Nipocalimab in Chronic Inflammatory Demyelinating Polyneuropathy (CIDP): Diagnostic Adjudication of the First 110 Patients of the Phase 2/3 ARISE Study

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Introduction

- Chronic inflammatory demyelinating polyneuropathy (CIDP) is a rare, chronic autoimmune disease of the peripheral nervous system characterized by progressive weakness and impaired sensation.[1,2]
- The clinical presentation of CIDP is heterogeneous, including a typical phenotype (typical-CIDP) and variants (variant-CIDP). Diagnosis of CIDP is challenging because of diverse clinical presentations often leading to misdiagnosis in nearly 50% cases.[3,4]
- The ongoing ARISE phase 2/3 multicenter, randomized, double-blind, placebo-controlled, withdrawal study (NCT05327114) evaluates the efficacy and safety of neonatal fragment crystallizable receptor (FcRn) blocker nipocalimab in adults with CIDP.
- An external independent 4-member CIDP Adjudication Committee (CAC) was established to confirm CIDP diagnosis, per European Academy of Neurology/Peripheral Nerve Society 2021 criteria, before enrollment in ARISE study.

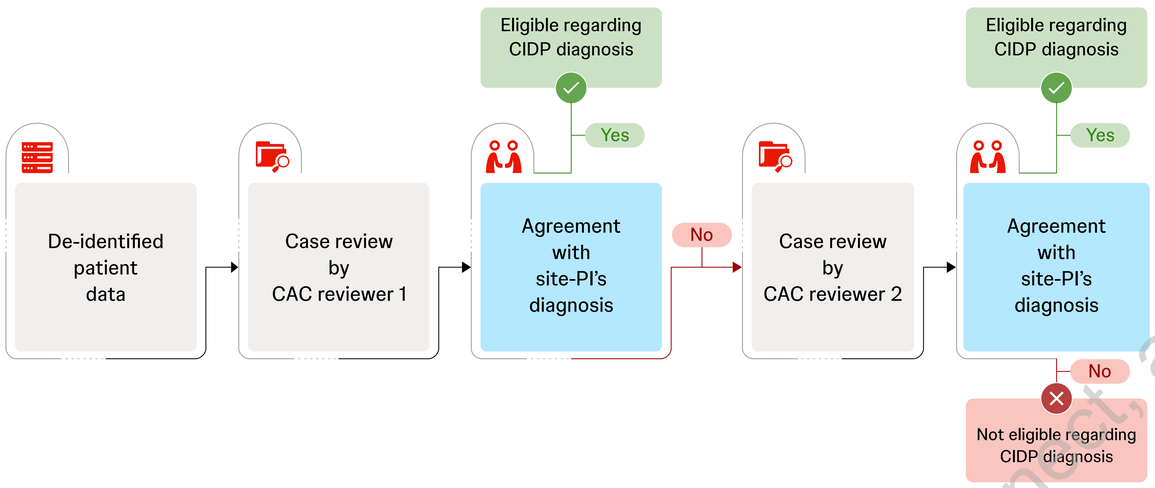
Objective

- **To report CAC adjudication results and demographics/ CIDP-type distribution of the first 110 cases in ARISE.**

Methods

- De-identified patient data submitted by site principal investigators (site-PI) are reviewed by the CAC-reviewers (**Figure 1**).

Figure 1: CAC adjudication process



CAC=CIDP adjudication committee, **CIDP**=Chronic inflammatory demyelinating polyneuropathy, **Site PI**=Site principal investigator.

Key Takeaways

- **Diagnosing CIDP can be challenging; including a second diagnostic adjudicator increased the number of patients considered eligible for the trial.**
- **Eligible patients from the ongoing ARISE study reflect the real-world demographics and distribution of CIDP sub-types.**

Results

Baseline characteristics

- In 110 patients, the median age was 57 years and majority were male, (74 [67.3%]); (**Table 1**).

Table 1: Baseline characteristics of all patients

Characteristics (N=110)	All (N=110)	Eligible (n=80)
Age, year, median (range)	57(21–90)	56 (21–90)
Sex, Male n (%)	74 (67.3%)	53 (66.2%)
Region, n		
NA	14 (12.7%)	8 (10.0%)
LATAM	2 (1.8%)	2 (2.5%)
APAC	62 (56.4%)	49 (61.2%)
EMEA	32 (29.1%)	21 (26.3%)
CIDP participants with diabetes mellitus, n (%)	23 (20.9%)	18 (22.5%)

APAC=Asia-Pacific; **CIDP**=Chronic inflammatory demyelinating polyneuropathy; **EMEA**=Europe, the Middle East and Africa; **LATAM**=Latim America; **NA**=North America.

CIDP adjudication

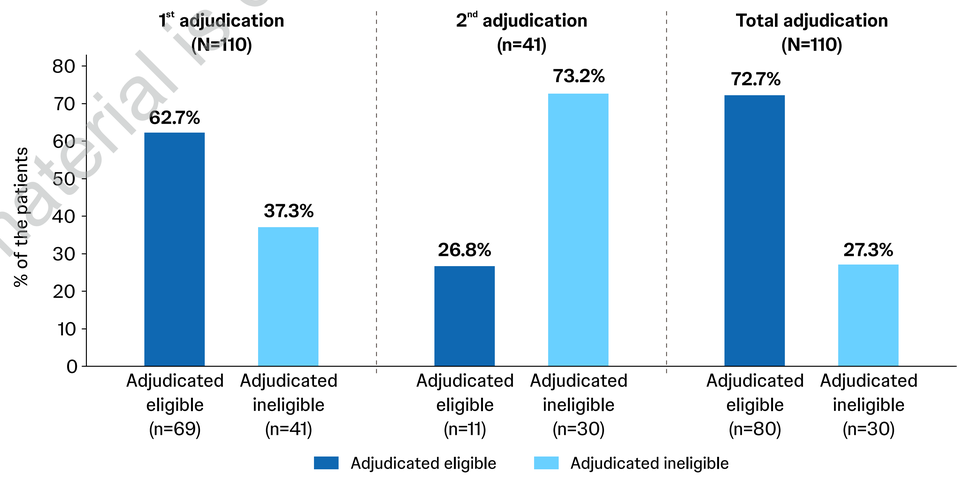
- Of first 110 patients, CAC adjudicated 80/110 (72.7%) patients as eligible (**Figure 2**). See **Table 2** for breakdowns of typical-CIDP vs. variant-CIDP.
  - Agreement of first CAC-reviewer with site-PI adjudicated 69/110 (62.7%) patients as eligible.
  - For 41/110 (37.3%) disagreed cases, the agreement of second CAC-reviewer with site-PI adjudicated 11/41 (26.8%) patients as eligible and remaining 30/110 (27.3%) patients were adjudicated as ineligible.
  - Thus, having a second CAC-reviewer resulted in 10% more eligible patients.

Table 2: Participants with typical Vs variant-CIDP

CIDP type	Adjudicated eligible			Adjudicated ineligible
	1st Adjudication n=69	2nd Adjudication n=11	Total Adjudication N=80	N=30
Typical-CIDP, n (%)	52 (75.3%)	10 (90.9%)	62 (77.5%)	24 (80.0%)
Variant-CIDP, n (%)	17 (24.7%)	1 (9.1%)	18 (22.5%)	6 (20.0 %)

CIDP=Chronic inflammatory demyelinating polyneuropathy.

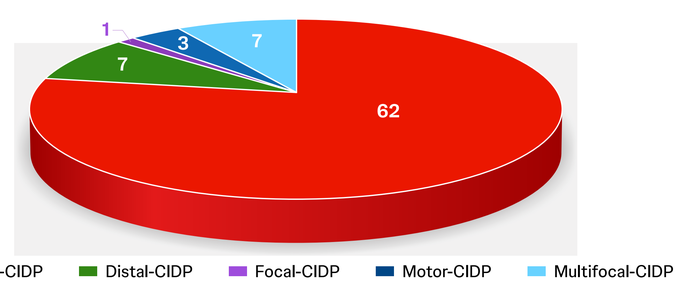
Figure 2: Diagnostic adjudication (N=110)



CIDP Sub-types in eligible patients

- Amongst 80 eligible participants, of the 18 variant-CIDP, 7 the breakdowns of the different variants are shown in **Figure 3**.

Figure 3: CIDP sub-types in eligible patients (N=80)

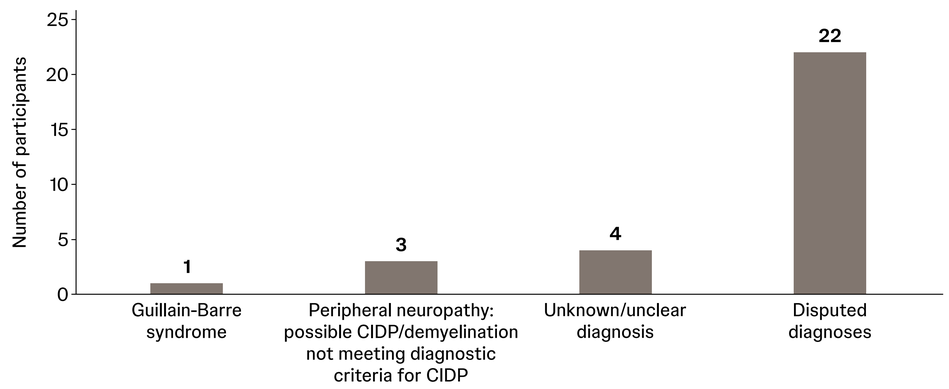


CIDP=Chronic inflammatory demyelinating polyneuropathy.

Reasons for adjudicating ineligible

- Amongst 30 ineligible participants, the most common reason was disputed diagnoses by adjudicators, 22 (73.3%), followed by Unknown/unclear diagnosis, 4 (13.3%) (**Figure 4**).

Figure 4: Reasons for adjudication as ineligible (N=30)

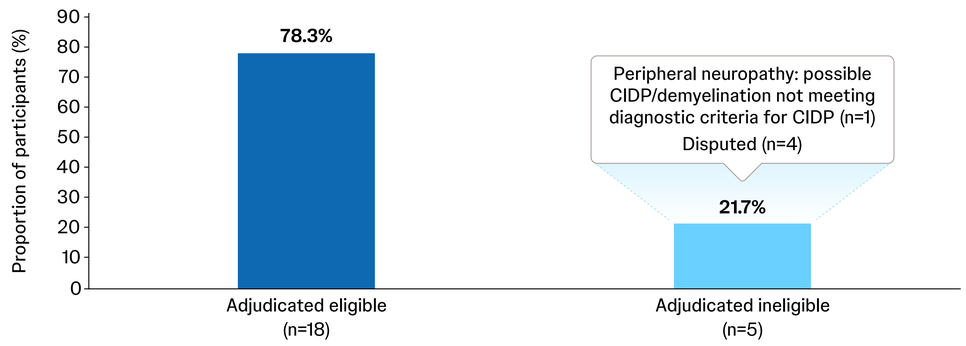


Note: "Disputed"=ineligible cases for which 2 adjudicators provided different alternate diagnoses (**note**: one adjudicator may have indicated "unknown/unclear" and the other provided an alternate diagnosis). **"Unknown/unclear"**=ineligible cases for which both adjudicators agreed the diagnosis is "unknown/unclear".

Adjudication of CIDP patients with diabetes mellitus

- Amongst 23 patients with diabetes mellitus, 18 (78.3%) were adjudicated as eligible.
- 5 (21.7%) participants were adjudicated as ineligible, 1 due to Peripheral neuropathy: possible CIDP/demyelination not meeting diagnostic criteria for CIDP, and 4 due to disputed diagnosis (**Figure 5**).

Figure 5: CIDP adjudication in patients with diabetes mellitus (N=23)



CIDP=Chronic inflammatory demyelinating polyneuropathy.

PRESENTED AT: American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) Annual Meeting; San Francisco, CA, USA; October 29–November 1, 2025. **REFERENCES: 1.** Bunschoten C et al., *Lancet Neurol.* 2019;18(8):784–794. **2.** Vallat JM et al., *Lancet Neurol.* 2010;9(4):402–412. **3.** Allen JA et al., *US Neurol.* 2017;13(1):26–34. **4.** Van den Bergh PY et al., *Eur J Neurol.* 2021;00:1–28. **ACKNOWLEDGMENTS:** The authors thank the participants and investigators for their participation in the study. Kalpana Tilekar, PhD (SIRO Medical Writing Pvt. Ltd., India,) and Doyel Mitra, PhD (Johnson & Johnson) provided editorial assistance. Layout design for this presentation was provided by Amit Kavle (SIRO Medical Writing Pvt. Ltd., India), with funding from Johnson & Johnson. **DISCLOSURES: Ken Gorson:** Consultant for Johnson & Johnson, argenX, Annexon, and Sanofi. **Richard Lewis:** Consultant/Advisory Boards, Adjudication Committee member of Alexion (CIDP; MMN), Annexon (GBS, CIDP), argenX (CIDP), Avilar (anti-MAG), BioCryst (CIDP) CSL Behring (CIDP), Dianthus (CIDP, MG), Grifols (CIDP, MMN), Johnson & Johnson (CIDP), Immunovant (CIDP, MMN), Nervosave (CMT), Nuvig (CIDP), Sanofi (GBS, CIDP, MMN), Seismic (Anti-MAG), Takeda (CIDP), TGTX (CIDP); DSMB for Boehringer Ingleheim, Intellia (TTR); MAB for GBS-CIDP FI. Speaker: Medscape. Royalties: Up to Date (CIDP). **Thomas Harbo:** Adjudication committee member of Johnson & Johnson (CIDP), argenX (CIDP, MMN), Sanofi (CIDP), Dianthus (CIDP, MMN); Consultant for Argenx (CIDP), Dianthus (CIDP, MMN), Annexon (GBS), Nuvig (CIDP), Biocryst (CIDP); Honoraria from Takeda (CIDP). **Jonathan Katz:** Consultant for Dianthus, Johnson & Johnson, Immunovant; Advisory board member of Sanofi, Grifols. **Kolster Rachel, Lisa Ford, Phillippe Linscheid,** and **Bob Murray:** Employees of Johnson & Johnson and may hold stocks or stock options in Johnson & Johnson. This study was sponsored by Johnson & Johnson.