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# Positive Interim Data of Vidofludimus Calcium in Progressive Multiple Sclerosis

## Phase 2 CALLIPER Trial

October 10, 2023

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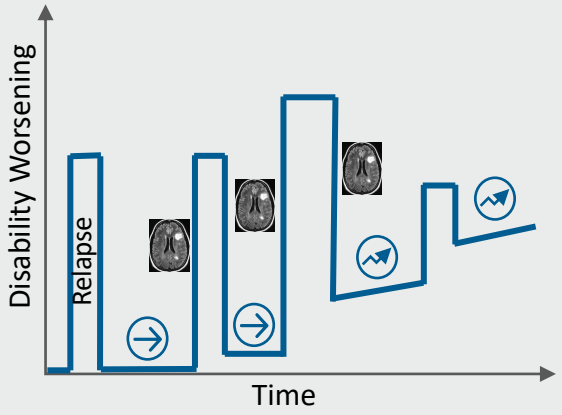
# Disability Worsens Over Time in All Forms of MS

## The Different Indications Have Different Paths and Drivers of the Disability Progression

### Relapsing Forms of MS (RMS)

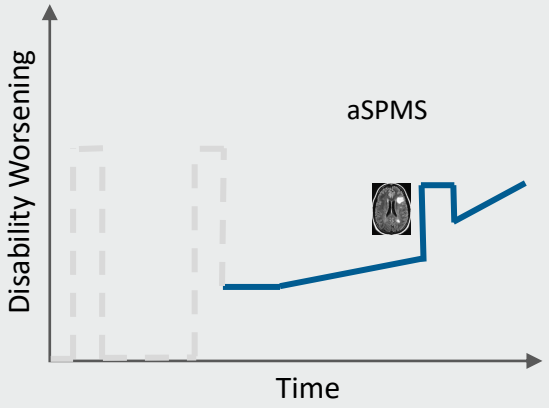
#### RRMS

- Relapses and MRI lesions dominate clinical course




#### Active SPMS

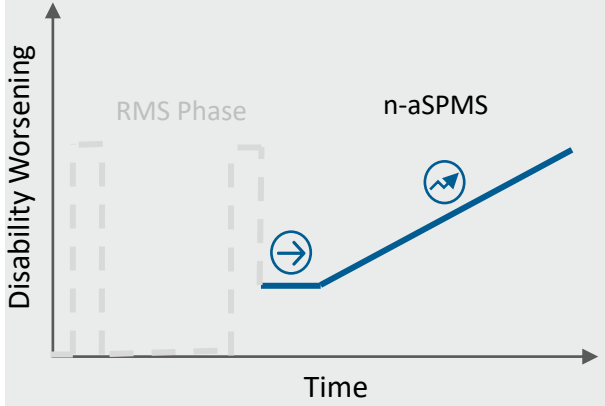
- Fewer relapses and lesions with continuous disability progression




### Progressive Forms of MS (PMS)

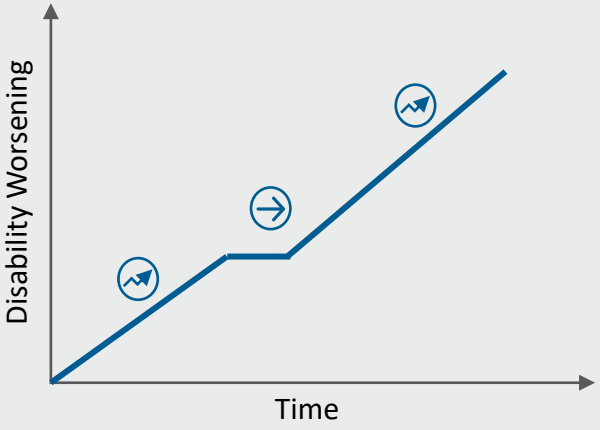
#### Non-Active SPMS

- Relapses have stopped, but disability progression continues




#### PPMS

- Disability worsening without relapses from the start




**Relapses & MRI lesions / focal inflammation (RAW)**

**Smoldering disease and progression independent of relapse activity (PIRA)***

Adapted from Kretzschmar A., MSVirtual2020; *Lublin FD, et al. Brain. 2022 Sep 14;145(9):3147-3161

MS: multiple sclerosis; MRI: magnetic resonance imaging; RAW: relapse-associated worsening; PIRA: progression independent of relapse activity; RRMS: relapsing-remitting MS; SPMS: secondary progressive MS; PPMS: primary progressive MS; a: active; n-a: non-active



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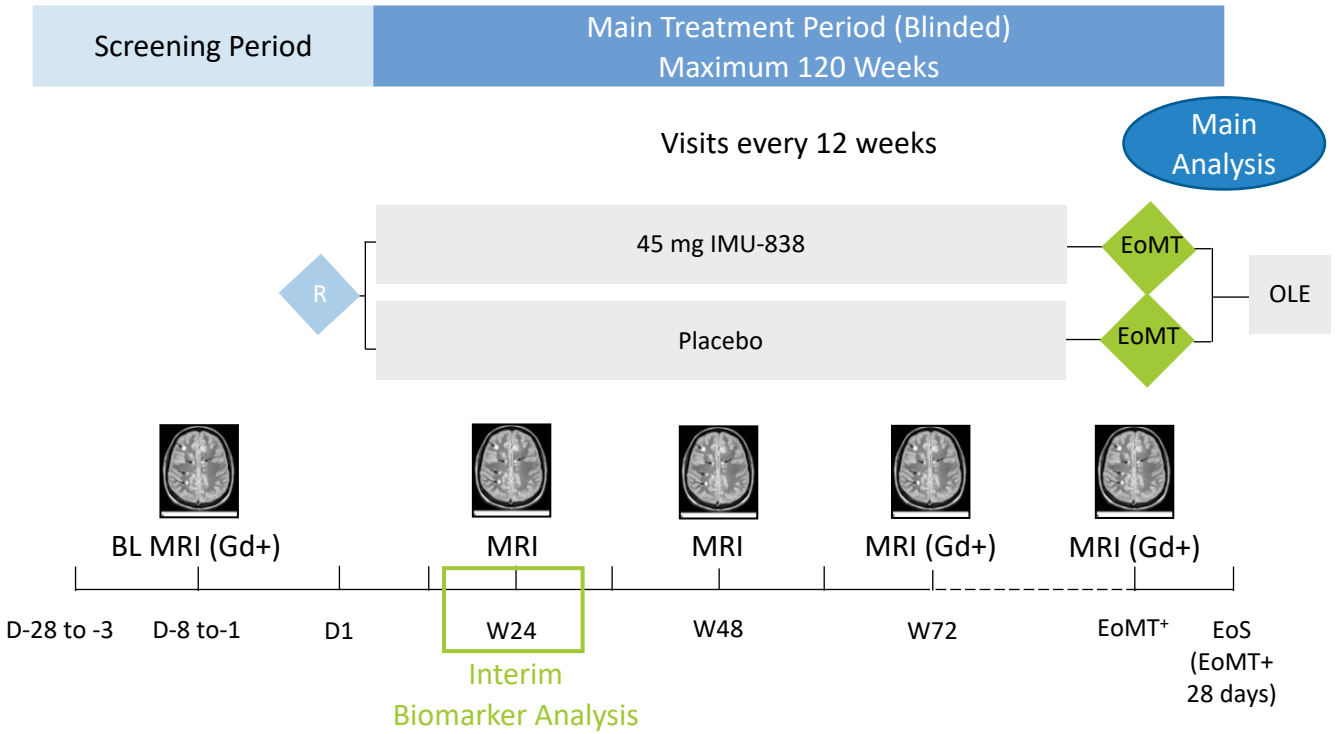
# Phase 2 CALLIPER Trial

Background Information

# CALLIPER: Ongoing Phase 2 Clinical Trial in Progressive Multiple Sclerosis (PMS)




## Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase 2 Trial*

- Coordinating Investigator: Robert J. Fox, M.D., Cleveland Clinic
- 467 patients enrolled at more than 70 sites in North America, Western, Central and Eastern Europe
- Randomization to 45 mg vidofludimus calcium or placebo QD
- Primary endpoint: annualized rate of percent brain volume change up to 120 weeks
- Blinded 120-week main treatment period
- Optional, approximately 8-year, open-label extension period

## Included Patient Population: Progressive Forms of MS

- Adult patients aged 18 to 65 years
- PPMS or SPMS diagnosis (Revised McDonald criteria 2017)
- EDSS score at screening between 3.0 to 6.5
- No evidence of relapse in last 24 months before randomization
- Evidence of disability progression

*NCT05054140 +EoMT: at W120 or when last enrolled patient reaches W72

BL: baseline; D: day; EoMT: end of main treatment period; EoS: end of study; MRI: magnetic resonance imaging; Gd+: gadolinium-enhancing; OLE: open-label extension; R: randomization; W: week; PPMS: primary progressive multiple sclerosis; SPMS: secondary progressive multiple sclerosis; EDSS: Expanded Disability Status Scale; QD: quaque die = once-daily



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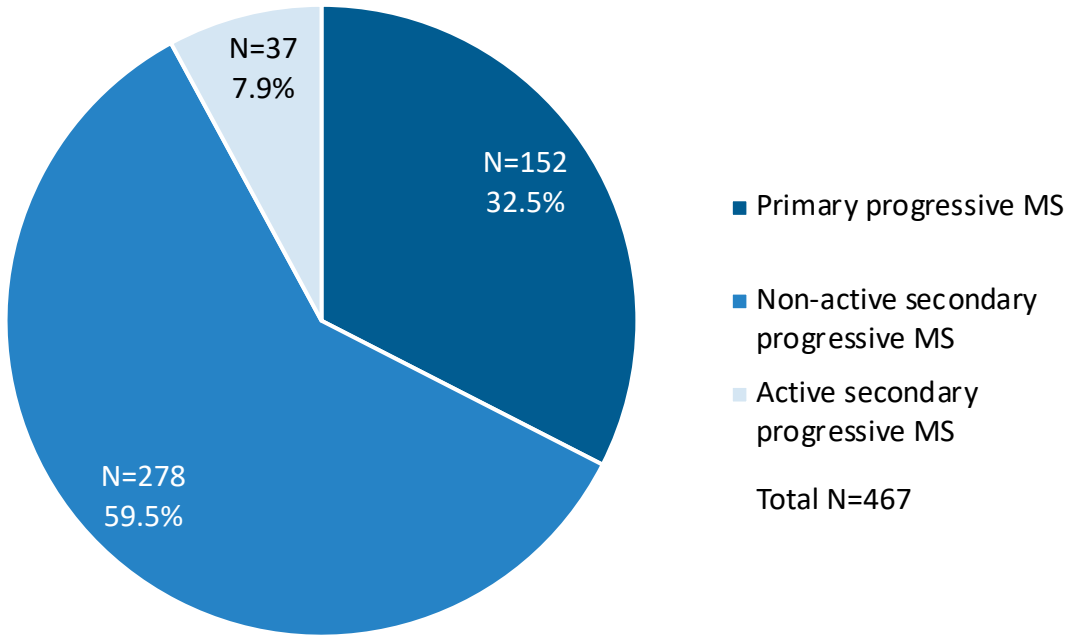
# Patient Demographics and Baseline Characteristics

## Total Study Population of 467 Enrolled Patients

### Progressive Disease Subtypes




### Baseline Characteristics

| Baseline Patient Characteristics | Total (N=467) |
|---|---|
| Age [years], median (min-max) | 51.0 (21-65) |
| Gender (n and % female) | 302 (64.7 %) |
| Race (n and % White) | 460 (98.7 %) |
| BMI [kg/m^2], median (min-max) | 25.0 [15.8 – 46.6] |
| SDMT [points], median (min-max) | 35.0 [0-180] |
| EDSS at Visit 1, median (min-max) | 5.5 [2.5-6.5] |
| MS relapses during last 24 h, median (min-max) | 0.0 [0-1] |

Disease subtype information are used as diagnosis entered by investigator at study entry
BMI: body mass index; SDMT: Symbol Digit Modalities Test; EDSS: Expanded Disability Status Scale

# Interim Analysis of the Phase 2 CALLIPER Trial

## Prospectively Planned Interim Biomarker Analysis

- Interim analysis for biomarkers serum neurofilament light chain (NfL) and glial fibrillary acidic protein (GFAP), when approximately half of the enrolled subjects (≈225 patients) have completed 24 weeks of treatment
- No clinical endpoints evaluated to protect scientific integrity of final analysis; no formal inferential statistical analysis performed
- Data analysis prepared by an unblinded statistician – company, investigators and patients remain blinded to individual treatment assignments
- Of the patients included, data are presented only for those patients with baseline and post-dose values available
- Independent Data Monitoring Committee performed unblinded safety analysis: **no new safety alerts; recommended to continue this trial without changes**

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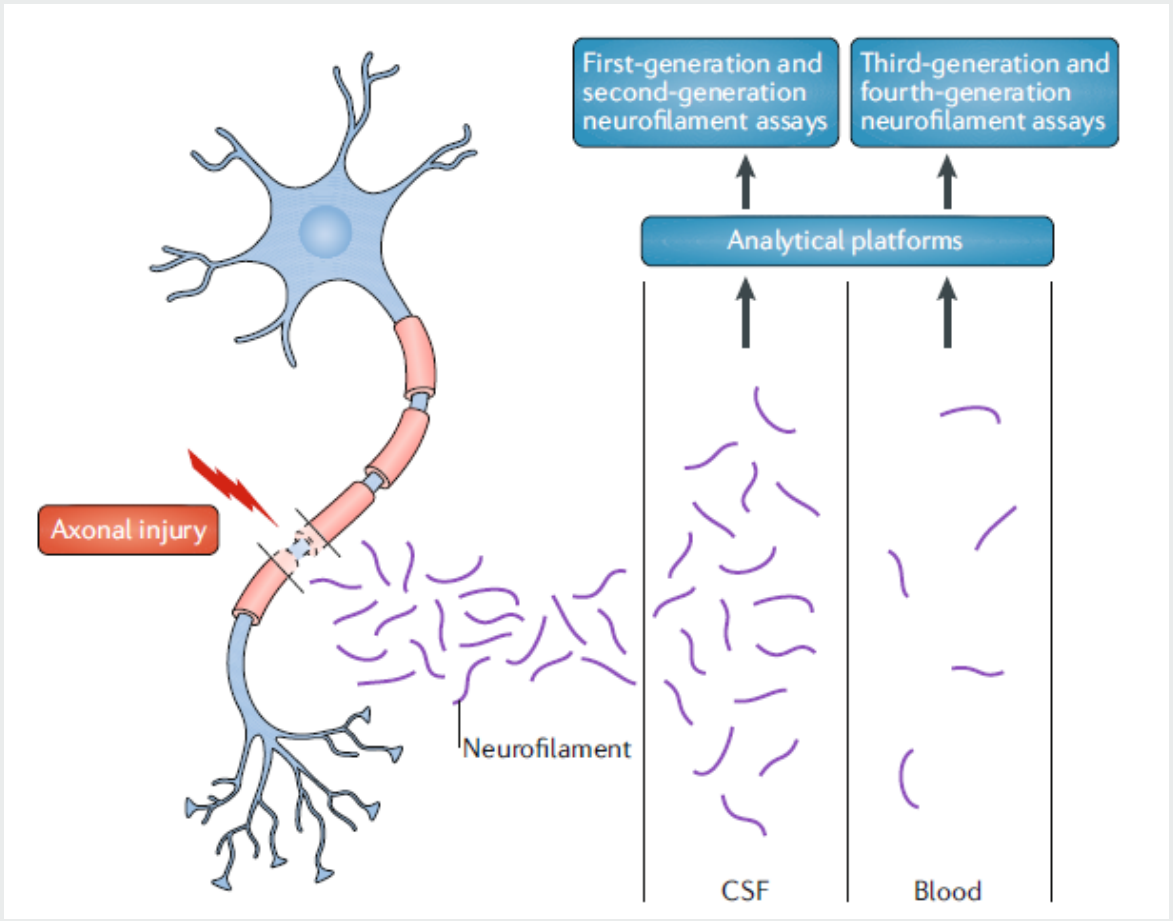
# Neurofilament Light Chain (NfL)

Background Information

# Neurofilaments Are Neuronal Proteins That Release Several Peptides Measurable in Blood (Upon Neuronal Cell Death)

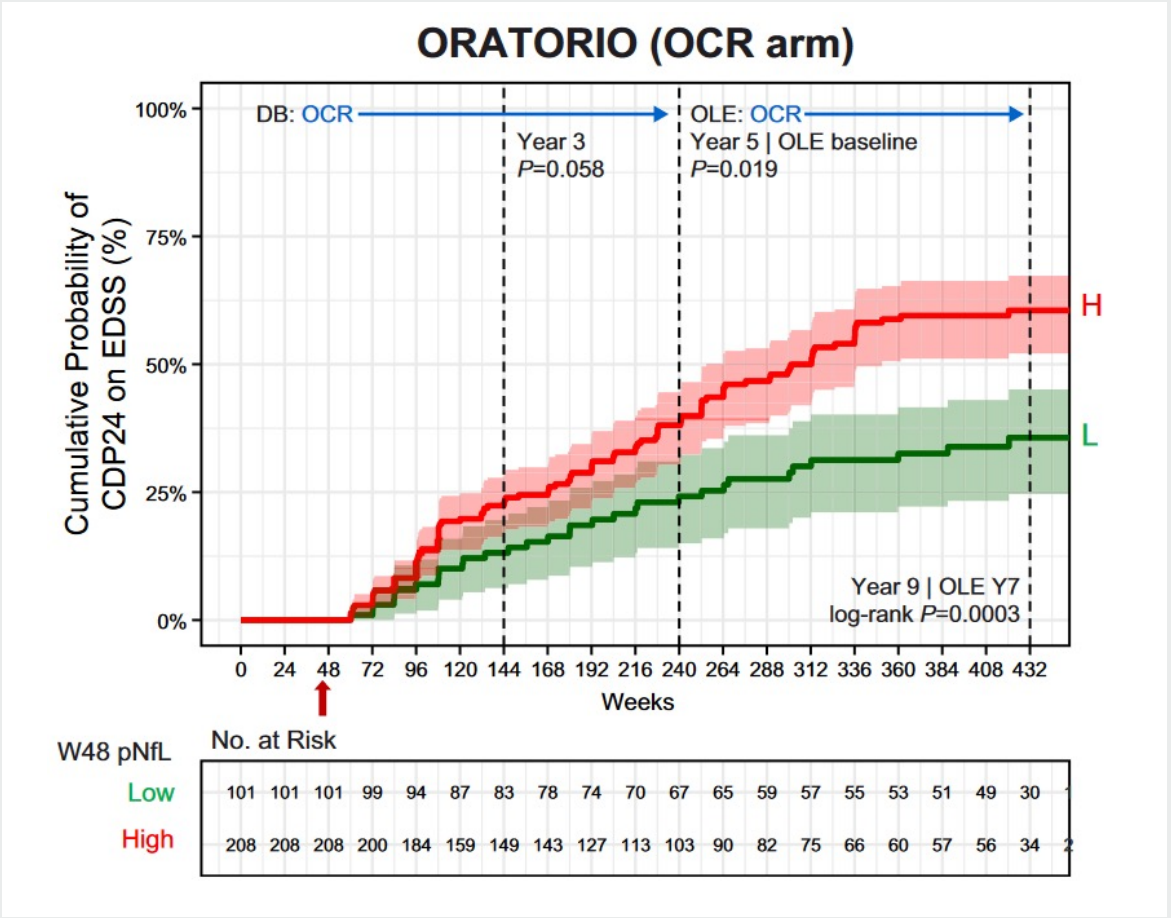
## Cross-Disease Neurologic Biomarker for Neurogenerative Diseases

- Neurofilaments are highly specific neuronal proteins that, during neuronal injury, release several peptides into cerebrospinal fluid (CSF) and are eventually also measurable in blood
- Comprises 85% of central nervous system (CNS) cytoskeleton proteins
- Elevated blood concentrations of neurofilament light chain (NfL) found to correlate with an increase in the number of relapses, and MRI disease activity




Left: Kuhle J. et al., Mult Scler. 2013;19(12):1597-1603; Kuhle J. et al., Neurology. 2019;92(10):e1007-e1015; Gaiottino J. et al., PLoS One. 2013;8(9):e75091; Morris JR, Lasek RJ, J Cell Biol. 1982 Jan;92(1):192-8; Fuchs E, Cleveland DW, Science. 1998;279(5350):514-519; Bridel C. et al., JAMA Neurol. 2019;76(9):1035-1048 / Right: Khalil M. et al., Nat Rev Neurol 14, 577–589 (2018) / MRI: magnetic resonance imaging

# PPMS Patients Treated with Ocrelizumab That Achieved Lower Levels of NfL Had a Lower Risk for Future Disability




## Ocrelizumab ORATORIO Study in PPMS as Historical Comparison

- Blood NfL levels re-baselined at Week 48, an optimized cut-off was created between high (H) and low (L) NfL levels
- Patients then followed in continuing double-blind and/or OLE treatment with ocrelizumab, monitored for 24-week CDP over 8 years

Findings:

- Relationship found between Week 48 blood NfL and risk for subsequent 24-week CDP in PPMS patients
- **Patients with low NfL levels have a lower risk of future disability worsening**

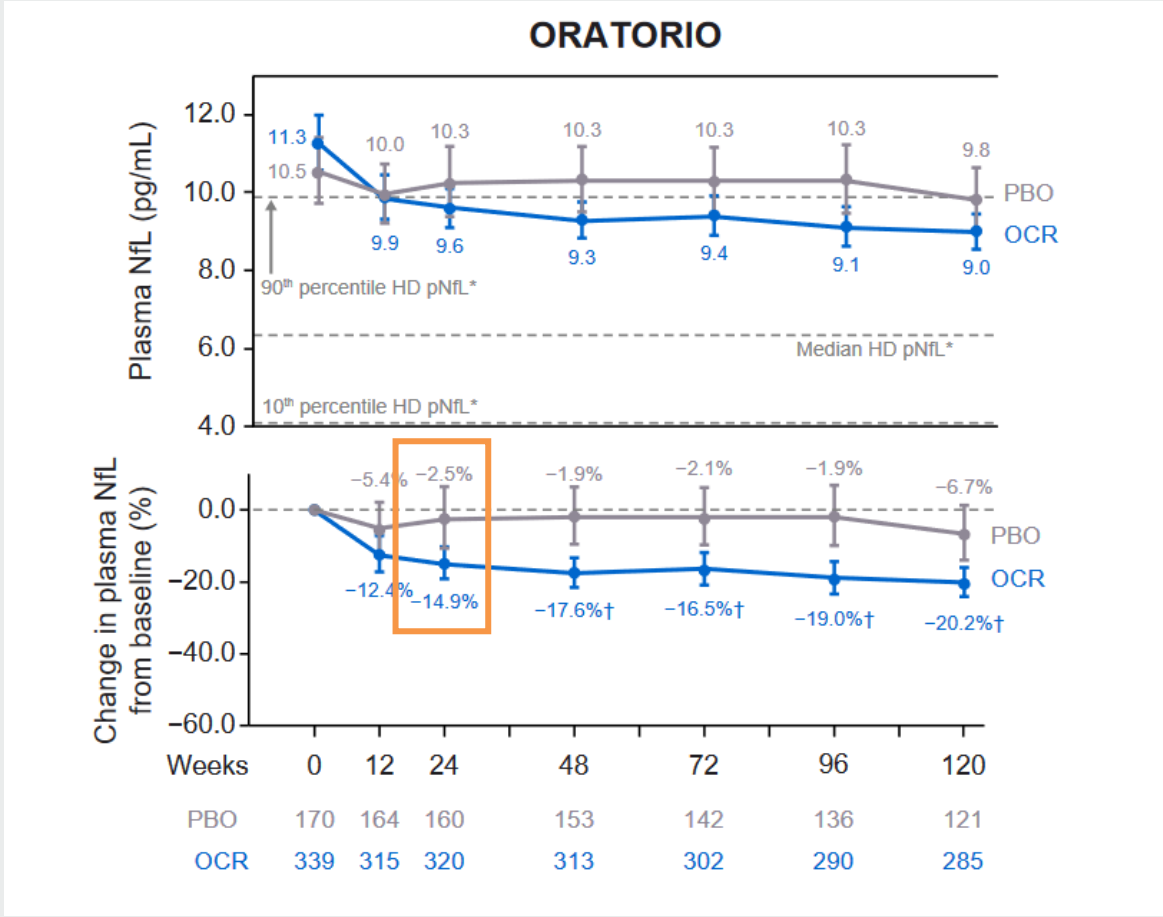
Bar-Or A. et al., EBioMedicine. 2023 Jul;93:104662

PPMS: primary progressive multiple sclerosis; OCR: ocrelizumab; DB: double-blind; OLE: open-label extension; EDSS: Expanded Disability Status Scale; H: high; L: low; pNfL: plasma neurofilament light; sNfL: serum neurofilament light; CDP: confirmed disability progression

# Historical Comparison: Ocrelizumab, the Only Approved Drug for PPMS, Reduced Blood NfL Levels in the ORATORIO Study

## ORATORIO Showed a 12.4 % Delta for 24-Week Serum NfL Levels for Ocrelizumab Versus Placebo

- Blood NfL levels (geometric mean and 95% CI, top) and relative change from baseline (% reduction in GM and 95% CI, bottom) during the controlled treatment in ORATORIO regulatory trial for PPMS
- Spread of NfL levels at Week 24 ocrelizumab versus placebo: **Δ** of 12.4 %
- Ocrelizumab was approved based on ORATORIO study results for PPMS




NfL levels from the HD cohort were adjusted to median ages in ORATORIO (47 years) to determine median, 10th percentile, and 90th percentile levels

†Significant reduction in NfL following ocrelizumab treatment vs. comparator arms; plots show GMs of NfL and 95% CIs

Bar-Or A. et al., EBioMedicine. 2023 Jul;93:104662

PPMS: primary progressive multiple sclerosis; OCR: ocrelizumab; PBO: placebo; HD: healthy donor; pNfL: plasma neurofilament light; sNfL: serum neurofilament light; CI: confidence interval; GM = geometric mean; CI = confidence interval



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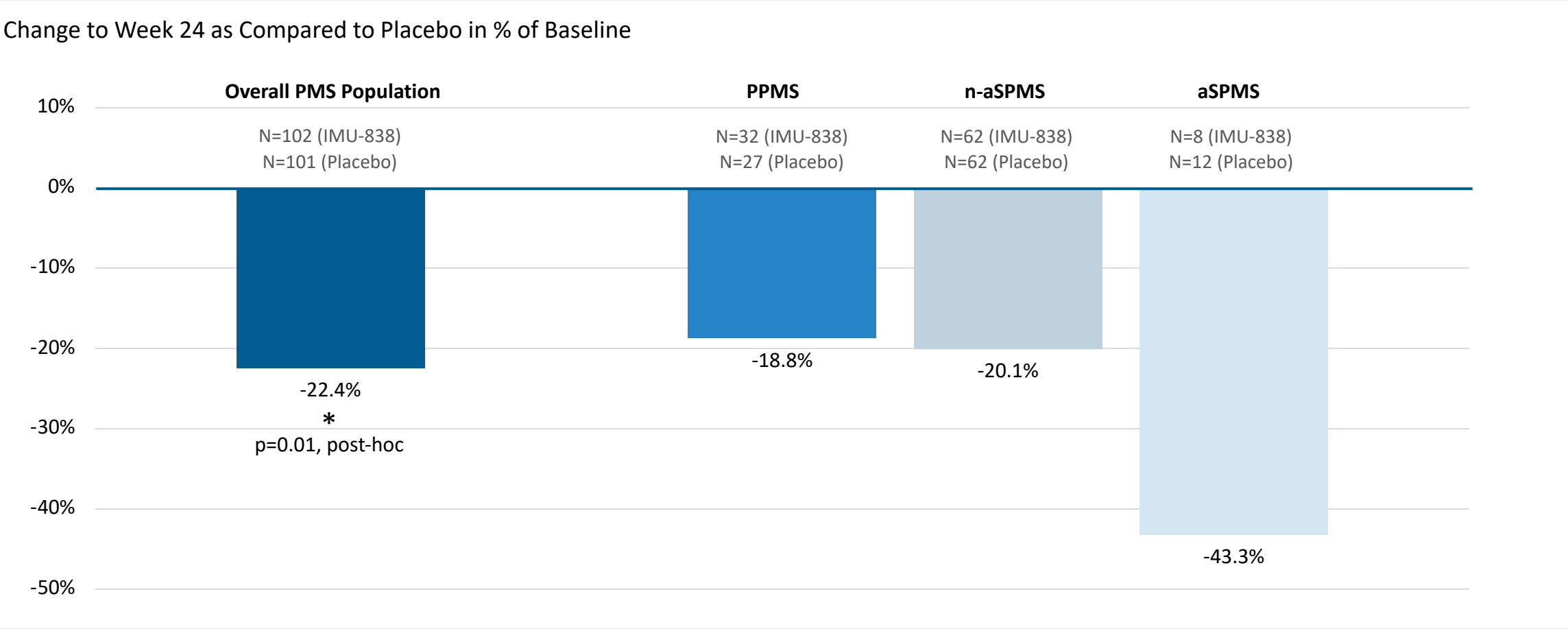
# Neurofilament Light Chain (NfL)

## Interim Analysis of the Phase 2 CALLIPER Trial

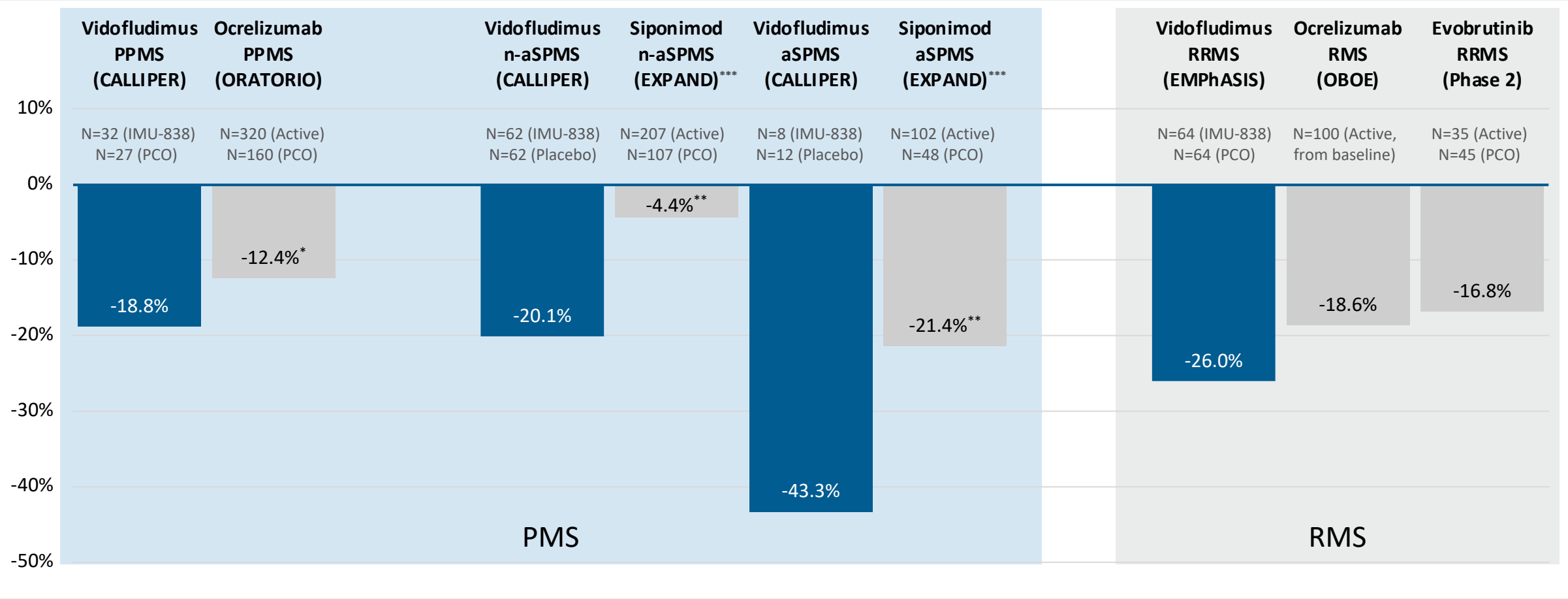
# Improvements in Serum NfL for Vidofludimus Calcium Consistent Throughout the Overall PMS Population and All Subtypes




Standard deviation for change from baseline in % of baseline: CALLIPER week 24: IMU-838 35.7%, PPMS: IMU-838 7.1%, n-aSPMS: IMU-838 14.7%, aSPMS: IMU-838 10.3%, 95% Hodges-Lehmann confidence bound EMPhASIS week 24 for 45mg IMU-838: lower boundary -41.0%, upper boundary -12.0%, includes all randomized patients with available neurofilament data at interim analysis, arithmetic mean value for group averages; aSPMS and n-aSPMS designation as per diagnosis by clinical investigator at study entry
RRMS: relapsing-remitting multiple sclerosis; PPMS: primary progressive multiple sclerosis; SPMS: secondary progressive multiple sclerosis; n-a: non-active; a: active

# NfL Reduction Compares Favorably with Other MS Therapies

## CALLIPER Interim Data Compared to Select Historical Trials




N = Number of patients in the 45 mg IMU-838 groups, only patients with both baseline and week 24 values considered for change from baseline analysis, arithmetic mean value for group averages; includes all randomized patients with available Nfl data at interim analysis
Standard deviation for change from baseline in % of baseline: CALLIPER week 24: IMU-838 35.7%; 95% Hodges-Lehmann confidence bound EMPhASIS week 24 for 45mg IMU-838: lower boundary -41.0%, upper boundary -12.0%
ORATORIO: Bar-Or A. et al., EBioMedicine. 2023 Jul;93:104662; EXPAND: Leppert D., et al., Neurology. 2022 May 24;98(21):e2120-e2131; OBOE: Cross A. et al., Neurology Apr 2019, 92 (15 Supplement) S56.008; evobrutinib: Kuhle J. et al., AAN 2021 Virtual Congress
*plasma NfL levels; ** 12-month data; *** Displayed are data for subpopulation without relapses (n-aSPMS) and with relapses (aSPMS); PCO: placebo; PPMS: primary progressive multiple sclerosis; SPMS: secondary progressive multiple sclerosis; RRMS: relapsing-remitting multiple sclerosis; RMS: relapsing multiple sclerosis; n-a: non-active; a: active



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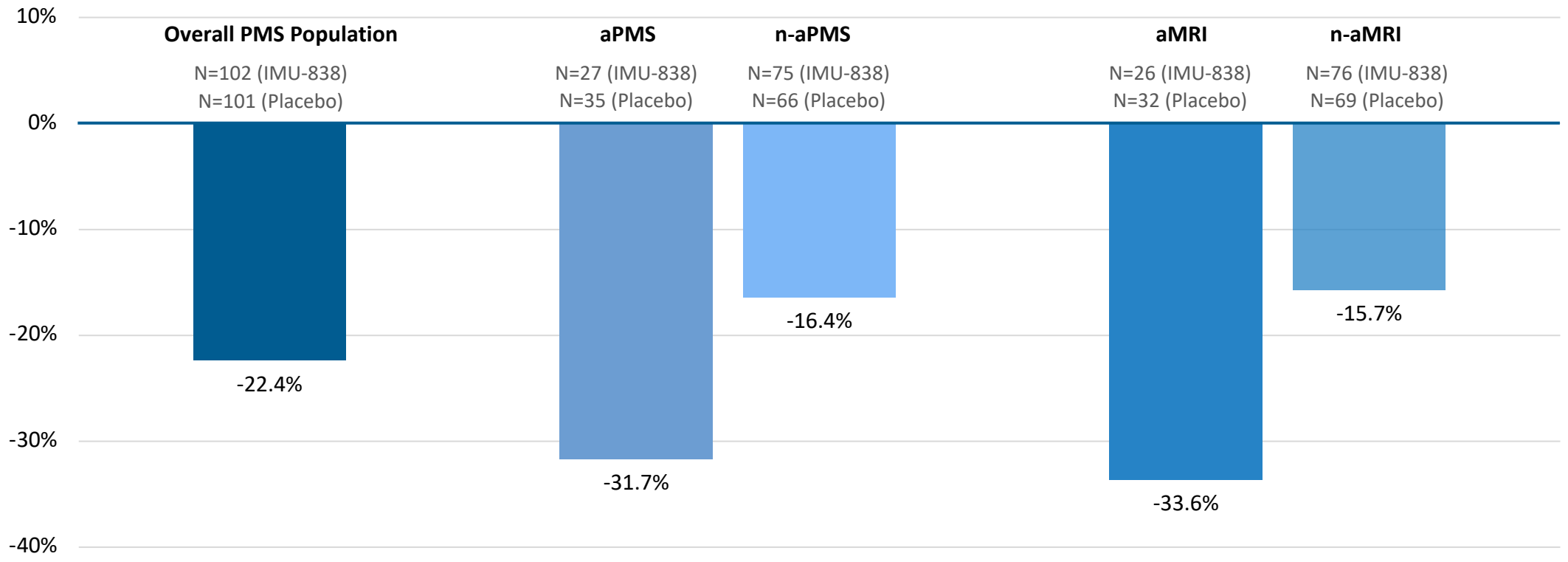
# Improvements in Serum NfL for Vidofludimus Calcium in Patients With/Without Disease or MRI Activity

Change to Week 24 as Compared to Placebo in % of Baseline




Active Disease = any MS disease activity shown as <new or enlarging T2 MRI lesions> OR <new Gd+ MRI lesions> OR <relapse>; non-active Disease = all but active disease
Active MRI = activity shown as <new or enlarging T2 MRI lesions> OR <new G+ MRI lesions>; non-active MRI = all but active MRI
Standard deviation for change from baseline in % of baseline: CALLIPER week 24: IMU-838 35.7%, active disease 48.2%, non-active disease 30.1%, active MRI 48.7%, non-active MRI 30.1%; 95% Hodges-Lehmann confidence bound EMPhASIS week 24 for 45mg IMU-838: lower boundary -41.0%, upper boundary -12.0%, includes all randomized patients with available neurofilament data at interim analysis, arithmetic mean value for group averages, includes all randomized patients with available neurofilament data at interim analysis / RRMS: relapsing-remitting multiple sclerosis; n-a: non-active; a: active



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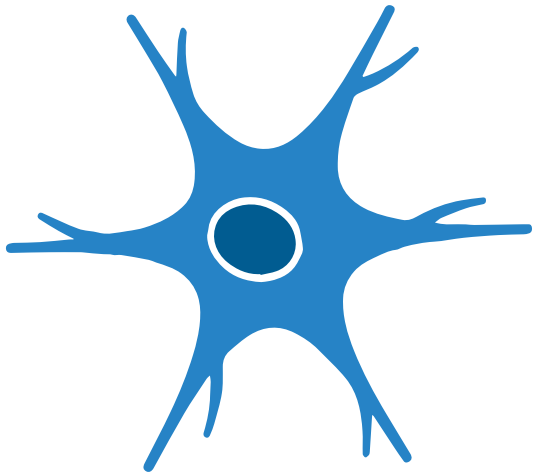
# Vidofludimus Calcium Shows Lowering of NfL at Week 24 in Patients with Non-Active PMS Disease ("Smoldering Disease")

## First-in-Class Nurr1 Activator, Targeting Improvement of Physical Ability of MS Patients

### Nurr1 Activator

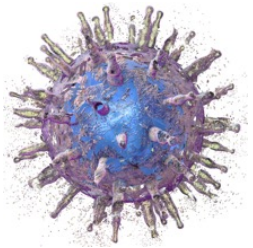
- Protecting neurons from cell death
- Continuous effect independent from focal inflammation



### DHODH Inhibitor

- Selective anti-inflammatory effect reduces focal inflammation
- Antiviral effect prevents reactivation of EBV and could stop cross reactive immune responses

Blocking of Th17/Th1 cytokines



Nurr1: nuclear receptor related 1; DHODH: dihydroorotate dehydrogenase; EBV: Epstein-Barr virus



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# Substantive Reduction of Serum NfL Levels Observed in CALLIPER Interim Analysis – Promising Signal for Study Readout


- NfL levels reduced by 22.4% versus placebo in vidofludimus calcium treatment arm
- Reduction of NfL consistently shown across all subgroup analyses
- NfL effect observed in non-active SPMS reinforces vidofludimus calcium's neuroprotective potential
- NfL interim results at least comparable with historical studies
- Data from other studies hint that lowering of NfL during continuing treatment in PPMS patients may reduce future disability worsening

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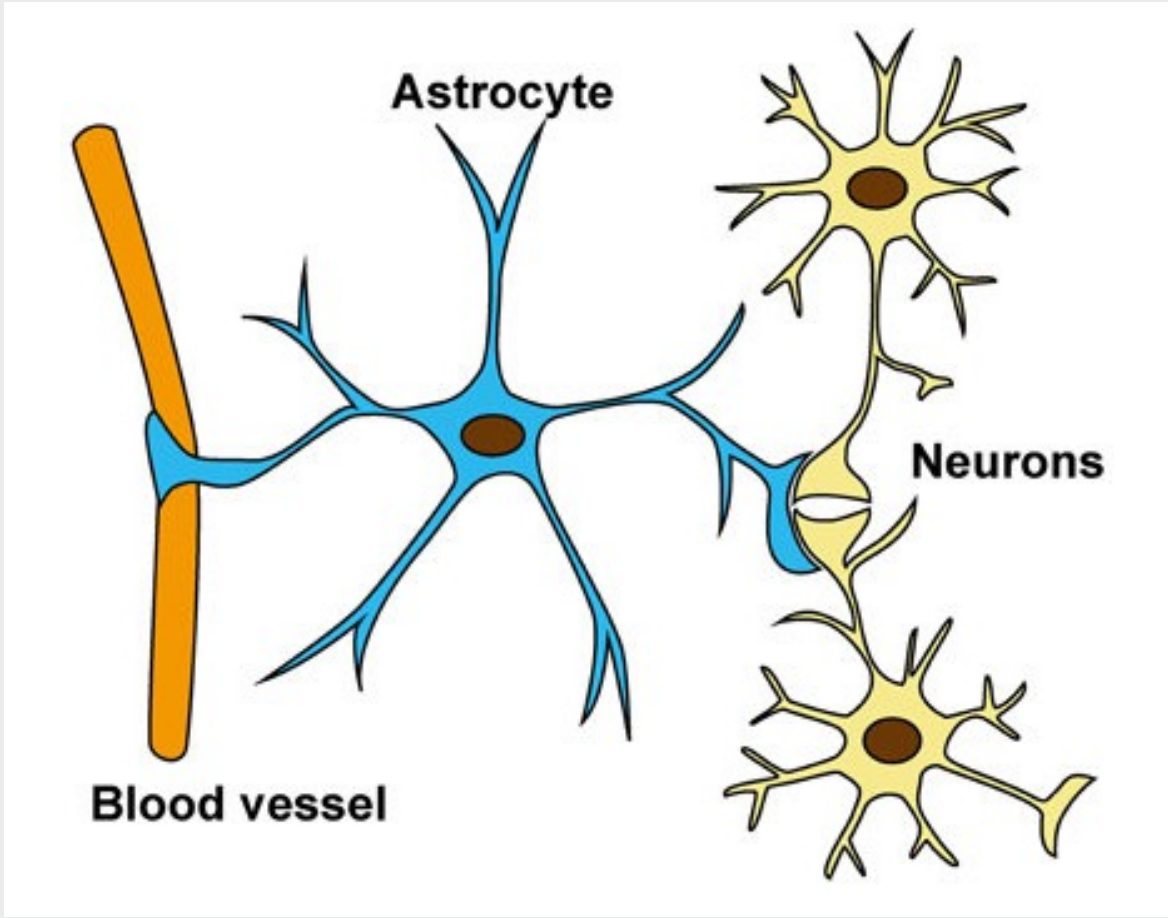
# Glial Fibrillary Acidic Protein (GFAP)

Interim Analysis of the Phase 2 CALLIPER Trial

# Biology of Glial Fibrillary Acidic Protein (GFAP)

## GFAP is a Non-Neuronal Biomarker Presumably Related to Diffuse Brain Disease

- Astrocytes are the most numerous non-neuronal cells in the human central nervous system (CNS)
  - Provide cytoskeleton structure
  - Perform metabolic, structural, homeostatic, and neuroprotective tasks
- Astrocytes are the main source of GFAP
  - GFAP is therefore not a direct marker of neurodegeneration
  - Presumably of a more diffuse glial activation in diffuse chronic-active brain disease such as non-relapsing PMS[1]
  - Relatively stable biomarker generally thought to evolve more slowly and with less amplitude than NfL[2]



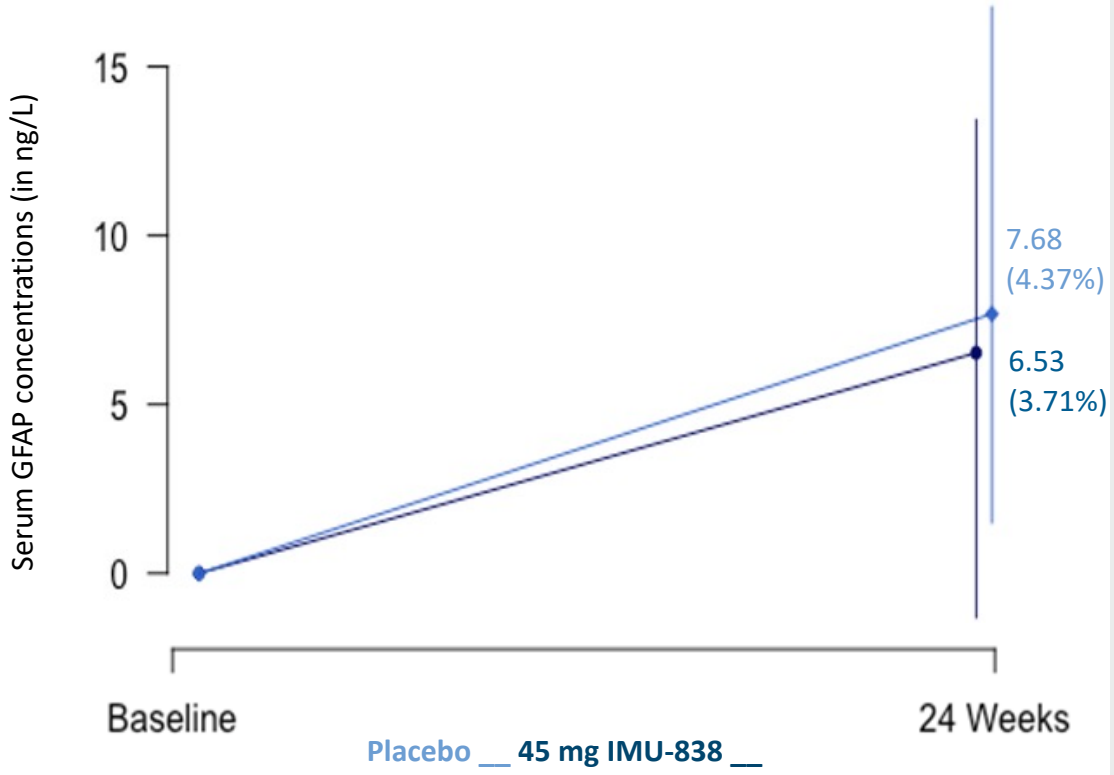

[1] Absinta M. et al. Nature. 2021 Sep; 597(7878): 709-714; [2] Meier S. at al. JAMA Neurol. 2023 Feb 6;80(3):287–97; picture: Harada K. et al., Front Neurosci. 2016 Jan 12;9:499

# Promising Early Signal for GFAP in the Overall PMS Population

## Change in GFAP as Compared to Normalized Baseline

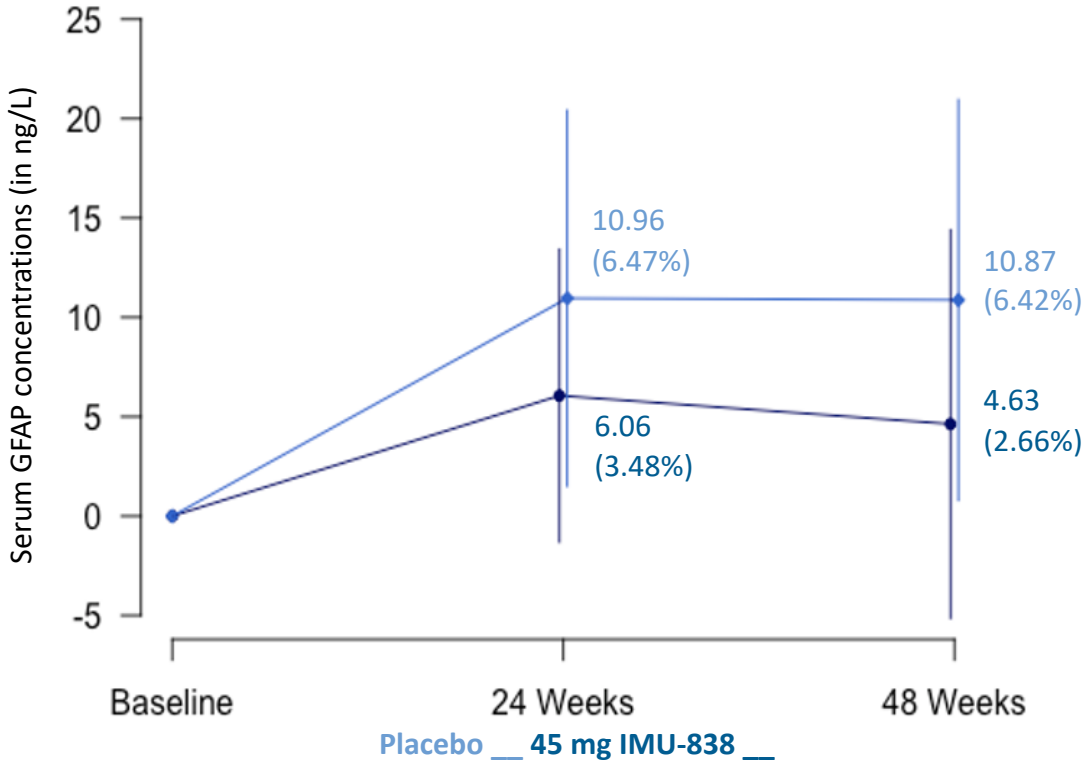
### Total Interim Analysis Population (24-Week Completer)

N=102 (45 mg IMU-838), N=101 (Placebo)




### 48-Week Completer Subpopulation

N=41 (45 mg IMU-838), N=38 (Placebo)




N = Number of patients in the corresponding treatment groups, only patients with both, baseline value and a week 24 and/or week 48 value, are considered for this change from baseline analysis, baseline normalized between treatment arms
The graphs display the change in nominal group averages from baseline and in parentheses displayed as change from baseline in % of baseline
Arithmetic mean value for group averages and standard error, includes all randomized patients with available neurofilament data at interim analysis



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# Promising Signal for GFAP Observed in CALLIPER Interim Analysis


- Although early, interim GFAP data showed a promising initial signal
- Progression of GFAP response is generally thought to evolve more slowly and with lower amplitude than NfL
- Company believes that a longer follow-up may further strengthen this signal



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# Positive Interim Biomarker Data of Vidofludimus Calcium in Progressive Multiple Sclerosis (PMS)

- Biomarker evidence that vidofludimus calcium's activity extends beyond the previously observed anti-inflammatory effects, thereby further reinforcing its neuroprotective potential
- Vidofludimus calcium aiming to address high unmet medical need in non-active SPMS where no relevant treatments are available in the US
- Overall CALLIPER trial ongoing; brain volume data of the full 467 patients expected in April of 2025
- Results of this interim analysis may inform the ability to potentially reduce PIRA events in the ongoing phase 3 ENSURE program in RMS



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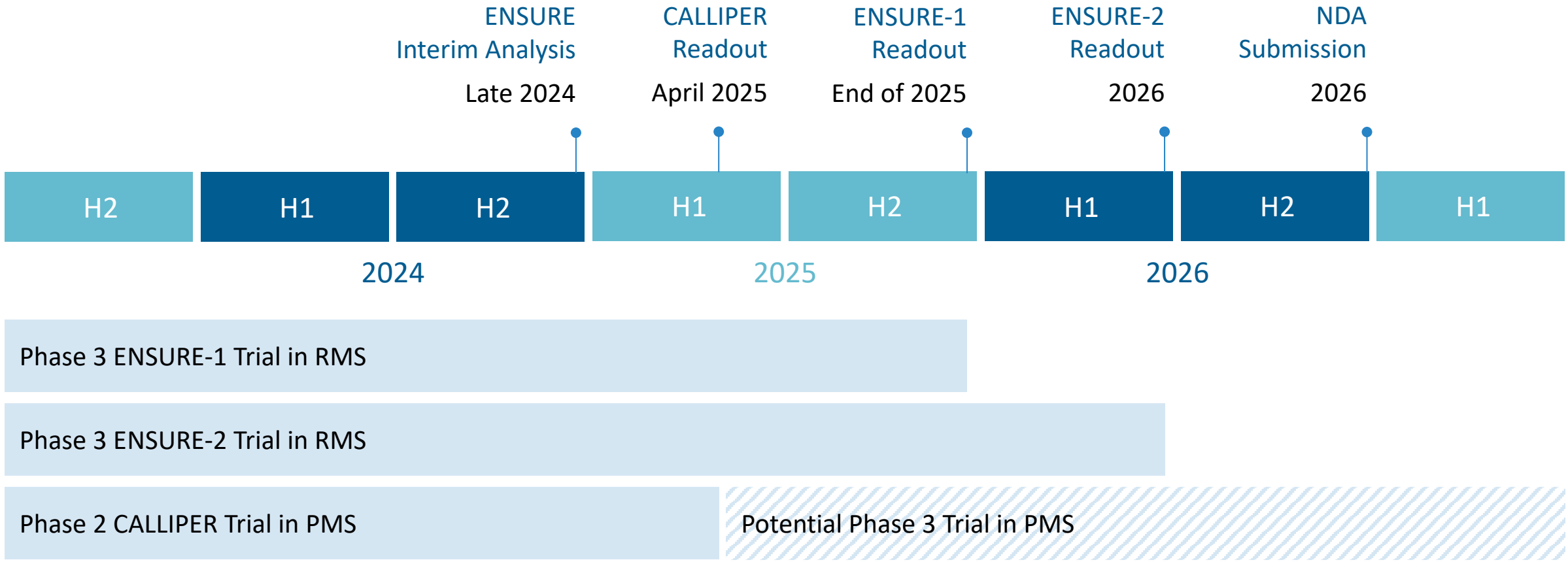
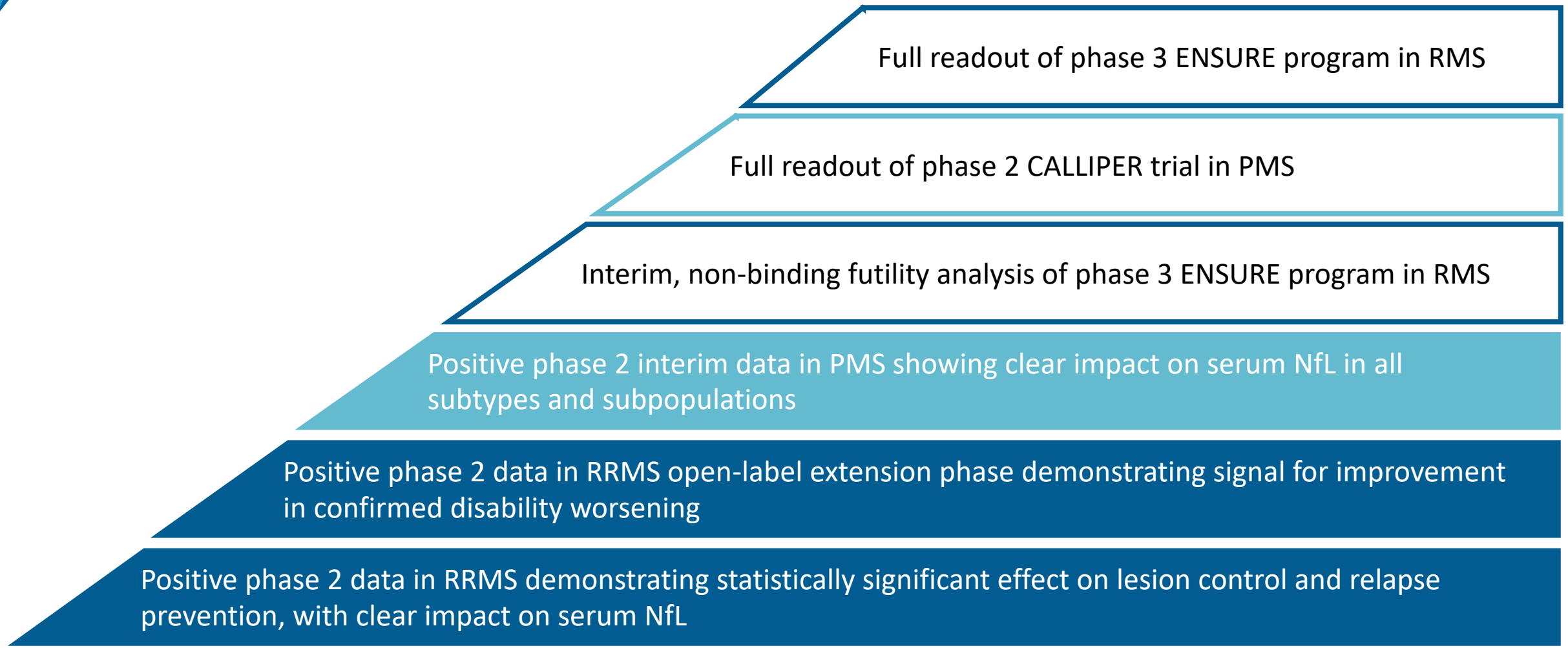
# Vidofludimus Calcium in MS: Straightforward Path Towards Potential Regulatory Approval




Although we currently believe that each of these goals is achievable, they are each dependent on numerous factors, most of which are not under our direct control and can be difficult to predict. We plan to periodically review this assessment and provide updates of material changes as appropriate.

# Consistent and Differentiated Results to Date in Both RMS and PMS

## Assembling the Basis for Potential Regulatory Approvals




RMS: relapsing multiple sclerosis; PMS: progressive multiple sclerosis; NfL: neurofilament light chain; RRMS: relapsing-remitting multiple sclerosis



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# Q&A Session

Interim Analysis of the Phase 2 CALLIPER Trial

# Thank You!


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# Backup

Interim Analysis of the Phase 2 CALLIPER Trial

# Key Challenge in All Forms of MS: Disability Worsening Over Time

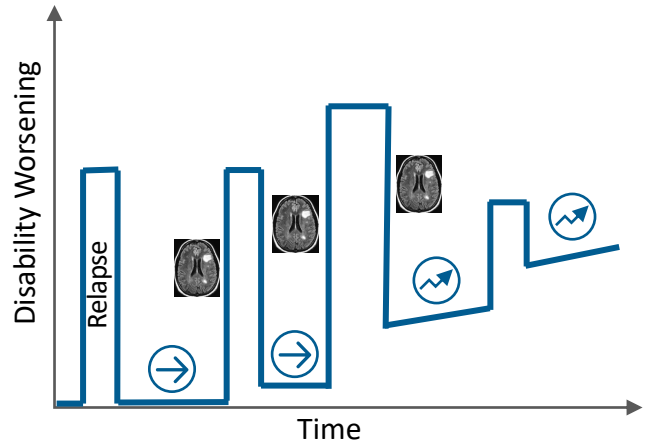
**RRMS:**

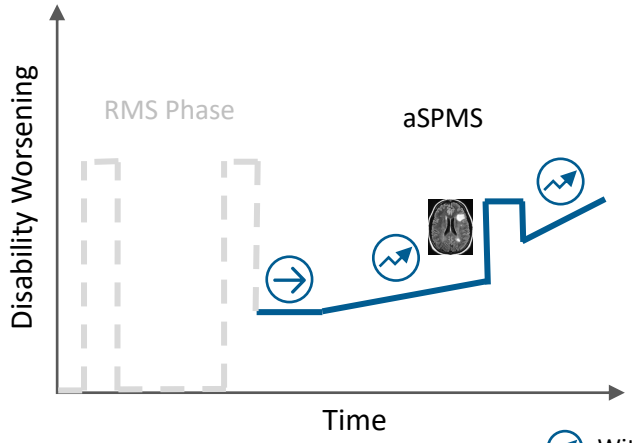
- Dominated by focal inflammatory disease (MRI lesions) and relapses
- Disability progression caused by RAW and PIRA almost equally*
- RAW and PIRA contributing to disability worsening
- Treated with approved anti-inflammatory drugs

**Active SPMS:**

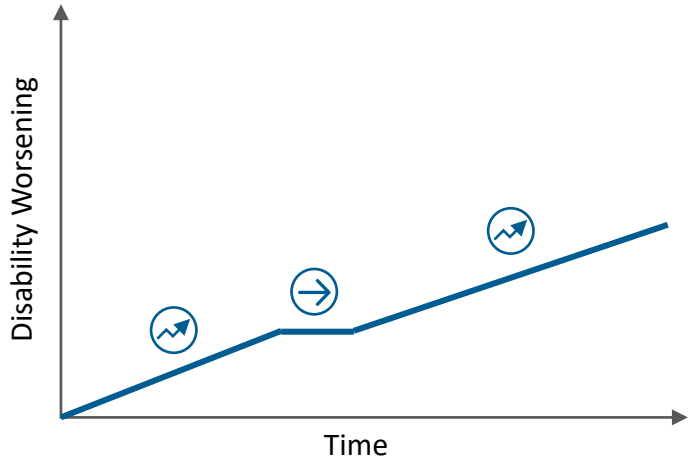
- Patients with RMS can develop aSPMS
- Increase in disability with only small number of relapses and occasional MRI lesions measurable
- Higher contribution for disability by PIRA over RAW*

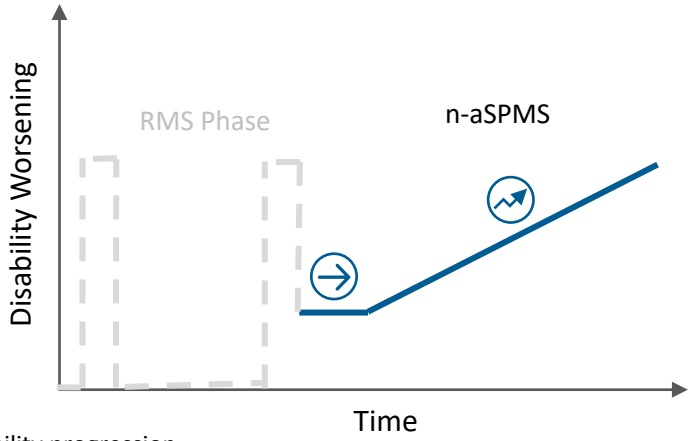
Relapsing Forms of MS (RMS)




Progressive Forms of MS (PMS)




With disability progression

Without disability progression

**PPMS:**

- Patients worsen on disability over time since diagnosis despite no relapses and new MRI lesions measurable
- Substantial disability worsening
- Ocrelizumab only approved therapy in PPMS

**Non-Active SPMS:**

- Patients with RMS or aSPMS can develop n-aSPMS
- Increase in disability without relapses and new MRI lesions driven by PIRA*
- No treatments available
- Generally considered the most difficult-to-treat MS patient population

Adapted from Kretzschmar A., MSVirtual2020; *Lublin FD, et al. Brain. 2022 Sep 14;145(9):3147-3161

MS: multiple sclerosis; MRI: magnetic resonance imaging; RAW: relapse-associated worsening; PIRA: progression independent of relapse activity; RRMS: relapsing-remitting MS; SPMS: secondary progressive MS; PPMS: primary progressive MS; a: active; n-a: non-active



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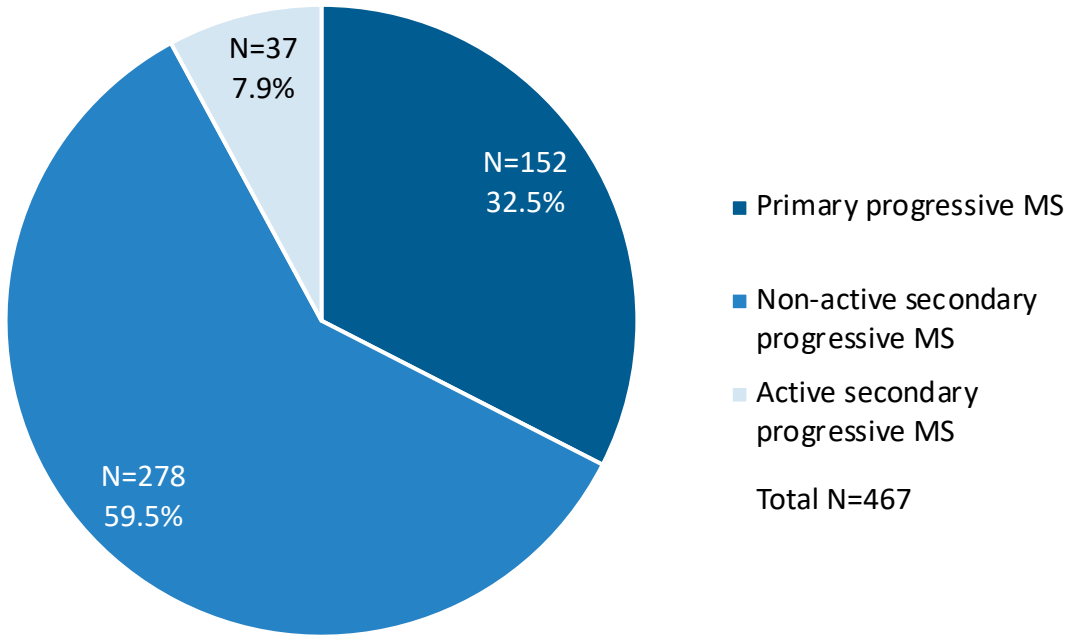
# Patient Demographics and Baseline Characteristics

## Total Study Population of 467 Enrolled Patients

### Progressive Disease Subtypes



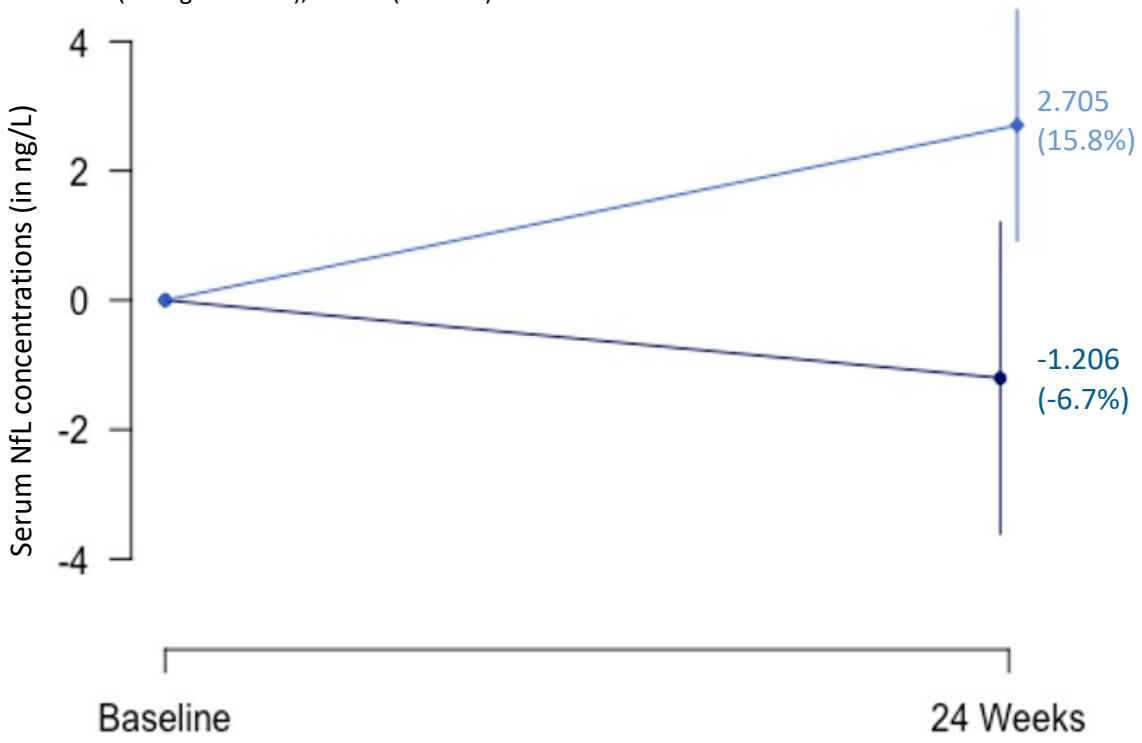

### Baseline Characteristics

| Baseline Patient Characteristics | | Total (N=467) |
|---|---|---|
| Age [years], median (min-max) | | 51.0 (21-65) |
| Gender (n and % female) | | 302 (64.7 %) |
| Race (n and % White) | | 460 (98.7 %) |
| Country | Ukraine (n and %) | 127 (27.2 %) |
| | Poland (n and %) | 102 (21.8 %) |
| | Bulgaria (n and %) | 95 (20.3 %) |
| BMI [kg/m^2], median (min-max) | | 25.0 [15.8 – 46.6] |
| SDMT [points], median (min-max) | | 35.0 [0-180] |
| EDSS at Visit 1, median (min-max) | | 5.5 [2.5-6.5] |
| MS relapses during last 24 h, median (min-max) | | 0.0 [0-1] |

Disease subtype information are used as diagnosis entered by investigator at study entry
BMI: body mass index; SDMT: Symbol Digit Modalities Test; EDSS: Expanded Disability Status Scale

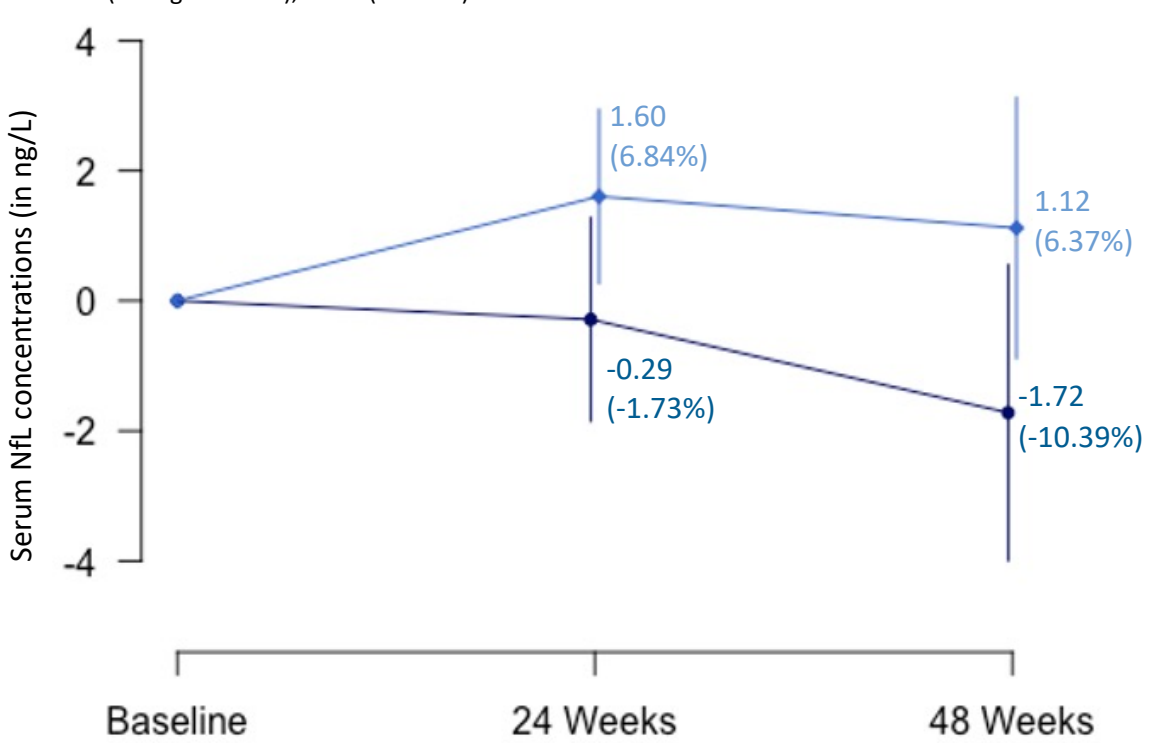
# Overall PMS Population: Change in Serum NfL
## Compared to Normalized Baseline

### Total Interim Analysis Population (24-Week Completer)
N=102 (45 mg IMU-838), N=101 (Placebo)




Placebo __ **45 mg IMU-838** __

### 48-Week Completer Subpopulation
N=41 (45 mg IMU-838), N=38 (Placebo)




Placebo __ **45 mg IMU-838** __

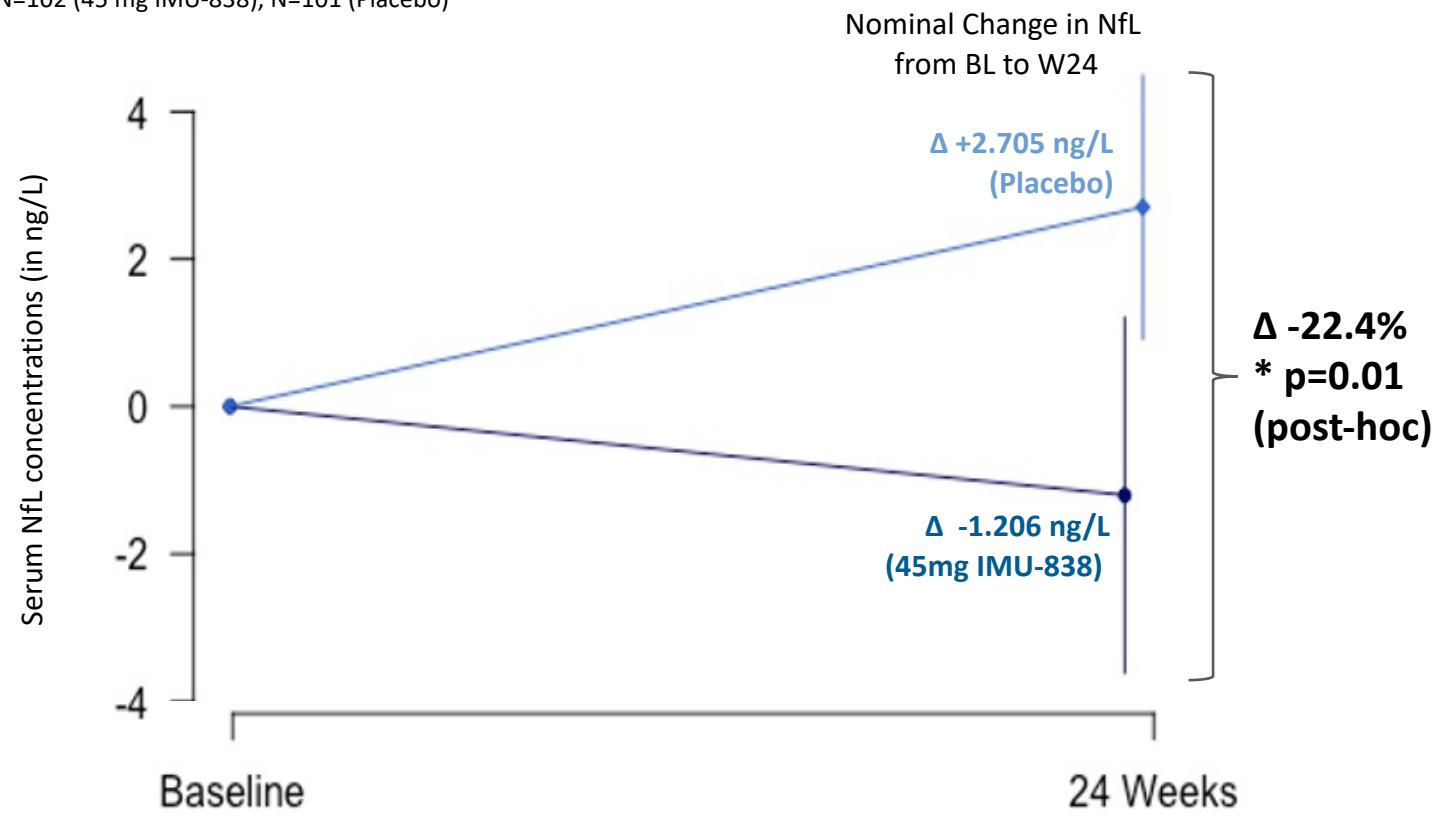
N = Number of patients in the corresponding treatment groups, only patients with both, baseline value and a week 24 and/or week 48 value, are considered for this change from baseline analysis, baseline normalized between treatment arms
The graphs display the change in nominal group averages from baseline and in parentheses displayed as change from baseline in % of baseline
Arithmetic mean value for group averages and standard error, includes all randomized patients with available data at interim analysis

# Overall PMS Population: Change in Serum NfL

## Post-Hoc Statistical Analysis of Change from Baseline to Week 24

Total Interim Analysis Population (24-Week Completer)

N=102 (45 mg IMU-838), N=101 (Placebo)




Post-Hoc Statistical Analysis:

The nominal change in NfL is significantly different.

Overall group difference: -3.91

95% CI of difference: -6.93 to -0.89

Unpaired T-test:

two-tailed **p-value = 0.01**

BL: baseline; W24: week 24; 95%CI: 95% confidence interval, NfL: neurofilament light chain

N = Number of patients in the corresponding treatment groups, only patients with both, baseline value and a week 24 value, are considered for this change from baseline analysis, baseline normalized between treatment arms. The graphs display the change in nominal group averages from baseline and in parentheses displayed as change from baseline in % of baseline. Arithmetic mean value for group averages and standard error, includes all randomized patients with available data at interim analysis.



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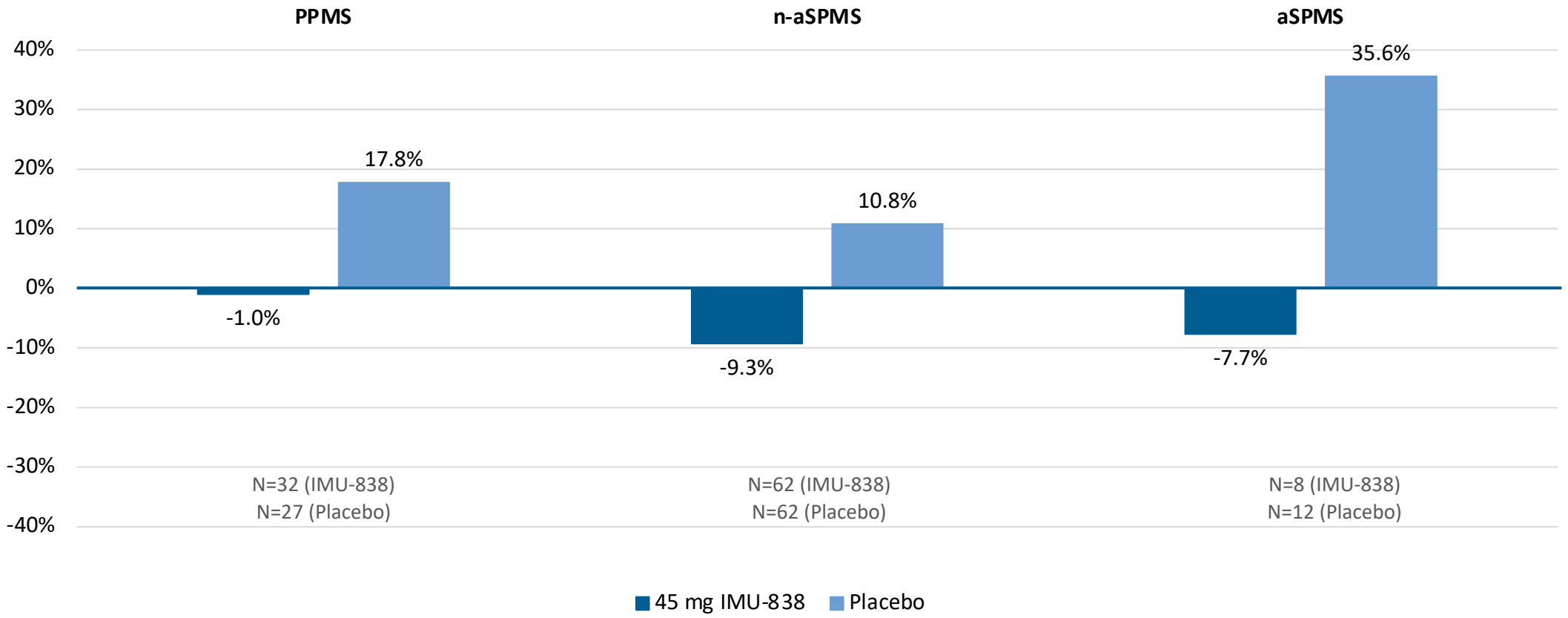
# Change in Serum NfL by PMS Disease Subtype

## Change from Baseline to Week 24 in % of Baseline




Standard deviation for change from baseline in % of baseline: PPMS: IMU-838 7.1%, placebo 7.8%; n-aSPMS: IMU-838 14.7%, placebo 9.4%, aSPMS: IMU-838 10.3%, placebo 10.3%, arithmetic mean value for group averages
Includes all randomized patients with available neurofilament data at interim analysis, dose of 45 mg once daily IMU-838 versus placebo; active and non-active SPMS designation as per diagnosis by clinical investigator at study entry
PPMS: primary progressive multiple sclerosis; SPMS: secondary progressive multiple sclerosis; n-a: non-active; a: active



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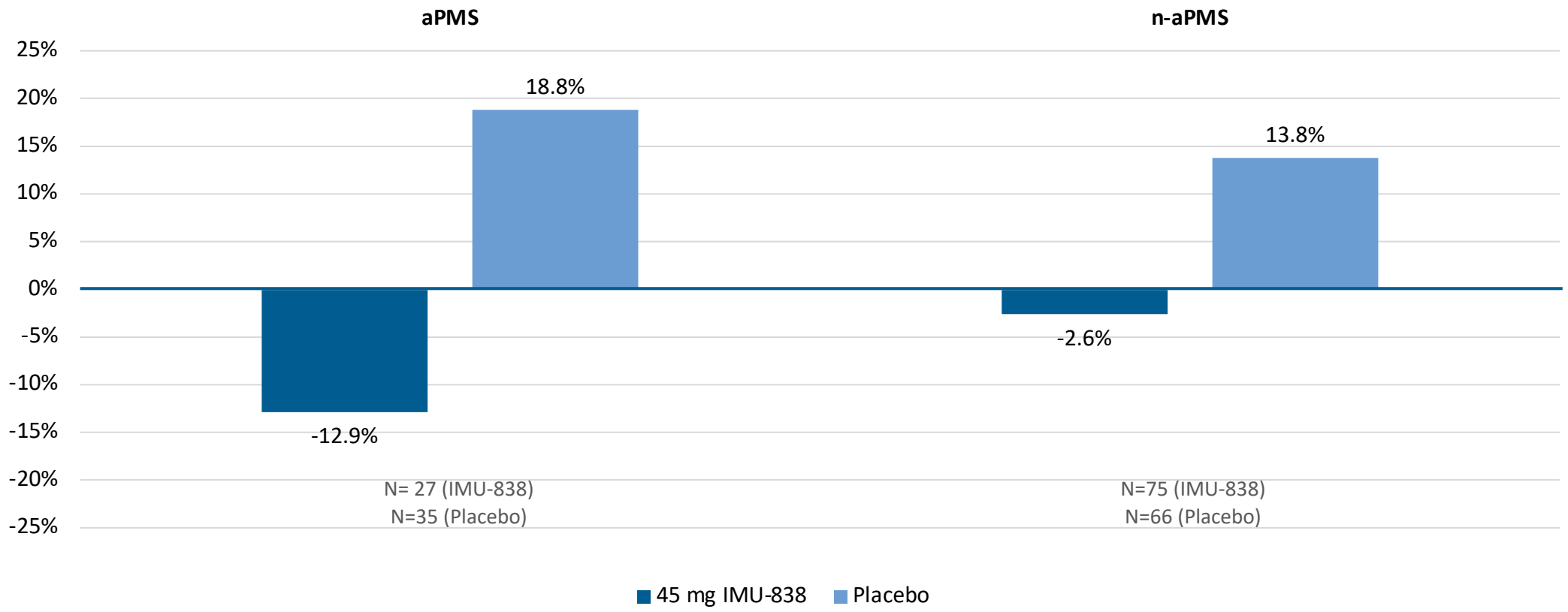
# Change in Serum NfL by Active Disease Status During Study

## Change from Baseline to Week 24 in % of Baseline, 45 mg of Vidofludimus Calcium




Active Disease = any MS disease activity shown as <new or enlarging T2 MRI lesions> OR <new Gd+ MRI lesions> OR <relapse>; non-active Disease = all but active disease
Standard deviation for change from baseline in % of baseline: active disease 48.2%, placebo 96.2%; non-active disease: IMU-838 30.1%, placebo 46.7%, group average are given as arithmetic mean
Includes all randomized patients with available neurofilament data at interim analysis / n-a: non-active; a: active



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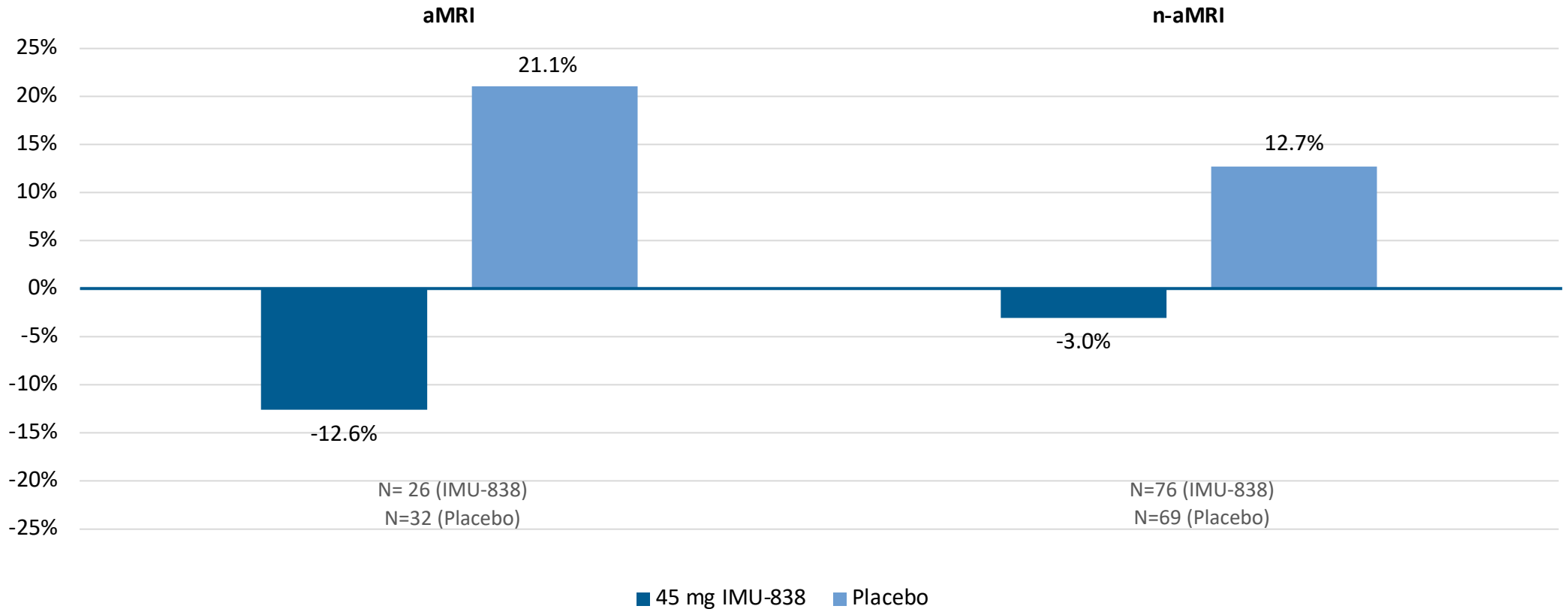
# Change in Serum NfL by MRI Activity During Study

## Change from Baseline to Week 24 in % of Baseline, 45 mg of Vidofludimus Calcium




Active MRI = activity shown as <new or enlarging T2 MRI lesions> OR <new G+ MRI lesions>; non-active MRI = all but active MRI
Standard deviation for change from baseline in % of baseline: active MRI 48.7%, placebo 99.7%; non-active MRI: IMU-838 30.1%, placebo 46.0%, group average are given as arithmetic mean
Includes all randomized patients with available neurofilament data at interim analysis / MRI: magnetic resonance imaging; n-a: non-active; a: active