Immunic Therapeutics

Developing Selective Oral Therapies in Immunology

NASDAQ: IMUX | April 18, 2024

Noble Capital Markets Emerging Growth Virtual Healthcare Equity Conference

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Forward-looking statements included in this presentation are based on information available to Immunic as of the date of this presentation. Immunic does not undertake any obligation to update such forward-looking statements except as required by applicable law.

Our Mission

We are developing a pipeline of next-generation selective oral therapies focused on offering patients with chronic inflammatory and autoimmune diseases new and clinically meaningful treatment options.

Advanced Clinical Pipeline

Well Differentiated Programs in Various Phases of Clinical Development

Program	Preclinical	Phase 1	Phase 2	Phase 3
Vidofludimus Calcium (IMU-838)	Relapsing Multiple Sclerosis (RMS) – ENSURE Trials			
	Progressive Multiple Sclerosis (PMS) – CALLIPER Trial			
	Ulcerative Colitis (UC) – CALDOSE-1 Trial			
IMU-856	Celiac Disease			
IMU-381	Gastrointestinal Diseases			

■ Completed or ongoing ■ In preparation or planned

Immunic THERAPEUTICS

Vidofludimus Calcium in Multiple Sclerosis (MS)

Targeted to Elevate the Standard of Care With a Holistic Solution for the Full Spectrum of MS Patients

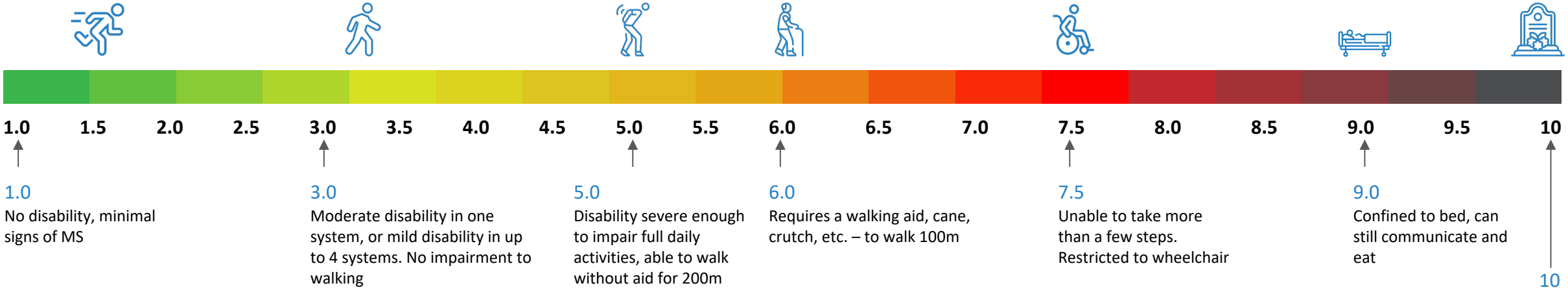
MS is a Lifelong Neurodegenerative Disease

Lifelong Disease Requiring Decades of Therapy

- ~2.8 million people affected worldwide (~1M in US)[1]
- Often diagnosed in younger adults (3:1 women:men)
- Epidemiologic study showed a clear association between EBV infection and occurrence of MS; 32-fold increased risk in EBV-infected patients[2]

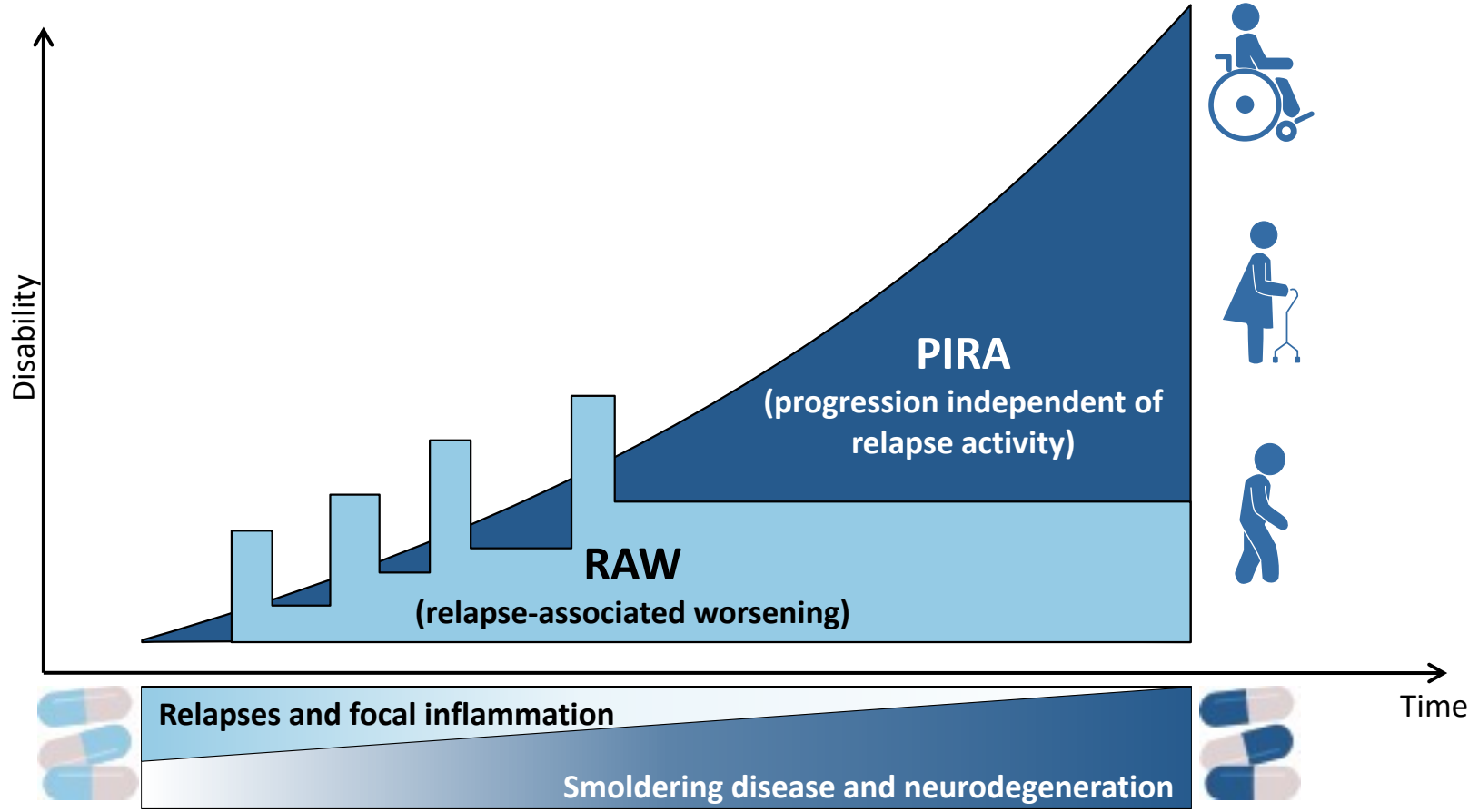
Therapeutic Goal: Preventing Disability Worsening

- Key unmet need prevention or slowing of long-term disability worsening
- Historical focus has been on prevention of relapses via broad immunosuppression



[1] MS International Federation (2020): Atlas of MS, https://www.atlasofms.org/map/global/epidemiology/number-of-people-with-ms; Illustration adapted from: VOX, https://futurism.com/reversal-of-multiple-sclerosis-via-risky-stem-cell-treatment-confirmed, and Multiple Sclerosis Trust, https://www.mstrust.org.uk/; [2] Bjornevik K. et al., Science. 10.1126/science.abj8222; PML: progressive multifocal leukoencephalopathy; M: million; Source: mistrust.org.uk

Underlying “Invisible Disability Accumulation” Contributes to Multiple Sclerosis Progression Over Time



Newer data shows that half of the disability accumulation in relapsing MS comes from PIRA and is contributed to the underlying “invisible disability accumulation” or “smoldering disease”[1]

Graphic adapted from Kretzschmar A., Symposium „Every Journey Begins with a Single Step: Visualizing the Chronic Nature of MS”, MSVirtual2020 / 8th Joint ACTRIMS-ECTRIMS Meeting

[1] Lublin FD, et al. Brain. 2022 Sep 14;145(9):3147-3161; Müller J, et al. JAMA Neurol. 2023;80(11):1232–1245

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Vidofludimus Calcium Aimed to Go Above and Beyond Current Care to Comprehensively Address Patients' Needs

Targeted to Elevate the Standard of Care With a Holistic Solution for MS Patients

Uniquely matched to the multi-faceted neurodegeneration of smoldering and active MS

- Neuroprotective effects
- Anti-inflammatory effects
- Anti-viral effects

Seeks to provide unrivaled safety, tolerability & convenience

- Targeted to set the new standard for patient preference, exceeding all options including glatiramer acetate

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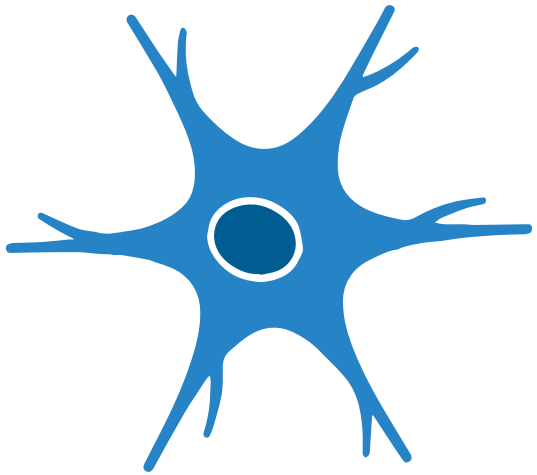
Vidofludimus Calcium Addresses Smoldering Neurodegeneration

First-in-Class Nurr1 Activator, Targeting Improvement of Physical Ability of Multiple Sclerosis Patients

Nurr1 Activator

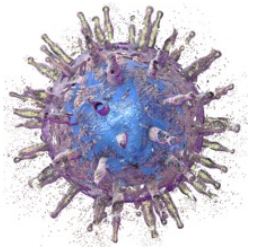
- Protecting neurons from cell death
- Continuous effect independent from focal inflammation



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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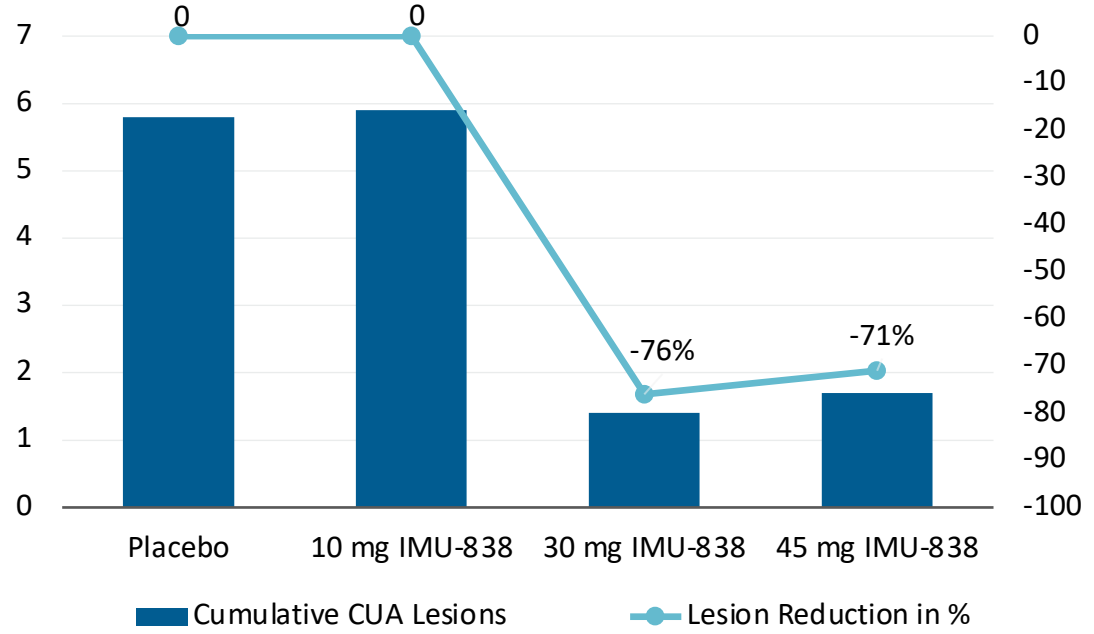
EMPhASIS Trial: Strong Reduction of MRI Lesion Activity

Primary Endpoint Hit With High Statistical Significance, Pooled Cohorts 1 & 2

Vidofludimus Calcium Showed Strong Activity on Primary Study Endpoint in Phase 2 EMPhASIS Trial

- Double-blind, placebo-controlled, randomized, parallel-group phase 2 trial in RRMS
- Blinded main treatment period of 24 weeks
- Randomized 268 patients in 36 centers across four European countries
- Cohort 1: 30 and 45 mg or placebo
- Cohort 2: 10 mg or placebo
- Extended treatment period of up to 9.5 years to observe long-term safety is ongoing

Study endpoint:
Reduction in cumulative CUA lesions up to week 24



Primary and key secondary endpoints met with high statistical significance (primary: p = 0.0002 / key secondary: p < 0.0001)

As Cohort 2 only allowed MRI machines of 1.5T, pooled data of Cohorts 1 & 2 only include patients that were evaluated at MRI field strength of 1.5 Tesla. Modified full analysis set C1/C2 (N10 = 47, N30 = 65, N45 = 66, NPBO C1 = 59, NPBO C2 = 12)
Data displayed are as adjusted mean values. Estimates are adjusted for baseline volume of T2 lesions and baseline number of Gd+ lesions (0, >=1) using a generalized linear model with a negative binomial distribution and a logarithmic link function. Log transformation of time from first investigational medicinal product (IMP) dose to date of last MRI assessment with non-missing values is used as offset term. RRMS: relapsing-remitting multiple sclerosis; MRI: magnetic resonance imaging; CUA: cumulative unique active, Gd+: gadolinium-enhancing

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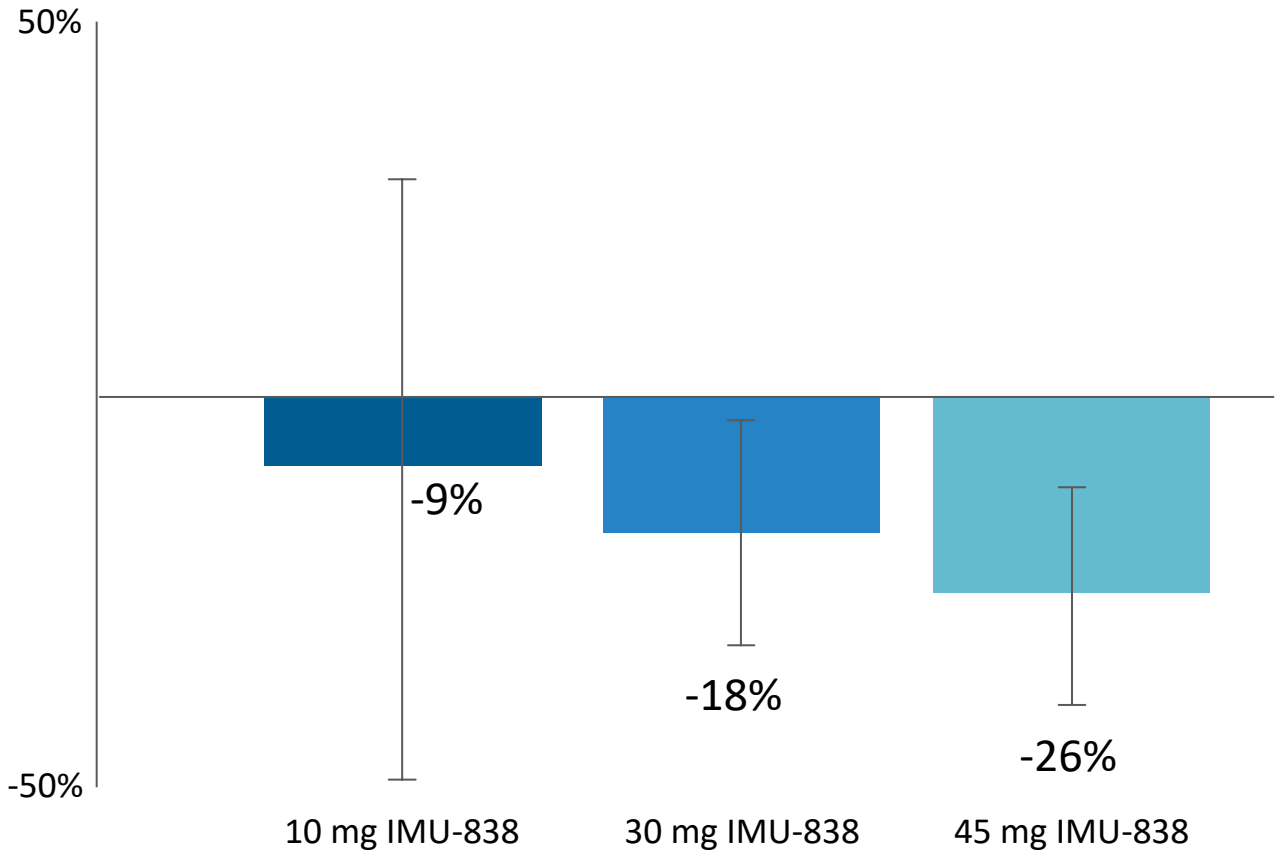
EMPhASIS Trial: Reduction of Serum NfL Concentrations Observed

Versus Placebo After 24 Weeks, Pooled Cohorts 1 & 2



Vidofludimus calcium showed a remarkable reduction in NfL levels in all active doses tested compared with placebo

- The relative change of serum NfL versus placebo is proportional to vidofludimus calcium dose.
- Higher doses are expected to show stronger neuroprotective effects.

Displayed are median values of differences between percentage change of serum neurofilament light chain concentration (Hodges-Lehmann estimation), treatment vs. placebo
Data shows 10 mg versus placebo for Cohort 2 and 30/45 mg versus placebo for Cohort 1; NfL: neurofilament light chain

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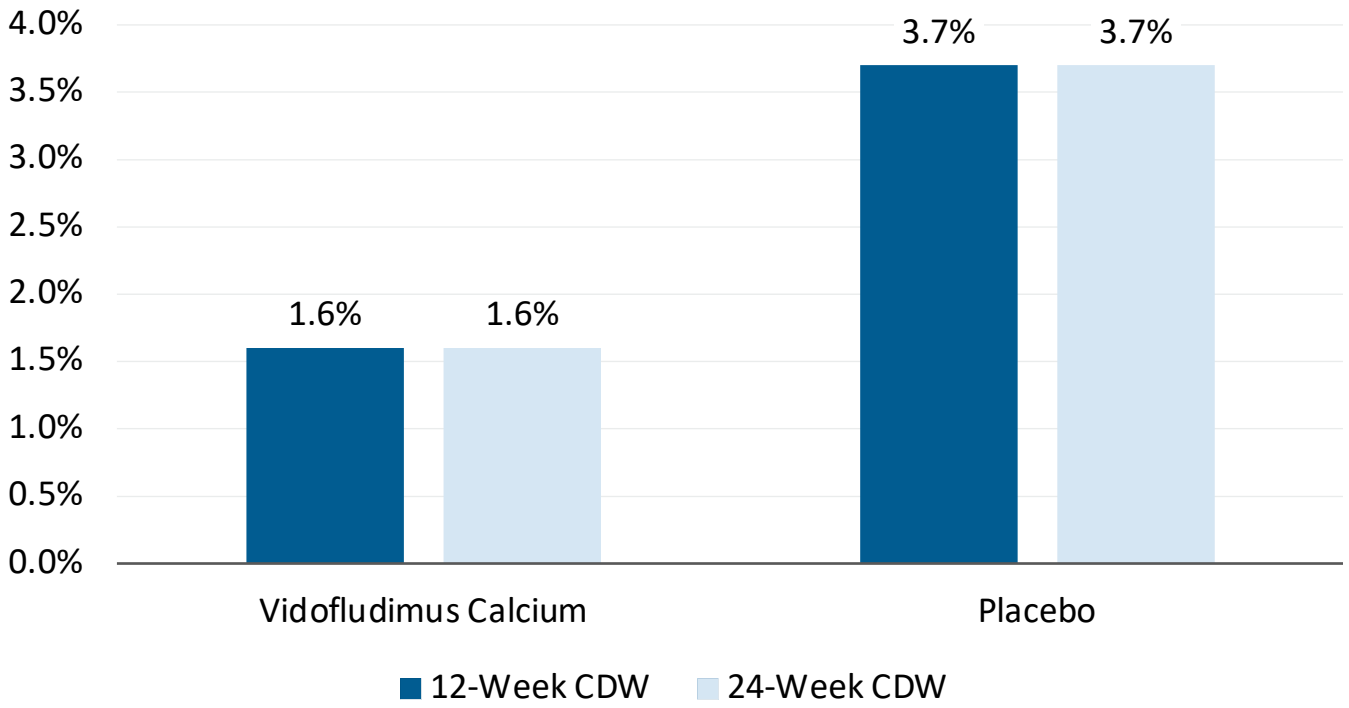
EMPhASIS Trial: Confirmed Disability Worsening Events

End of 24-Week Blinded Treatment Period

CDW Events at the End of the 24-Week Blinded Treatment Period



CDW: confirmed disability worsening; EDSS: Expanded Disability Status Scale
Only disability worsenings with a trigger point during the 24-wek blinded treatment period are considered. The EDSS increases during the blinded treatment phase were subsequently confirmed during open-label extension phase of the trial. Patients at risk in this analysis are 187 for vidofludimus calcium (pooling 10, 30 and 45 mg data) and 81 for placebo. The trigger event is an EDSS progression defined as an increase in the EDSS compared to Baseline of at least 1.5 points if Baseline EDSS = 0, of at least 1.0 points if Baseline EDSS of 1-5, or of at least 0.5 points if Baseline EDSS ≥ 5.5
12-week CDW: The confirmation event is at least 77 days after the trigger event. At the confirmation event and each assessment between trigger and possible confirmation event, EDSS must be at least as high as at the trigger event.
24-week CDW is are defined analogously, the only difference being the time interval between trigger event and confirmation visit, which is at least 161 days.
Full analysis set pooled cohorts 1&2 (N10 = 47, N30 = 71, N45 = 69, NPBO C1 = 69, NPBO C2 = 12)

Data confirms a signal in preventing 12-week and 24-week confirmed disability worsening events as compared to placebo. Confirmatory data will be obtained in the phase 3 ENSURE clinical program.

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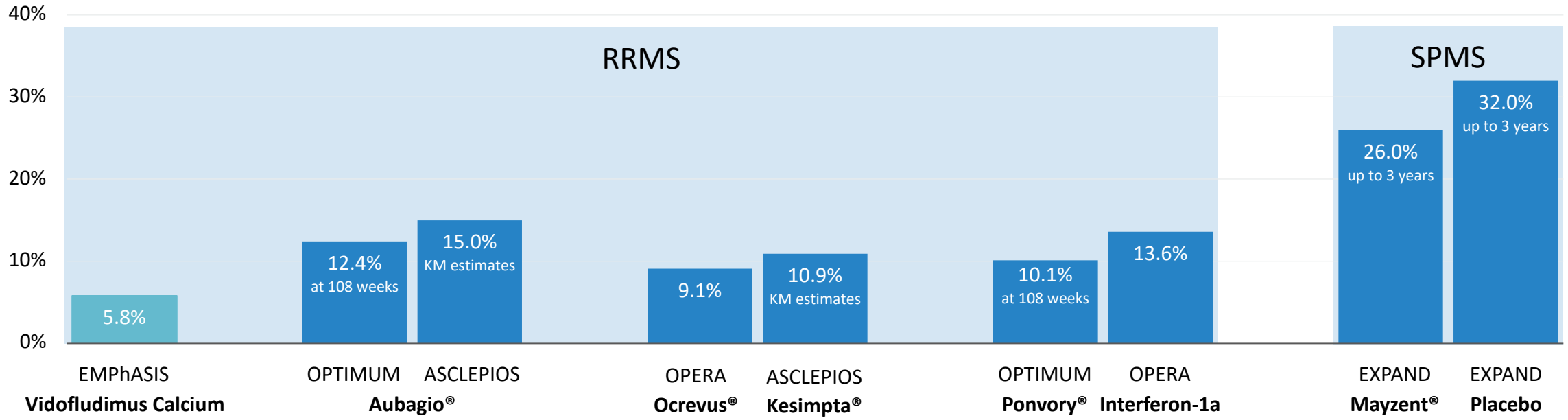
12-Week Confirmed Disease Worsening after 2 Years (96 Weeks)

EMPhASIS Data from OLE Interim Analysis 2022 Compared to Select Historical Trials

Patients With 12-Week/3-Months Confirmed Disability Worsening (% of Patients at Risk)



The trigger event is any EDSS progression during the open-label extension (OLE) period defined as an increase in the EDSS compared to start of the OLE period (Baseline) of at least 1.5 points if Baseline EDSS = 0, of at least 1.0 points if Baseline EDSS of 1-5, or of at least 0.5 points if Baseline EDSS ≥ 5.5. Patients with RRMS at risk in this EMPhASIS analysis are 158 at 96 weeks. Data cut-off was Oct 16, 2022. This includes all patients randomized to either placebo or any dose of vidofludimus calcium during the 24-week blinded treatment period and then continued with open-label treatment with either 30 mg or 45 mg vidofludimus calcium. Survival rates and times estimated by the Kaplan-Meier method. 95% CI for rates based on Greenwood's formula.; 12-week CDW: The confirmation event is at least 77 days after the trigger event. At the confirmation event and each assessment between trigger and possible confirmation event, EDSS must be at least as high as at the trigger event.; 24-week CDW is are defined analogously, the only difference being the time interval between trigger event and confirmation visit, which is at least 161 days.; KM: graphical estimates from published Kaplan-Meier curves; EDSS: Expanded Disability Status Scale; RRMS: relapsing-remitting multiple sclerosis; SPMS: secondary progressive multiple sclerosis. All trials performed in relapsing-remitting Multiple Sclerosis. Except EXPAND trial was performed in patients with active and non-active secondary progressive MS (SPMS).; Vidofludimus Calcium: Immunic data; OPTIMUM: Kappos et al. 2021; ASCLEPIOS: Hauser et al. 2020; EXPAND: Kappos et al. 2018; ULTIMATE: Steinman et al. 2022; OPERA: Hauser et al. 2017

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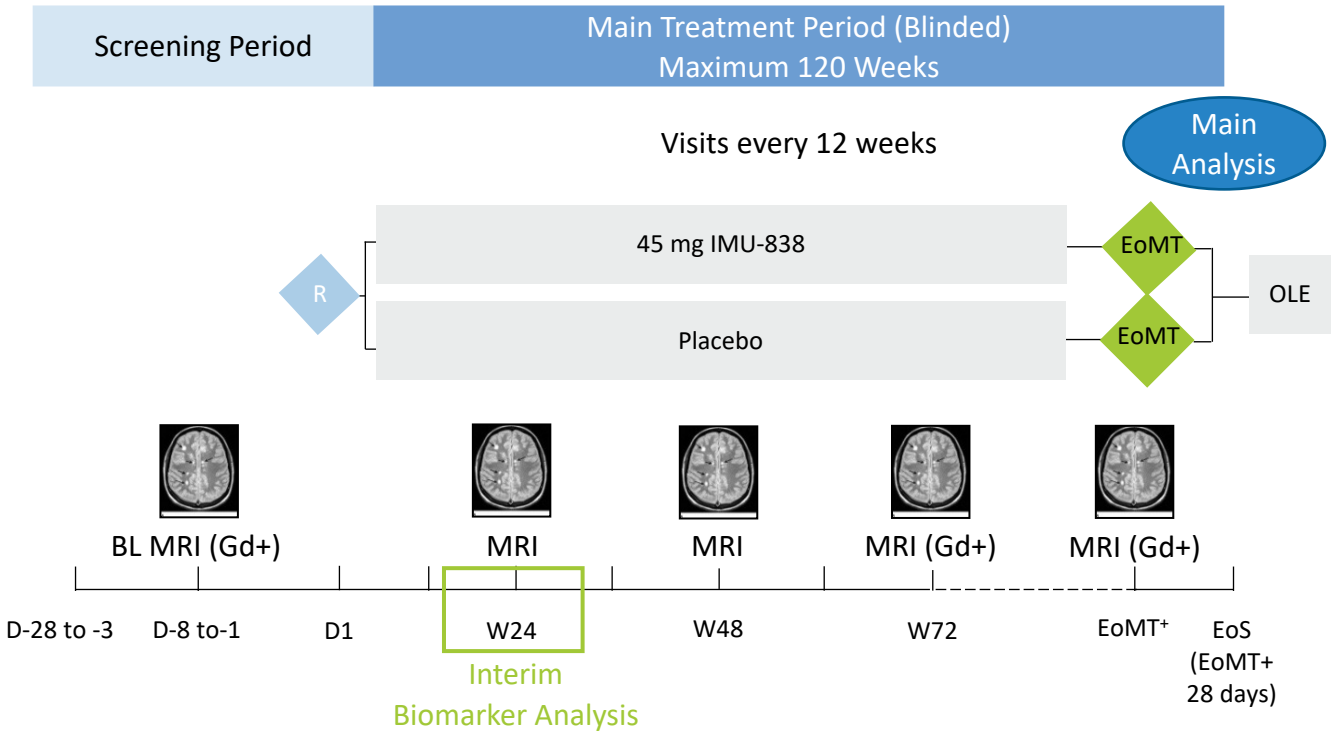
CALLIPER: Ongoing Phase 2 Clinical Trial in Progressive Multiple Sclerosis (PMS)



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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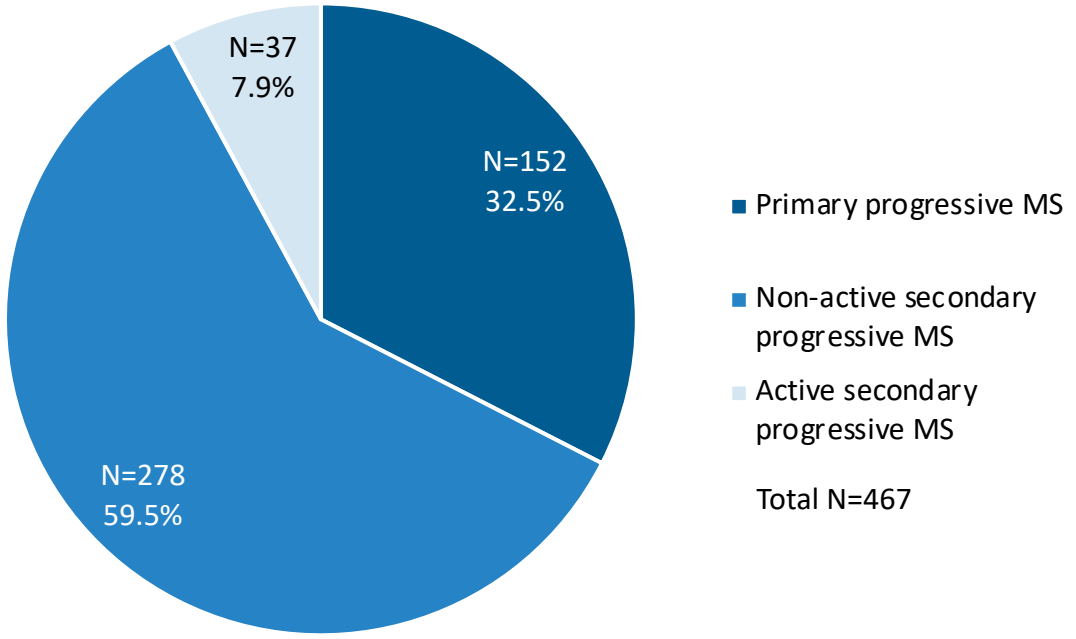
CALLIPER: Patient Demographics and Baseline Characteristics

Total Study Population of 467 Enrolled Patients

Progressive Disease Subtypes

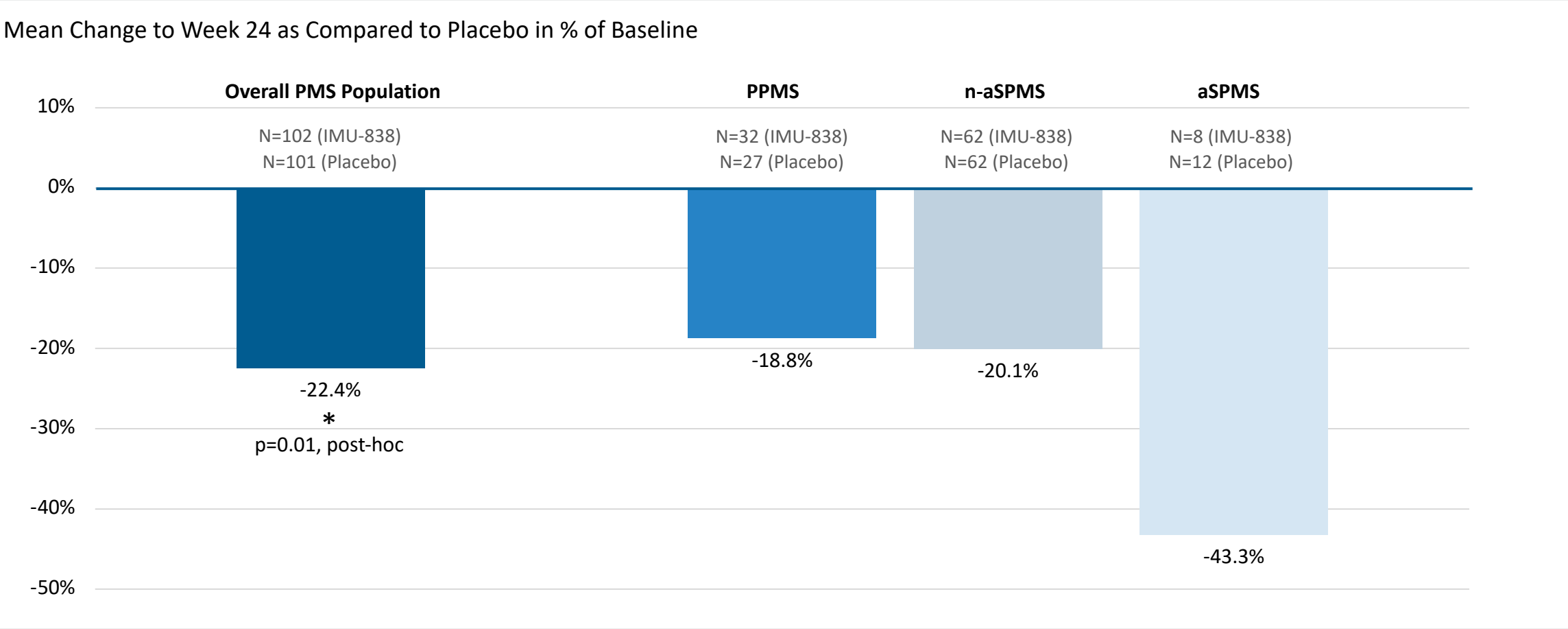


Baseline Characteristics

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 months, median (min-max)	0.0 [0-1]

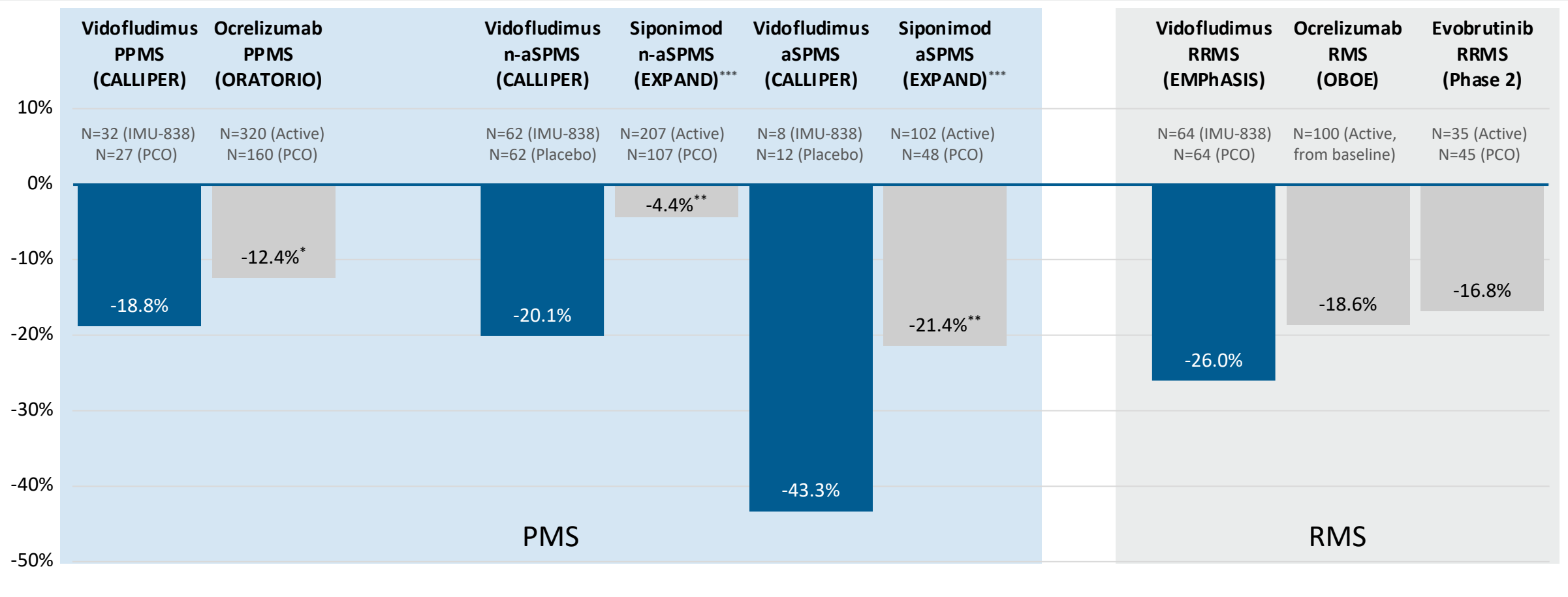
Disease subtype information are used as diagnosis entered by investigator at study entry
BMI: body mass index; SDMT: Symbol Digit Modalities Test; EDSS: Expanded Disability Status Scale

Interim Biomarker Analysis: 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

Interim Biomarker Analysis: NfL Reduction Compares Favorably with Other MS Therapies



CALLIPER: 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, geometric mean; *** 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

Unrivaled Safety and Tolerability Profile Observed in Multiple Clinical Trials

- Safety profile similar to placebo: no general safety signals observed in clinical trials so far
- No increased rates of diarrhea, neutropenia, or alopecia
- No increased rates of infections and infestations or hematology values
- Drug exposure tested in more than 1,800 human subjects and patients, to date
- Low rates of adverse events
- No signals for hepatotoxicity or elevations of liver enzymes and no Hy's law cases observed

Vidofludimus Calcium's Safety Profile to Date is Unique

	PML risk	Increased number of infections	Vaccination limitations	Gastrointestinal toxicities, incl. diarrhea	Cardiovascular risks, incl. blood pressure	Lymphopenia	Neutropenia	Risk of liver injury	Increased risk of cancer	Macular edema
Vidofludimus Calcium	●	●	●	●	●	●	●	●	●	●

● Favorable profile

PML: progressive multifocal leukoencephalopathy

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Straightforward Approval Strategy in Multiple Sclerosis

Enables Clear Demonstration of Effect on Smoldering MS

Phase 3 ENSURE Program in RMS[1]

- Two identical pivotal trials in RMS patients
- Goal: Low risk clinical program for regulatory approval of vidofludimus calcium
- Dosage: 30 mg vidofludimus calcium QD

Phase 2 CALLIPER Trial in PMS[2]

- Phase 2 trial in PMS patients
- Goal: Demonstrate vidofludimus calcium's potential for neuroprotective activity in a non-relapse setting
- Dosage: 45 mg vidofludimus calcium QD

Intended to Provide a Straightforward Path Towards Potential Regulatory Approval:

- Immunic believes that the phase 3 ENSURE program provides a straight-forward path towards regulatory approval of vidofludimus calcium in RMS.
- CALLIPER is designed to corroborate vidofludimus calcium's neuroprotective potential to support the drug's unique profile.

[1] ClinicalTrials.gov: NCT05134441 & NCT05201638; [2] ClinicalTrials.gov: NCT05054140
RMS: relapsing multiple sclerosis; PMS: progressive multiple sclerosis; QD: quaque die = once-daily

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IMU-856

Restoring a Healthy Gut through Renewal of the Bowel Wall

IMU-856 Could Be the Perfect New Solution for Treating Gastrointestinal Disorders Without Harming the Immune System

- Innovative oral therapeutic approach applicable to a broad range of gastrointestinal disorders
- Targets physiological intestinal epithelial regeneration
- Achieves gut wall healing without immunosuppression

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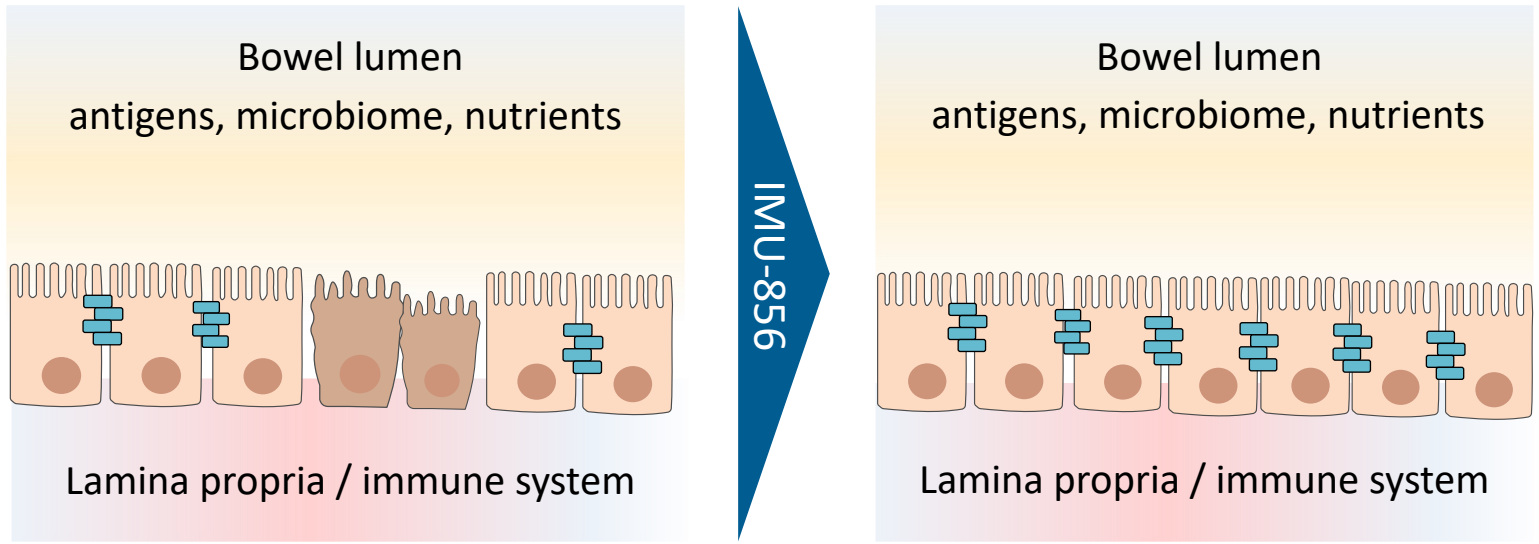
Once-Daily, Oral IMU-856 Aims to Regenerate the Gut Wall and Barrier Function by a New Innovative Targeted Mechanism



IMU-856:

- First-in-class modulator of sirtuin 6 (SIRT6), targets physiological intestinal epithelial regeneration and restoration of barrier function
- Provides protection and enhances transport of nutrients
- This new approach avoids immunosuppression

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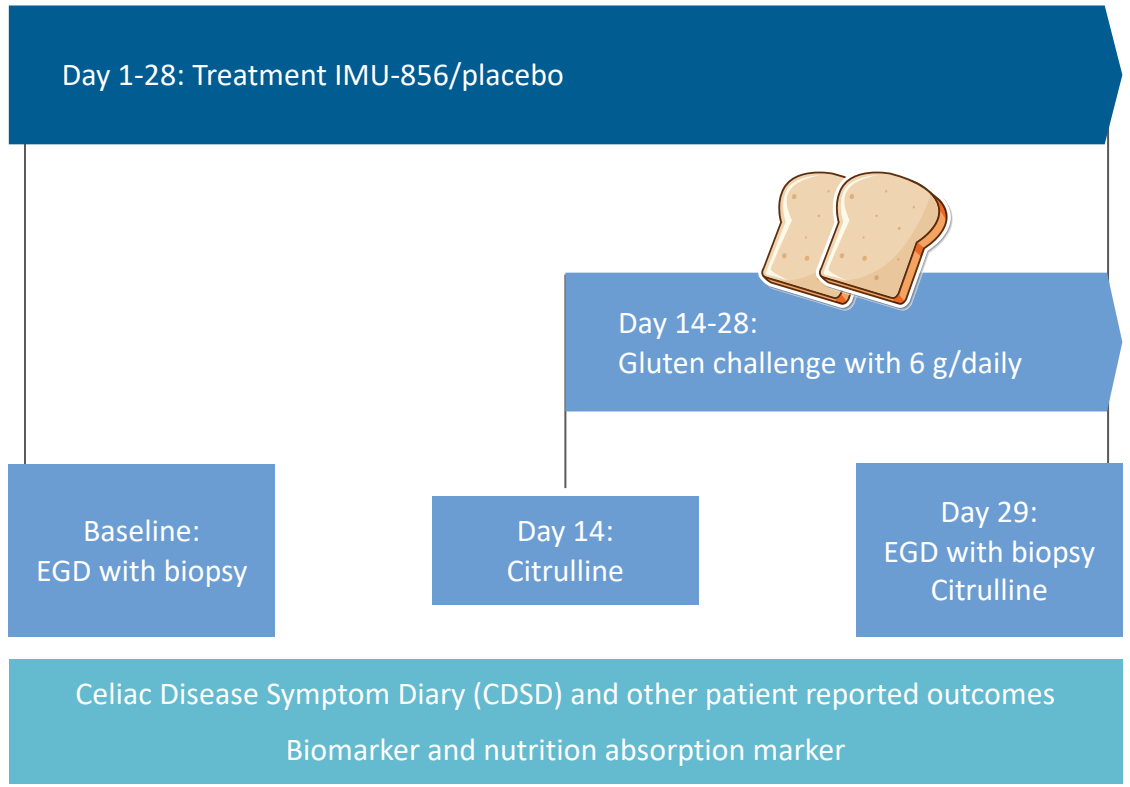
IMU-856 Demonstrated Clinical Proof-of-Concept in a Phase 1b Clinical Trial in Celiac Disease

Proof-of-Concept Study Designed as a Gluten Challenge Trial

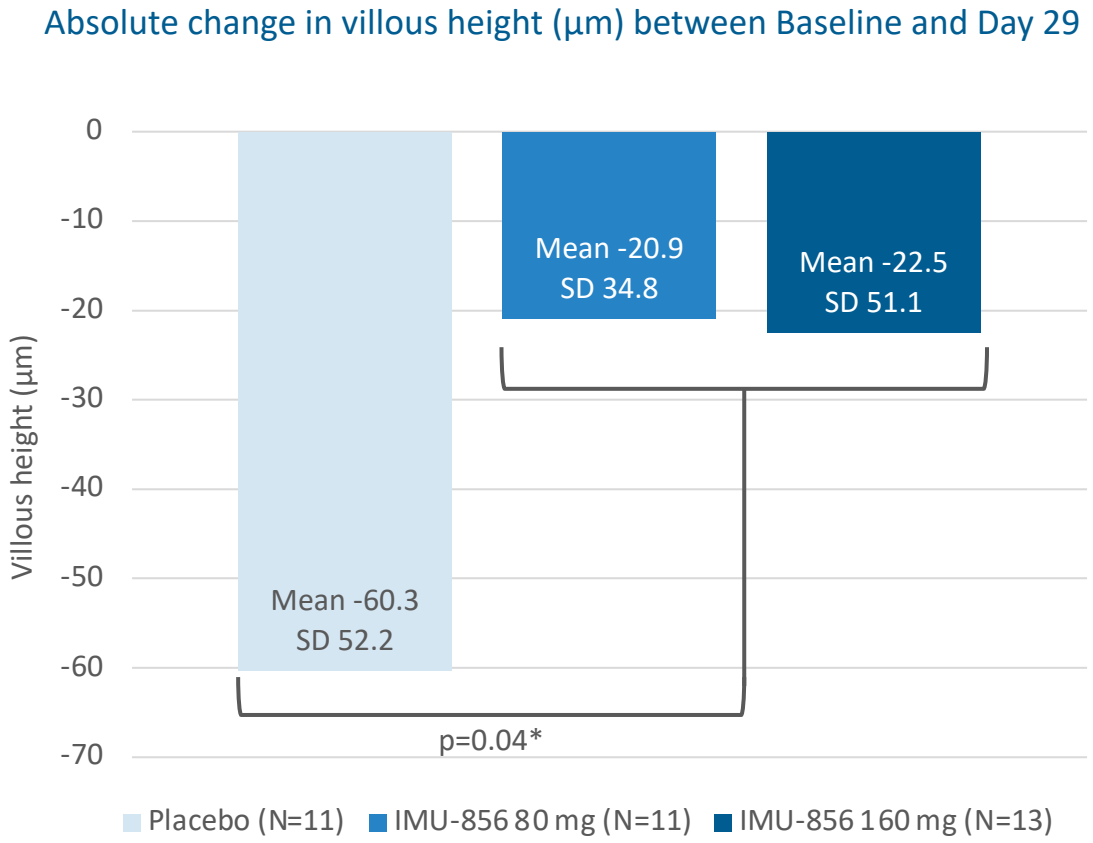
- **Celiac disease used as disease model to provide clinical proof-of-activity of IMU-856 in a 28-day trial setting**
- Designed to explore effects of gluten challenge in a celiac disease patient population
- Dosing: 80 and 160 mg QD of IMU-856, or placebo
- 43 patients enrolled (IMU-856: N=29)
- Assessed safety, tolerability, pharmacokinetics, and pharmacodynamics of IMU-856
- Proof-of-concept: measured histological changes, blood biomarkers of epithelial mass, nutrient uptake and disease-related symptoms

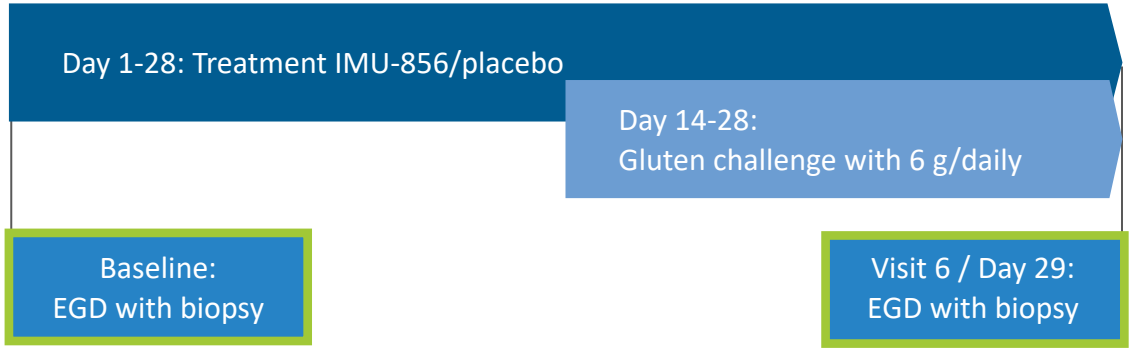
Flow Chart of Phase 1b Clinical Trial in Celiac Disease



QD: quaque die = once-daily; EGD: esophagogastroduodenoscopy

IMU-856 Protected Against Gluten-Induced Decrease in Villous Height as Compared to Placebo



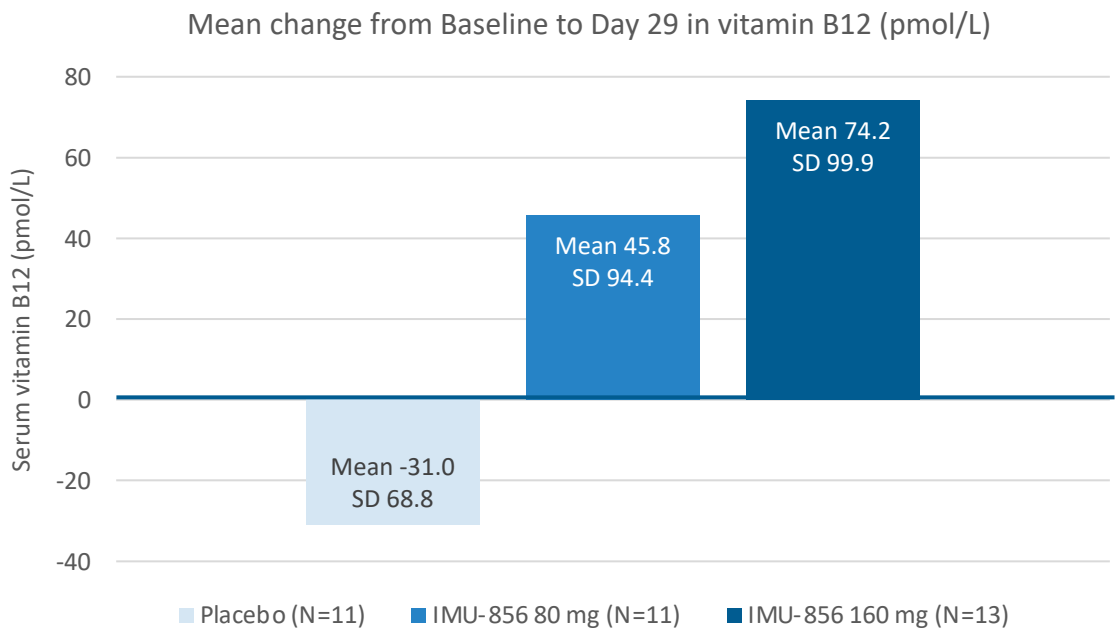


- Substantial protection for IMU-856 treatment groups as compared to placebo
- Reached statistical significance* for this objective readout which is known to be relevant to influence future medical complications of celiac disease
- Assessed by central pathology laboratory and blinded pathology reader

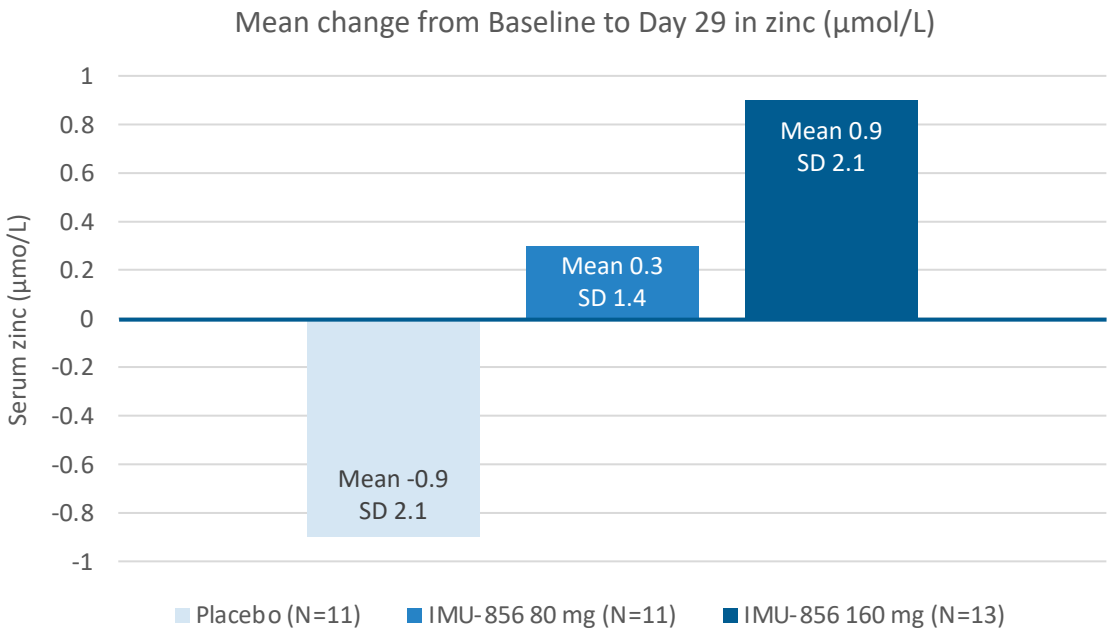
* Wilcoxon Two-Sample Test comparison between pooled IMU-856 groups and placebo, performed as post-hoc exploratory statistical analysis
Disease Analysis Set: N=35/43 included in histology analysis set. 8 patients not included in this analysis due to early termination. Gluten Challenge for 15 days with 6 g daily. Central pathology laboratory: Jilab Inc. Tampere, Finland
EGD: esophagogastroduodenoscopy; SD: standard deviation

IMU-856 Treatment Resulted in Enhanced Uptake of Actively Transported Essential Nutrients Vitamin B12 and Zinc

Vitamin B12



Zinc



SD: standard deviation

IMU-856 Uniquely Suited for Potential Use in a Broad Spectrum of Serious Gastrointestinal Diseases

Demonstrated clinical proof-of-concept: Positive effects shown in a phase 1b clinical trial on **gastrointestinal architecture and function** applicable to multiple diseases with histological damage

Celiac Disease
>2 million patients[1]

- High unmet medical need, currently no approved drugs
- Phase 2 trial to demonstrate histological and functional improvement in patients with ongoing active celiac disease

Inflammatory Bowel Disease
>1 million patients[2]

- Potential synergies in combination with IL-23 or anti-integrin treatments to break efficacy ceiling

Short Bowel Syndrome
High-value orphan indication

- High unmet medical need indication with large commercial potential
- Potential for rapid assessment in a small study

[1] https://www.niddk.nih.gov/health-information/digestive-diseases/celiac-disease/definition-facts [2] Lewis JD, et al. Gastroenterology. 2023;165(5):1197-1205.e2

Immunic THERAPEUTICS

Immunic Therapeutics

Summary

Summary: Advanced Pipeline of Next-Generation Oral Therapies

Advanced clinical pipeline:

well-differentiated investigational medicines in various phases of clinical development

RMS phase 3 program of vidofludimus calcium ongoing

intended to provide a straightforward path towards regulatory approval

PMS phase 2 trial of vidofludimus calcium ongoing

designed to corroborate vidofludimus calcium's neuroprotective potential

Vidofludimus calcium active in UC:

maintenance therapy in moderate-to-severe UC patients showed significant benefit in clinical remission

IMU-856 for intestinal barrier function:

demonstrated clinical proof-of-concept in phase 1b trial in celiac disease; in preparations for phase 2 testing

Cash runway into Q3/2025

Cash position: USD 46.7 million (as of Dec 31, 2023) plus up to USD 240 million raised in January 2024

Summary: Several Clinical Value Inflection Points Ahead

IMU-838 in PMS	▪ Readout phase 2 CALLIPER trial estimated for April 2025
IMU-838 in RMS	▪ Interim futility analysis phase 3 ENSURE program estimated for late 2024 ▪ Readout first phase 3 ENSURE trial estimated for Q2/2026, second in H2/2026
IMU-856	▪ Phase 2 clinical trial in preparation ▪ Applicable to a multitude of gastrointestinal disorders

Immunic THERAPEUTICS

Thank You!

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