



Clinical trial results:

Randomized, multicenter, double-blind, placebo-controlled, parallel-group phase III study to investigate the efficacy, safety, and tolerability of 2 different doses of IgPro20 (subcutaneous immunoglobulin) for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) – the PATH study

Summary

EudraCT number	2011-003448-28
Trial protocol	DE CZ ES FI NL AT GB IT BE LT PL EE
Global end of trial date	20 September 2016

Results information

Result version number	v1 (current)
This version publication date	14 October 2017
First version publication date	14 October 2017

Trial information

Trial identification

Sponsor protocol code	IgPro20_3003
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01545076
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	CSL Behring GmbH
Sponsor organisation address	Emil-von-Behring-Strasse 76, Marburg, Germany,
Public contact	Trial Disclosure Manager, CSL Behring GmbH, clinicaltrials@cslbehring.com
Scientific contact	Trial Disclosure Manager, CSL Behring GmbH, clinicaltrials@cslbehring.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	10 November 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 September 2016
Global end of trial reached?	Yes
Global end of trial date	20 September 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine the efficacy of 2 different doses of IgPro20 (0.2 g/kg bw and/or 0.4 g/kg bw) in the maintenance treatment of CIDP in comparison to placebo.

Protection of trial subjects:

This study was carried out in accordance with the ICH (International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) Good Clinical Practice (GCP) guidelines, the Declaration of Helsinki (version 2008), and standard operating procedures for clinical research and development at CSL Behring GmbH and the Contract Research Organizations (CROs) involved.

The study was conducted under a protocol reviewed and approved by an IEC / IRB; the study was conducted by scientifically and medically qualified persons; the benefits of the study were in proportion to the risks; the rights and welfare of the subjects were respected; the physicians conducting the study did not find the hazards to outweigh the potential benefits; the results reported are accurate, and each subject or subject's legal guardian gave his or her written informed consent before any protocol-driven tests or evaluations were performed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 March 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Netherlands: 10
Country: Number of subjects enrolled	Poland: 10
Country: Number of subjects enrolled	Spain: 21
Country: Number of subjects enrolled	United Kingdom: 7
Country: Number of subjects enrolled	Belgium: 2
Country: Number of subjects enrolled	Czech Republic: 7
Country: Number of subjects enrolled	Estonia: 3
Country: Number of subjects enrolled	Finland: 1
Country: Number of subjects enrolled	France: 13
Country: Number of subjects enrolled	Germany: 65
Country: Number of subjects enrolled	Italy: 41
Country: Number of subjects enrolled	Australia: 8
Country: Number of subjects enrolled	Canada: 25
Country: Number of subjects enrolled	Israel: 4

Country: Number of subjects enrolled	Japan: 17
Country: Number of subjects enrolled	United States: 42
Worldwide total number of subjects	276
EEA total number of subjects	180

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	191
From 65 to 84 years	85
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Of the 276 subjects screened, 31 were found not eligible. Therefore, 245 eligible subjects with CIDP entered the IgG Dependency Period during which time no IVIG was administered. Out of these, 208 subjects who experienced CIDP deterioration during the IgG Dependency Period qualified for the IgPro10 Restabilization Period.

Period 1

Period 1 title	IgPro10 Restabilization
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	IgPro10
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Arm description:

Subjects who experienced CIDP deterioration during the IgG Dependency Period started up to 13 weeks of IVIG treatment with IgPro10 during the IgPro10 Restabilization Period. Of the 208 subjects that started this period, 207 received IgPro10.

Arm type	Experimental
Investigational medicinal product name	IgPro10
Investigational medicinal product code	
Other name	Privigen
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

IgPro10 as 1 loading dose of 2 g/kg bw, followed by 3 or 4 maintenance doses (depending on time needed for restabilization) of 1 g/kg bw every 3 weeks.

Number of subjects in period 1	IgPro10
Started	208
Completed	172
Not completed	36
Consent withdrawn by subject	7
Physician decision	2
Failure to meet randomization criteria	22
Adverse event, non-fatal	4
Protocol deviation	1

Period 2

Period 2 title	IgPro20 Subcutaneous (SC) Treatment
Is this the baseline period?	Yes ^[1]
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Data analyst, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
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Arm title	IgPro20 (0.2)
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Arm description:

IgPro20 at a dose of 0.2 g/kg bw

Arm type	Experimental
Investigational medicinal product name	IgPro20
Investigational medicinal product code	
Other name	Hizentra
Pharmaceutical forms	Solution for infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

Weekly subcutaneous (SC) infusion of IgPro20 at 0.2 g/kg bw for up to 24 weeks.

Arm title	IgPro20 (0.4)
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Arm description:

IgPro20 at a dose of 0.4 g/kg bw

Arm type	Experimental
Investigational medicinal product name	IgPro20
Investigational medicinal product code	
Other name	Hizentra
Pharmaceutical forms	Solution for infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

Weekly subcutaneous (SC) infusion of IgPro20 at 0.4 g/kg bw for up to 24 weeks.

Arm title	Placebo
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Arm description:

2% human albumin solution

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

Weekly SC infusion for up to 24 weeks.

Notes:

[1] - Period 1 is not the baseline period. It is expected that period 1 will be the baseline period.

Justification: The study was designed for IgPro20 SC randomization, therefore this is the subject population that should be used as the baseline.

Number of subjects in period 2^[2]	IgPro20 (0.2)	IgPro20 (0.4)	Placebo
Started	57	58	57
Completed	36	39	21
Not completed	21	19	36
Consent withdrawn by subject	2	8	3
Physician decision	-	-	1
Adverse event, non-fatal	1	1	-
Lack of efficacy	18	10	32

Notes:

[2] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: The study was designed for IgPro20 SC randomization, therefore this is the subject population that should be used as the baseline.

Baseline characteristics

Reporting groups

Reporting group title	IgPro20 (0.2)
Reporting group description: IgPro20 at a dose of 0.2 g/kg bw	
Reporting group title	IgPro20 (0.4)
Reporting group description: IgPro20 at a dose of 0.4 g/kg bw	
Reporting group title	Placebo
Reporting group description: 2% human albumin solution	

Reporting group values	IgPro20 (0.2)	IgPro20 (0.4)	Placebo
Number of subjects	57	58	57
Age categorical			
Units: Subjects			
Adults (18-64 years)	41	40	41
From 65-84 years	16	18	16
Age continuous			
Units: years			
arithmetic mean	57.5	56.6	55.9
standard deviation	± 12.02	± 13.62	± 12.64
Gender categorical			
Units: Subjects			
Female	15	27	20
Male	42	31	37

Reporting group values	Total		
Number of subjects	172		
Age categorical			
Units: Subjects			
Adults (18-64 years)	122		
From 65-84 years	50		
Age continuous			
Units: years			
arithmetic mean	-		
standard deviation	-		
Gender categorical			
Units: Subjects			
Female	62		
Male	110		

End points

End points reporting groups

Reporting group title	IgPro10
Reporting group description: Subjects who experienced CIDP deterioration during the IgG Dependency Period started up to 13 weeks of IVIG treatment with IgPro10 during the IgPro10 Restabilization Period. Of the 208 subjects that started this period, 207 received IgPro10.	
Reporting group title	IgPro20 (0.2)
Reporting group description: IgPro20 at a dose of 0.2 g/kg bw	
Reporting group title	IgPro20 (0.4)
Reporting group description: IgPro20 at a dose of 0.4 g/kg bw	
Reporting group title	Placebo
Reporting group description: 2% human albumin solution	
Subject analysis set title	ITTS
Subject analysis set type	Intention-to-treat
Subject analysis set description: Intention-to-treat Set (ITTS): The ITTS consists of all randomized subjects who received at least 1 dose of IgPro20 / placebo and satisfied inclusion criterion #1 (diagnosis of CIDP).	
Subject analysis set title	SDS
Subject analysis set type	Safety analysis
Subject analysis set description: Safety Data Set (SDS): The SDS consists of all randomized subjects who received at least 1 dose of IgPro20 or placebo.	
Subject analysis set title	PSDS
Subject analysis set type	Safety analysis
Subject analysis set description: Pre-randomization Safety Data Set (PSDS): The PSDS was based on all subjects enrolled into the study who received at least 1 dose of IgPro10 before randomization.	
Subject analysis set title	RSDS
Subject analysis set type	Safety analysis
Subject analysis set description: Rescue Medication Safety Data Set (RSDS): The RSDS consists of subjects of the SDS who received at least 1 dose of IgPro10 rescue medication.	

Primary: Percentage (%) of subjects who relapse or are withdrawn for any other reason during the SC treatment period (ITTS)

End point title	Percentage (%) of subjects who relapse or are withdrawn for any other reason during the SC treatment period (ITTS)
End point description: Relapse is defined as an increase of at least 1 INCAT score point (except for the increase from 0 to 1 in the upper limb score). The INCAT score is a 10-point scale that covers the functionality of legs and arms, and has been successfully used to measure treatment effects in various CIDP studies. Scores for arm disability range from 0 ("No upper limb problems") to 5 ("Inability to use either arm for any purposeful movement"), and scores for leg disability range from 0 ("Walking not affected") to 5 ("Restricted to wheelchair, unable to stand and walk a few steps with help"). The INCAT (total) score is the sum of these 2 scores and ranges from 0 to 10. For the "adjusted" INCAT score, changes in the function of the upper limbs from 0 (normal) to 1 (minor symptoms) or from 1 to 0 were not recorded as deterioration or improvement because these changes are not considered clinically significant.	
End point type	Primary

End point timeframe:

Up to 25 weeks

End point values	IgPro20 (0.2)	IgPro20 (0.4)	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	57	58	57	
Units: Percent of subjects				
number (not applicable)	38.6	32.8	63.2	

Statistical analyses

Statistical analysis title	CIDP Relapse or Withdrawal (IgPro20, 0.2)
Comparison groups	IgPro20 (0.2) v Placebo
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.007
Method	Fisher exact
Parameter estimate	Mean difference (final values)
Point estimate	-24.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-40.7
upper limit	-6.21

Statistical analysis title	CIDP Relapse or Withdrawal (IgPro20, 0.4)
Comparison groups	IgPro20 (0.4) v Placebo
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Fisher exact
Parameter estimate	Mean difference (final values)
Point estimate	-30.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-46
upper limit	-12.2

Secondary: Change from baseline in Inflammatory Neuropathy Cause and Treatment (INCAT) total scores during the SC treatment period (ITTS)

End point title	Change from baseline in Inflammatory Neuropathy Cause and Treatment (INCAT) total scores during the SC treatment period (ITTS)
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End point description:

The INCAT score is a 10-point scale that covers the functionality of legs and arms, and has been successfully used to measure treatment effects in various CIDP studies. Scores for arm disability range from 0 ("No upper limb problems") to 5 ("Inability to use either arm for any purposeful movement"), and scores for leg disability range from 0 ("Walking not affected") to 5 ("Restricted to wheelchair, unable to stand and walk a few steps with help"). The INCAT (total) score is the sum of these 2 scores and ranges from 0 to 10. For the "adjusted" INCAT score, changes in the function of the upper limbs from 0 (normal) to 1 (minor symptoms) or from 1 to 0 were not recorded as deterioration or improvement because these changes are not considered clinically significant.

End point type	Secondary
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End point timeframe:

Baseline and up to 25 weeks

End point values	IgPro20 (0.2)	IgPro20 (0.4)	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	57	57	
Units: Scores on scale				
median (full range (min-max))	0 (-2 to 5)	0 (-2 to 3)	1 (-1 to 4)	

Statistical analyses

Statistical analysis title	Median difference from Baseline (IgPro20, 0.2)
Comparison groups	IgPro20 (0.2) v Placebo
Number of subjects included in analysis	113
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.005
Method	Wilcoxon rank sum
Parameter estimate	Median difference (final values)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	0

Statistical analysis title	Median difference from Baseline (IgPro20, 0.4)
Comparison groups	IgPro20 (0.4) v Placebo

Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Wilcoxon rank sum
Parameter estimate	Median difference (final values)
Point estimate	-1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	0

Secondary: Change from baseline in mean grip strength during the SC treatment period (ITTS)

End point title	Change from baseline in mean grip strength during the SC treatment period (ITTS)
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End point description:

The hand-held Vigorimeter is a device that measures the strength of small muscles in the hand; ie, grip strength. Subjects squeezed a rubber bulb lying between the palm of the hand and the thumb and index fingers. The pressure was recorded via a rubber tube on a nanometer and expressed in kilopascal. At each assessment, the subjects squeezed 3 times with each hand. The mean grip strength of each hand was determined.

End point type	Secondary
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End point timeframe:

Baseline and up to 25 weeks

End point values	IgPro20 (0.2)	IgPro20 (0.4)	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	57	57	
Units: Kilopascal (kPa)				
median (full range (min-max))	-0.6 (-80 to 55)	-2.7 (-80 to 55)	-6.6 (-51 to 22)	

Statistical analyses

Statistical analysis title	Median difference from Baseline (IgPro20, 0.2)
Comparison groups	IgPro20 (0.2) v Placebo
Number of subjects included in analysis	113
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.004
Method	Wilcoxon rank sum
Parameter estimate	Median difference (final values)
Point estimate	7.6

Confidence interval	
level	95 %
sides	2-sided
lower limit	2
upper limit	14

Statistical analysis title	Median difference from Baseline (IgPro20, 0.4)
Comparison groups	Placebo v IgPro20 (0.4)
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.014
Method	Wilcoxon rank sum
Parameter estimate	Median difference (final values)
Point estimate	5.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	11.7

Secondary: Change from baseline in Medical Research Council (MRC) sum scores during the SC treatment period (ITTS)

End point title	Change from baseline in Medical Research Council (MRC) sum scores during the SC treatment period (ITTS)
End point description:	
An adapted version of the MRC sum score was used in the study. The MRC sum score is the sum of all 16 muscle scores, and ranges from 0 (paralysis) to 80 (normal strength).	
End point type	Secondary
End point timeframe:	
Baseline and up to 25 weeks	

End point values	IgPro20 (0.2)	IgPro20 (0.4)	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	57	57	
Units: scores on a scale				
median (full range (min-max))	0 (-16 to 14)	0 (-12 to 7)	-2 (-19 to 6)	

Statistical analyses

Statistical analysis title	Median difference from baseline (IgPro20, 0.2)
Comparison groups	Placebo v IgPro20 (0.2)
Number of subjects included in analysis	113
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.003
Method	Wilcoxon rank sum
Parameter estimate	Median difference (final values)
Point estimate	2
Confidence interval	
level	95 %
sides	2-sided
lower limit	1
upper limit	4

Statistical analysis title	Median difference from baseline (IgPro20, 0.4)
Comparison groups	Placebo v IgPro20 (0.4)
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.002
Method	Wilcoxon rank sum
Parameter estimate	Median difference (final values)
Point estimate	2
Confidence interval	
level	95 %
sides	2-sided
lower limit	1
upper limit	4

Secondary: Change from baseline in Rasch-built Overall Disability Scale (R-ODS) scores during the SC Treatment Period (ITTS)

End point title	Change from baseline in Rasch-built Overall Disability Scale (R-ODS) scores during the SC Treatment Period (ITTS)
End point description: The R-ODS centile score captures activity and social participation in subjects with CIDP. The R-ODS centile score ranges from 0 (most severe activity and social participation limitations) to 100 (no activity and social participation limitations).	
End point type	Secondary
End point timeframe: Baseline and up to 25 weeks	

End point values	IgPro20 (0.2)	IgPro20 (0.4)	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	53	53	52	
Units: scores on a scale				
median (full range (min-max))	-2 (-41 to 100)	0 (-49 to 17)	-3 (-43 to 13)	

Statistical analyses

Statistical analysis title	Median difference from Baseline (IgPro20, 0.2)
Comparison groups	IgPro20 (0.2) v Placebo
Number of subjects included in analysis	105
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.03
Method	Wilcoxon rank sum
Parameter estimate	Median difference (final values)
Point estimate	3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	9

Statistical analysis title	Median difference from Baseline (IgPro20, 0.4)
Comparison groups	IgPro20 (0.4) v Placebo
Number of subjects included in analysis	105
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Wilcoxon rank sum
Parameter estimate	Median difference (final values)
Point estimate	5
Confidence interval	
level	95 %
sides	2-sided
lower limit	2
upper limit	9

Secondary: Rate of adverse events per IgPro20 infusion during the SC treatment period (SDS)

End point title	Rate of adverse events per IgPro20 infusion during the SC treatment period (SDS)
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End point description:

End point type	Secondary
End point timeframe:	
Up to 28 weeks	

End point values	IgPro20 (0.2)	IgPro20 (0.4)	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	57	58	57	
Units: Rate/Infusion				
number (not applicable)	0.079	0.051	0.034	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with adverse events during the SC Treatment Period (SDS)

End point title	Number of subjects with adverse events during the SC Treatment Period (SDS)
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End point description:

End point type	Secondary
End point timeframe:	
Up to 28 weeks	

End point values	IgPro20 (0.2)	IgPro20 (0.4)	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	57	58	57	
Units: Subjects				
number (not applicable)	33	30	21	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with adverse events during the SC Treatment Period (SDS)

End point title	Percentage of subjects with adverse events during the SC Treatment Period (SDS)
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End point description:

End point type	Secondary
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End point timeframe:

Up to 28 weeks

End point values	IgPro20 (0.2)	IgPro20 (0.4)	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	57	58	57	
Units: Percent of Subjects				
number (not applicable)	57.9	51.7	36.8	

Statistical analyses

No statistical analyses for this end point

Secondary: Time to improvement during IgPro10 Re-stabilization Therapy (PSDS)

End point title	Time to improvement during IgPro10 Re-stabilization Therapy (PSDS)
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End point description:

Improvement is defined as an INCAT score decrease by 1 point (except for the decrease from 1 to 0 in the upper limb score), R-ODS improvement by at least 4 points, or Mean Grip strength improvement by at least 8 kPa in one hand.

End point type	Secondary
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End point timeframe:

Up to 13 weeks

End point values	IgPro10			
Subject group type	Reporting group			
Number of subjects analysed	207			
Units: Days				
median (confidence interval 95%)	23 (22 to 23)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in mean grip strength during IgPro10 Re-stabilization Therapy (PSDS)

End point title	Change in mean grip strength during IgPro10 Re-stabilization Therapy (PSDS)
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End point description:

End point type	Secondary
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End point timeframe:

Reference Visit and up to 13 weeks

End point values	IgPro10			
Subject group type	Reporting group			
Number of subjects analysed	202			
Units: kPa				
arithmetic mean (standard deviation)	11.27 (± 16.89)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in MRC sum score during IgPro10 Re-stabilization Therapy (PSDS)

End point title	Change in MRC sum score during IgPro10 Re-stabilization Therapy (PSDS)
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End point description:

End point type	Secondary
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End point timeframe:

Reference Visit and up to 13 weeks

End point values	IgPro10			
Subject group type	Reporting group			
Number of subjects analysed	203			
Units: Scores on a scale				
arithmetic mean (standard deviation)	3.4 (± 4.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in R-ODS during IgPro10 Re-stabilization Therapy (PSDS)

End point title	Change in R-ODS during IgPro10 Re-stabilization Therapy (PSDS)
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End point description:

End point type	Secondary
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End point timeframe:

Reference Visit and up to 13 weeks

End point values	IgPro10			
Subject group type	Reporting group			
Number of subjects analysed	166			
Units: Scores on a scale				
arithmetic mean (standard deviation)	4.7 (\pm 14.14)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in INCAT during IgPro10 Re-stabilization Therapy (PSDS)

End point title	Change in INCAT during IgPro10 Re-stabilization Therapy (PSDS)
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End point description:

End point type	Secondary
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End point timeframe:

Reference Visit and up to 13 weeks

End point values	IgPro10			
Subject group type	Reporting group			
Number of subjects analysed	205			
Units: Scores on a scale				
arithmetic mean (standard deviation)	-1.1 (\pm 1.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Rate of adverse events per IgPro10 infusion during Re-stabilization Therapy (PSDS)

End point title	Rate of adverse events per IgPro10 infusion during Re-stabilization Therapy (PSDS)
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End point description:

End point type	Secondary
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End point timeframe:

Up to 13 weeks

End point values	IgPro10			
Subject group type	Reporting group			
Number of subjects analysed	207			
Units: Rate/Infusion				
number (not applicable)	0.175			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with adverse events during IgPro10 Re-stabilization Therapy (PSDS)

End point title	Number of subjects with adverse events during IgPro10 Re-stabilization Therapy (PSDS)
End point description:	
End point type	Secondary
End point timeframe:	
Up to 13 weeks	

End point values	IgPro10			
Subject group type	Reporting group			
Number of subjects analysed	207			
Units: Subjects				
number (not applicable)	100			

Statistical analyses

No statistical analyses for this end point

Secondary: Percent of subjects with adverse events during IgPro10 Re-stabilization Therapy (PSDS)

End point title	Percent of subjects with adverse events during IgPro10 Re-stabilization Therapy (PSDS)
End point description:	
End point type	Secondary
End point timeframe:	
Up to 13 weeks	

End point values	IgPro10			
Subject group type	Reporting group			
Number of subjects analysed	207			
Units: Percent of Subjects				
number (not applicable)	48.3			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in mean grip strength during IgPro10 Rescue Therapy (RSDS)

End point title	Change in mean grip strength during IgPro10 Rescue Therapy (RSDS)
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End point description:

End point type	Secondary
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End point timeframe:

Before first rescue IgPro10 infusion and up to 13 weeks

End point values	IgPro10			
Subject group type	Reporting group			
Number of subjects analysed	35			
Units: kPa				
arithmetic mean (standard deviation)	16.3 (± 17.58)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in MRC sum score during IgPro10 Rescue Therapy (RSDS)

End point title	Change in MRC sum score during IgPro10 Rescue Therapy (RSDS)
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End point description:

End point type	Secondary
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End point timeframe:

Before first rescue IgPro10 infusion and up to 13 weeks

End point values	IgPro10			
Subject group type	Reporting group			
Number of subjects analysed	35			
Units: Scores on a scale				
arithmetic mean (standard deviation)	6.8 (\pm 5.28)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in R-ODS during IgPro10 Rescue Therapy (RSDS)

End point title	Change in R-ODS during IgPro10 Rescue Therapy (RSDS)
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End point description:

End point type	Secondary
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End point timeframe:

Before first rescue IgPro10 infusion and up to 13 weeks

End point values	IgPro10			
Subject group type	Reporting group			
Number of subjects analysed	29			
Units: Scores on a scale				
arithmetic mean (standard deviation)	14 (\pm 14.69)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in INCAT during IgPro10 Rescue Therapy (RSDS)

End point title	Change in INCAT during IgPro10 Rescue Therapy (RSDS)
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End point description:

End point type	Secondary
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End point timeframe:

Before first rescue IgPro10 infusion and up to 13 weeks

End point values	IgPro10			
Subject group type	Reporting group			
Number of subjects analysed	45			
Units: Scores on a scale				
arithmetic mean (standard deviation)	-1.3 (\pm 1.31)			

Statistical analyses

No statistical analyses for this end point

Secondary: Time to improvement after CIDP relapse during IgPro10 Rescue Therapy (RSDS)

End point title	Time to improvement after CIDP relapse during IgPro10 Rescue Therapy (RSDS)
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End point description:

Improvement is defined as a decrease in INCAT score (except for the decrease from 1 to 0 in the upper limb score) back to or below the baseline score

End point type	Secondary
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End point timeframe:

Up to 13 weeks

End point values	IgPro10			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: Days				
median (confidence interval 95%)	23 (22 to 49)			

Statistical analyses

No statistical analyses for this end point

Secondary: Rate of adverse events per IgPro10 infusion during Rescue Therapy (RSDS)

End point title	Rate of adverse events per IgPro10 infusion during Rescue Therapy (RSDS)
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End point description:

End point type	Secondary
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End point timeframe:

Up to 13 weeks

End point values	IgPro10			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: Rate/Infusion				
number (not applicable)	0.142			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with adverse events during IgPro10 Rescue Therapy (RSDS)

End point title	Number of subjects with adverse events during IgPro10 Rescue Therapy (RSDS)
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End point description:

End point type	Secondary
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End point timeframe:

Up to 13 weeks

End point values	IgPro10			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: Subjects				
number (not applicable)	17			

Statistical analyses

No statistical analyses for this end point

Secondary: Percent of subjects with adverse events during IgPro10 Rescue Therapy (RSDS)

End point title	Percent of subjects with adverse events during IgPro10 Rescue Therapy (RSDS)
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End point description:

End point type	Secondary
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End point timeframe:

Up to 13 weeks

End point values	IgPro10			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: Percent of Subjects				
number (not applicable)	28.3			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

4.5 years

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	14.1
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Reporting groups

Reporting group title	IgPro10 Restabilization
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Reporting group description:

PSDS

Reporting group title	IgPro20 (0.2)
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Reporting group description:

SDS

Reporting group title	IgPro20 (0.4)
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Reporting group description:

SDS

Reporting group title	Placebo
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Reporting group description:

SDS

Reporting group title	IgPro10 Rescue
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Reporting group description:

RSDS

Serious adverse events	IgPro10 Restabilization	IgPro20 (0.2)	IgPro20 (0.4)
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 207 (5.31%)	3 / 57 (5.26%)	2 / 58 (3.45%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
Blood pressure diastolic increased			
subjects affected / exposed	1 / 207 (0.48%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
B-cell lymphoma			
subjects affected / exposed	0 / 207 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac disorders			
Cardiac failure congestive			
subjects affected / exposed	1 / 207 (0.48%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	1 / 207 (0.48%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Migraine			
subjects affected / exposed	1 / 207 (0.48%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic inflammatory demyelinating polyradiculoneuropathy			
subjects affected / exposed	2 / 207 (0.97%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 207 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 207 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	1 / 207 (0.48%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Inguinal hernia			

subjects affected / exposed	0 / 207 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 207 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	1 / 207 (0.48%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 207 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	1 / 207 (0.48%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	1 / 207 (0.48%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary hypertension			
subjects affected / exposed	0 / 207 (0.00%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	1 / 207 (0.48%)	0 / 57 (0.00%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Dermatitis allergic			
subjects affected / exposed	0 / 207 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthropathy			
subjects affected / exposed	0 / 207 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
subjects affected / exposed	0 / 207 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fracture nonunion			
subjects affected / exposed	0 / 207 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Sepsis			
subjects affected / exposed	0 / 207 (0.00%)	0 / 57 (0.00%)	1 / 58 (1.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	0 / 207 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 207 (0.00%)	1 / 57 (1.75%)	0 / 58 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serious adverse events			
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 57 (1.75%)	2 / 60 (3.33%)	
number of deaths (all causes)	0	0	

number of deaths resulting from adverse events	0	0	
Investigations			
Blood pressure diastolic increased			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
B-cell lymphoma			
subjects affected / exposed	0 / 57 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Cardiac failure congestive			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Migraine			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic inflammatory demyelinating polyradiculoneuropathy			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	0 / 57 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Inguinal hernia			
subjects affected / exposed	1 / 57 (1.75%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	0 / 57 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			

subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary hypertension			
subjects affected / exposed	0 / 57 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis allergic			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthropathy			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthralgia			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture nonunion			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Sepsis			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Bacterial infection			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	IgPro10 Restabilization	IgPro20 (0.2)	IgPro20 (0.4)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	50 / 207 (24.15%)	22 / 57 (38.60%)	20 / 58 (34.48%)
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	5 / 207 (2.42%)	3 / 57 (5.26%)	1 / 58 (1.72%)
occurrences (all)	5	8	1
Nervous system disorders			
Headache			
subjects affected / exposed	34 / 207 (16.43%)	4 / 57 (7.02%)	4 / 58 (6.90%)
occurrences (all)	53	5	4
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	5 / 207 (2.42%)	5 / 57 (8.77%)	0 / 58 (0.00%)
occurrences (all)	11	5	0
Infusion site erythema			
subjects affected / exposed	0 / 207 (0.00%)	5 / 57 (8.77%)	10 / 58 (17.24%)
occurrences (all)	0	11	28
Infusion site swelling			
subjects affected / exposed	0 / 207 (0.00%)	5 / 57 (8.77%)	6 / 58 (10.34%)
occurrences (all)	0	8	8
Infusion site induration			
subjects affected / exposed	0 / 207 (0.00%)	2 / 57 (3.51%)	3 / 58 (5.17%)
occurrences (all)	0	10	3

Infusion site pain subjects affected / exposed occurrences (all)	0 / 207 (0.00%) 0	3 / 57 (5.26%) 15	2 / 58 (3.45%) 2
Infusion site warmth subjects affected / exposed occurrences (all)	0 / 207 (0.00%) 0	0 / 57 (0.00%) 0	3 / 58 (5.17%) 3
Gastrointestinal disorders Nausea subjects affected / exposed occurrences (all)	10 / 207 (4.83%) 12	0 / 57 (0.00%) 0	1 / 58 (1.72%) 1
Musculoskeletal and connective tissue disorders Pain in extremity subjects affected / exposed occurrences (all)	3 / 207 (1.45%) 3	1 / 57 (1.75%) 1	3 / 58 (5.17%) 3
Arthralgia subjects affected / exposed occurrences (all)	3 / 207 (1.45%) 3	3 / 57 (5.26%) 3	1 / 58 (1.72%) 1
Back pain subjects affected / exposed occurrences (all)	5 / 207 (2.42%) 5	3 / 57 (5.26%) 4	1 / 58 (1.72%) 1
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all)	12 / 207 (5.80%) 12	4 / 57 (7.02%) 6	2 / 58 (3.45%) 2
Urinary tract infection subjects affected / exposed occurrences (all)	1 / 207 (0.48%) 2	1 / 57 (1.75%) 1	0 / 58 (0.00%) 0
Upper respiratory tract infection subjects affected / exposed occurrences (all)	2 / 207 (0.97%) 2	3 / 57 (5.26%) 3	2 / 58 (3.45%) 2

Non-serious adverse events	Placebo	IgPro10 Rescue	
Total subjects affected by non-serious adverse events subjects affected / exposed	15 / 57 (26.32%)	7 / 60 (11.67%)	
Injury, poisoning and procedural complications			

Fall subjects affected / exposed occurrences (all)	0 / 57 (0.00%) 0	0 / 60 (0.00%) 0	
Nervous system disorders Headache subjects affected / exposed occurrences (all)	2 / 57 (3.51%) 2	4 / 60 (6.67%) 6	
General disorders and administration site conditions Fatigue subjects affected / exposed occurrences (all) Infusion site erythema subjects affected / exposed occurrences (all) Infusion site swelling subjects affected / exposed occurrences (all) Infusion site induration subjects affected / exposed occurrences (all) Infusion site pain subjects affected / exposed occurrences (all) Infusion site warmth subjects affected / exposed occurrences (all)	1 / 57 (1.75%) 1 0 / 57 (0.00%) 0 2 / 57 (3.51%) 2 1 / 57 (1.75%) 1 2 / 57 (3.51%) 2 0 / 57 (0.00%) 0	0 / 60 (0.00%) 0 0 / 60 (0.00%) 0 0 / 60 (0.00%) 0 0 / 60 (0.00%) 0 0 / 60 (0.00%) 0	
Gastrointestinal disorders Nausea subjects affected / exposed occurrences (all)	2 / 57 (3.51%) 2	4 / 60 (6.67%) 4	
Musculoskeletal and connective tissue disorders Pain in extremity subjects affected / exposed occurrences (all) Arthralgia	0 / 57 (0.00%) 0	0 / 60 (0.00%) 0	

subjects affected / exposed occurrences (all)	1 / 57 (1.75%) 1	0 / 60 (0.00%) 0	
Back pain subjects affected / exposed occurrences (all)	1 / 57 (1.75%) 1	1 / 60 (1.67%) 1	
Infections and infestations			
Nasopharyngitis subjects affected / exposed occurrences (all)	1 / 57 (1.75%) 1	1 / 60 (1.67%) 1	
Urinary tract infection subjects affected / exposed occurrences (all)	3 / 57 (5.26%) 3	0 / 60 (0.00%) 0	
Upper respiratory tract infection subjects affected / exposed occurrences (all)	2 / 57 (3.51%) 2	0 / 60 (0.00%) 0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 November 2011	<ul style="list-style-type: none">-Updated with regard to measurements and information on the occurrence of hemolysis-Changes in timing of SC treatment: allowed to be performed on 1 or 2 consecutive days each study week-A change in dosing for loading and rescue with IVIG: a total dose of ≤ 200 g was to be administered for subjects with a body weight greater than 100 kg
12 April 2013	<ul style="list-style-type: none">-‘IVIG Withdrawal Period’ was changed to the ‘IgG Dependency Test Period’. Daily self-assessments (R-ODS score and grip strength) were added to prove subjects’ ongoing need for IVIG-The schedule and loading / maintenance dosing for the IgPro10 Rescue Period was revised to match the IgPro10 Restabilization Period. The dosing was continued until the I-NCAT score was back to the result at the Rescue Reference Visit-Additional safety assessment at 4 weeks after final administration of IgPro20-Addition of laboratory parameters (blood urea nitrogen, gamma-glutamyltransferase)
11 September 2014	<ul style="list-style-type: none">-Number of SC infusion sites in parallel no longer specified, focus on maximum rate and volume per site allowed per protocol; volume per infusion site increased to 50 mL-Addition of new post-marketing adverse reactions and precautions for IgPro20 (Thrombotic Events and Aseptic Meningitis Syndrome)-Addition of interim safety analysis (March 2014) summary, which revealed no additional safety issue-Deletion of inclusion criterion #2, reducing the length of time required for pre-study IVIG to 8 weeks-Addition of Screening Period details: assessments could now be performed over > 1 visit; eligibility had to be determined before Screening efficacy measurements were performed and Screening IVIG was administered
08 December 2015	<ul style="list-style-type: none">-Adverse reactions and precautions were updated per current safety information for IgPro10 (Transfusion-related Acute Lung Injury)-Definition of “CIDP relapse” was clarified to be applicable to IgPro10 Restabilization as well as when it occurs during the SC Treatment Period

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

For endpoint, "Time to CIDP relapse or withdrawal due to any other reason during the SC treatment period (ITTS)", for the Placebo group the median time was 79.0 days (95% CI: 57.0 to 125.0). Other median times could not be calculated.

Notes: