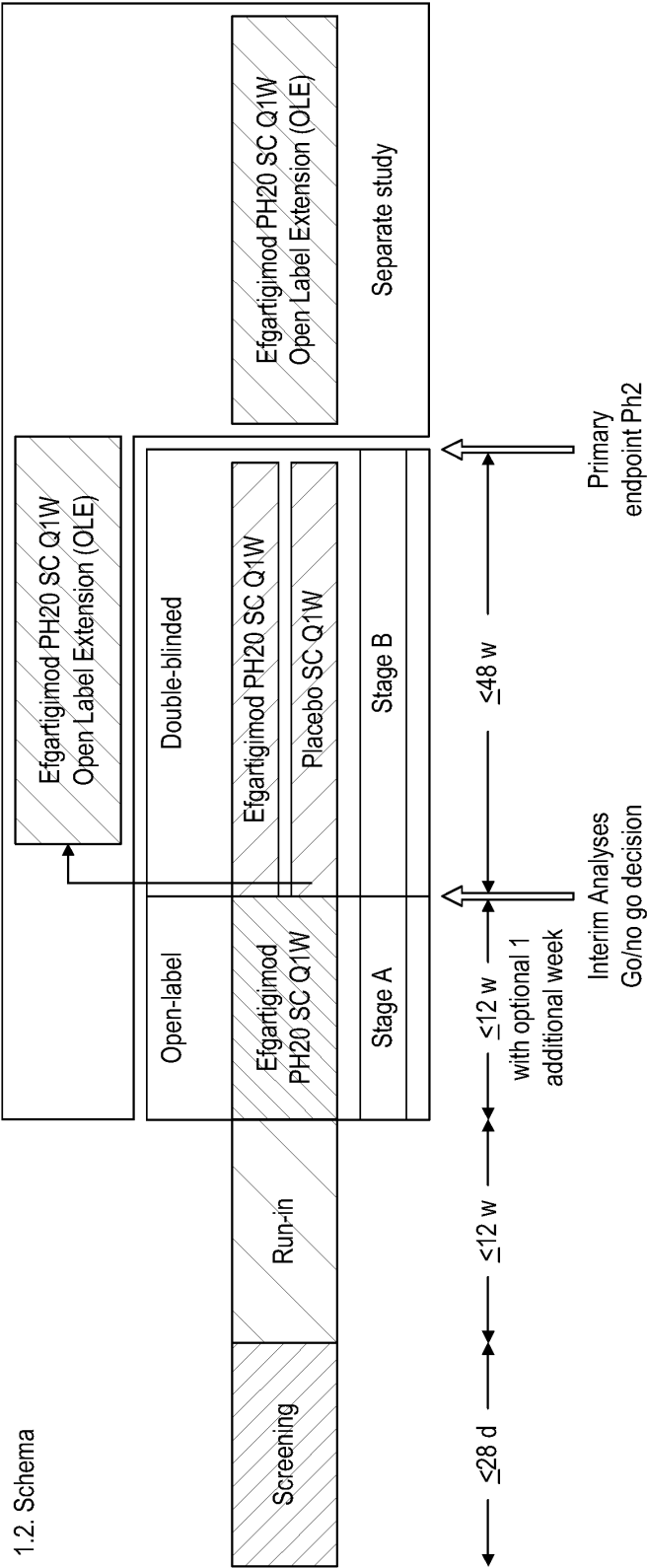




Abbreviations: d=day; efgartigimod PH20 SC=efgartigimod with rHuPH20 (co-formulation) for SC administration; OLE=open-label extension; placebo=placebo with rHuPH20; Q1W=once a week; rHuPH20=recombinant human hyaluronidase PH20; SC=subcutaneous(ly); q1w=once weekly; w=week

Note: Patients who show ECI only at the last visit of the 12-weeks Stage A period may be allowed to extend Stage A for a further week with 1 additional consecutive visit in order to get ECI confirmed at a consecutive visit. Only patients with confirmed ECI will be randomized and receive double-blind IMP in Stage B.

Note: Approximately 360 patients aged 18 years and older are planned to be enrolled in Stage A.

Note: After the first 30 patients have reached the end of Stage A, an interim analysis will be conducted on the proportion of patients with confirmed ECI for a go/no-go decision to continue the trial.

FIG. 1

11.9. Appendix 9: Inflammatory Rasch-built Overall Disability Scale (I-RODS)

RODS for GBS - CIDP - MGUSP

INSTRUCTIONS: This is a questionnaire about the relationship between daily activities and your health. Your answers give information about how your polyneuropathy affects your daily and social activities and to what degree you are able to perform your usual activities.

Answer each question by marking the correct box ("x"). If you are not sure about your ability to perform a task, you are still requested to mark an answer that comes as close as possible to your judged ability to complete such a task. All questions should be completed. You can only choose one answer to each question. If your situation fluctuates, your answer should be based on how you *usually* perform the task.

If you need assistance or you are using special devices to perform the activity, you are requested to mark "possible, but with some difficulty". In case you never perform the activity due to your polyneuropathy mark "not possible".

Are you able to

Mark the best option with "x"

Task	Not possible to perform [0]	Possible, but with some difficulty [1]	Possible, without any difficulty [2]
1 Read a newspaper/book?	☐	☐	☐
2 Eat?	☐	☐	☐
3 Brush your teeth?	☐	☐	☐
4 Wash upper body?	☐	☐	☐
5 Sit on the toilet?	☐	☐	☐
6 Make a sandwich?	☐	☐	☐
7 Dress upper body?	☐	☐	☐
8 Wash lower body?	☐	☐	☐
9 Move a chair?	☐	☐	☐
10 Turn a key in a lock?	☐	☐	☐
11 Go to the general practitioner?	☐	☐	☐
12 Take a shower?	☐	☐	☐
13 Do the dishes?	☐	☐	☐
14 Do the shopping?	☐	☐	☐
15 Catch an object (e.g., ball)?	☐	☐	☐
16 Bend and pick up an object?	☐	☐	☐
17 Walk one flight of stairs?	☐	☐	☐
18 Travel by public transportation?	☐	☐	☐
19 Walk and avoid obstacles?	☐	☐	☐
20 Walk outdoor < 1km?	☐	☐	☐
21 Carry and put down a heavy object?	☐	☐	☐
22 Dance?	☐	☐	☐
23 Stand for hours?	☐	☐	☐
24 Run?	☐	☐	☐

FIG. 2

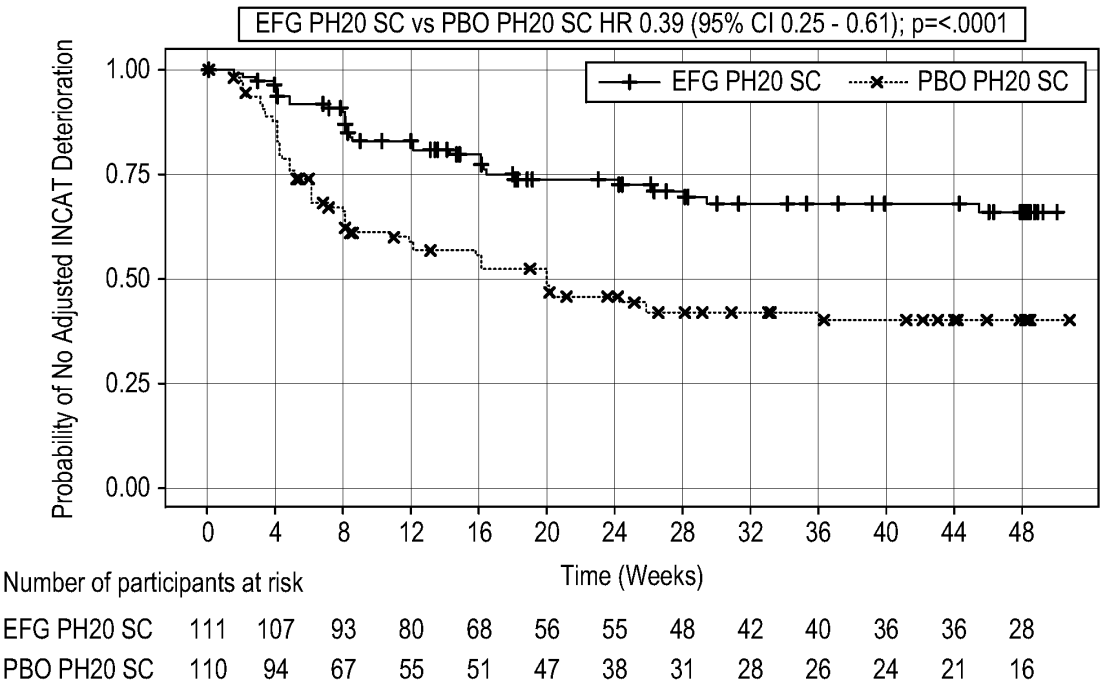


FIG. 3A

	Efgartigimod PH20 SC (N=111)	Placebo PH20 SC (N=110)
Time to First Adjusted INCAT Score Deterioration (days)		
Median (95% CI)	NC (NC; NC)	140.0 (75.0; NC)
Estimated percentage of clinical deterioration at week 24 (95% CI)	26.2 (18.6; 36.2)	54.3 (44.8; 64.4)
Estimated percentage of clinical deterioration at week 48 (95% CI)	34.0 (24.9; 45.2)	59.8 (50.0; 69.9)

FIG. 3B

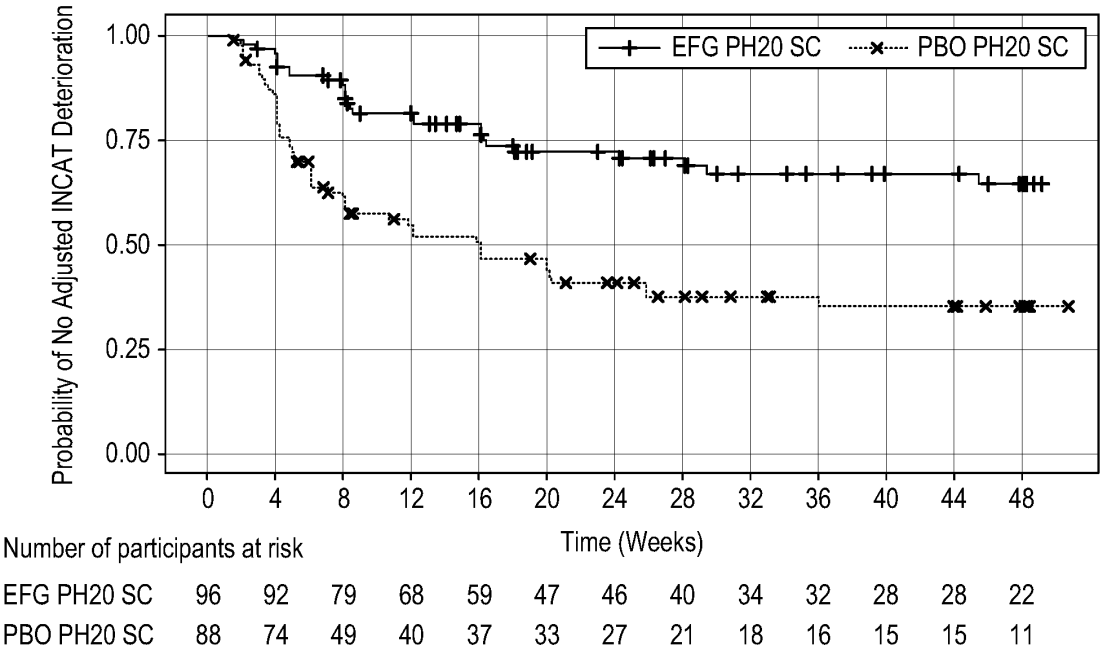


FIG. 4A

	Efgartigimod PH20 SC (N=96)	Placebo PH20 SC (N=88)
Time to First Adjusted INCAT Score Deterioration (days)		
Median (95% CI)	NC (NC; NC)	113.0 (56.0; 181.0)
Estimated percentage of clinical deterioration at week 24 (95% CI)	27.8 (19.5; 38.7)	59.2 (48.5; 70.1)
Estimated percentage of clinical deterioration at week 48 (95% CI)	35.5 (25.5; 47.9)	64.9 (53.8; 75.9)

FIG. 4B

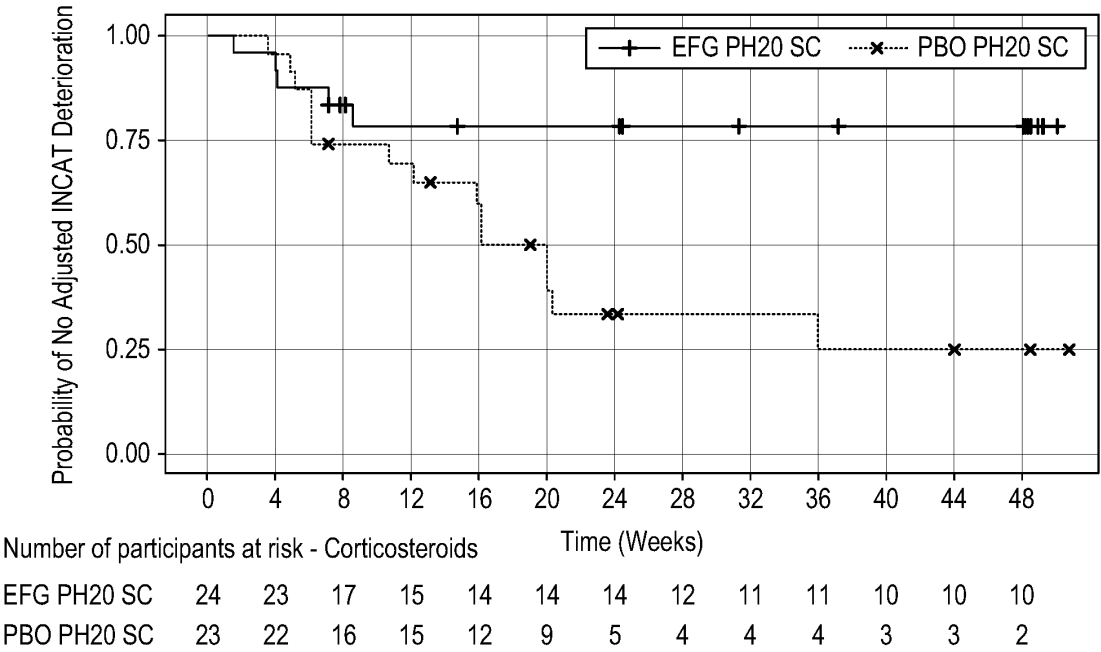


FIG. 5A

	Corticosteroids (N=47)
	Median (95% CI)
EFG (N=24)	NC (NC; NC)
Plb (N=23)	113.0 (75.0; 252.0)

FIG. 5B

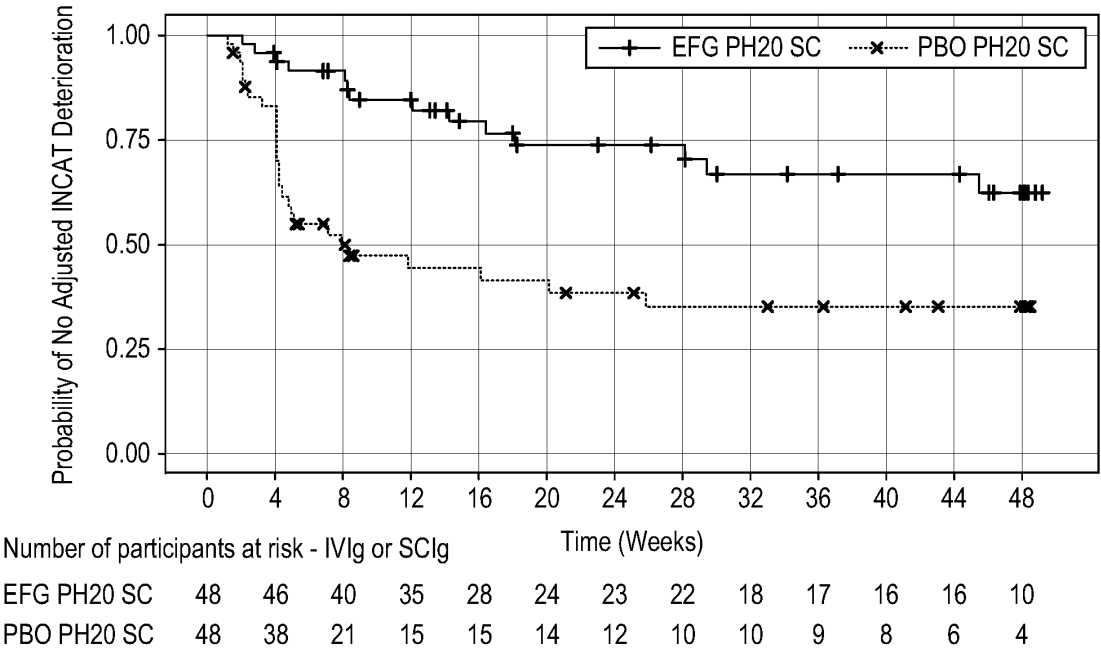


FIG. 5C

	IVIg or SCIg (N=96)
	Median (95% CI)
EFG (N=48)	NC (206.0; NC)
Plb (N=48)	56.0 (30.0; 181.0)

FIG. 5D

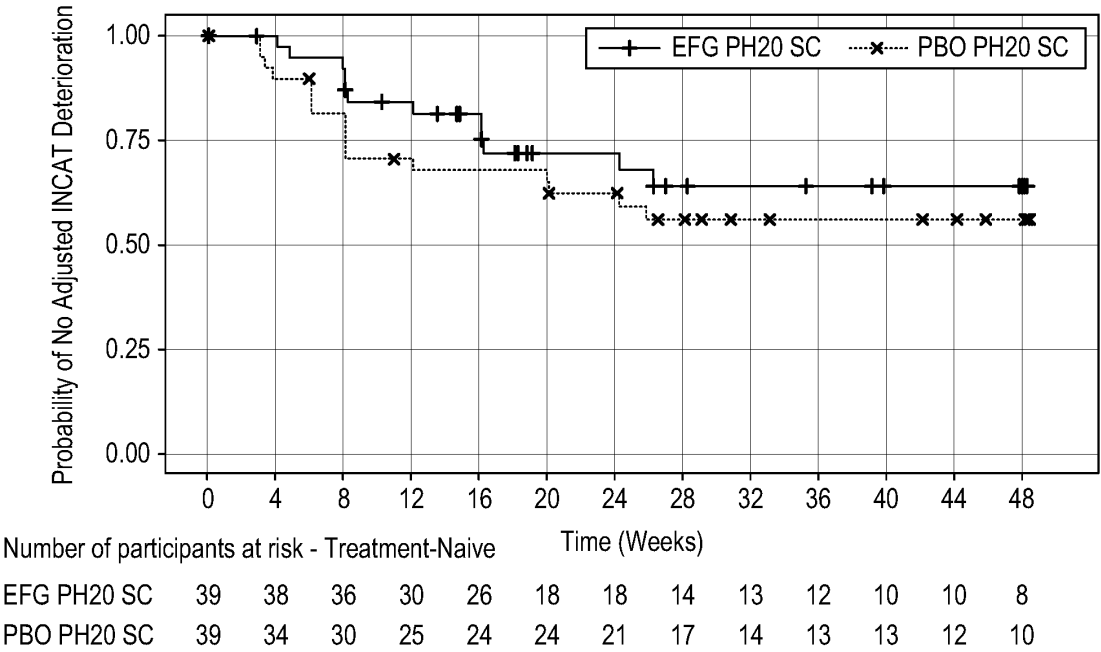


FIG. 5E

	Treatment-naïve (N=78)
	Median (95% CI)
EFG (N=39)	NC (170.0; NC)
Plb (N=39)	NC (140.0; NC)

FIG. 5F

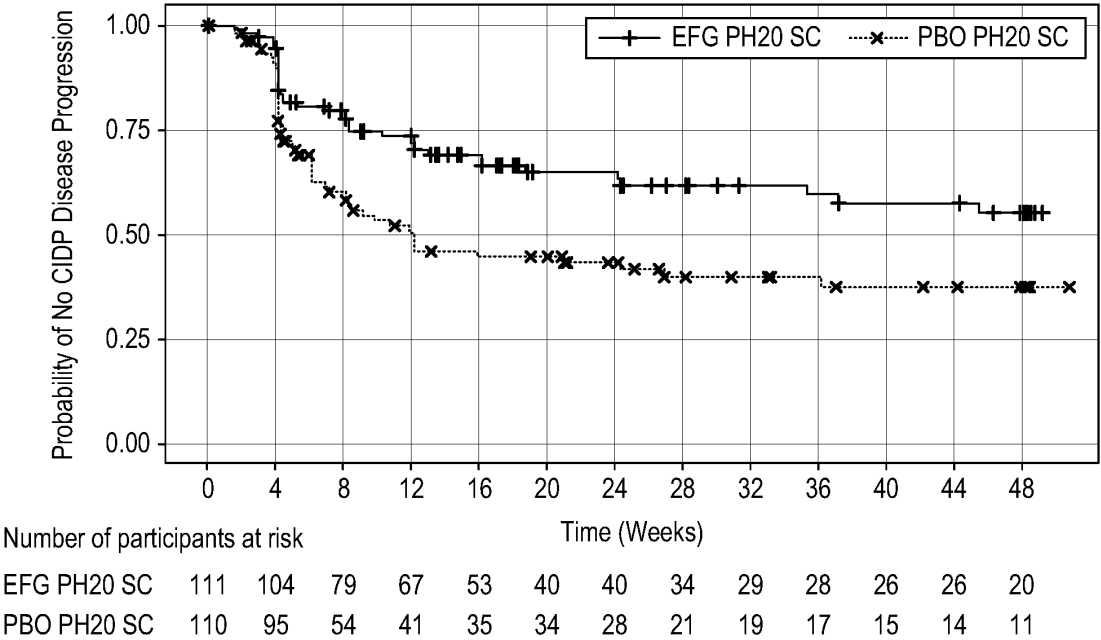


FIG. 6A

	Efgartigimod PH20 SC (N=111)	Placebo PH20 SC (N=110)
Time to CIDP Disease Progression		
Number of events	40 (36.0%)	57 (51.8%)
Comparision efgartigimod PH20 SC vs Placebo PH20 SC		
HR (95% CI)	0.537 (0.354; 0.814)	
p-value	0.0034	

FIG. 6B