SUPPLEMENTAL MATERIAL

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CIDP01 coinvestigators

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CIDP01 inclusion criteria

To be eligible to participate in this study, all of the following criteria must have been met:

1. An IRB/IEC-approved written informed consent form was signed and dated by the study participant
2. The study participant was considered reliable and capable of adhering to the protocol visit schedule, or medication intake according to the judgment of the investigator.
3. Study participant was ≥18 years of age at Visit 1 (Screening).
4. Study participant had a documented definite or probable diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP) according to the EFNS/PNS criteria 2010.
5. Study participant had an Ig-dependency confirmed by clinical examination during therapy or upon interruption or reduction of therapy within 18 months prior to Screening and documented in medical history (i.e., that a decrease or withdrawal of Ig was attempted that resulted in a clinically relevant decrease in function).
6. Study participant was on a stable dosage (not more than ±20% deviation) for SCIg or IVIg and a fixed interval for at least 4 months of either treatment, e.g., once weekly ±2 days for SCIg or every 2 to 6 weeks ±5 days IVIg, respectively, for stability in functioning between dosing.
7. Female study participants of childbearing potential must have had a negative serum pregnancy test at the Screening Visit, which was confirmed to be negative by urine testing prior to the first dose of investigational medicinal product at Week 1 (Visit 2) and prior to further dosing at each study visit thereafter. Female study participants of childbearing potential must have agreed to use a highly effective method of birth control, during the study and for a period of 3 months after their final dose of IMP. Highly effective forms of birth control are methods which achieve a failure rate of less than 1% per year when used consistently and correctly. According to the ICH M3 R2, highly effective methods of birth control include:
    - Progesterone-only hormonal contraceptives (oral, implant, injectable) associated with

inhibition of ovulation (which must be stable for at least 1 full month prior to Screening [Visit 1] and should remain stable during the study).

- Progesterone-releasing intrauterine systems or the TCu 380A intrauterine device.
- Vasectomized partner (provided sole partner and partner has medical proof of surgical success).
- True heterosexual sexual abstinence is an acceptable form of contraception when this is in line with the preferred and usual lifestyle of the person. Periodic abstinence (e.g., calendar, ovulation, symptothermal, post-ovulation methods), declaration of abstinence for the duration of the study, and withdrawal are not acceptable methods of contraception.

Women who did not agree to use birth control must have been of non-childbearing potential, defined as being:

- Postmenopausal (for at least 2 years before the Screening Visit), verified by serum follicle-stimulating hormone level >40 mIU/mL at the Screening Visit, or
- Permanently sterilised (e.g., bilateral tubal occlusion, hysterectomy, bilateral salpingectomy), or
- Congenitally sterile.

8. Male study participants with a partner of childbearing potential must have been willing to use a condom when sexually active during the study and for 3 months after the final administration of IMP. In addition, the female partner of childbearing potential of a male study participant must have been willing to use a highly effective method of contraception (as above), during the study period and for 3 months after the final administration of IMP. Sperm donation was not permitted during the study and for 3 months after final administration of IMP.

CIDP01 exclusion criteria

Study participants were not permitted to enroll in the study if any of the following criteria were met:

Exclusion criteria related to study participation

1. Study participant had previously received treatment in this study or study participant had previously been exposed to rozanolixizumab.
2. Study participant had participated in another study of an IMP (or a medical device) within the previous 30 days of Screening Visit or was currently participating in another study of an IMP (or a medical device). For experimental biological agents refer to Exclusion Criterion 26.

Exclusion criteria related to CIDP diagnosis

3. Study participant had a current diagnosis or had a history of Type 1 or Type 2 diabetes mellitus and/or hemoglobin A1c level >6.0%.
4. Study participant had IgM paraproteinemia.
5. Study participant had known IgM-mediated neuropathy (e.g., multifocal motor neuropathy).
6. Clinical or known evidence of associated systemic diseases that might have caused neuropathy, including but not limited to connective tissue disease, Lyme disease, Castleman's disease and systemic lupus erythematosus, malignant plasma cell dysplasia, or treatment with agents that might lead to neuropathy (e.g., amiodarone therapy).
7. Study participants had an average dose of less than 0·4g IgG/kg/month over the past 4 months.

Exclusion criteria related to health status/safety of the study participants

8. Female study participant who was pregnant or lactating.
9. Study participant had any medical (acute or chronic illness) or psychiatric condition that, in the opinion of the investigator, could harm the study participant or would compromise the study participant's ability to participate in this study.
10. Study participant had 12-lead ECG with abnormalities considered to be clinically significant upon medical review.

11. Study participant had renal impairment, defined as:

    - Serum creatinine level of ≥1.4mg/dL for females and ≥1.5 mg/dL for males at Screening Visit.

12. Study participant had an absolute neutrophil count <1500/mm^3 (1.5 x 10^9/L).

13. Study participant had >2 x upper limit of normal (ULN) of any of the following: alanine aminotransferase (ALT), aspartate aminotransferase (AST), or alkaline phosphatase (ALP), or >ULN total bilirubin (≥1.5 x ULN total bilirubin if known Gilbert's syndrome). If the study participant had elevations only in total bilirubin that were >ULN and <1.5 x ULN, fractionate bilirubin to identify possible undiagnosed Gilbert's syndrome (i.e., direct bilirubin <35%). For randomised study participants with a baseline result >ULN for ALT, AST, ALP, or total bilirubin, a baseline diagnosis and/or the cause of any clinically meaningful elevation must have been understood and recorded in the eCRF.

    If study participant had >ULN ALT, AST, or ALP that did not meet the exclusion limit at Screening, the tests were to be repeated, if possible, prior to dosing to ensure there was no further ongoing clinically relevant increase. In case of a clinically relevant increase, inclusion of the study participant must have been discussed with the Medical Monitor. Tests that result in ALT, AST, or ALP up to 25% above the exclusion limit may have been repeated once for confirmation. This included rescreening.

14. Study participant had a history of alcohol use disorder or other substance use disorder (as per Diagnostic and Statistical Manual of Mental Disorders-5 [American Psychiatric Association, 2013]) within 12 months of Screening Visit.

15. Study participant had a history of clinically relevant ongoing chronic infections including but not limited to human immunodeficiency virus (HIV), hepatitis B, hepatitis C, or tested positive for HIV (anti-human immunodeficiency virus [HIV] 1 or anti-HIV2 antibodies), hepatitis B (hepatitis B surface antigen [HBsAg] positive or hepatitis B core antibody test [HBcAb] positive without positive hepatitis B surface antibody [HBsAb]), or hepatitis C antibody (HCAb) at the Screening Visit.

16. Study participants with known tuberculosis (TB) infection, at high risk of acquiring TB infection, or latent TB infection (LTBI), or current/history of non-tuberculosis mycobacteria (NTMB) were to be excluded.

a. Known TB infection whether present or past was defined as:

- Active TB infection or clinical signs and symptoms suggestive of TB (pulmonary or extrapulmonary).
- History of active TB infection involving any organ system or findings in other organ systems consistent with TB infection.
- Any historical evidence by radiography or other imaging modalities consistent with previously active TB infection.

b. High risk of acquiring TB infection was defined as:

- Known exposure to another person with active TB infection within the 3 months prior to Screening.
- Time spent in a healthcare delivery setting or institution where individuals infected with TB were housed and where the risk of transmission of infection was high.

c. LTBI

d. NTMB was defined as a group of lung infections caused by mycobacteria different from *Mycobacterium tuberculosis* infections.

17. Study participant had a family history of primary immunodeficiency.

18. Study participant had a clinically relevant active infection (e.g., sepsis, pneumonia, abscess) or had had a serious infection (resulting in hospitalization or requiring parenteral antibiotic treatment) within 6 weeks prior to the first dose of IMP.

19. Study participant had active neoplastic disease or history of neoplastic disease within 5 years of Screening Visit (except for basal or squamous cell carcinoma of the skin or carcinoma in situ of the uterine cervix which had been definitively treated with SOC approaches).

20. Study participant had a lifetime history of suicide attempt (including an active attempt, interrupted attempt, or aborted attempt), or had suicidal ideation in the past 6 months as indicated by a “yes” answer to numbers 4 or 5 on the Screening Columbia Suicide Severity Rating Scale (C-SSRS).

21. Study participant had any planned elective surgery due to occur during the study dosing period which, in the opinion of the investigator, could interfere with study procedures.

22. Study participant had a history of known inflammatory bowel disease, active diverticular disease, or a history of confirmed duodenal, gastric, or esophageal ulceration in the past 6 months.

Exclusion criteria related to the IMP/concomitant medications/procedures

23. Study participant had a known hypersensitivity to any components of the IMP.
24. Study participant had a history of hyperprolinemia since L-proline is a constituent of rozanolixizumab.
25. Study participant had received a live vaccination within 8 weeks prior to the Baseline Visit; or intended to have a live vaccination during the course of the study or within 7 weeks following the final dose of IMP.
26. Study participant had received any experimental biological agent within or outside of a clinical study in the past 3 months or within 5 half-lives prior to Baseline (whichever is longer).
27. Study participant had had prior treatment with rituximab, ofatumumab, or ocrelizumab in the 6 months prior to the Baseline Visit or Study participant had had prior treatment with rituximab, ofatumumab, or ocrelizumab in the 12 months prior to Baseline and B cells were not within the normal range.
28. Study participant had been treated with immunosuppressants, biologics, and other therapies in the recent timeframe OR had been on permitted medications but had not been on stable dosing regimens of those medications.

CIDP01 outcomes

Primary efficacy variable

- Change from Baseline to Week 13 (Day 85) in iRODS score

Other efficacy variables

- Subject experienced CIDP relapse (iRODS) up to Week 13 (Day 85) after first treatment
- Time to CIDP relapse (iRODS) during the Treatment Period
- Values and change from Baseline in iRODS scores at each scheduled assessment during the Treatment and Observation Periods
- Subject experienced CIDP relapse (adjusted INCAT) up to Week 13 (Day 85) after first treatment
- Time to CIDP relapse (adjusted INCAT) during the Treatment Period
- Values and change from Baseline in adjusted INCAT score at each scheduled assessment during the Treatment and Observation Periods
- Subject experienced CIDP relapse (maximum grip strength as assessed by site personnel) up to Week 13 (Day 85) after first treatment
- Time to CIDP relapse (maximum grip strength as assessed by site personnel) during the Treatment Period
- Values and change from Baseline in maximum grip strength score (maximum of 3 assessments) taken by site personnel at each scheduled assessment during the Treatment and Observation Periods
- Values and change from Baseline in daily maximum grip strength score (maximum of 3 assessments) taken by the subject at the same time each day during the Treatment and Observation Periods
- Values and change from Baseline in Rasch-built, modified-interval Medical Research Council scale (RT-MRC) sum score at each scheduled assessment during the Treatment and Observation Periods
- Values and change from Baseline in fatigue at each scheduled assessment during the Treatment and Observation Periods
- Values and change from Baseline in CIDP patient-reported outcome (PRO) instrument at each scheduled assessment during the Treatment and Observation

Periods

- Values and change from Baseline in Patient Global Impressions of Severity (PGIS) at each scheduled assessment during the Treatment and Observation Periods
- Patient Global Impressions of Change (PGIC) at each scheduled assessment during the Treatment and Observations Periods
- Subjects receiving rescue medication during Treatment Period
- Time to rescue medication administration during Treatment Period

Other variables

Pharmacokinetic variable

- Plasma concentration of rozanolixizumab at each scheduled assessment during the Treatment Period

Pharmacodynamic variables

- Minimum value and maximum decrease (absolute and percentage) from Baseline in total serum IgG concentration during the study
- Value and change (absolute and percentage) from Baseline in total serum IgG concentrations at each scheduled assessment during Treatment and Observation Periods
- Value and change (absolute and percentage) from Baseline in serum IgG subclass concentrations at each scheduled assessment during Treatment and Observation Periods
- Value and change (absolute and percentage) from Baseline in NF-L levels at each scheduled assessment during Treatment and Observation Periods

Exploratory pharmacogenetics variables

- Genetic and epigenetic changes that may be measured to understand the cause, progression, and appropriate treatment of CIDP

Exploratory ribonucleic acid (RNA), protein, and metabolite variables

- RNA, protein, and metabolite changes that may be measured to understand the cause, progression, and appropriate treatment of CIDP
- Exploratory biomarkers such as but not limited to B-cell activating factor and Circulating Immune Complexes may be measured to evaluate the effect of

rozanolixizumab

- Change from Baseline relating to mechanism of action, disease activity, treatment response, and clinical outcome at each scheduled assessment during the Treatment and Observation Periods

Immunological variables

- Values and change from Baseline in serum immunoglobulin concentrations (total immunoglobulin A, IgE, and IgM) at each scheduled assessment during Treatment and Observation Periods
- Values and change from Baseline in serum complement levels (C3 and C4) and plasma complement levels (C3a and C5a) at each scheduled assessment during Treatment Period
- ADA (anti-rozanolixizumab antibodies) status (negative or confirmed positive) and the confirmed positive titer at each scheduled assessment during Treatment and Observation Periods
- Values and change from Baseline in cytokines at each scheduled assessment during Treatment and Observation Periods
- Change in CIDP-specific auto-antibody levels in serum from Baseline during Treatment and Observation Periods
- Values and change from Baseline in Tetanus- and influenza A virus-specific IgG antibodies during Treatment and Observation Periods

Safety variables

- Occurrence of TEAEs
- TEAEs leading to withdrawal of IMP
- Vital sign values and changes from Baseline (systolic and diastolic BP, temperature, pulse rate, and body weight) at each scheduled assessment during Treatment and Observation Periods
- 12-lead ECG values and change from Baseline at each scheduled assessment during Treatment and Observation Periods
- Laboratory values and changes from Baseline at each scheduled assessment during Treatment and Observation Periods (hematology, clinical chemistry, and urinalysis)
- Tuberculosis Signs and Symptoms Questionnaire at each scheduled assessment during

Treatment and Observation Periods

- Values and change from Baseline in concentrations of total protein, albumin, α- and β-globulins at each scheduled assessment during Treatment and Observation Periods

CIDP04 outcomes

Primary safety variable

- Occurrence of TEAEs

Other safety variables

- TEAEs leading to permanent withdrawal of IMP
- Vital signs values and changes from Baseline (systolic and diastolic BP, PR, body temperature, and body weight) at each scheduled assessment during the Treatment and Observation Periods
- Physical examination findings
- Neurological examination findings
- 12-lead ECG values and change from Baseline at each scheduled assessment during the Treatment and Observation Periods
- Laboratory values and changes from Baseline at each scheduled assessment during the Treatment and Observation Periods (hematology, clinical chemistry, and urinalysis)
- Tuberculosis Signs and Symptoms Questionnaire at each scheduled assessment during the Treatment and Observation Periods
- Values and change from Baseline in concentrations of total protein, albumin, α- and β-globulins at each scheduled assessment during the Treatment and Observation Periods

Other variables

Efficacy variables

- CIDP relapse (iRODS) was defined as a clinically important deterioration from Baseline in iRODS score, i.e., a minimum clinically important differences-SE (MCID-SE) of ≤-1.96
- CIDP relapse (adjusted INCAT) was defined as an increase from Baseline of at least 1 point in the adjusted INCAT score. The adjusted score is identical to the INCAT disability score except for the exclusion of changes in upper limb function from 0 (normal) to 1 (minor symptoms) or from 1 to 0
- CIDP relapse (maximum grip strength as assessed by site personnel) was defined as a clinically important deterioration from Baseline in grip strength as measured by site

personnel, i.e., a decline of >14 kPa

The other efficacy variables were:

- Values and absolute change from Baseline in iRODS scores at each scheduled assessment during the Treatment and Observation Periods
- Study participant experienced CIDP relapse (iRODS) up to Week 25 and Week 77 (where applicable) from Baseline
- Time to CIDP relapse (iRODS) during the Treatment Period from Baseline
- Study participant experienced CIDP relapse (adjusted INCAT) up to Week 25 and Week 77 (where applicable) from Baseline
- Time to CIDP relapse (adjusted INCAT) during the Treatment Periods from Baseline
- Values and absolute change from Baseline in adjusted INCAT score at each scheduled assessment during the Treatment and Observation Periods
- Study participant experienced CIDP relapse (maximum grip strength as assessed by site personnel) up to Week 25 and Week 77 (where applicable) from Baseline
- Time to CIDP relapse (maximum grip strength as assessed by site personnel) during the Treatment Periods from Baseline
- Values and absolute change from Baseline in maximum grip strength score (maximum of 3 assessments) taken by site personnel at each scheduled assessment during the Treatment and Observation Periods
- Values and absolute change from Baseline in RT-MRC sum score at each scheduled assessment during the Treatment and Observation Periods
- Study participants receiving rescue medication during Treatment Periods
- Time to rescue medication administration during Treatment Periods

Patient-reported outcome variables

- Values and change from Baseline in fatigue domain scores at each scheduled assessment during the Treatment and Observation Periods
- Values and change from Baseline in CIDP PRO instrument domain scores at each scheduled assessment during the Treatment and Observation Periods
- Values and change from Baseline in PGIS at each scheduled assessment during the Treatment and Observation Periods

- PGIC value at each scheduled assessment during the Treatment and Observations Periods

Pharmacokinetic variable

- Plasma concentration of rozanolixizumab at each scheduled assessment during the Treatment Periods

Pharmacodynamic variables

- Minimum value and maximum decrease (absolute and percentage) from Baseline in total serum IgG concentration during the study
- Values and change (absolute and percentage) from Baseline in total serum IgG concentrations at each scheduled assessment during Treatment and Observation Periods
- Values and change (absolute and percentage) from Baseline in serum IgG subclass concentrations at each scheduled assessment during Treatment and Observation Periods
- Values and change (absolute and percentage) from Baseline in NF-L levels at each scheduled assessment during Treatment and Observation Periods

Immunological variables

- Values and change from Baseline in serum immunoglobulin concentrations (total IgA, IgE, and IgM) at each scheduled assessment during Treatment and Observation Periods
- Values and change from Baseline in serum complement levels (C3 and C4) and plasma complement levels (C3a and C5a) at each scheduled assessment during Treatment Period
- ADA (anti-rozanolixizumab antibodies) status (negative or confirmed positive) and the confirmed positive titer at each scheduled assessment during Treatment and Observation Periods
- Values and change from Baseline in cytokines at each scheduled assessment during Treatment and Observation Periods
- Change in CIDP-specific auto-antibody levels in serum from Baseline during Treatment and Observation Periods
- Values and change from Baseline in tetanus- and influenza A virus-specific IgG

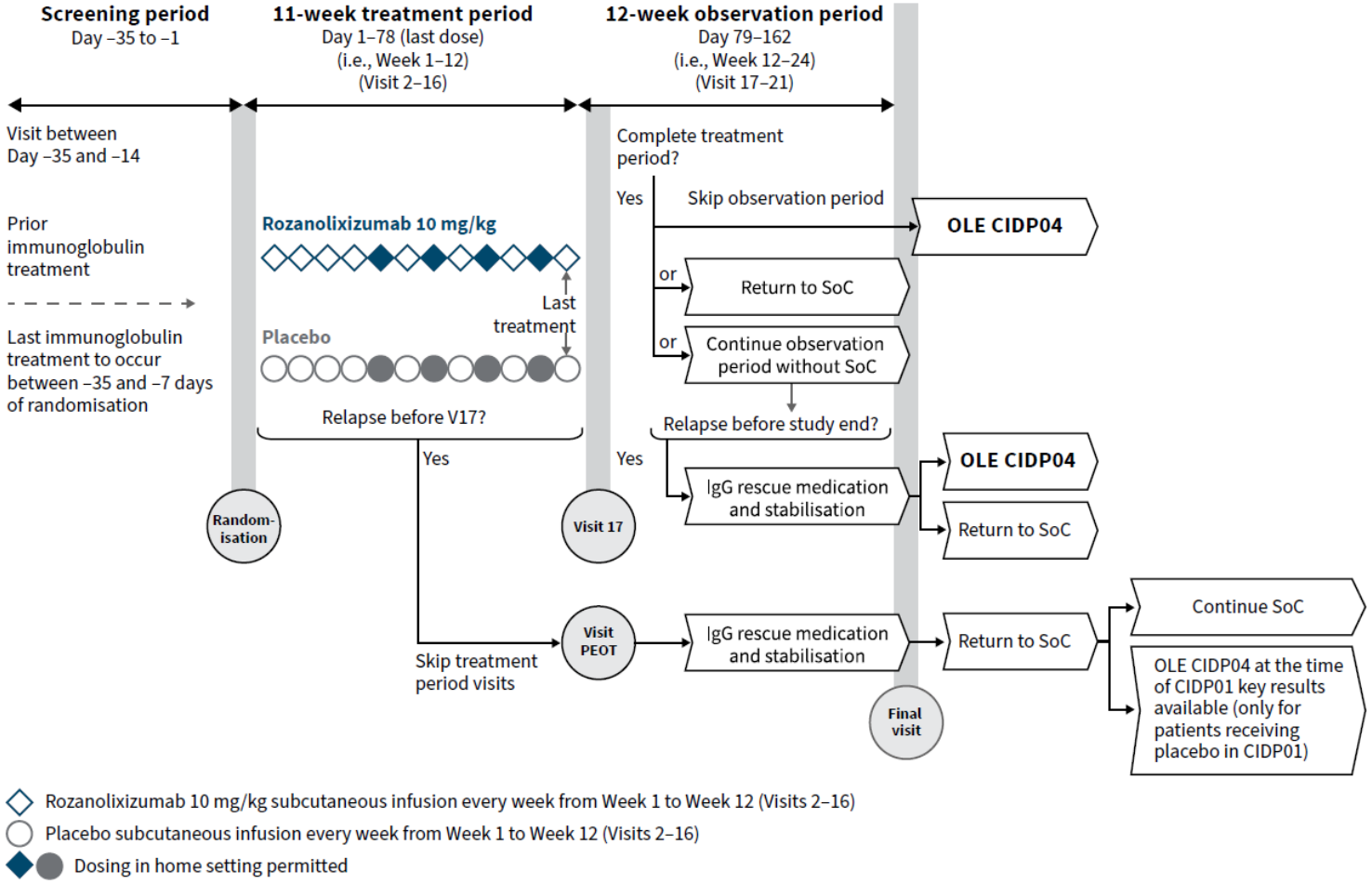
antibodies during Treatment and Observation Periods

Exploratory biomarkers

- Protein and metabolite changes that may be measured to understand the cause, progression, and appropriate treatment of CIDP
- Exploratory biomarkers such as, but not limited to, B-cell activating factor and Circulating Immune Complexes may be measured to evaluate the effect of rozanolixizumab
- Absolute change from Baseline relating to mechanism of action, disease activity, treatment response, and clinical outcome at each scheduled assessment during the Treatment and Observation Periods

Supplemental Figure 1 CIDP01 study design

OLE, open-label extension; PEOT, premature end of treatment; SoC, standard of care; V, visit.



Supplemental Table 1 Rozanolixizumab. (A) 7 mg/kg and (B) 10 mg/kg dose administered according to patient bodyweight

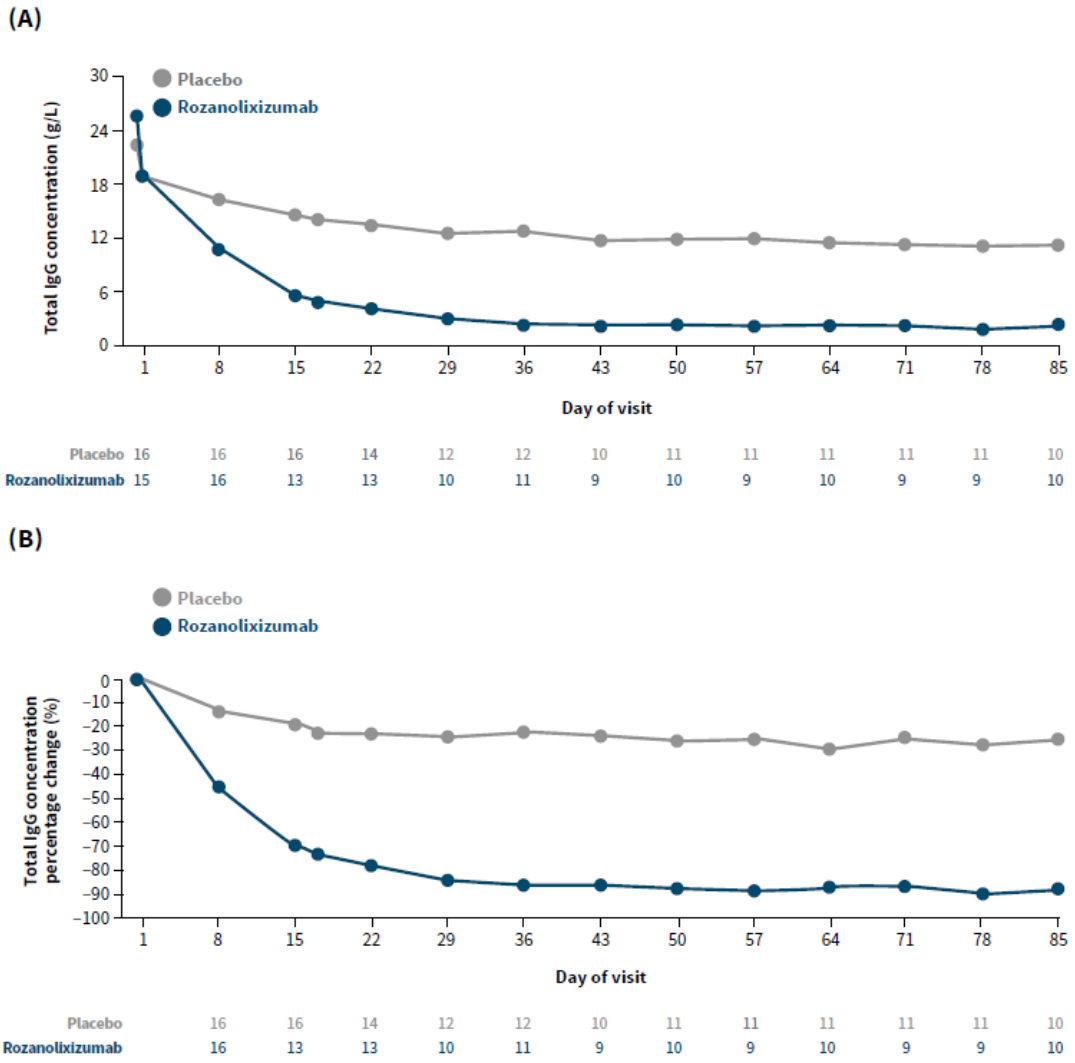
(**A**)

Bodyweight	Dose (mg)
40 to <49 kg	280
49 to <69 kg	420
69 to <89 kg	560
89 to <109 kg	700
109 to <129 kg	840
129 to <149 kg	980
149 to <169 kg	1120
169 to <170 kg	1260

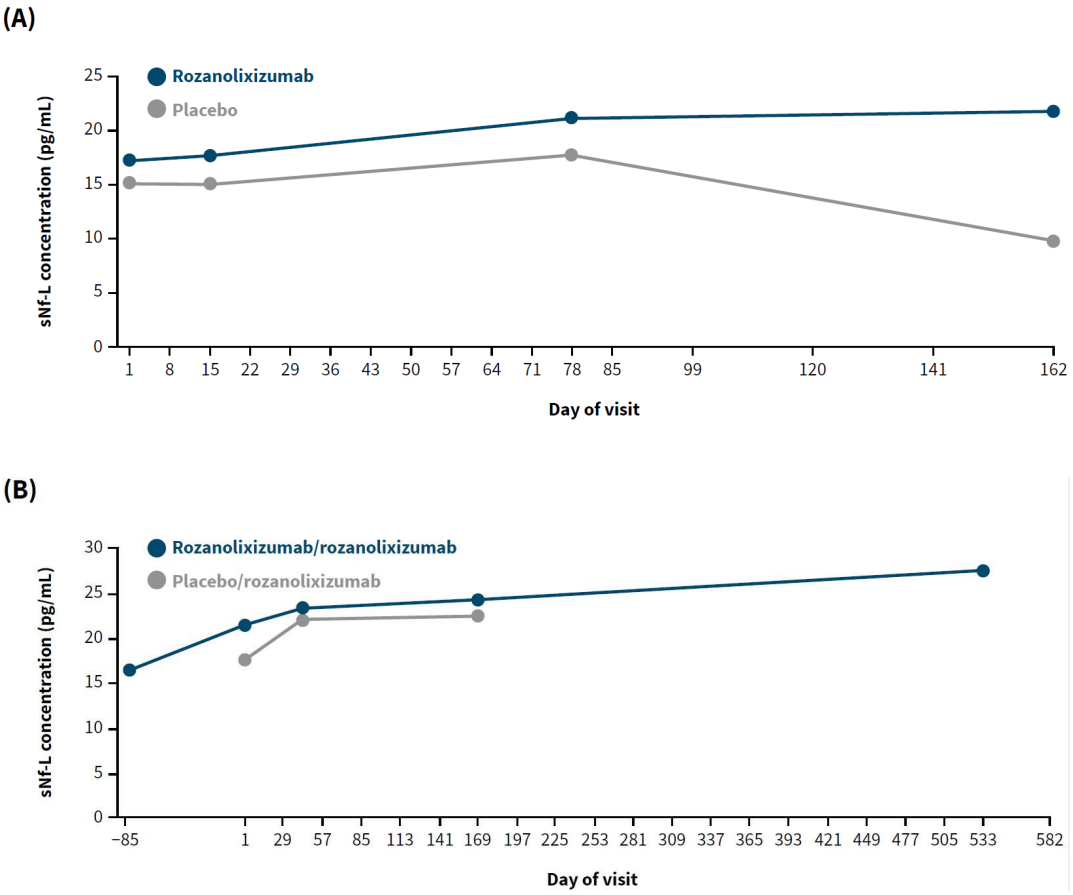
(**B**)

Bodyweight	Dose (mg)
40 to <49 kg	420
49 to <63 kg	560
63 to <77 kg	700
77 to <91 kg	840
91 to <105 kg	980
105 to <119 kg	1120
119 to <133 kg	1260
133 to <147 kg	1400
147 to <161 kg	1540
161 to <170 kg	1680

Supplemental Figure 2 CIDP01 change in serum total IgG concentration over time. (A) Absolute. (B) Percentage. IgG normal range 7–16 g/L. IgG, immunoglobulin G



Supplemental Figure 3 Change in sNf-L concentration over time. (A). CIDP01. (B) CIDP04. Negative study days denote days in CIDP01, with Day 1 denoting Day 1 of CIDP04. NF-L normal range 2.8–19 pg/mL. sNF-L, serum neurofilament light chain



Supplemental Table 2 CIDP01 baseline characteristics of patients who relapsed vs those who did not (iRODS, adjusted INCAT disability scale, and maximum grip strength combined assessment)

	Placebo		Rozanolixizumab	
	Relapsed (n=8)*	**Did not relapse (n=8)**	**Relapsed (n=7)***	**Did not relapse (n=8)**
Duration of disease (years), mean (range)	6.63 (1.9–20.1)	5.74 (1.8–22.9)	4.84 (2.2–8.7)	2.53 (0.9–49.0)
Disease severity, mean (SD)				
iRODS logit location score	2.5 (2.6)	2.5 (2.9)	1.8 (3.5)	1.3 (3.0)
iRODS centile metric score	62.6 (17.5)	62.9 (19.3)	58.0 (23.1)	55.0 (19.6)
Adjusted INCAT disability score	2.9 (1.7)	2.6 (1.9)	3.6 (2.2)	4.0 (1.5)
Clinician-assessed grip strength, maximum score	84.6 (21.8)	69.6 (28.0)	68.6 (33.8)	62.8 (34.2)
Patient-assessed grip strength, maximum score	76.8 (28.4)	70.9 (30.4)	68.1 (43.3)	78.3 (27.0)
Previous immunoglobulin treatment, n (%)	8 (100)	8 (100)	7 (100)	8 (100)
Subcutaneous	0	3 (38)	0	0
Intravenous	8 (100)	5 (63)	7 (100)	8 (100)

*One patient in each treatment group who did not relapse whilst in the study but discontinued before Day 85 were not included in this analysis.

INCAT, Inflammatory Neuropathy Cause and Treatment; iRODS, inflammatory Rasch-built Overall Disability Scale; SD, standard deviation.

Supplemental Table 3 CIDP04 baseline characteristics

Characteristic	Placebo (n=11)	Rozanolixizumab (n=10)
Age (years), median (range)	59.0 (52–67)	60.5 (24–79)
Male, n (%)	7 (64)	4 (40)
Weight (kg), mean (SD)	98.1 (13.7)	84.7 (16.0)
Race, n (%)		
Asian	1 (9)	0
Black	0	0
White	8 (73)	9 (90)
Other/mixed	0	1 (10)
Missing	2 (18)	0
Ethnicity, n (%)		
Hispanic or Latino	0	0
Not Hispanic or Latino	9 (82)	10 (100)
Missing	2 (18)	0
Regions, n (%)		
America	4 (36)	5 (50)
Europe	7 (64)	5 (50)
Duration of disease (years), median (range)	6.0 (2.0–23.2)	2.9 (1.1–49.2)
Disease severity at baseline, mean (SD)		
iRODS logit location score	3.2 (3.0)	1.8 (3.5)
iRODS centile metric score	67.2 (20.1)	58.2 (23.1)
Adjusted INCAT disability score	2.2 (1.6)	4.0 (1.9)
Clinician-assessed grip strength, maximum score	91.6 (30.6)	63.0 (40.1)
CIDP medication at baseline, n (%)		
Corticosteroids	0	0
Other immunosuppressants	1 (9)	0

CIDP, chronic inflammatory demyelinating polyradiculoneuropathy; INCAT, Inflammatory Neuropathy Cause and Treatment; iRODS, inflammatory Rasch-built Overall Disability Scale; SD, standard deviation.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	1–2
	2b	Specific objectives or hypotheses	2
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	2
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	2
	4b	Settings and locations where the data were collected	2

Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	2
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	2–3
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	3
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	2
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	2
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	2

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	2
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	2
	11b	If relevant, description of the similarity of interventions	2
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	3
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	3
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	3–4
	13b	For each group, losses and exclusions after randomisation, together with reasons	3
Recruitment	14a	Dates defining the periods of recruitment and follow-up	3
	14b	Why the trial ended or was stopped	N/A

Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	5
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	3–4
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	6
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	3–5
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	7–8
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	6–9
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	1–2, 6–9
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	6–9

Other information			
Registration	23	Registration number and name of trial registry	2
Protocol	24	Where the full trial protocol can be accessed, if available	9–10
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	9

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.