



# Oculis' Late-stage Breakthrough Innovation in Neuro-Ophthalmology

**Orestis Briasoulis, MD, MSc**  
Senior Vice-President, Global Medical Affairs

Honorary Assoc. Professor  
Division of Medicine, UCL

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# Oculis (Nasdaq / XICE: OCS)

Global biopharmaceutical company advancing two registrational-stage candidates in ophthalmology and neuro-ophthalmology, addressing significant unmet medical needs

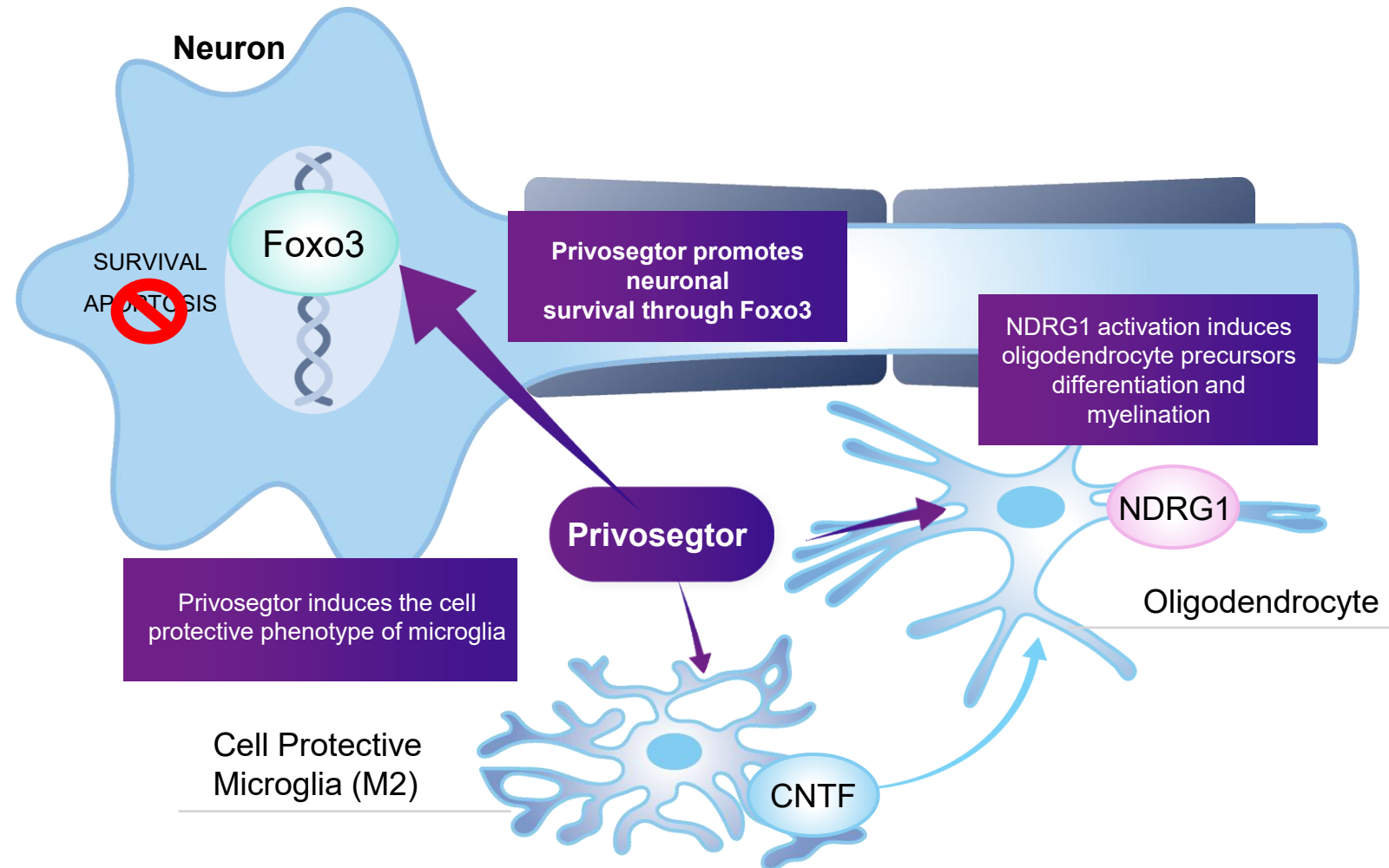
|                     | Candidate                                                 | Phase 1                                                                | Phase 2 | Phase 3 | Upcoming Anticipated Value Catalysts                                                |
|---------------------|-----------------------------------------------------------|------------------------------------------------------------------------|---------|---------|-------------------------------------------------------------------------------------|
| OPHTHALMOLOGY       | <b>Licaminlimab</b><br>Genotype-based development program | TNFR1 Mediated Dry Eye Disease                                         |         |         | PREDICT-1 TLR in around year-end 2026                                               |
| NEURO-OPHTHALMOLOGY | <b>Privosegtor</b><br>Neuroprotective candidate           | Optic Neuritis <u>Breakthrough Therapy and PRIME designations, SPA</u> |         |         | PIONEER-1 enrollment completion in 2027<br>PIONEER-2 trial initiation in Q4 2026    |
|                     |                                                           | NAION                                                                  |         |         | PIONEER-3 trial initiation in Q4 2026                                               |
|                     |                                                           | Acute MS relapses                                                      |         |         | Cross-reference optic neuritis IND for new IND submission in MS relapses in Q4 2026 |

IND: investigational new drug, MS: multiple sclerosis, NAION: non-arteritic anterior ischemic optic neuropathy, PRIME: priority medicine, SPA: special protocol assessment, TLR: topline results.  
3 Privosegtor and Licaminlimab are investigational drugs, their safety or efficacy has not been established, and they have not received regulatory approval for commercial use in any country.



# Privosegtor Is a Novel Neuroprotective Candidate with Broad Potential for Neuro-axonal Diseases

- Peptoid small molecule that **crosses blood brain** and **retinal barriers**
- Developed using a hybrid drug discovery approach that combined rational medicinal chemistry design with phenotypic drug selection for its unique ability to **promote neuro-axonal survival**, validated across multiple in vitro injury models: **apoptosis, oxidation, and inflammation**
- Confirmed **neuro-axonal survival** in vivo in glaucoma, MS, and optic neuritis models
- FDA **Breakthrough Therapy Designation** and EMA **PRiority Medicines (PRIME)** designations granted for optic neuritis



# Successful Phase 2 ACUITY Trial Investigated Safety and Efficacy of Privosegtor in Optic Neuritis

## Study Design

- Randomized, double-masked, placebo-controlled study
- Multi-center, 6-month trial with 36 patients randomized (mITT: 33)

## Key Endpoints

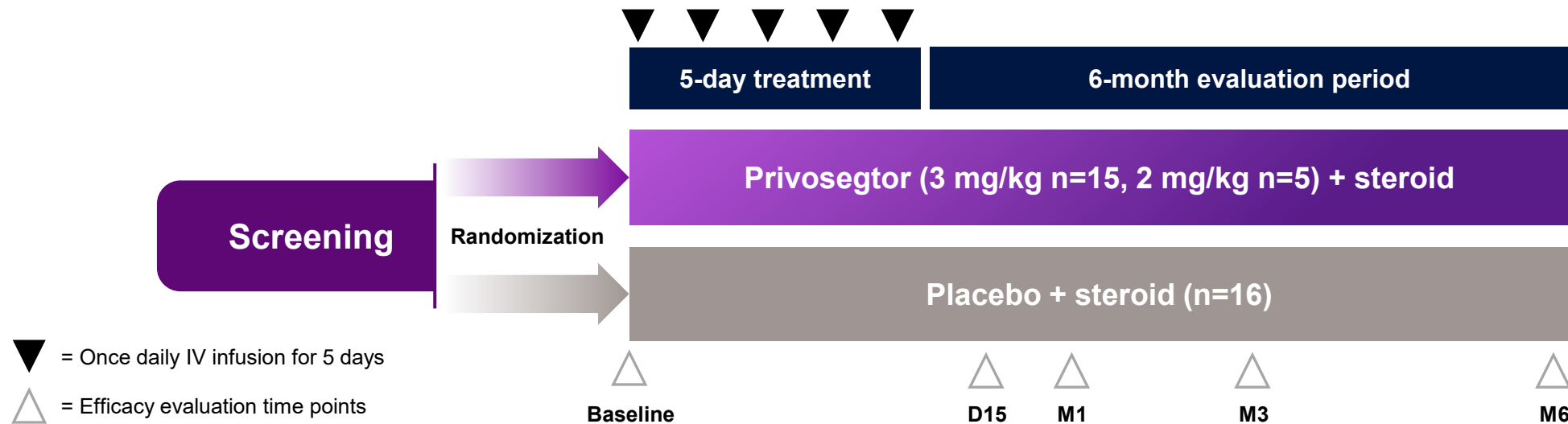
**Primary:** Safety

**Secondary:**

- Function: Low Contrast Visual Acuity
- Anatomy: GCIPL and RNFL thickness
- Biology: Neurofilament Light Chain levels

## Study Population

- Unilateral ON with a demyelinating origin
- Onset of visual loss symptoms in the last 12 days before randomization



# Safety Profile Reported in ACUITY Phase 2 Trial Showed No AEs Leading to Drug Withdrawal or Study Discontinuation

- No AEs leading to drug withdrawal or study discontinuation
- No drug-related serious adverse events (SAEs)

| Event, n (%)                                                        | Privosegtor + steroid    |                         |                          | Placebo + steroid<br>(N = 14) |
|---------------------------------------------------------------------|--------------------------|-------------------------|--------------------------|-------------------------------|
|                                                                     | 2 mg/kg/day<br>(N = 4)   | 3 mg/kg/day<br>(N = 15) | Pooled<br>(N = 19)       |                               |
| At least one TEAE<br><i>Related to study treatment</i>              | 4 (100.0%)<br>4 (100.0%) | 12 (80.0%)<br>6 (40.0%) | 16 (84.2%)<br>10 (52.6%) | 14 (100.0%)<br>6 (42.9%)      |
| At least one grade ≥2 TEAE<br><i>Related to study drug</i>          | 2 (50.0%)<br>0           | 9 (60.0%)<br>2 (13.3%)  | 11 (57.9%)<br>2 (10.5%)  | 6 (42.9%)<br>0                |
| At least one serious TEAE<br><i>Related to study drug</i>           | 0<br>0                   | 1 (6.7%)<br>0           | 1 (5.3%)<br>0            | 1 (7.1%)<br>0                 |
| At least one SAE leading to death                                   | 0                        | 0                       | 0                        | 0                             |
| At least one TEAE leading to a dose reduction                       | 0                        | 0                       | 0                        | 0                             |
| At least one TEAE leading to a dose interruption                    | 0                        | 0                       | 0                        | 0                             |
| At least one TEAE leading to a drug withdrawn                       | 0                        | 0                       | 0                        | 0                             |
| At least one TEAE leading to premature discontinuation of the study | 0                        | 0                       | 0                        | 0                             |

SAE: Serious Adverse Event; TEAE: Treatment-Emergent Adverse Event

Villoslada P, et al. Neurology. 2026; 106(11\_Suppl 1);

Two (2) unrelated SAEs were reported: Hospitalization due to MS relapse (Privosegtor + steroid) and due to myelitis (placebo + steroid)



# Patients in the Privosegtor 3mg/kg/day Arm Achieved Clinically Meaningful and Sustained Improvement in Visual Function<sup>1</sup>

## FUNCTION

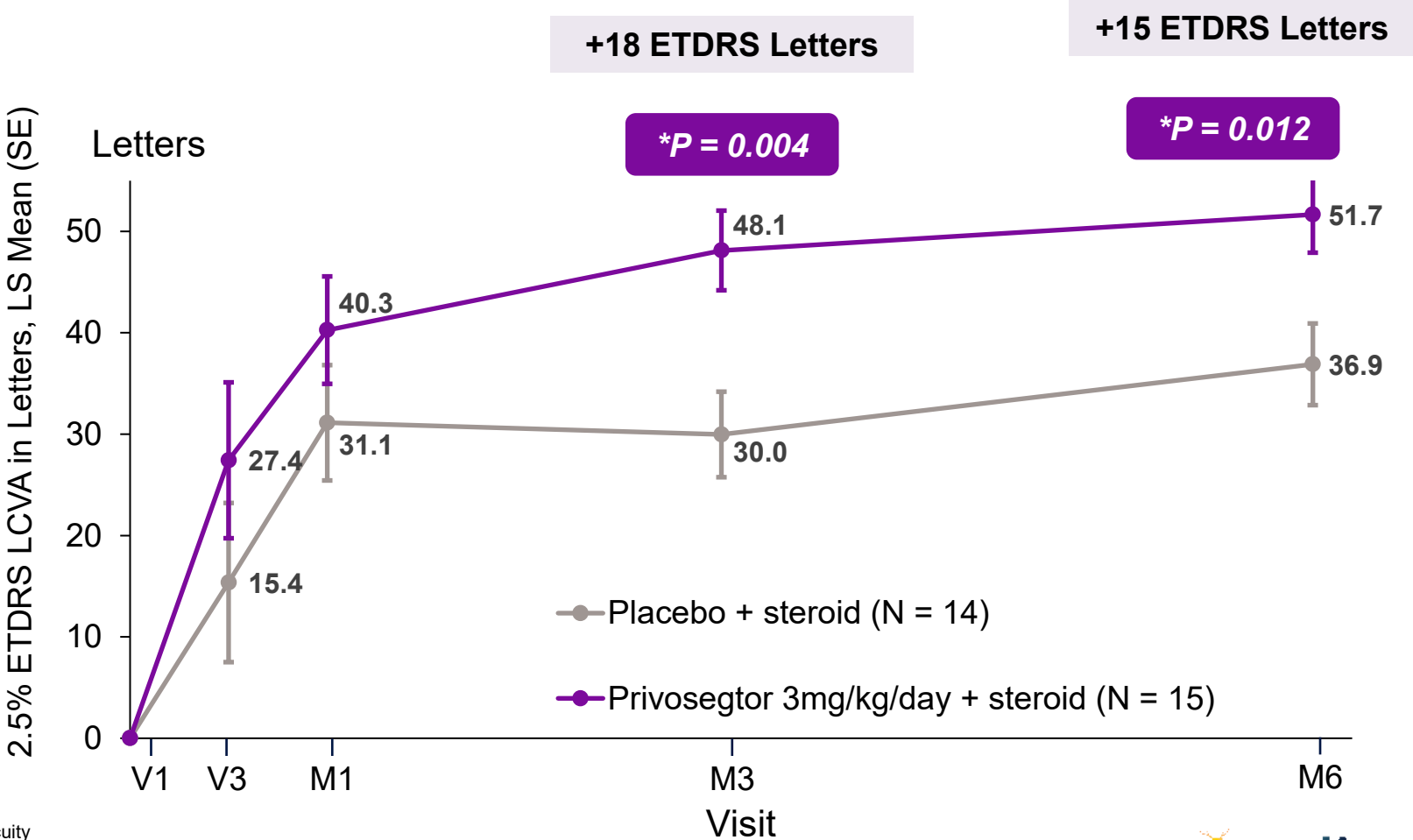
**LCVA:** Low-contrast visual acuity is often affected in patients with ON

### LCVA



**7 letters (1.5 lines) change in LCVA has clinical relevance<sup>2</sup>**

2.5% ETDRS LCVA in the Affected Eye: MMRM, LS Mean Change From Baseline, mITT



ETDRS: Early Treatment Diabetic Retinopathy Study; LCVA: Low Contrast Visual Acuity

1. Villoslada P, et al. Neurology. 2026; 106(11\_Suppl 1); 2. Balcer LJ, et al. Mult Scler. 2017 Apr;23(5):734-747

\*Mixed Model for Repeated Measures (MMRM), Least-Squares Mean Change from Baseline: (2-sided nominal p-value), mITT population (affected eye): one placebo subject excluded from the mITT population in this analysis due to missing LCVA post-baseline assessments

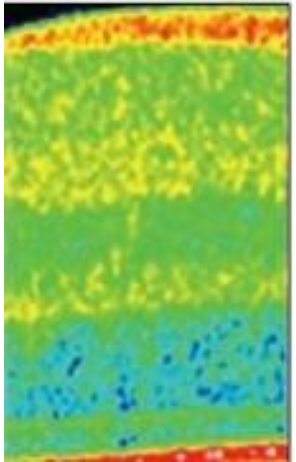
# Functional Improvement Correlated with Significant Preservation of Neurons in the Retina (RGCs)<sup>1</sup>

## ANATOMY

**GCIPL and RNFL:** layers of the retina measured by OCT to monitor nerve damage

Axons →

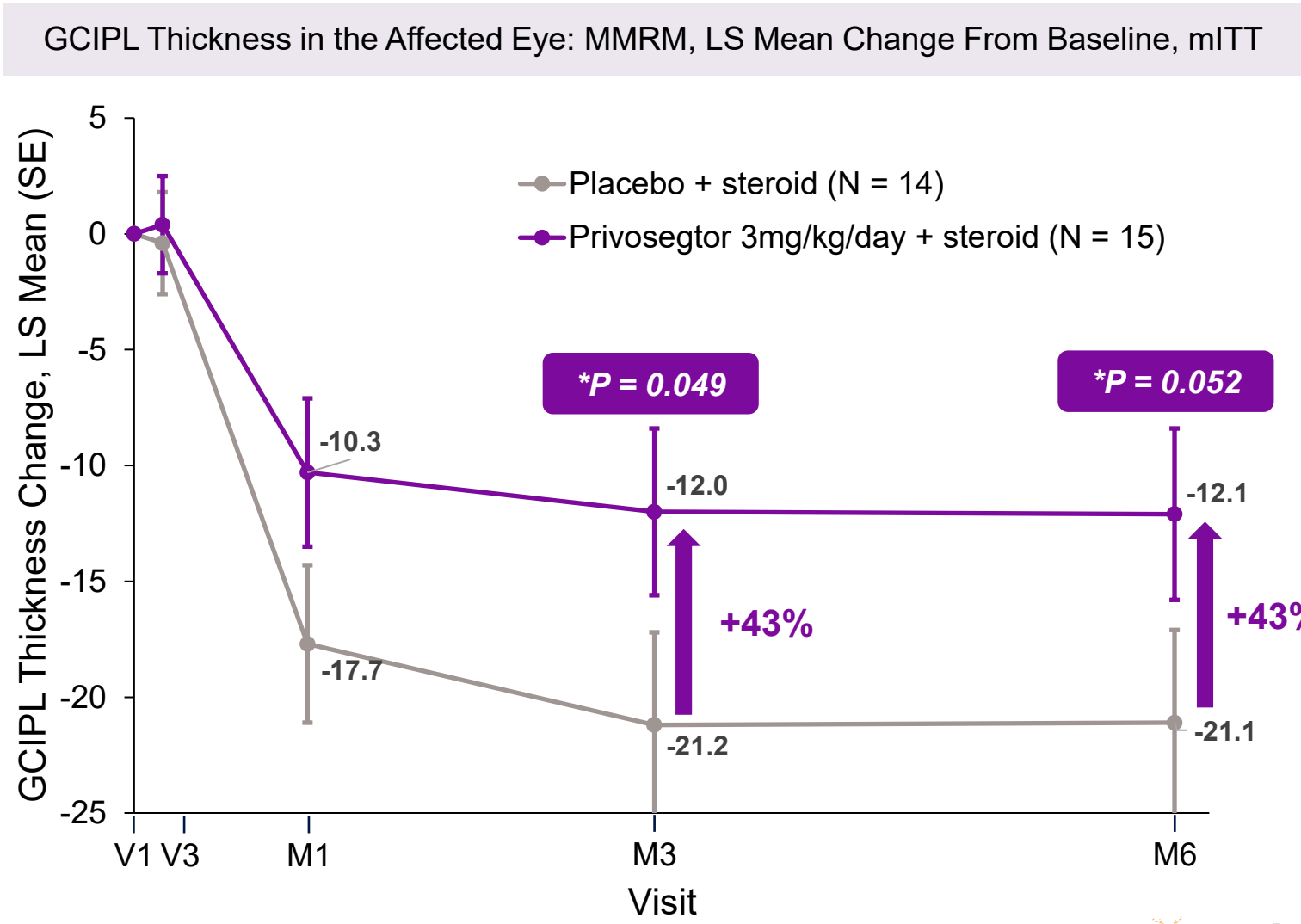
RGCs (neurons) →



RNFL thickness

GCIPL thickness

**Decrease in GCIPL predicts poor LCVA, VF and CVA<sup>2</sup>**



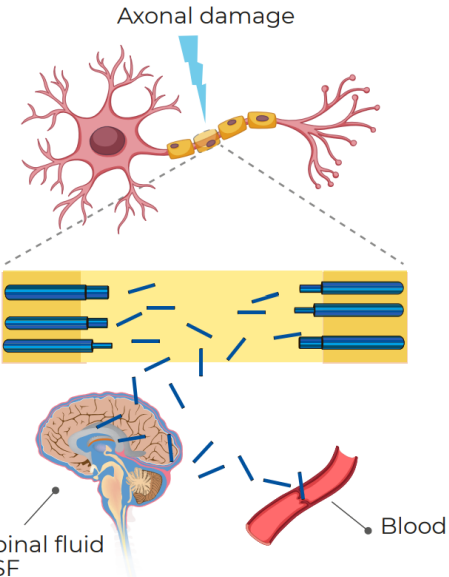
GC IPL: Ganglion Cell and Inner Plexiform Layer; RNFL: Retinal Nerve Fiber Layer; OCT: Optical Coherence Tomography; LCVA: Low Contrast Visual Acuity, VF: Visual Field, CVA: Color Visual Acuity.  
1. Villoslada P, et al. Neurology. 2026; 106(11\_Suppl 1); 2. Gabilondo et al. Ann Neurol. 2015 Mar;77(3):517-28.  
\*Mixed Model for Repeated Measures (MMRM); Least-Squares Mean Change from Baseline: (1-sided directional nominal p-value), mITT population (affected eye)



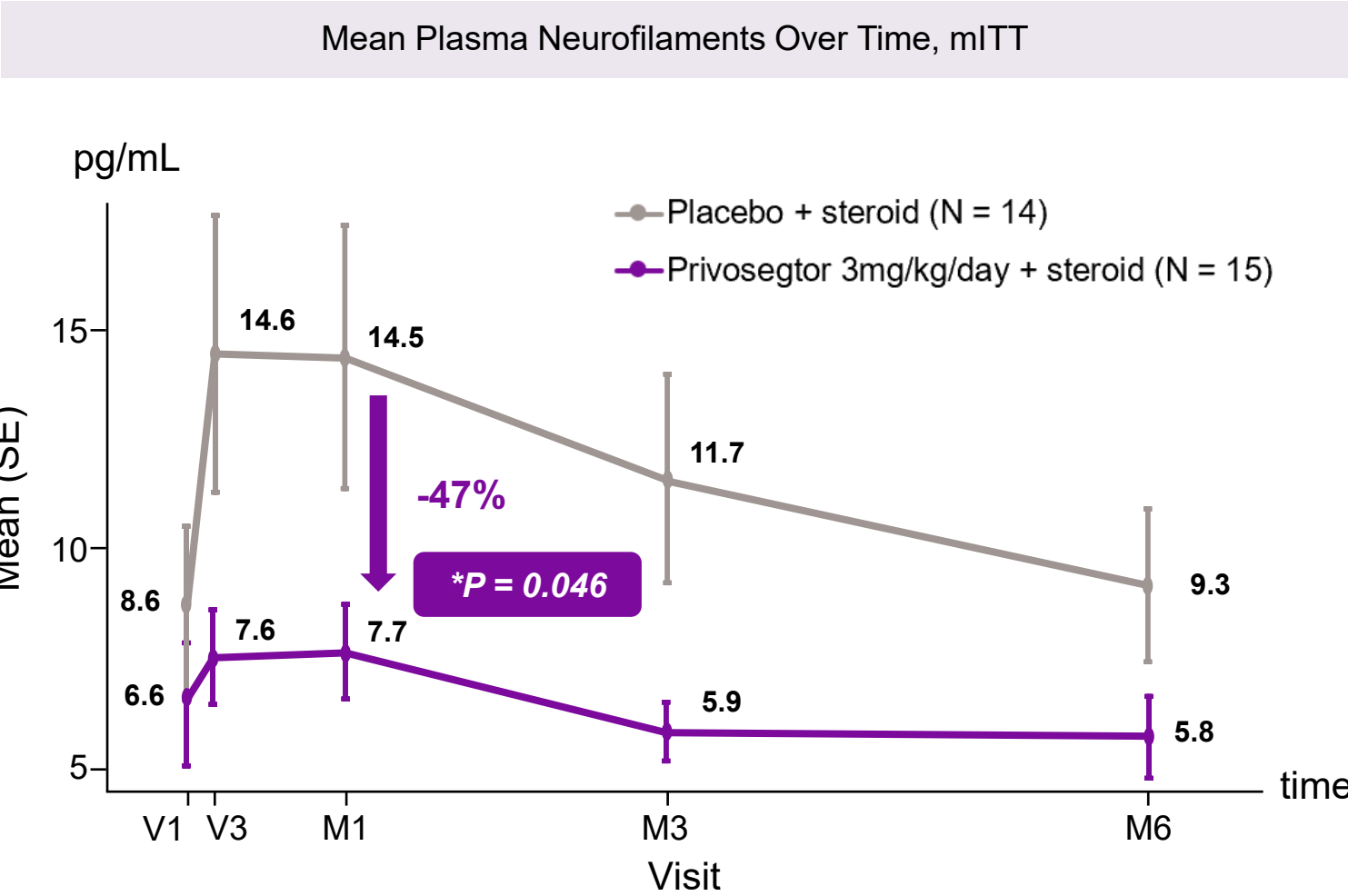
# Neuroprotective Benefits with Privosegtor Also Observed in Biological Sign of Neuronal and Axonal Death<sup>1</sup>

**BIOLOGY**

**Neurofilaments:** Released into CSF and blood as a result of axonal and neuronal death<sup>2</sup>



**Biomarker of neuroaxonal injury<sup>3</sup>**



# PIONEER-1 Registrational Trial Aligned with FDA under Special Protocol Assessment

Privosegtor has potential to be first neuroprotective medicine in Optic Neuritis

### Study Design

- Randomized, multicenter, double-masked, placebo-controlled study
- Primary analysis at Month 3; Safety follow-up through Month 12
- N: ~210, 2:1 randomization
- Privosegtor 3mg/kg/day + SoC (IV Methylprednisolone) vs. placebo + SoC

### Key Efficacy Endpoints

**Primary:**

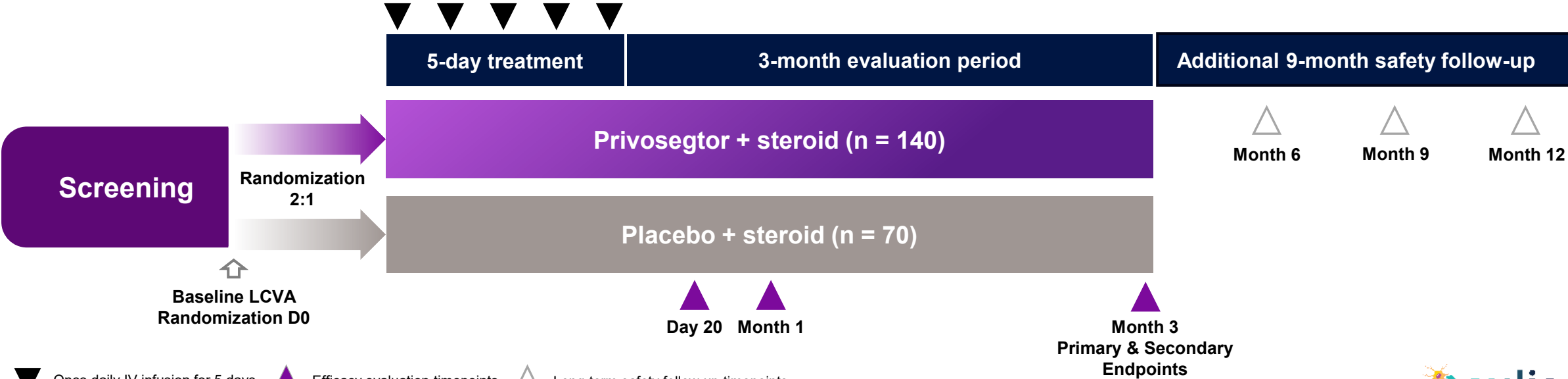
- Proportion (%) of ≥15 letter gainers at Month 3

**Secondary:**

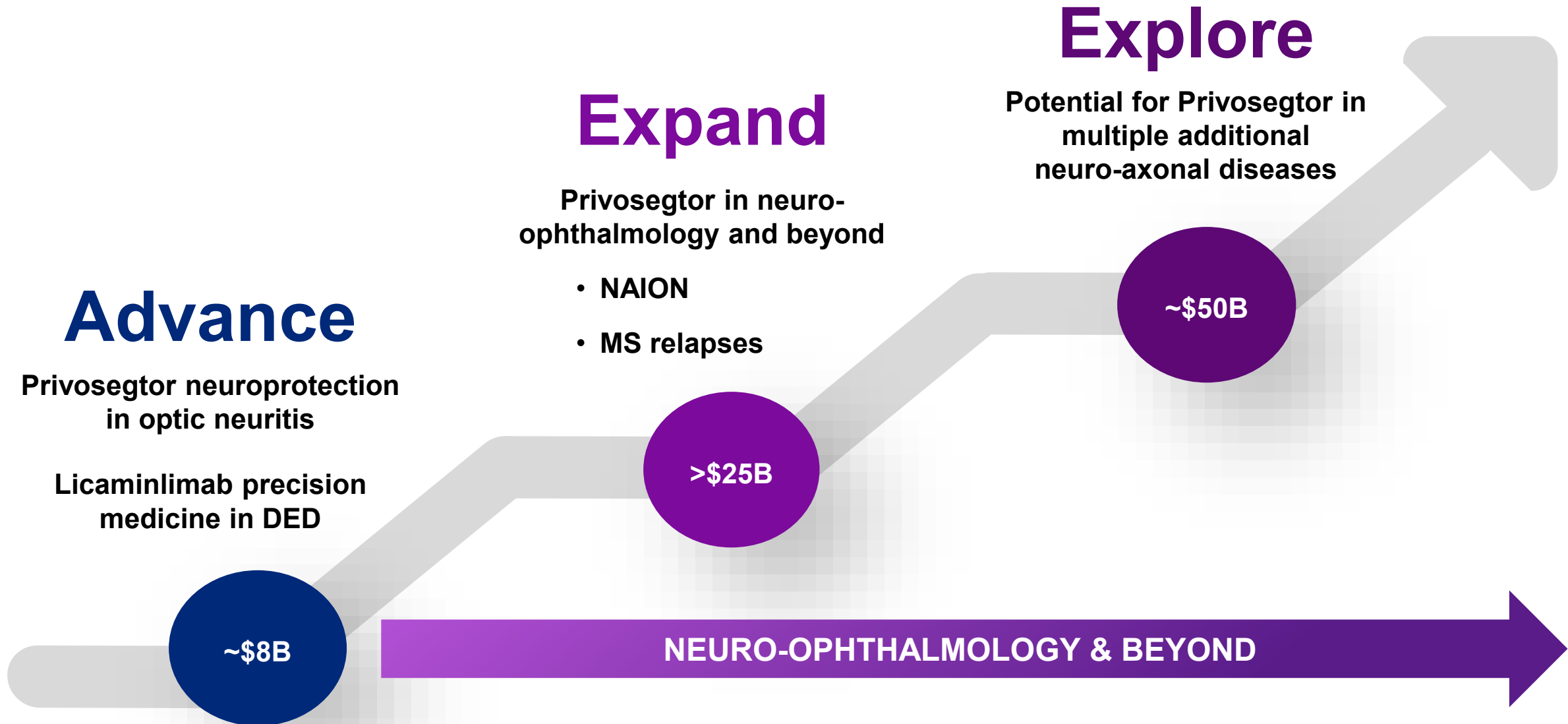
- Proportion (%) of ≥30 letter gainers at Month 3
- LCVA mean change from baseline at Month 3
- GCIPL mean change from baseline at Month 3
- sNfL mean change from baseline at Month 3

### Study Population

- All comers: including MS and non-MS optic neuritis
- Privosegtor treatment within 12 days from the first onset of symptoms



# Oculis Pipeline Development Strategic Evolution



DED: dry eye disease, NAION: Non-arteritic Anterior Ischemic Optic Neuropathy MS: Multiple Sclerosis.

1. DED Disease and Landscape report 2020 - 2024 market value estimate for G7, 2. MS Disease and Landscape report October 2024 – 2024 market value estimate for G7, 3. Acute optic neuropathy market estimated to 7B in US based on rare disease price analogues and annual incidence of ON and NAION, 4. Optic nerve disorders, Transparency Market Research, 5. Global Market Insights, March 2024

<https://www.gminsights.com/industry-analysis/neuroprotection-market>

# Thank you

