

CAPTIVATE Interim Analysis: A Pivotal Phase 3 Study of Claseprubart in Chronic Inflammatory Demyelinating Polyneuropathy



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Disclosures

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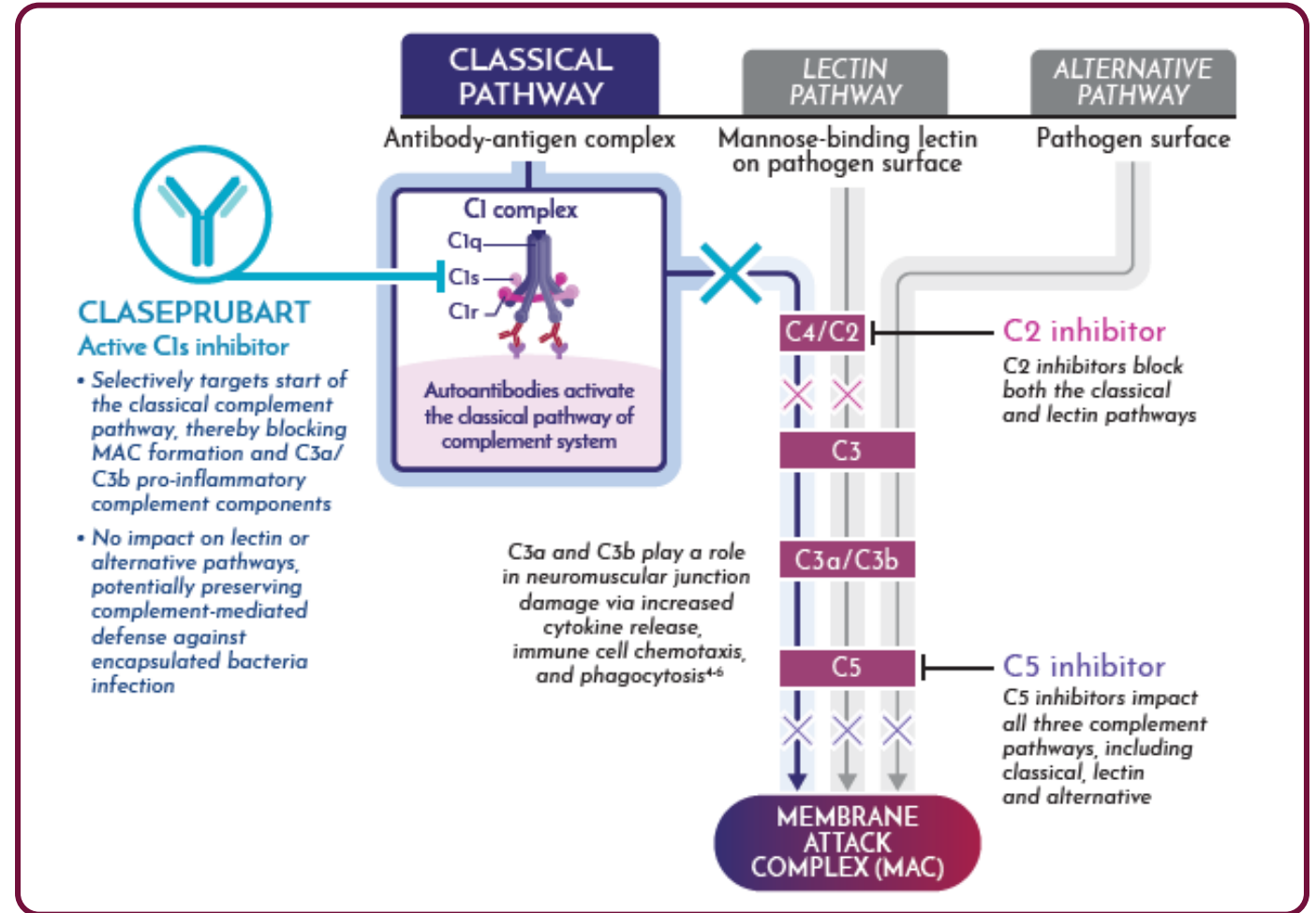
Richard Lewis' Disclosures:

- Consultant/Advisory Boards/Adjudication Committee: Azer-cel (MG) Alexion [CIDP; MMN]; Amgen (CIDP); Annexon [GBS, CIDP]; Argenx [CIDP]; CSL Behring [CIDP]; Dianthus [CIDP, MMN, MG]; Grifols [CIDP, MMN]; Immunovant (CIDP, MMN); J&J [CIDP]; Nervosave (CMT); Nuvig (CIDP); Sanofi [GBS, CIDP, MMN]; Seismic (Anti-MAG); Takeda [CIDP]; TG Therapeutics (CIDP)
- DSMB: Boehringer Ingelheim (resigned December 2025); Intellia (TTR)-chair; Cartesian (MG)- chair
- Medical Advisory Boards: GBS-CIDP Foundation International
- Speaker: Medscape; PeerView; CME Outfitters; Neurology Live;
- Royalties: Up to Date (CIDP)

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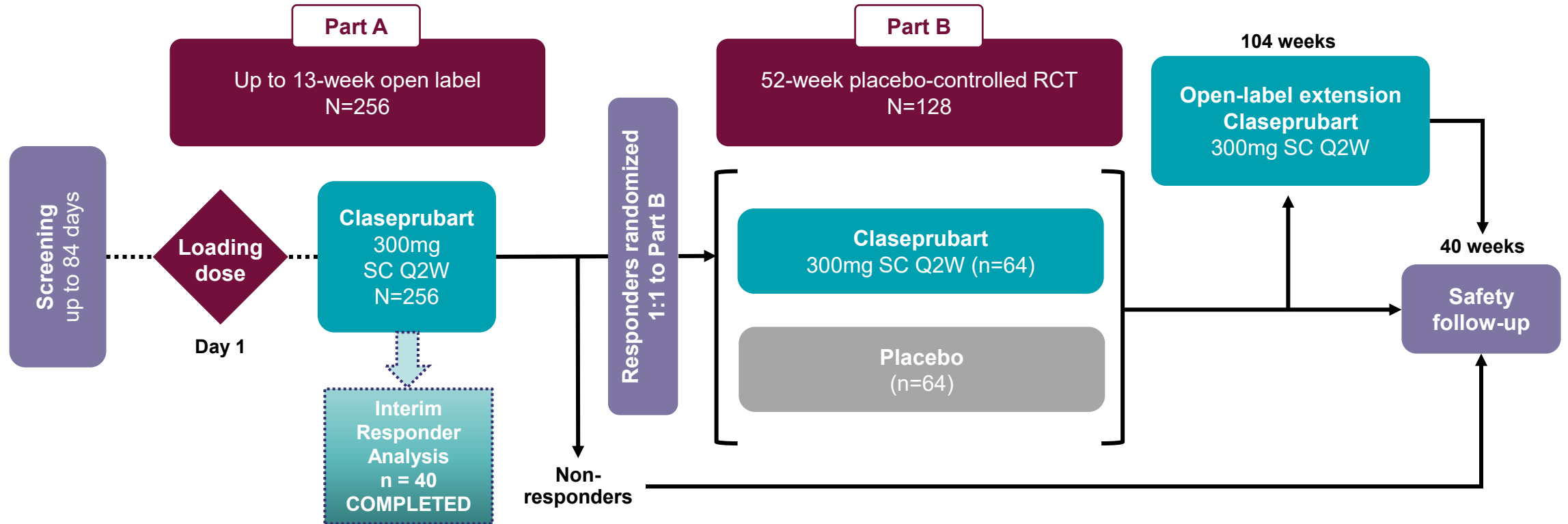
Claseprubart Inhibits the Classical Pathway

- Chronic inflammatory demyelinating polyneuropathy (CIDP) is a chronic, progressive, acquired autoimmune disease targeting peripheral nerves, resulting in demyelination.
- Increasing evidence suggests that **activation of the classical complement pathway plays a crucial role** in the pathophysiology of CIDP.¹
- Claseprubart (DNTH103) is an investigational, clinical-stage, potent monoclonal antibody engineered to **selectively target the classical pathway by inhibiting the active form of the C1s protein**, a clinically validated complement target.
- Targeting active C1s** in patients with **CIDP** is supported by **positive proof-of-concept results** with riliprubart (an active C1s inhibitor) **across broad patient groups**.²
- Claseprubart showed clinically meaningful improvements** in patients with **generalized myasthenia gravis**³, a known classical pathway complement-mediated neurological disease.



CAPTIVATE Study

Phase 3, global, multicenter, randomized, double-blind, placebo-controlled study



KEY DESIGN FEATURES



Single pivotal trial



No requirement for washout or deterioration



Broad global patient population in disease severity and past treatment experience



Part A: Demonstrate clinically meaningful improvement response beyond baseline



Part B: Randomized, placebo-controlled assessment of maintenance of response

Phase 3 Study Designed to Assess Claseprubart in a Broad Population of CIDP Patients



Target Population

- **Broad population of CIDP** patients with **active disease**
 - SoC-Treated, SoC-Refractory, or Treatment Naive
- **CIDP diagnosis and phenotype confirmed by an Independent Review Panel (ICRP):** Typical, motor or multifocal CIDP
- **INCAT Score between 2 and 9**
- Clinical Disease Activity Score (CDAS) ≥ 3 at Screening (active disease)

Part A: Open-Label

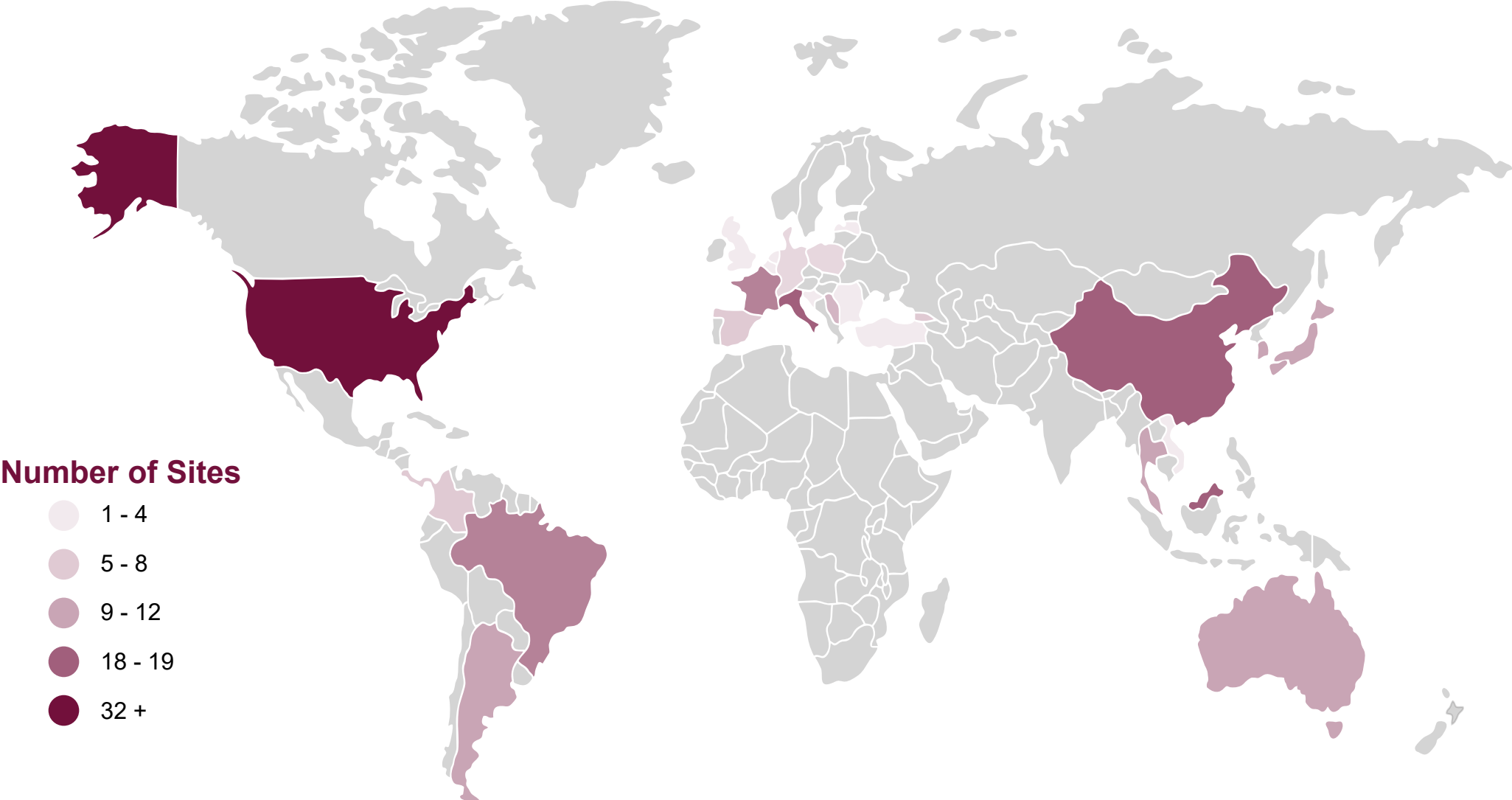
- **Last dose of Ig and tapering of steroids** completed 1 week prior to switching to claseprubart
- Responders identified by a clinically-meaningful improvement of **at least 1-point in INCAT with rigorous confirmation** at the following part A visit.
- Responders eligible for randomization to Part B upon **confirmation beginning at Week 7 through Week 13**
- Non-responders transition to **40-week safety follow-up**
- **COMPLETED:** An interim responder analysis on the first 40 patients with evaluable efficacy

Part B: Blinded, Randomized Withdrawal, Placebo-controlled, Relapse Prevention Design

- Claseprubart vs. placebo (1:1), **up to 52 weeks**
- **Primary endpoint:** Time to relapse (≥ 1 -point increase in adjusted INCAT)
- **Secondary endpoints:** I-RODS, Grip Strength, MRC-SS
- Participants exit Part B upon relapse or completion
- Eligible participants may enter an **optional open-label extension for up to 2 years**

Map of Trial Sites and Countries

As of September 2026, 199 sites activated across 30 countries



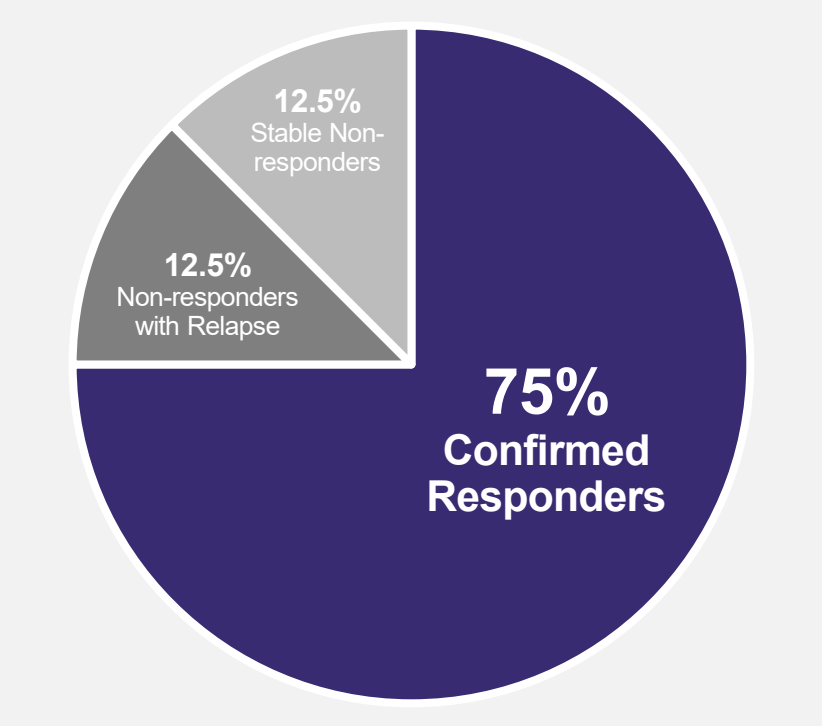
Baseline Characteristics

First 40 Enrolled Part A

	Claseprubart 300mg Q2W (n=40)
Age, (years)	
Mean (SD)	56.9 (12.5)
Median (range)	59.5 (31-74)
Male, n (%)	26 (65.0)
CIDP Diagnosis, n (%)	
Typical	35 (87.5)
Multifocal	2 (5.0)
Motor	3 (7.5)
Mean Time Since Diagnosis, years (SD)	4.2 (6.1)
Prior Treatment, n (%)	
SoC-Treated	27 (67.5)
Immunoglobulin	19 (47.5)
Oral Corticosteroids	8 (20.0)
SoC-Refractory	9 (22.5)
Treatment Naive	4 (10.0)
Baseline Efficacy Measures	
INCAT, mean (SD)	4.0 (1.21)
Grip Strength, mean kPa (SD)	41.4 (20.0)
I-RODS, mean (SD)	47.9 (13.7)
MRC-SS, mean (SD)	50.5 (5.6)

Part A Interim Responder Findings

Breakdown of First 40 Participants
Completing CAPTIVATE Part A



Summary of Change from Baseline at Last Evaluable Visit

Mean (SD)	Confirmed Responders (n=30)	Non-Responders (n=10)
INCAT <i>Decrease is improvement mean (SD)</i>	-1.6 (0.89)	0.7 (1.06)
Grip Strength <i>Increase is improvement mean (SD)</i>	15.9 (12.78)	-7.5 (12.19)
MRC-SS <i>Increase is improvement mean (SD)</i>	5.1 (3.93)	-2.3 (8.82)
I-RODS <i>Increase is improvement mean (SD)</i>	8.9 (12.08)	-3.0 (10.69)

Consistent and clinically meaningful results across multiple efficacy measures
from first 30 confirmed responders in Part A

Claseprubart Was Generally Well-Tolerated

Part A Interim Analysis

n, (%)	Claseprubart 300mg Q2W (N=40)
Patients with any Adverse event (AEs)	24 (60%)
Grade 3 (Not treatment-related) ¹	1 (3%)
Treatment-Related Infections	0 (0%)
Patients with any Serious AE (SAEs) ¹	1 (3%)
Treatment-Related SAEs	0 (0%)
Serious Infections	0 (0%)
AE leading to discontinuation	0 (0%)

All but 1 AE (Grade 3) were mild or moderate in severity with no treatment-related or serious infections, no related SAEs, or discontinuations due to safety.

1. One grade 3 SAE of ureterolithiasis (not treatment-related) was reported in a patient with a history of ureterolithiasis prior to enrollment; the patient continued in the study. Data is from per protocol interim analysis from first 40 participants to complete Part A with evaluable efficacy data.

Key Findings

- **CAPTIVATE** is enrolling a **broad, globally diverse** CIDP patient population spanning **disease severity** and **prior treatment experience**
- **75% of the futility cohort in open-label Part A achieved at least a 1-point confirmed INCAT response above clinical baseline on maintenance therapy** with a meaningful mean improvement of 1.6
- The INCAT response was supported by **meaningful mean improvement in every secondary efficacy metric**
- Safety profile remains **benign and consistent** with claseprubart experience in other indications
- The interim CAPTIVATE findings support the **therapeutic potential of classical pathway inhibition** and continued evaluation of claseprubart in **CIDP**

