Immunic Therapeutics

IMU-838 Phase 2 Data EMPhASIS Trial in RRMS

NASDAQ: IMUX | September 14, 2020

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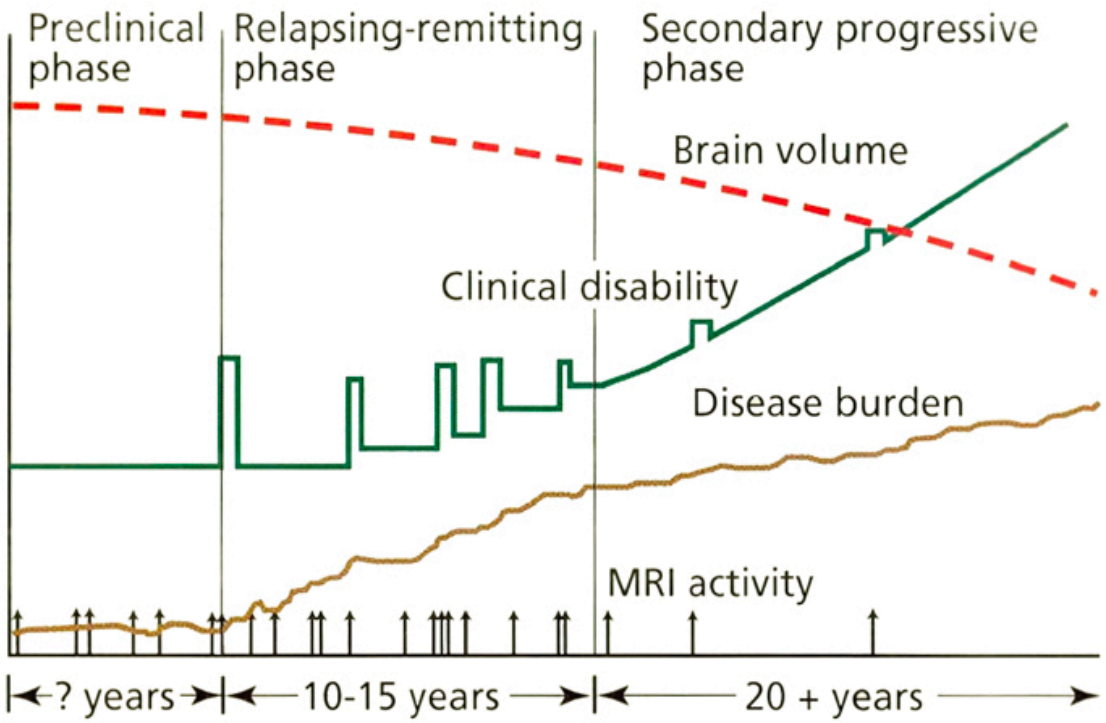
Forward-looking statements included in this presentation are based on information available to Immunic as of the date of this presentation. Immunic does not undertake any obligation to update such forward- looking statements except as required by applicable law.

Targeting Multiple Sclerosis (MS)

IMU-838 is Intended to be a Selective, Once-Daily Medication for RRMS Patients With a **Well-Balanced Combination of Favorable Safety and Convenience Profile with Robust Clinical Activity**

Treatment Compliance and Persistence are Important Considerations for Life-Long Diseases such as MS

MS Disease Course[1]



Nonadherence or Nonpersistence of MS Treatments Can Lead to Greater Risk for Negative Clinical Outcomes[2]

- Real-life 12-months discontinuation rates of MS treatments

	USA[3]	Canada[4]
Fingolimod	26%	24%
Dimethyl fumarate	44%	30%
Teriflunomide	50%	25%
Natalizumab	N/A	29%

For a life-long disease, patients require easy, convenient and safe therapies that allow them to avoid treatment interruptions.

[1] Adapted from Fox RJ, Cohen JA: Multiple sclerosis: the importance of early recognition and treatment. Cleve Clin J of Med, 2001; 68:157–70
[2] Tan H, et al. Impact of adherence to disease-modifying therapies on clinical and economic outcomes among patients with multiple sclerosis. Adv Ther. 2011;28(1):51-61
[3] Johnson et al., J Manag Care Spec Pharm. 2017;23(8):844-52
[4] Duquette P, Yeung M, Mouallif S, Nakhaipour HR, Haddad P, Schecter R 2019 PLoS ONE 14(1): e0210417. https://doi.org/10.1371/journal.pone.0210417

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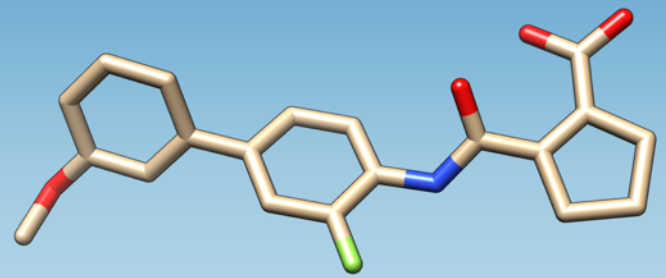
IMU-838 Positioned to be a New Safe and Efficacious Treatment Option for Early RRMS Patients

IMU-838 could provide RRMS patients with a **distinctive combination of robust efficacy combined with favorable safety and tolerability** due to uniquely blending of properties:



1. **Robust MRI lesion suppression of IMU-838** compares favorably to other first-line and oral base medications commercially available in RRMS.
2. **Very low discontinuation rate** for IMU-838 treated RRMS patients, substantially below placebo, indicates an encouraging combination of tolerability and efficacy.
3. **Absence of hepatotoxicity signals** and other relevant adverse events leading to discontinuations distinguishes IMU-838 well from other oral RRMS treatments.
4. **A robust decrease in serum neurofilament light chain**, a biomarker for axonal damage, was observed in both IMU-838 arms but not in the placebo arm and provides evidence of IMU-838's potential neuroprotective activity.

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EMPhASIS: Phase 2 Study Overview in RRMS

Coordinating Investigator

Robert Fox (Cleveland Clinic)

Included Patient Population: RRMS With Relevant Disease Activity

- Male or female (18 ≥ age ≤ 55)
- RRMS diagnosis (Revised McDonald criteria 2017)
- Evidence of disease activity based on relapse and MRI criteria
- Baseline EDSS: 0 ≥ EDSS ≤ 4.0
- Performed in Central and Eastern Europe

Blinded Treatment Period

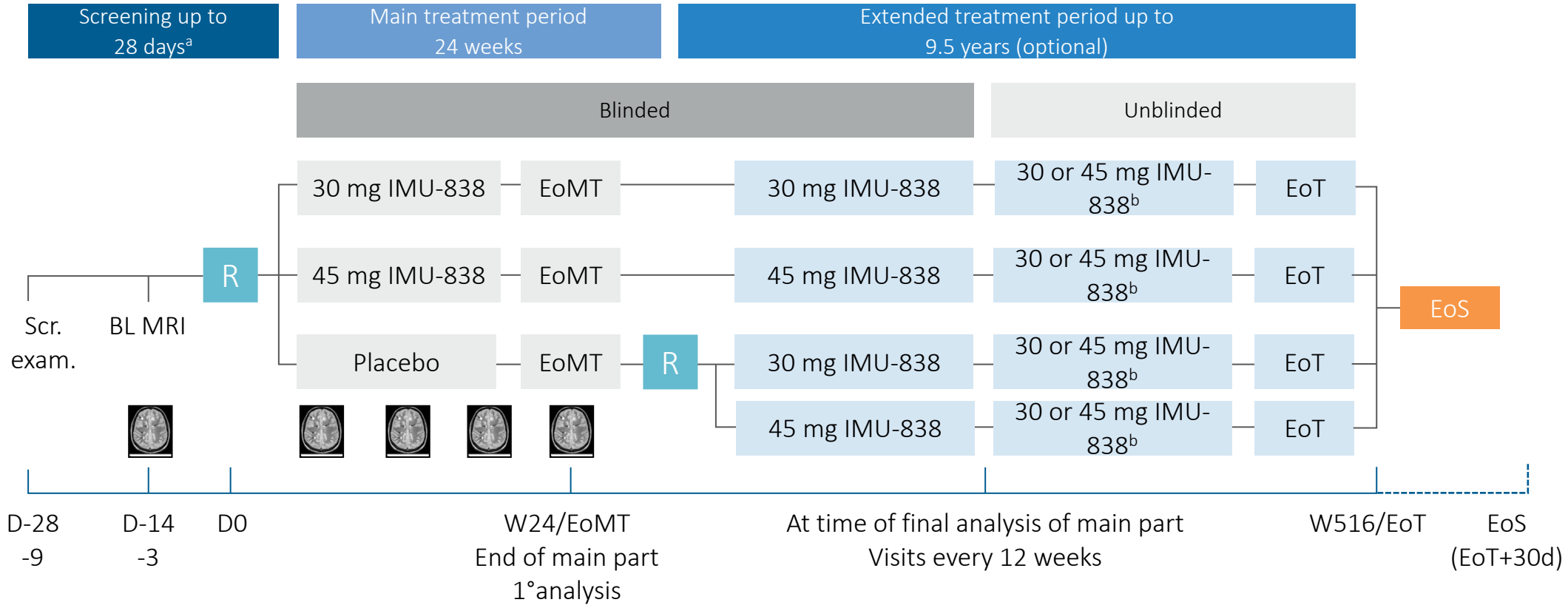
- Parallel group design with placebo control
- Overall blinded treatment period of 24 weeks
- MRI every six weeks

Extended Treatment Period

- Up to 9.5 years
- Extension study to observe long-term safety

www.clinicaltrials.gov: NCT03846219

EMPhASIS: Phase 2 Trial Design in RRMS



Key study endpoints: to evaluate the **cumulative number of new combined unique active lesions up to Week 24**

- **Primary endpoint: 45 mg IMU-838 vs. placebo**
- **Key secondary endpoint: 30 mg IMU-838 vs. placebo**

a) Can be interrupted/extended, if the baseline MRI must be repeated due to poor quality (to be done as soon as possible). If results of the central MRI assessment are not available in time for randomization, the screening period can be extended by up to 7 days, if needed.
b) After unblinding of the main treatment period, the investigator can decide with the patient if and at which dose the treatment will be continued.
BL = baseline; exam. = examination; D = day; EoMT = end of main treatment; EoS = end of trial; EoT = end of treatment; MRI = magnetic resonance imaging; R = randomization; Scr. = screening; W = week

Phase 2 Data EMPhASIS Trial

Efficacy

Study Met Primary and Key Secondary Endpoints

High Statistical Significance and Robust Results Regarding Suppression of CUA MRI Lesions

		Analysis Set	IMU-838	Placebo	Suppression of CUA MRI Lesions IMU-838 vs. Placebo	p-value (1-sided)
Primary Endpoint	45 mg IMU-838 vs. Placebo	Full Analysis Set*	N=69	N=69	**62%**	**0.0002**
Key Secondary Endpoint	30 mg IMU-838 vs. Placebo	Full Analysis Set*	N=71		**70%**	**<0.0001**

Robust efficacy demonstrated for both investigated doses of IMU-838 with high statistical significance.

CUA MRI Lesions: combined unique active magnetic resonance imaging lesions. Sum of the number of all new Gadolinium-enhanced lesions on T1-weighted magnetic resonance imaging (MRI) and the number of all new or substantially enlarged lesions on T2-weighted MRI (non-enhancing on T1-weighted MRI), avoiding double counting.

Estimates are adjusted for baseline volume of T2 lesions, MRI field strength (1.5 or 3.0 Tesla), 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 IMP dose to date of last MRI assessment is used as offset term.

*The Full Analysis set is the primary statistical analysis set as recommended as intent-to-treat (ITT) analysis by regulatory guidance. As per the pre-defined statistical analysis plan, it contains the data of all randomized patients who received at least one dose of IMP, analysis of all data as randomized and includes imputation of missing values.

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Study Results 1: Robust Efficacy

The **Robust MRI Lesion Suppression of IMU-838** Compares Favorably to Other First-Line and Oral Base Medications Commercially Available in RRMS.*

	IMU-838	IMU-838	Glatiramer acetate[1]	Teriflunomide[2]	Dimethyl fumarate[3]	Fingolimod[4]	Siponimod[5]
Administration	Oral	Oral	Injectable	Oral	Oral	Oral	Oral
Daily dose	45 mg QD	30 mg QD	20 mg QD	14 mg QD	240 mg TID	1.25 mg QD	2 mg QD
MRI Endpoint	Cumulative CUA lesions	Cumulative CUA lesions	Cumulative Gd lesions	Mean CUA lesions/scan	Cumulative Gd lesions	Cumulative Gd lesions	Cumulative CUA lesions
Treatment Duration	24 weeks	24 weeks	9 months	36 weeks	24 weeks	6 months	3 months
Suppression of MRI Activity	**62%**	**70%**	**29%**	**61%**	**69%**	**43%**	**70%**

*The table summarizes the data on treatment/study discontinuation rates of the commercial dose in phase 2 trials of RRMS drugs. If the commercial dose was not included in the phase 2 trials, the dose closest to the commercial dose was shown. This high-level comparison is provided for illustrative purposes only, is based on publicly available data and does not purport to be a comprehensive comparison or depiction of the other trials. Larger data sets than are presented in this presentation are publicly available for certain of the compounds included on this slide. Please note that these results are taken from placebo-controlled trials, and these medications have not been tested in head-to-head assessments.

QD: quaque die = once-daily, TID: ter in die = three times daily

[1] Comi et al. Ann Neurol. 2001;49(3):290-297. [2] O'Connor et al. *Neurology*. 2006;66(6):894-900. [3] Kappos et al. Lancet. 2008;372(9648):1463-1472.. [4] Kappos et al. N Engl J Med. 2006;355(11):1124-1140. [5] Selmaj et al. Lancet Neurol. 2013;12(8):756-767.

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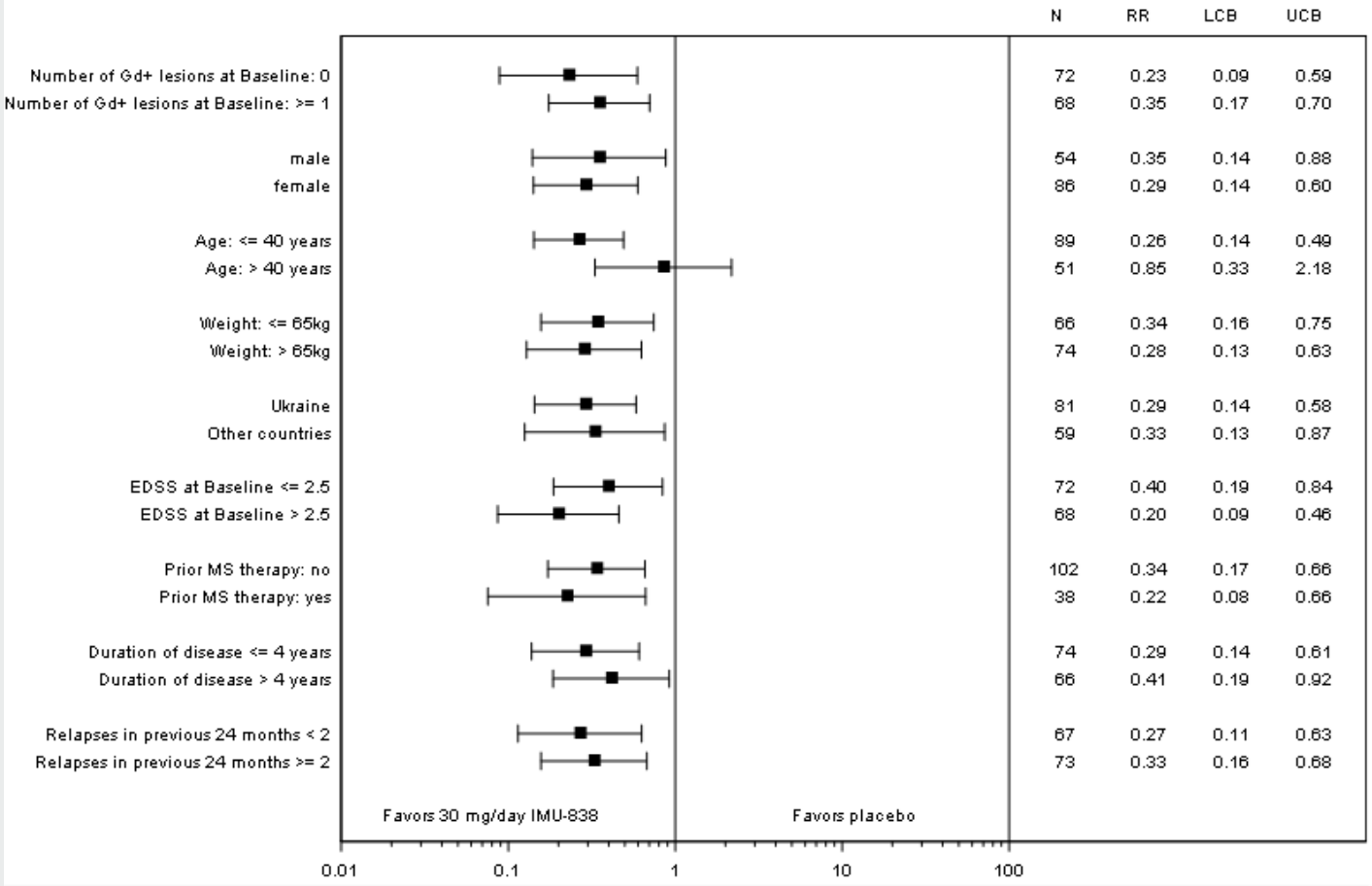
Subgroup Analysis CUA MRI Lesions 30mg IMU-838

Forest Plot



Efficacy effects of IMU-838 observed across many subgroups.

N: Number of Patients, RR: Rate Ratio, LCB: Lower 95% confidence bound, UCB: Upper 95% confidence bound

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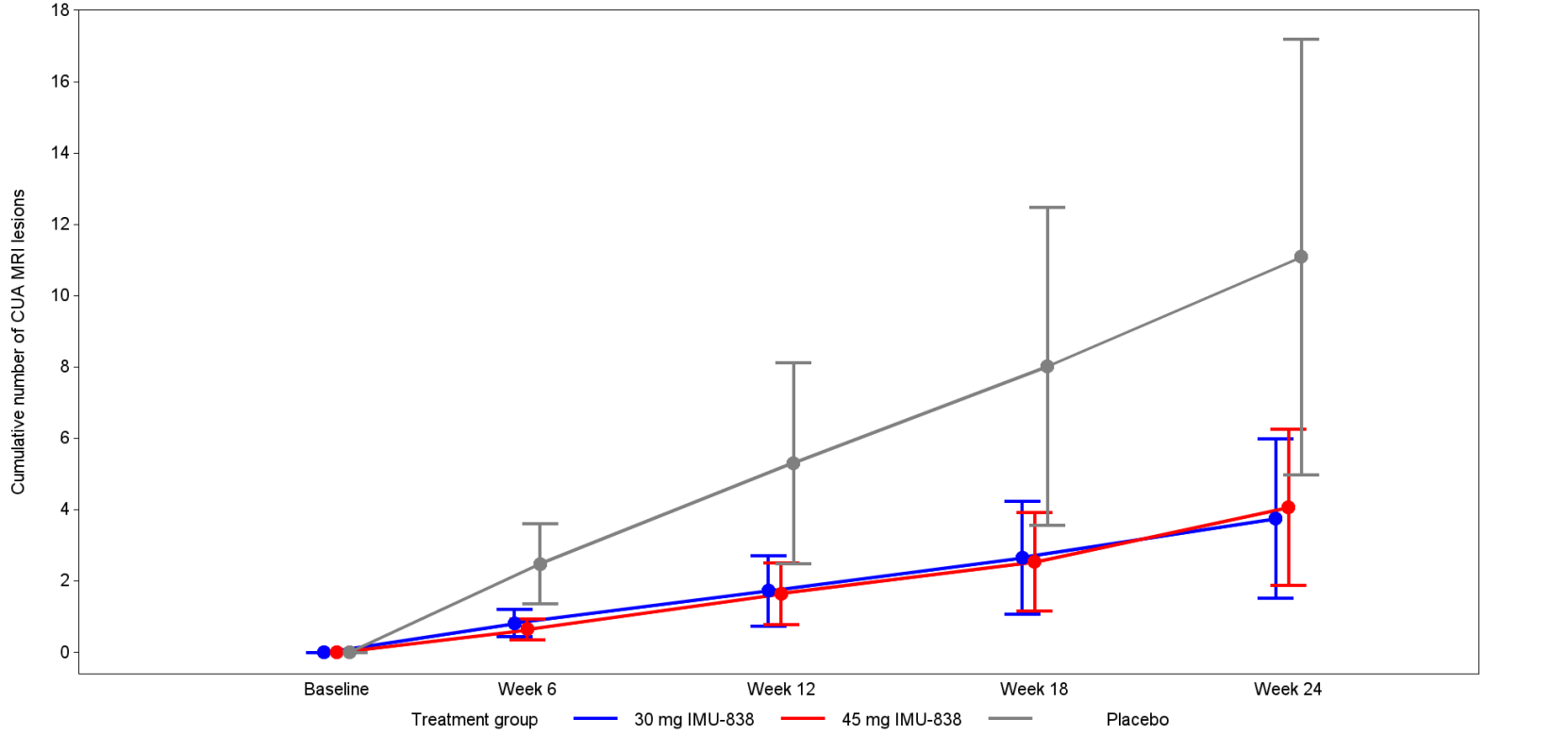
MRI: Cumulative Number of CUA MRI Lesions

Time Course



	30mg IMU-838	45mg IMU-838	Placebo
1.5T MRI	N=65	N=66	N=67
3T MRI	N=6	N=3	N=2

Effect of IMU-838 on MRI lesion suppression can be observed already at early time points.

Estimates are adjusted for baseline volume of T2 lesions, MRI field strength (1.5 or 3.0 Tesla), 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 IMP dose to date of last MRI assessment is used as offset term. The graph shows adjusted means of each treatment group and 95% confidence intervals.

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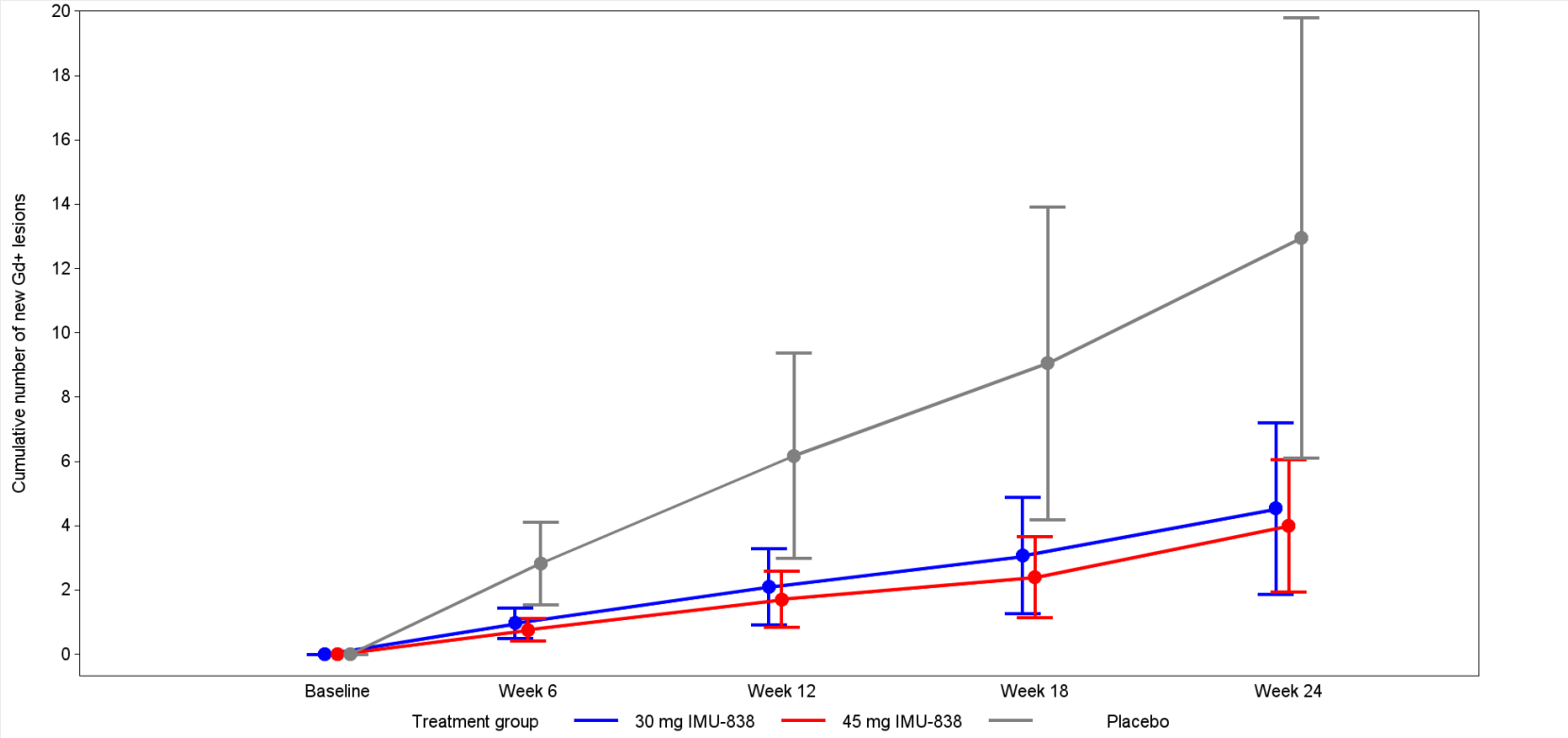
MRI: Cumulative Number of New Gd-Enhancing MRI Lesions

Time Course



	30mg IMU-838	45mg IMU-838	Placebo
1.5T MRI	N=65	N=66	N=67
3T MRI	N=6	N=3	N=2

Robust effect of IMU-838 on MRI lesion suppression can also be observed for Gd+ lesions.

The graph shows adjusted means of each treatment group and 95% confidence intervals.
Estimates are adjusted for MRI field strength (1.5 or 3.0 Tesla) 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 IMP dose to date of last MRI assessment is used as offset term.

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Secondary Endpoints: Relapse-Related Endpoints

Effect on Annualized Relapse Rate (ARR)

Treatment Group	N	Number of Relapses	Adjusted Mean ARR
30 mg IMU-838	71	13	0.39
45 mg IMU-838	69	16	0.48
Placebo	69	18	0.53

Despite the study's relatively small sample size and short duration of blinded treatment (24 weeks), a positive signal on ARR was detected.

Number of confirmed relapse events in each treatment arm were N=2 (30mg IMU-838), N=4 (45 mg IMU-838) and N=5 (Placebo).

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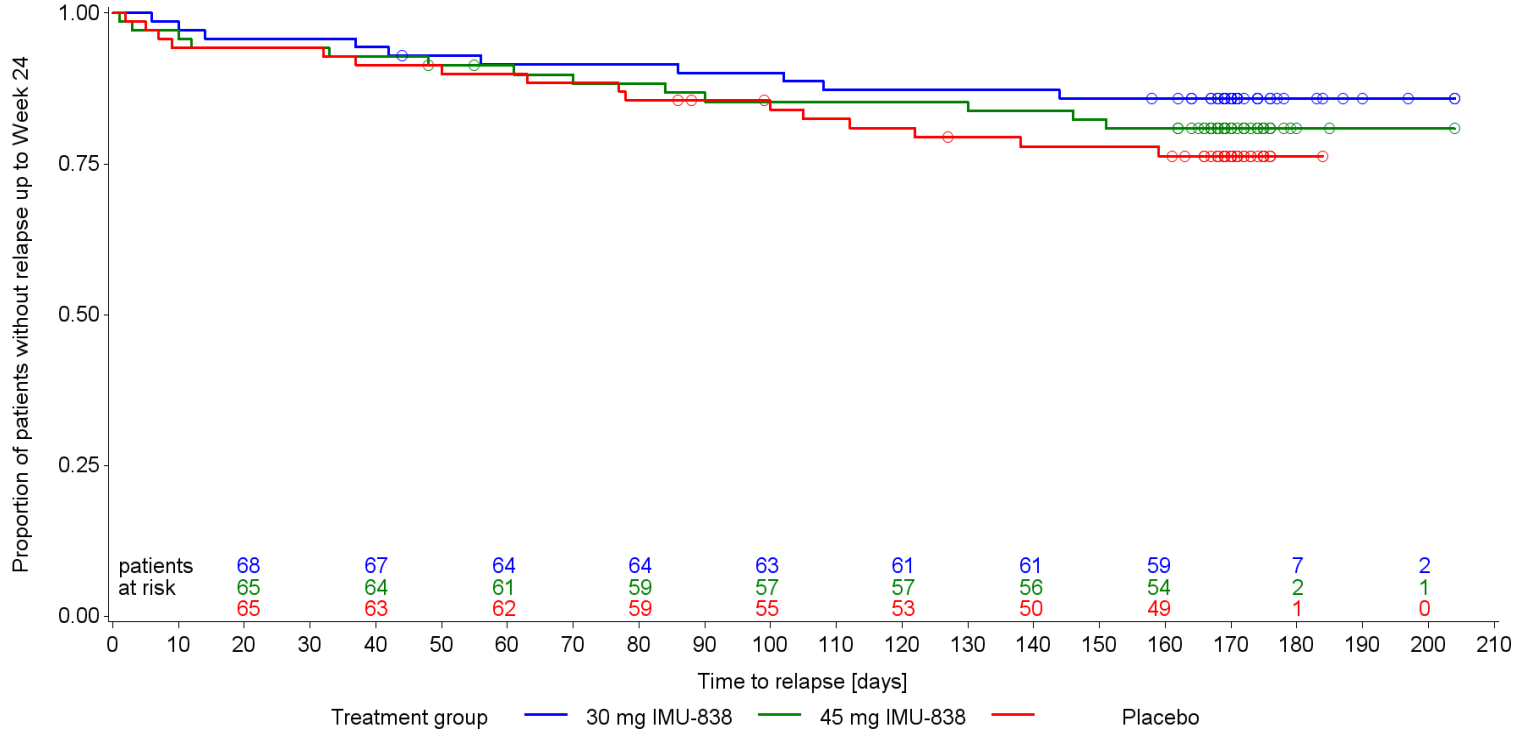
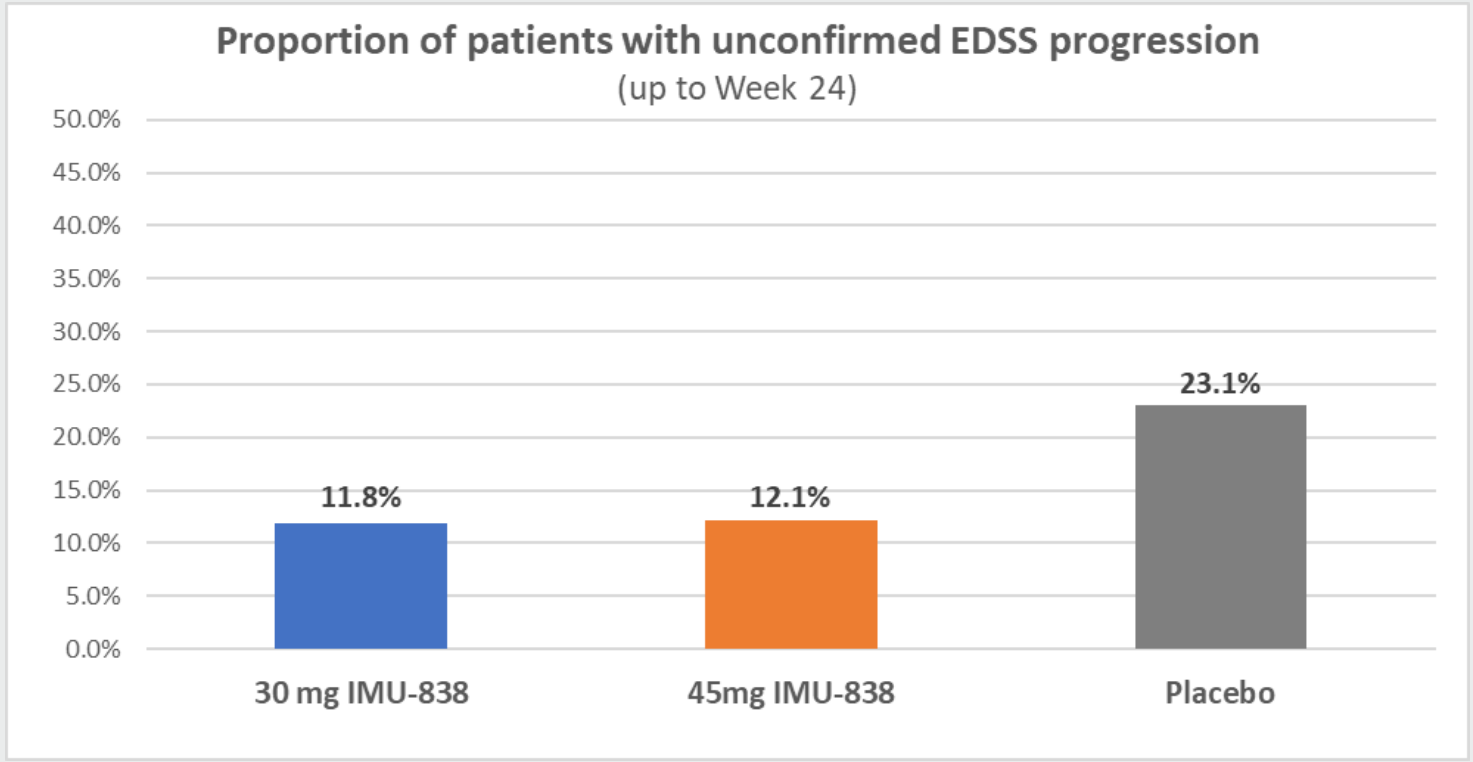
Time to Relapse
Kaplan Meier Analysis



Despite the study's relatively small sample size and short duration of blinded treatment (24 weeks), a positive signal on time to relapse was detected.

For patients with relapse up to Week 24 the time to first relapse is calculated as date of first relapse - date of first IMP.
Patients without relapse up to Week 24 were censored at the last visit date during the main treatment period, i.e. censoring time is calculated as last visit date - date of first IMP + 1.
Censored observations are marked with circles.

Unconfirmed Disability Progression Up to Week 24



Despite the study's relatively small sample size and short duration of blinded treatment (24 weeks), a positive signal on unconfirmed disability was detected.

EDSS progression is defined as an increase of the EDSS score compared to baseline of at least 1.0 point for patients with a baseline EDSS score of 1 to 4.0 or of at least 1.5 points for patients with a baseline EDSS score of 0. There is no confirmation of EDSS progression in this trial due to its short duration.
Patients with missing assessments at Week 24 without a progression at any time are set to missing.

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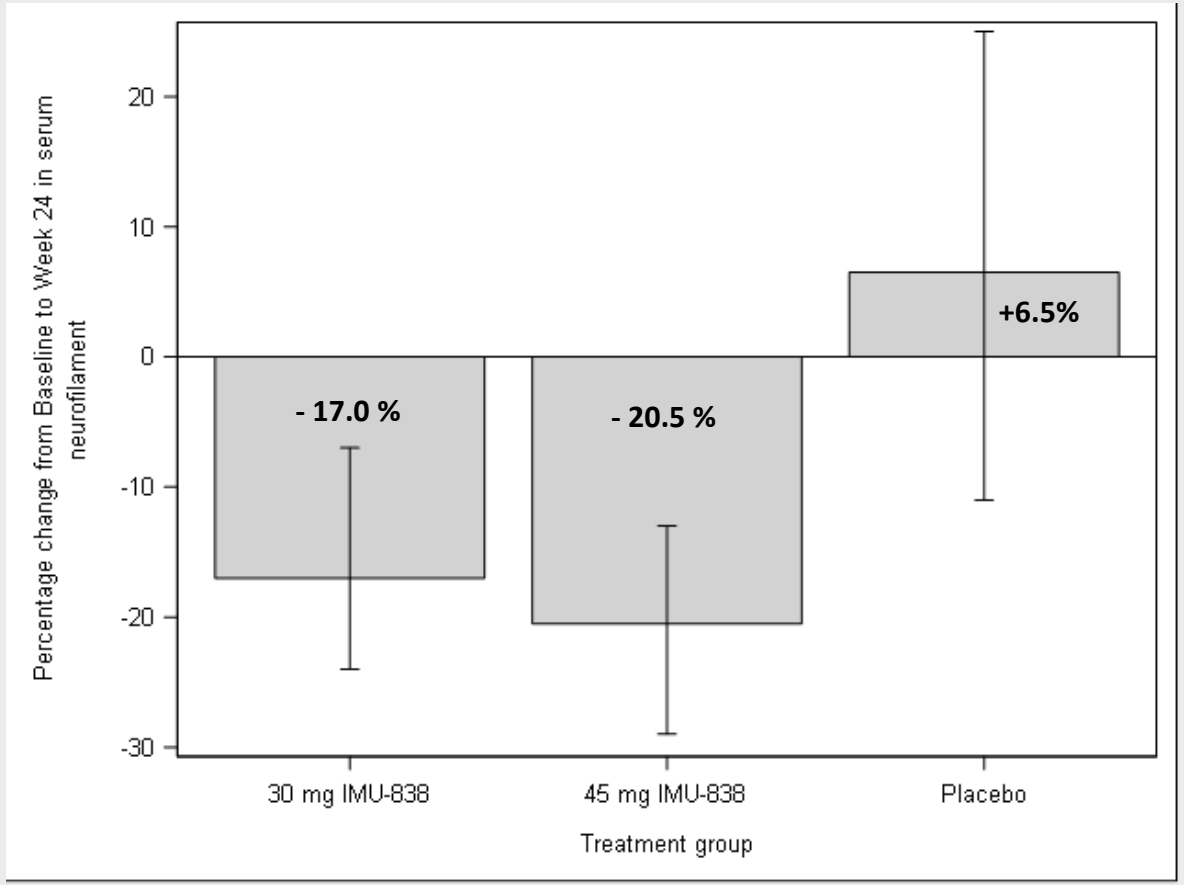
Neurofilament Light Chain in Serum

Biomarker for Axonal Damage



Robust decrease in serum neurofilament light chain provides evidence of potential neuroprotective activity for IMU-838.

Quantification of neurofilament light polypeptide (NEFL) by an electrochemiluminescent immunoassay (ECLIA) in blood serum samples

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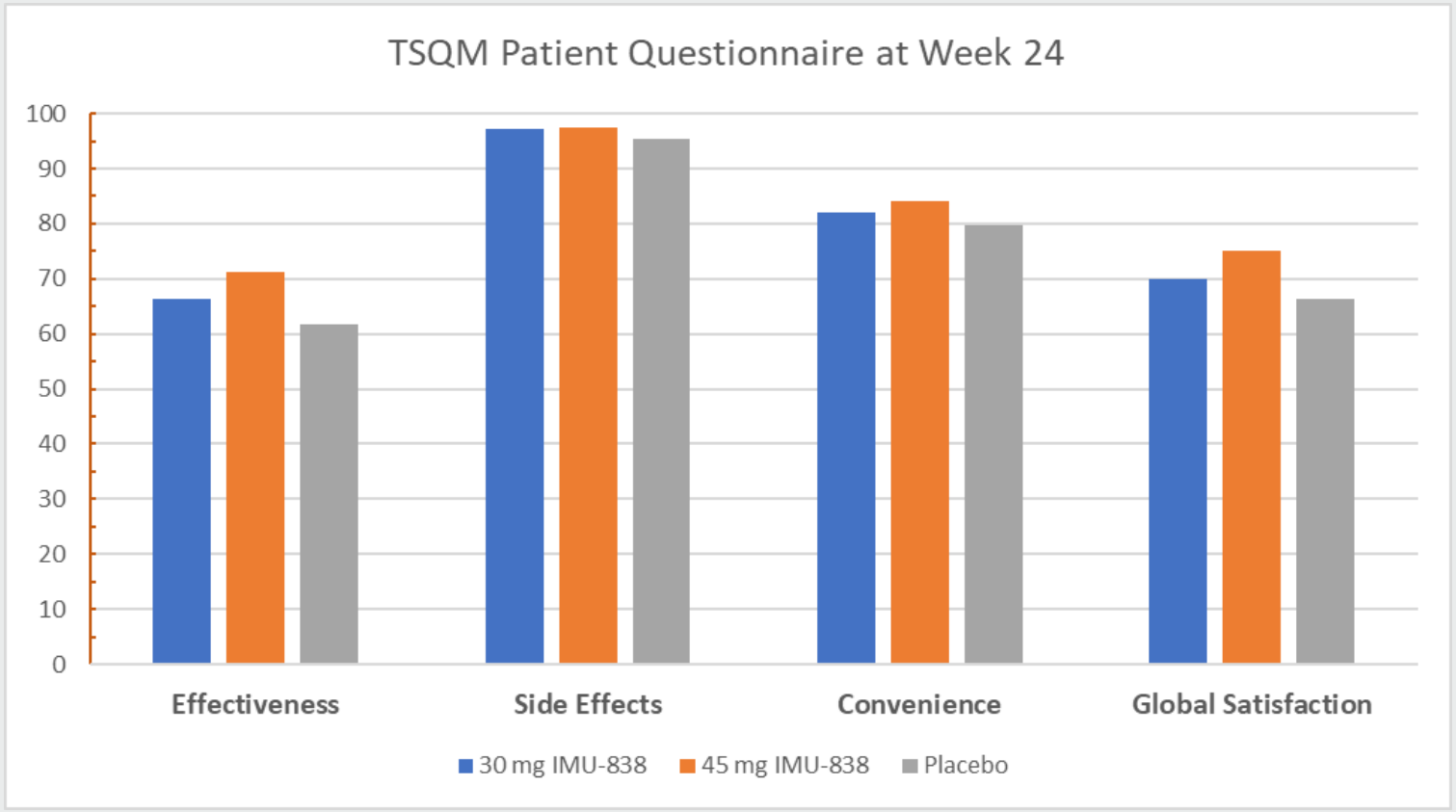
Patient Reported Outcome

Treatment Satisfaction Questionnaire for Medication (TSQM)



Patients have a perception of increased effectiveness versus placebo and show high satisfaction with IMU-838 treatment.

Treatment Satisfaction Questionnaire for Medication (TSQM), version 1.4 / Higher score generally indicates a more positive impression by the patient. / With license from IQVIA RDS Inc.

Reference: Atkinson MJ, Sinha A, Hass SL, et al. Validation of a general measure of treatment satisfaction, the Treatment Satisfaction Questionnaire for Medication (TSQM), using a national panel study of chronic disease. Health Qual Life Outcomes. 2004;2:12

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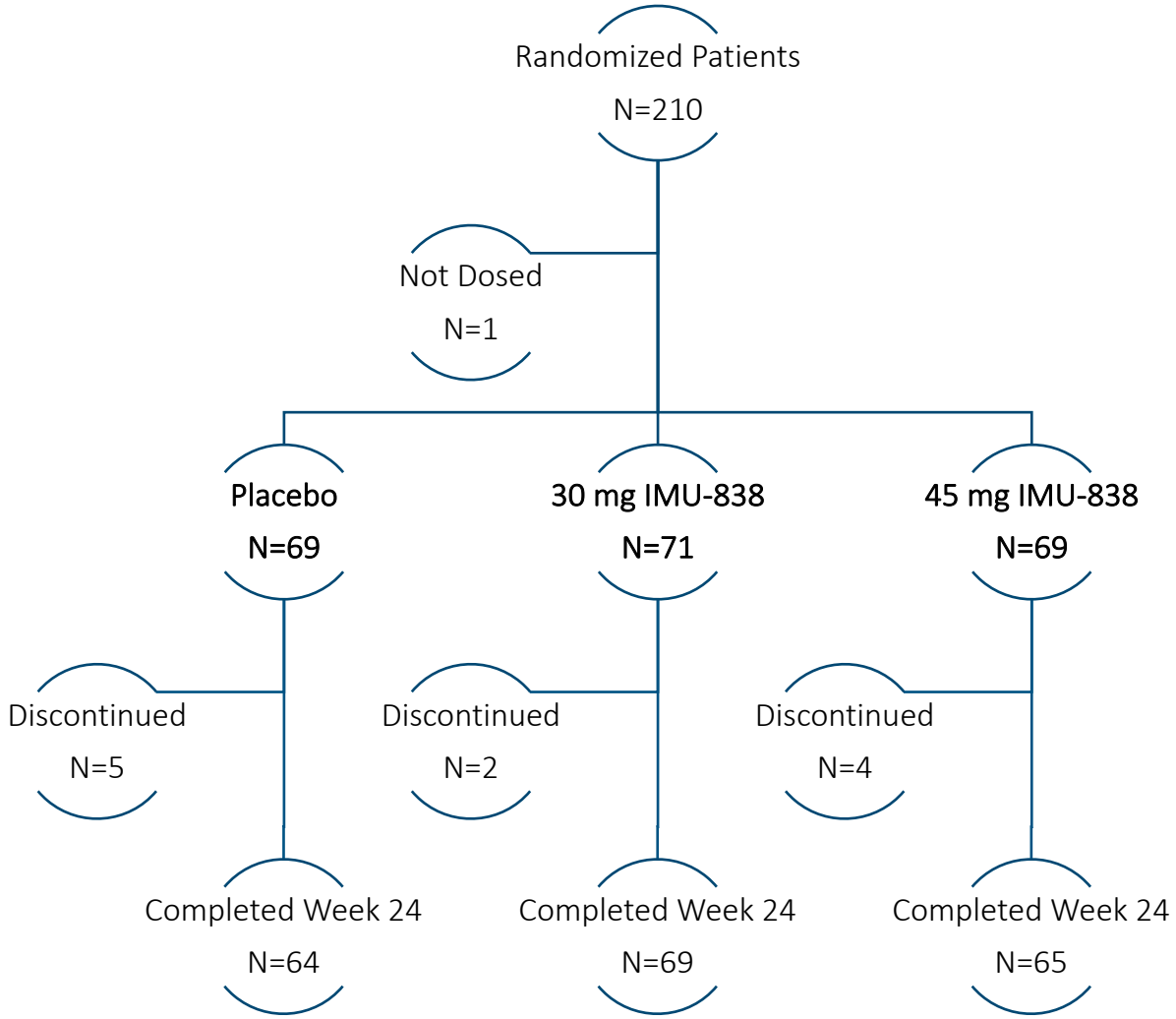
Conclusions Regarding Efficacy

- **Primary and key secondary endpoints met with high statistical significance**
  - Robust efficacy demonstrated for both investigated doses of IMU-838
- **Data on suppression of MRI activity encouraging and compares favorably to other first-line and oral medications in RRMS**
  - Robust effect on MRI lesion suppression observed early, also for Gd+ lesions
  - Number of patients without Gd+ lesions throughout the study substantially increased versus placebo
- **Secondary clinical endpoints also provided a noticeable signal and numerical benefit for IMU-838 treatment arms, as compared to placebo**
  - Positive signals on ARR, time to relapse, and unconfirmed disability, despite the study's relatively small sample size and short duration of blinded treatment
- **Biomarker data confirm objective effect of IMU-838 on axonal damage**
  - Robust decrease in serum neurofilament light chain provides evidence of potential neuroprotective activity
- **Patients report high satisfaction scores with IMU-838 treatment**

Phase 2 Data EMPhASIS Trial

Safety

Overall Treatment Discontinuations



Treatment Discontinuation Before Week 24 (all dosed patients until end of blinded treatment)		
Placebo	7.2 %	5/69
All IMU-838	4.3 %	6/140
30 mg IMU-838	2.8 %	2/71
45 mg IMU-838	5.8 %	4/69

Treatment discontinuations were very low in the IMU-838 treatment groups, even lower than in the placebo group, indicating an encouraging combination of tolerability and efficacy.

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Study Results 2: Low Discontinuation Rates

Low Discontinuation Rates for IMU-838 Treated RRMS Patients, Considerably Lower Than Placebo, Indicate an Overall Encouraging Tolerance Profile While Providing a Sense of Efficacy to Patients.*

	IMU-838	IMU-838	Glatiramer acetate[1]	Teriflunomide[2]	Dimethyl fumarate[3]	Fingolimod[4]	Siponimod[5]
Administration	Oral	Oral	Injectable	Oral	Oral	Oral	Oral
Daily Dose	45 mg QD	30 mg QD	20 mg QD	14 mg QD	240 mg TID	1.25 mg QD	2 mg QD
Treatment Period	24 weeks	24 weeks	9 months	36 weeks	24 weeks	6 months	3 months
Active Treatment	**5.8%**	**2.8%**	**5.9%**	**19.3%**	**15.6%**	**5.4%**	**14.3%**
Placebo	**7.2%**	**7.2%**	**5.8%**	**6.6%**	**9.2%**	**6.5%**	**8.9%**

*The table summarizes the data on treatment/study discontinuation rates of the commercial dose in phase 2 trials of RRMS drugs. If the commercial dose was not included in the phase 2 trials, the dose closest to the commercial dose was shown. This high-level comparison is provided for illustrative purposes only, is based on publicly available data and does not purport to be a comprehensive comparison or depiction of the other trials. Larger data sets than are presented in this presentation are publicly available for certain of the compounds included on this slide. Please note that these results are taken from placebo-controlled trials, and these medications have not been tested in head-to-head assessments.

QD: quaque die = once-daily, TID: ter in die = three times daily

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Overall Rate of Patients With Treatment Emergent Adverse Events

Treatment Group	Number of TEAE	Number of Patients with TEAE
30 mg IMU-838	70	32/71 (45.1%)
45 mg IMU-838	59	28/69 (40.6%)
Placebo	62	30/69 (43.5%)

There were 3 patients with serious treatment-emergent adverse events (SAE) in this trial:

- Placebo: Squamous cell carcinoma of the cervix
- 30 mg: open fracture, ureterolithiasis/hydronephrosis
- 45 mg: no treatment-emergent SAE reported

There were no on-study deaths in this trial.

TEAE: treatment-emergent adverse event

Most Common Treatment-Emergent Adverse Events

Adverse Events Present in More Than 1% of Study Population

		30 mg IMU-838			45 mg IMU-838			Placebo			Total		
		Number of TEAE (N#)	Number of Patients with TEAE (N)	Patients with TEAE (%)	Number of TEAE (N#)	Number of Patients with TEAE (N)	Patients with TEAE (%)	Number of TEAE (N#)	Number of Patients with TEAE (N)	Patients with TEAE (%)	Number of TEAE (N#)	Number of Patients with TEAE (N)	Patients with TEAE (%)
TEAE with High Incidence (>5% Incidence)	Nasopharyngitis	5	3	4.2	7	5	7.2	4	3	4.3	16	11	5.3
	Headache	3	3	4.2	5	4	5.8	4	4	5.8	12	11	5.3
TEAE with Medium Incidence (2-5% Incidence)	Respiratory Tract Infection Viral	0	0	0.0	2	2	2.9	3	3	4.3	5	5	2.4
	Upper Respiratory Tract Infection	2	2	2.8	0	0	0.0	3	3	4.3	5	5	2.4
TEAE with Low Incidence (1-2% Incidence)	Rash	3	2	2.8	2	2	2.9	0	0	0.0	5	4	1.9
	Nausea	1	1	1.4	2	2	2.9	1	1	1.4	4	4	1.9
	Fatigue	2	2	2.8	2	2	2.9	0	0	0.0	4	4	1.9
	Cystitis	1	1	1.4	3	3	4.3	0	0	0.0	4	4	1.9
	Hepatic Enzyme Increased	1	1	1.4	2	2	2.9	1	1	1.4	4	4	1.9
	Alopecia	3	3	4.2	1	1	1.4	0	0	0.0	4	4	1.9
	Back Pain	2	1	1.4	0	0	0.0	2	2	2.9	4	3	1.4
	Bronchitis	0	0	0.0	2	2	2.9	1	1	1.4	3	3	1.4
	Influenza	0	0	0.0	1	1	1.4	2	2	2.9	3	3	1.4
	Alanine Aminotransferase Increased	1	1	1.4	0	0	0.0	2	2	2.9	3	3	1.4

There were very few adverse events with medium and high incidence rate.

Displayed are treatment emergent adverse events (TEAE) that occurred in more than 1% of all study patients (safety population N=209), i.e. such TEAE occurred in at least 3 or more patients.

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Treatment-Emergent Adverse Events: Infections and Infestations

TEAE of SOC: Infections and Infestations	30 mg IMU-838			45 mg IMU-838			Placebo			Total		
	Number of TEAEs (N#)	Number of Patients with TEAE (N)	Patients with TEAE (%)	Number of TEAEs (N#)	Number of Patients with TEAE (N)	Patients with TEAE (%)	Number of TEAEs (N#)	Number of Patients with TEAE (N)	Patients with TEAE (%)	Number of TEAEs (N#)	Number of Patients with TEAE (N)	Patients with TEAE (%)
Total	18	13	18.3	22	16	23.2	21	16	23.2	61	45	21.5

There was no signal for an increase of infections and infestations during IMU-838 therapy, as compared to placebo.

TEAE: treatment-emergent adverse event
SOC: system organ class

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Treatment-Emergent Adverse Events: Severity

TEAE by Severity	30 mg IMU-838			45 mg IMU-838			Placebo			Total		
	Number of TEAE (N#)	Number of Patients with TEAE (N)	Patients with TEAE (%)	Number of TEAE (N#)	Number of Patients with TEAE (N)	Patients with TEAE (%)	Number of TEAE (N#)	Number of Patients with TEAE (N)	Patients with TEAE (%)	Number of TEAE (N#)	Number of Patients with TEAE (N)	Patients with TEAE (%)
Mild	50	29	40.8	38	21	30.4	46	23	33.3	134	73	34.9
Moderate	19	11	15.5	21	16	23.2	14	8	11.6	54	35	16.7
Severe	0	0	0	0	0	0	2	1*	1.4	2	1	0.5
Total	69	32	45.1	59	28	40.6	62	30	43.5	190	90	43.1

The observed adverse events were generally mild in nature.

Treatment-emergent adverse events (TEAE) are displayed by severity.
* One patient on placebo treatment experienced the severe adverse events of leukopenia and neutropenia.

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Phase 2 Data EMPhASIS Trial

Safety: Liver Events

EMPhASIS Trial: Overall Rate of Liver Events

There Was No Increase in Liver Events for the Pooled IMU-838 Treatment Arms Versus Placebo During Blinded Treatment Period

Treatment Group	Rate of Patients With Treatment-Emergent Adverse Events (TEAE)
	With any TEAE fulfilling predefined criteria as liver event
IMU-838	4.3% (6/140)
Placebo	4.3% (3/69)

Liver events, including both clinical adverse events and clinically significant liver laboratory changes, were as prevalent in placebo as in IMU-838 treatment arms.

TEAE: treatment-emergent adverse events
Renal events are TEAE with predetermined adverse event preferred terms related to renal function from MedRA Systems Organ Classes 'Renal and urinary disorder' or 'Investigations'.
Liver events are TEAE with predetermined adverse event preferred terms related to liver function from MedRA Systems Organ Classes 'Investigations' or 'Hepatobiliary disorders'.

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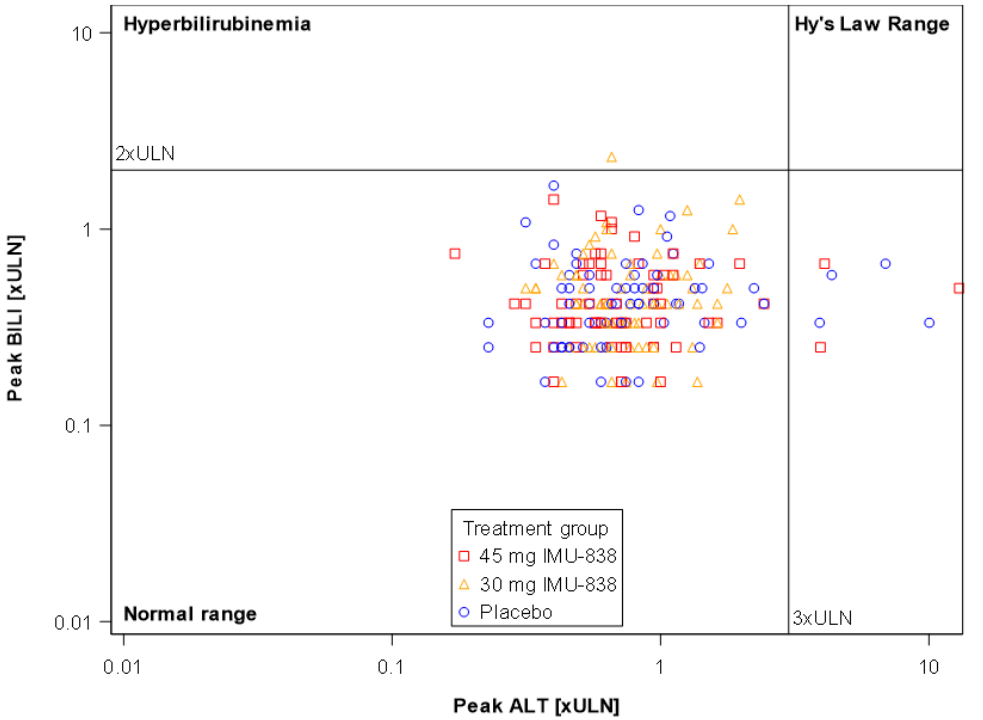
Absence of Hepatotoxicity Signals

Hy's Law Assessment for Drug-Induced Liver Injury

Absence of Hepatotoxicity Signals and Other Relevant Adverse Events Leading to Discontinuations Differentiates to Other Available Oral RRMS Medications.

Hy's Law Assessment (30mg IMU-838)



Liver Enzyme Elevations

	30 mg IMU-838	45 mg IMU-838	Placebo
Number of Patients	71	69	69
ALT or AST >5xULN	0 (0%)	1 (1.4%)	2 (2.9%)
ALT or AST >10xULN	0 (0%)	1 (1.4%)	1 (1.4%)
ALT or AST >15xULN	0 (0%)	0 (0%)	0 (0%)

No signal for hepatoxicity has been observed anywhere in the entire IMU-838 development program, including in the EMPhASIS trial.

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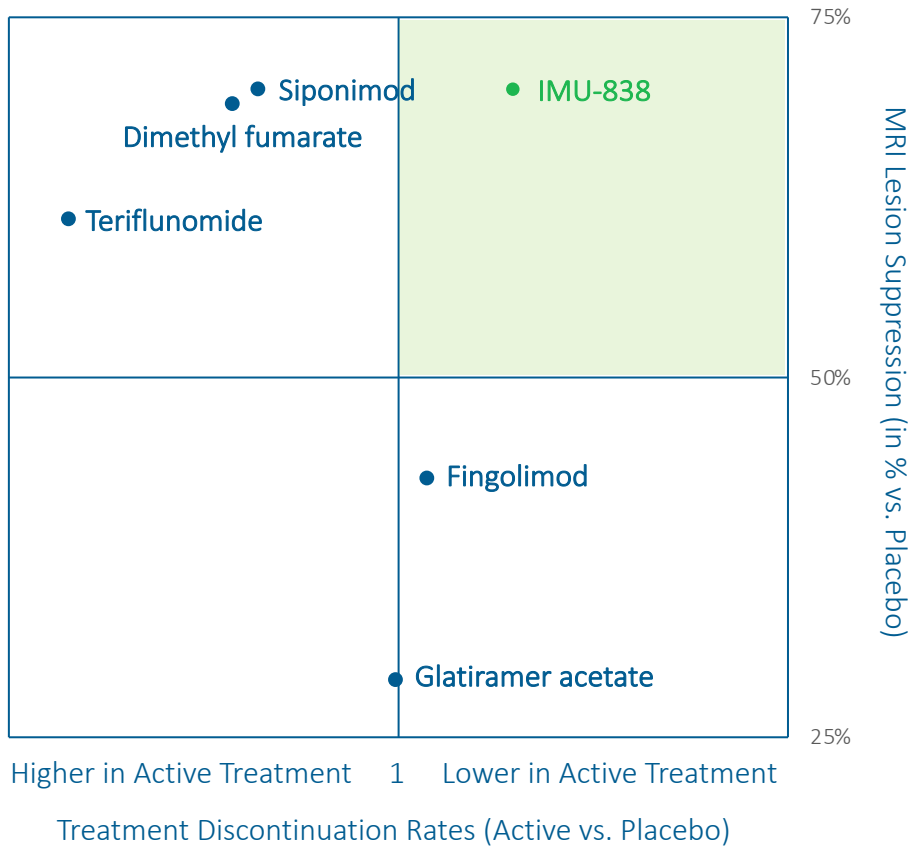
Conclusions Regarding Safety

- Consistent with prior data sets in other patient populations, administration of IMU-838 in this trial was observed to be well-tolerated
  - Providing further evidence of a favorable safety profile and replicating such safety profile in the RRMS patient population
  - In general, safety profile is similar to placebo
- Very low rate of treatment discontinuations, even lower than in the placebo group
  - IMU-838 discontinuation rate compares favorably to many other medications in RRMS
  - Indicates an encouraging combination of tolerability and efficacy
- Favorable safety profile of IMU-838 observed
  - Few adverse events with higher incidence rate (>2%)
  - Observed adverse events generally mild in nature
  - No increase in liver and kidney events as well as adverse events of special interest and hematuria, as compared to placebo
  - No signal for hepatotoxicity or elevations of liver enzymes
  - No generalized effect on serum uric acid (with 1-week dosing-in using half-dose)
  - No/rare adverse events indicating general immuno-suppressive or general antiproliferative effects
  - No increase of infections and infestations, as compared to placebo
  - No generalized effect on hematology laboratory values

IMU-838 Compared with First-Line and Oral Medications in RRMS



IMU-838 properties are matching well with current unmet medical need for early RRMS.

The chart depicts the MRI lesion suppression (primary endpoint of phase 2 study) versus the relationship of treatment discontinuation rates of active treatment versus placebo. Data are used from phase 2 trials only and using the commercial dose or the dose used designated for phase 3 trials. If the commercial dose was not included in the phase 2 trials, the dose closest to the commercial dose was shown. This high-level comparison is provided for illustrative purposes only, is based on publicly available data and does not purport to be a comprehensive comparison or depiction of the other trials (including phase 3 data of the same medications).

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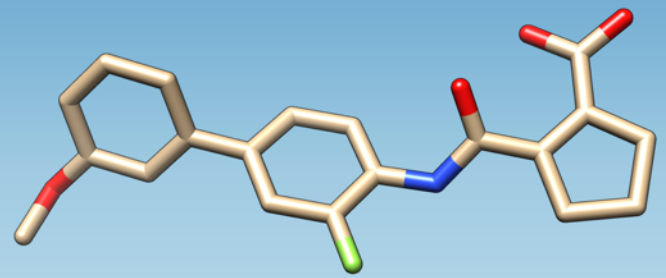
IMU-838 Positioned to be a New Safe and Efficacious Treatment Option for Early RRMS Patients

IMU-838 could provide RRMS patients with a **distinctive combination of robust efficacy combined with favorable safety and tolerability** due to uniquely blending of properties:



1. **Robust MRI lesion suppression of IMU-838** compares favorably to other first-line and oral base medications commercially available in RRMS.
2. **Very low discontinuation rate** for IMU-838 treated RRMS patients, substantially below placebo, indicates an encouraging combination of tolerability and efficacy.
3. **Absence of hepatotoxicity signals** and other relevant adverse events leading to discontinuations distinguishes IMU-838 well from other oral RRMS treatments.
4. **A robust decrease in serum neurofilament light chain**, a biomarker for axonal damage, was observed in both IMU-838 arms but not in the placebo arm and provides evidence of IMU-838's potential neuroprotective activity.

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Thank You!

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