator. §Signs or symptoms of CIDP were recorded as TEAEs (regardless of causality) if there was worsening or deterioration of CIDP observed.

ADHERE+ data cut-off: June 15, 2023.

Conclusions

Participants treated with efgartigimod PH20 SC demonstrated clinical benefits:

- 66.5% showed confirmed evidence of clinical improvement (ADHERE stage A)
- 61% reduced risk of relapse compared with placebo (ADHERE stage B)
- Improvements in functional ability from stage A baseline through ADHERE were maintained up to Week 24 of ADHERE+

99% of eligible participants rolled over from ADHERE to ADHERE+ (at the time of data cut-off):

- High (86%) retention and high (98.9%) compliance with treatment in ADHERE+
- Efgartigimod PH20 SC has the potential to be administered at home, by self or caregiver, increasing patient autonomy and convenience

Weekly efgartigimod PH20 SC was well tolerated:

- The safety profile was similar between ADHERE and ADHERE+, with no increased rate of TEAEs with increased exposure
- The safety profile was consistent with prior clinical trials in other autoimmune diseases[1–4]

A single, rapid (30–90s) injection of weekly efgartigimod PH20 SC was recently approved in the US for adult patients with CIDP, representing a new therapeutic option that may reduce treatment burden associated with CIDP

CIDP, chronic inflammatory demyelinating polyneuropathy; IgG, immunoglobulin G; PH20, recombinant human hyaluronidase PH20; s, second; SC, subcutaneous; TEAE, treatment-emergent adverse event.

1. Howard JF Jr, et al. *Lancet Neurol*. 2021. **2.** Goebeler M, et al. *Br J Dermatol.* 2022. **3.** Broome CM, et al. *Lancet*. 2023. **4.** Howard JF Jr, et al. *Front Neurol.* 2024.