Immunic Therapeutics

IMU-838 Phase 2 Data EMPhASIS Trial in RRMS

NASDAQ: IMUX | September 11, 2020

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This presentation contains “forward-looking statements” that involve substantial risks and uncertainties for purposes of the safe harbor within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These include statements regarding management’s intentions, plans, beliefs, expectations or forecasts for the future, and, therefore, you are cautioned not to place undue reliance on them. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. Immunic undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise, except to the extent required by law. We use words such as “anticipates,” “believes,” “plans,” “expects,” “projects,” “future,” “intends,” “may,” “will,” “should,” “could,” “estimates,” “predicts,” “potential,” “continue,” “guidance,” and similar expressions to identify these forward-looking statements that are intended to be covered by the safe-harbor provisions of the PSLRA.

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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.

IMU-838: Potential New Base Therapy for Relapsing-Remitting Multiple Sclerosis (RRMS)

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Development Pipeline

Program	Indication	Target	Preclinical	Phase 1	Phase 2	Phase 3
IMU-838	Multiple Sclerosis	DHODH	■	■	■	▪
	Ulcerative Colitis	DHODH	■	■	■	
	Crohn's Disease	DHODH	■	■		
	PSC	DHODH	■	■	■	Investigator-Sponsored Trial performed at Mayo Clinic / NIH
	COVID-19*	DHODH	■	■	■	▪
IMU-935	Psoriasis	RORγt	■	■		
	Orphan AI Diseases	RORγt	■	▪		
IMU-856	GI	Intestinal Barrier Function	■	■		

■ Completed or ongoing ▪ In preparation or planned

* Additional investigator-sponsored phase 2 clinical trial of IMU-838 in combination with oseltamivir in patients with moderate-to-severe COVID-19 ongoing in collaboration with the University Hospitals Coventry and Warwickshire NHS Trust, UK

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IMU-838: A Pipeline in a Pill

Broad Therapeutic Potential Driven by Medical Needs

1. Relapsing-Remitting Multiple Sclerosis
2. Ulcerative Colitis
3. Primary Sclerosing Cholangitis
4. COVID-19

- 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
  - **No/low PML risk** expected
  - Delivered **excellent phase 2 data** in RRMS
  - Achieving new standard on safety, tolerability, pharmacokinetics and treatment compliance
- **First in class treatment for UC**
  - Safe chronic therapy potentially without virus reactivation
  - Synergistic effect with anti-TNF mAb expected
- Potential **first treatment option for PSC**
  - No drug approved so far for this indication
  - Could allow accelerated path to approval
- **Triple attack on coronaviruses** using host-based mechanism
  - Strong antiviral and immunomodulatory effects

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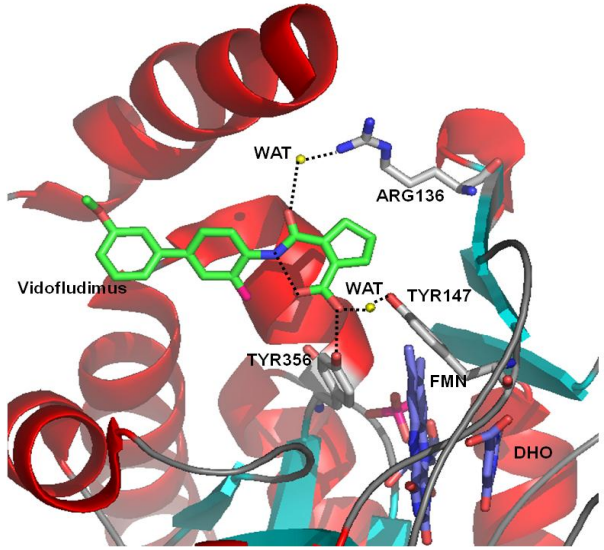
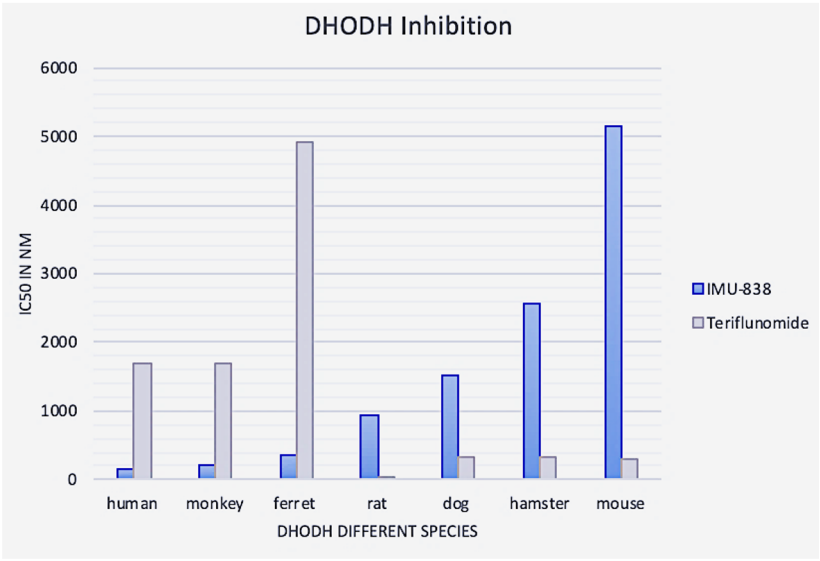
Broad Applicability

IMU-838: Mode of Action

IMU-838 Binds to DHODH and Inhibits DHODH

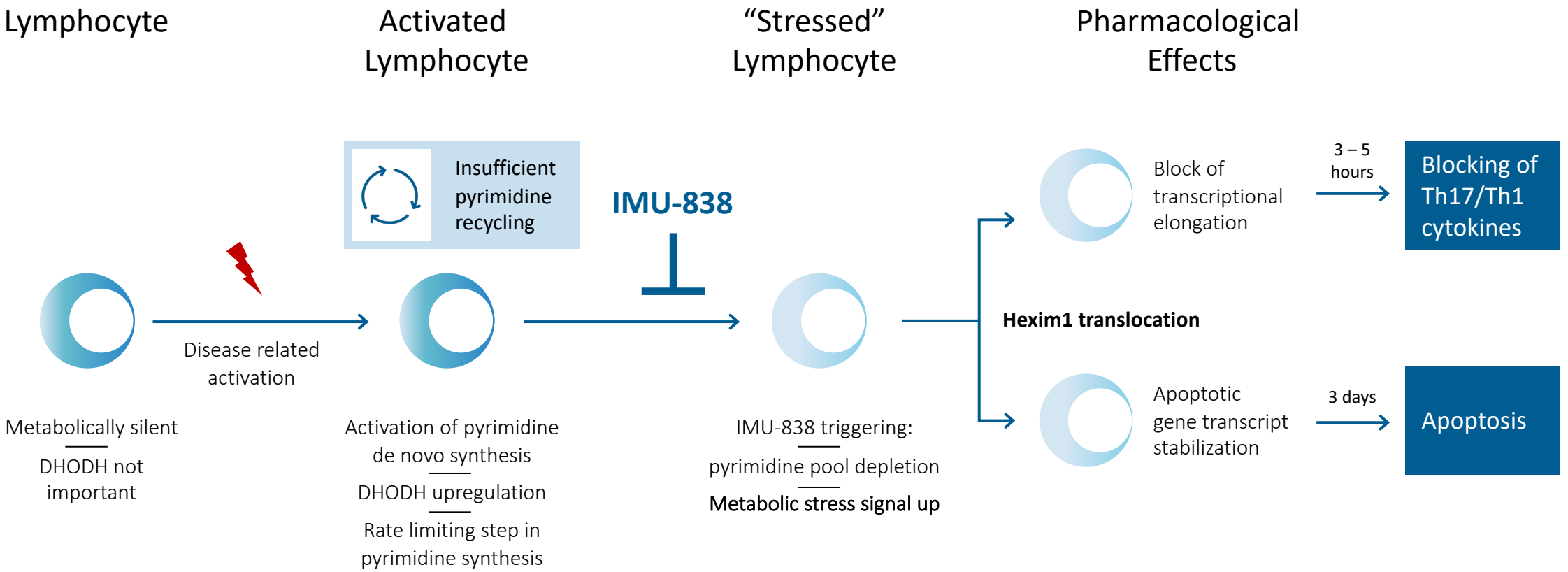
- IMU-838 binds into the DHO and Ubiquinone binding pocket
- IMU-838 exhibits high species selectivity, most potent on human DHODH with IC50 of ~160 nM





Left: Baumgartner et al., J. Med. Chem. 2006;49:1239-1247
Right: Immunic data

Mode of Action: DHODH Targeting Leads to Metabolic Stress in Metabolically Activated Cells



Adapted from Tan et al., 2016, Mol Cell 62

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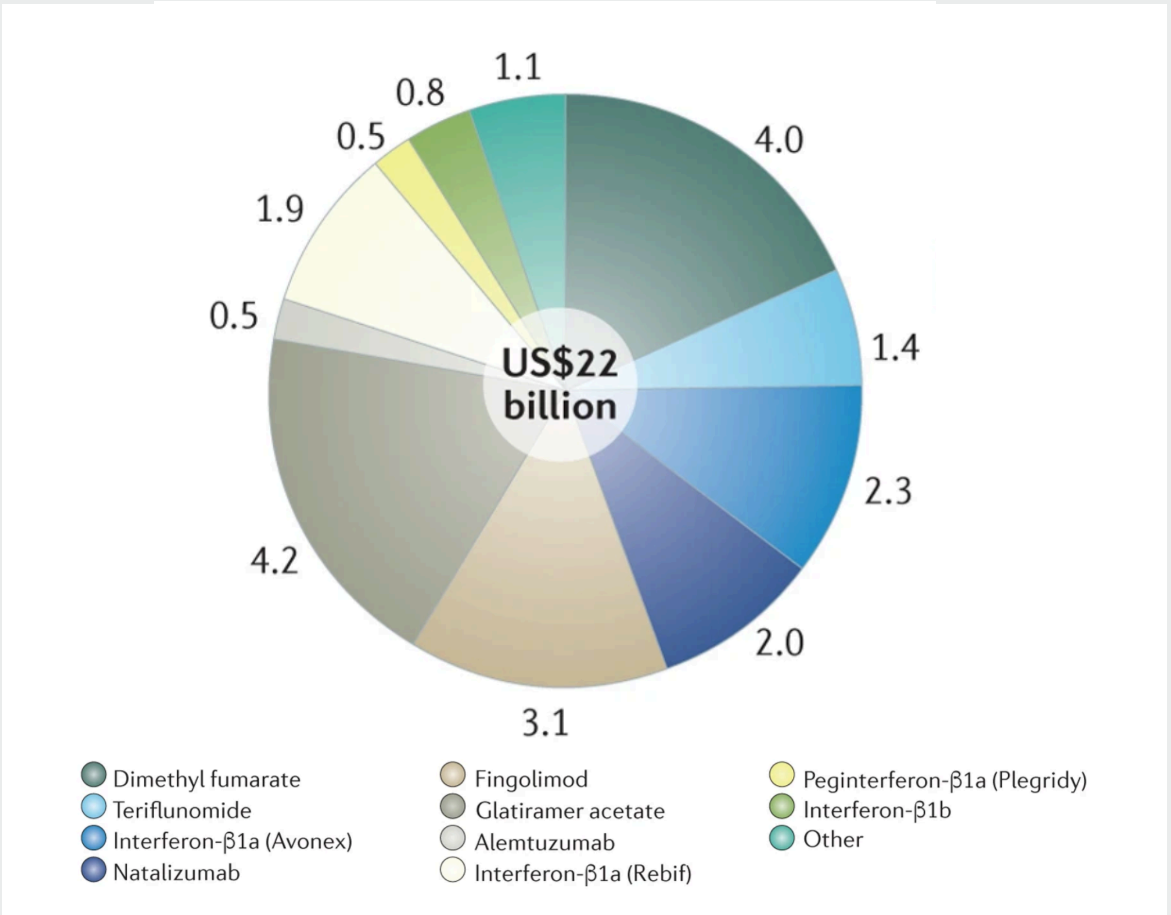
Targeting Multiple Sclerosis (MS)

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**

The Global MS Drug Market was 22 Billion USD in 2016

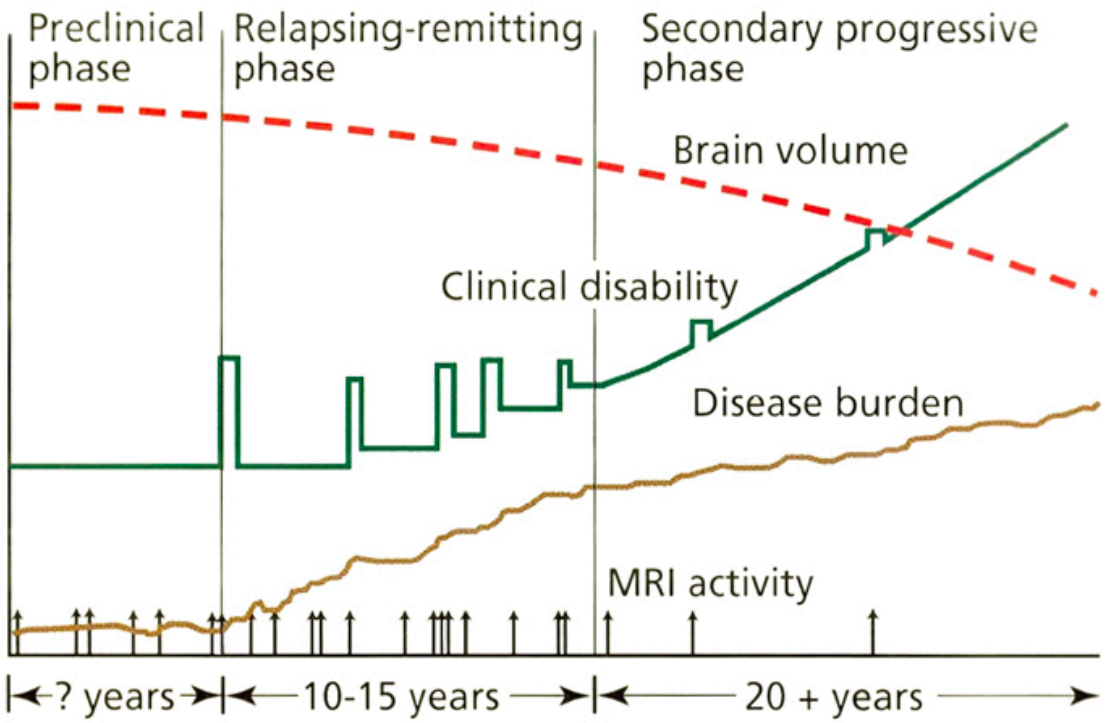


- Global market of MS drugs was USD 22 billion in 2016[1]
- Currently approved drugs include oral and injectable drugs
  - Early injectables
    - Interferons (e.g. Rebif®, Avonex®)
    - Glatiramer acetate
  - Oral drugs
    - Teriflunomide
    - Dimethyl fumarate
    - S1P modulators: Fingolimod, Siponimod, Ozanimod
  - High activity DMTs, infusions
    - Natalizumab
    - Ocrelizumab

[1] Westad, A., Venugopal, A. & Snyder, E. The multiple sclerosis market. Nature Reviews Drug Discovery 16, 675–676 (2017).

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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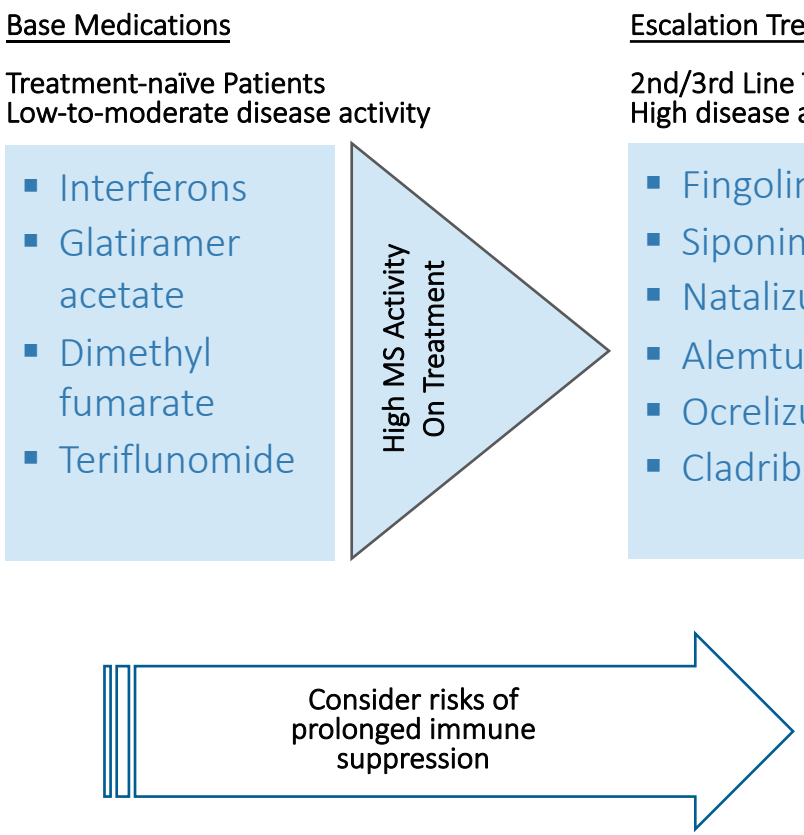
Current Treatment of RRMS

Escalation Treatment Approach in RRMS



- Currently, there is no specific guidance on which therapies/medications are used in which sequence.
- Typically, treatments are escalated over time considering:
  - Persistent high MS disease activity under treatment with base medications (relapse(s), disability worsening, MRI lesions),
  - Risks of long-term immunosuppression,
  - Patient preferences or risks perceptions, and
  - Safety/tolerability aspects.

Currently unaddressed medical need:
Oral base medications for MS patients with balance of good safety/tolerability/convenience profile and robust clinical activity

Left: Adapted from F.1. F. Grand'Maison, Neural Regeneration Research, 2018, 13, 1871-1874

MS Therapies: Current Shortcomings

Injectables: IFN-β1 and glatiramer acetate

- Uncomfortable administration
- Side-effects: flulike (IFNβ1) and rash (glatiramer acetate)
- Modest anti-inflammatory effects
- Essentially no new-starts except for glatiramer acetate

Orals: S1Ps, fumarates

- Pre-testing: blood tests; EKG first-dose monitoring (fingolimod)
- Risk discussion: cardiac (S1Ps) PML – small but non-zero; no risk stratification (S1Ps)
- Less disability slowing than inflammation would suggest

Infusions: natalizumab, anti-CD20s

- Frequent infusions (natalizumab)
- Risk discussion: PML (natalizumab > anti-CD20s); infections (anti-CD20s)
- Very long pharmacodynamics – 3-6 months (natalizumab); 6-12 months (anti-CD20s)
- Less disability slowing than inflammation would suggest

Personal opinion of Robert Fox, MD, Staff Neurologist, Mellen Center for MS Vice Chair for Research, Neurological Inst. Professor of Neurology, Cleveland Clinic, Cleveland, Ohio, as presented at Immunic's R&D Day on May 19, 2020: https://www.immunic-therapeutics.com/wp-content/uploads/2020/05/20200519_Immunic_RnD_Day_Robert-Fox.pdf

MS Therapies: Current List of Black Box Warnings and Risks

Drug	Risk/Warning	
Alemtuzumab (Lemtrada®)	**Autoimmunity, infusion reactions, and malignancies**. Thyroid disorders	**Black box warning**[1]
Natalizumab (Tysabri®)	Risk of **progressive multifocal leukoencephalopathy (PML)**, only accessible through special access program	**Black box warning**[2]
Cladribine (Mavenclad®)	Can increase the risk of **malignancy** and **fetal harm**	**Black box warning**[3]
DMF (Tecfidera®)	Risk of progressive multifocal leukoencephalopathy (PML), lymphopenia	FDA information[4]
Teriflunomide (Aubagio®)	**Hepatotoxicity**, neutropenia, accelerated elimination procedures, anaphylaxis, peripheral neuropathy, increased blood pressure	**Black box warning**, drug label[5]
Fingolimod (Gilenya®)	Risk of progressive multifocal leukoencephalopathy (PML), increased infections, liver injury, respiratory effects, blood pressure increase, posterior reversible encephalopathy syndrome (PRES), cutaneous malignancies, macular edema	Drug label[6]
Siponimod (Mayzent®)	Increased infections, liver injury, respiratory effects, blood pressure increase, macular edema, bradyarrhythmia and atrioventricular conduction delays	Drug Label[7]
Alpha Interferons	Alpha interferons may cause or **aggravate fatal or life-threatening neuropsychiatric, autoimmune, ischemic, and infectious disorders**	**Black box warning**[8]

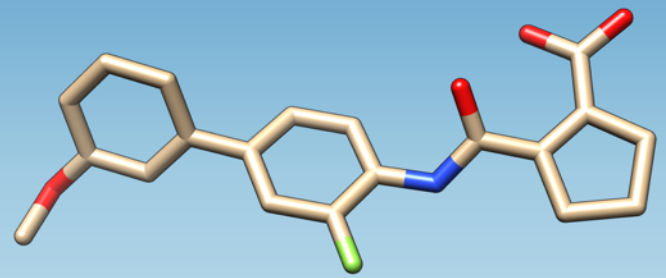
[1] https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/103948s5158lbl.pdf [2] https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/125104s0576lbl.pdf
[3] https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/022561s000lbl.pdf [4] https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-warns-about-case-rare-brain-infection-pml-ms-drug-tecfidera
[5] https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/202992s006lbl.pdf [6] https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022527s024lbl.pdf
[7] https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/209884s000lbl.pdf [8] https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/103964s5184lbl.pdf

Despite Many Therapies Approved (and Nearing Approval) for Relapsing Forms of MS, There Remains Ample Opportunity for a …

- Safe
- Oral
- Well-Tolerated
- Robust Anti-Inflammatory, with
- Neuroprotective Properties Beyond What Would be Expected by Reducing Inflammation.

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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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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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.

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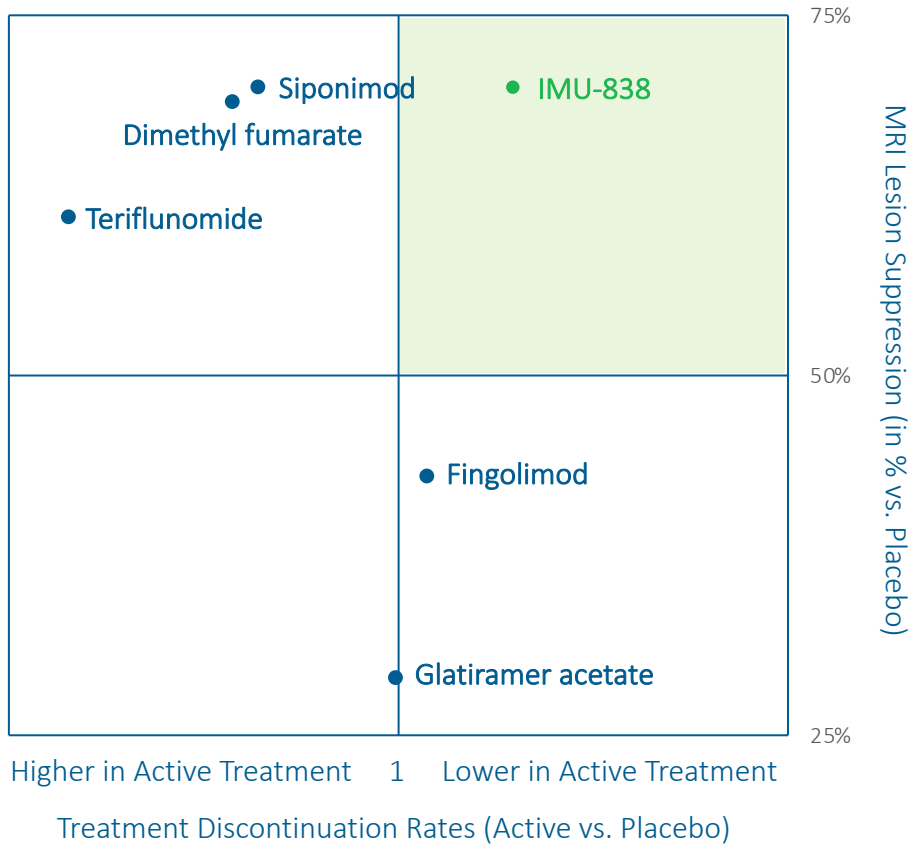
Relevant Comparators
First-Line and Oral Medications in RRMS



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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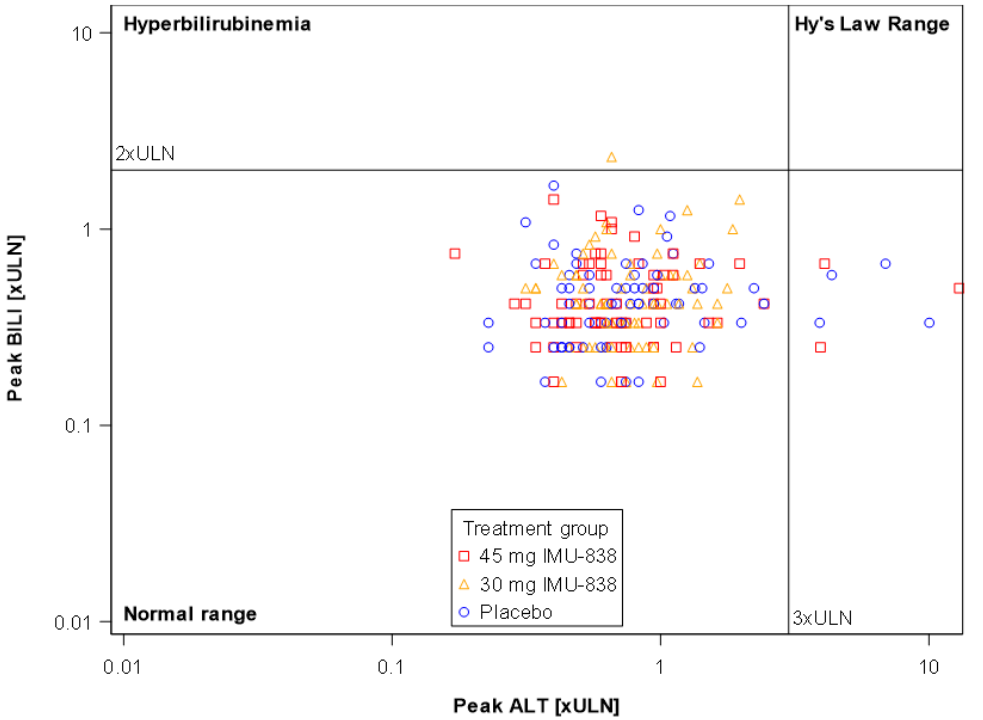
3) Absence of Hepatotoxicity Signals

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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IMU-838: Target Profile in RRMS

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

For Patient

- Convenient safety profile of an oral drug without adverse events disturbing social activities
- No/low PML risk
- Long treatment duration through less risk for discontinuation, high patient compliance

For Neurologist

- Robust clinical activity
- Easy on- and off-dosing
- Few monitoring requirements for treating neurologists
- No black box warning for hepatotoxicity

EMPhASIS Trial

Study Overview

EMPhASIS: Phase 2 Study Overview in RRMS

Coordinating Investigator

Robert Fox (Cleveland Clinic)

Blinded Main Treatment Period

- Parallel group design with placebo control
- Overall blinded treatment period of 24 weeks
- MRI every six weeks (BL, W6, W12, W18, W24)

Extended Treatment Period

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

www.clinicaltrials.gov: NCT03846219

EMPhASIS: Phase 2 Study Overview in RRMS

Included Patient Population: RRMS With Relevant Disease Activity

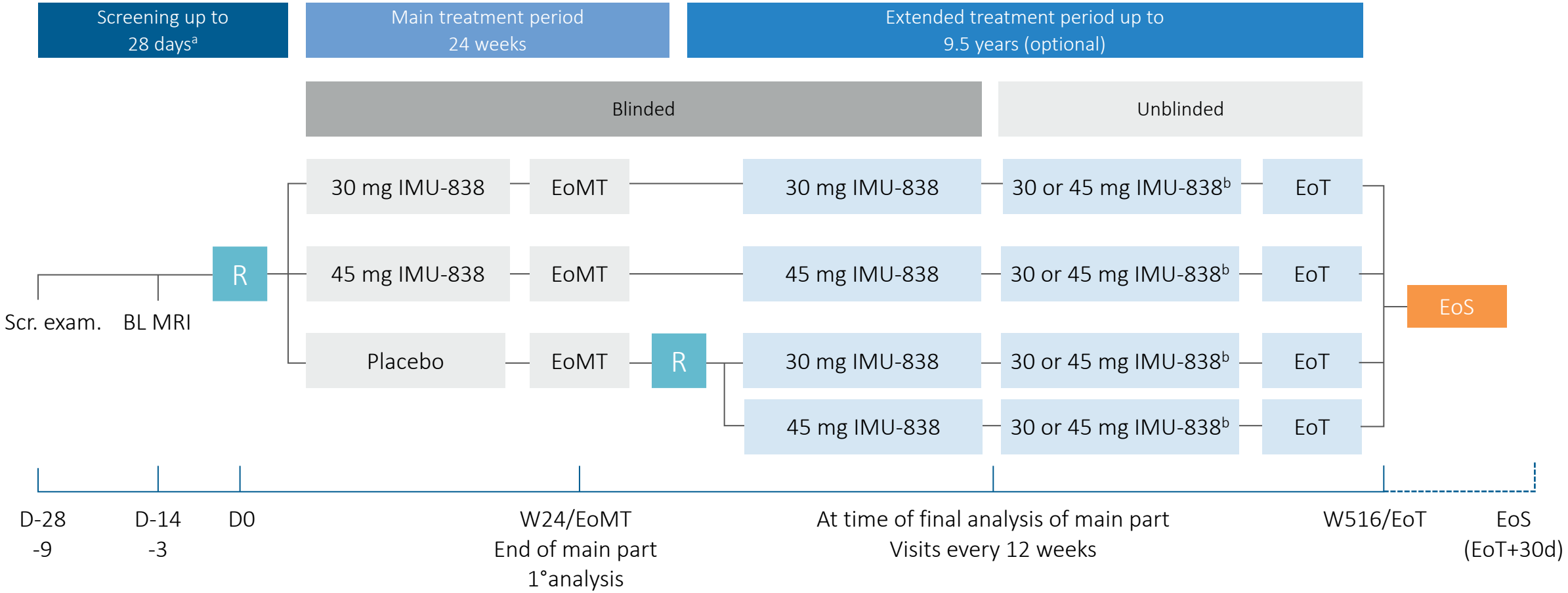
- Male or female (18 ≥ age ≤ 55)
- RRMS diagnosis (revised McDonald criteria 2017)
- Evidence of disease activity based on relapse (one relapse in last 12 months or two relapses in last 24 months) and MRI criteria (at least one Gd+ lesion in last six months before study)
- Baseline EDSS: 0 ≥ EDSS ≤ 4.0

Main Exclusion Criteria

- Non-RRMS forms of MS, other neurological diseases (NMO, MOG)
- Laboratory exclusions (platelet count <100,000/mm³, serum creatinine >1.5 x ULN, total bilirubin, ALT, or GGT >1.5 x ULN, serum uric acid levels >1.2 x ULN, indirect bilirubin >1.2 x ULN, lymphocyte count <800/mm³, neutrophil count <1,500/mm³, positive HBsAg, HBcAb, HCV-Ab, HIV or IFNγ release for Tbc)
- No use of corticosteroids for 30 days before any MRI
- Known history of nephrolithiasis or gout
- Known or suspected Gilbert syndrome

www.clinicaltrials.gov: NCT03846219

EMPhASIS: Phase 2 Trial Design in RRMS



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

EMPhASIS: Primary and Key Secondary Efficacy Endpoints

Key Study Endpoints

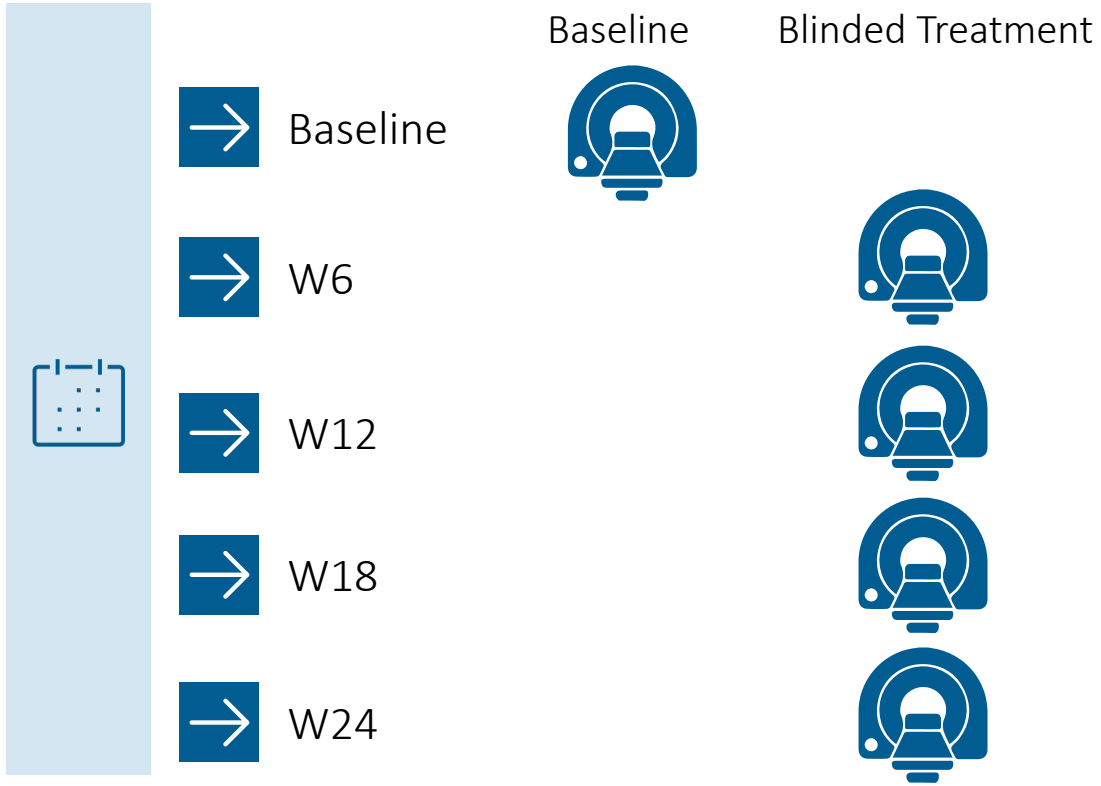
To evaluate the efficacy of IMU-838 as compared to placebo based on the **cumulative number of new combined unique active lesions up to Week 24**

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

Combined Unique Active (CUA) Lesions

Sum of the number of all new Gd-enhanced (Gd+) 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.

All MRI Scans Were Assessed Centrally by an Independent MRI Reading Center Only



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4

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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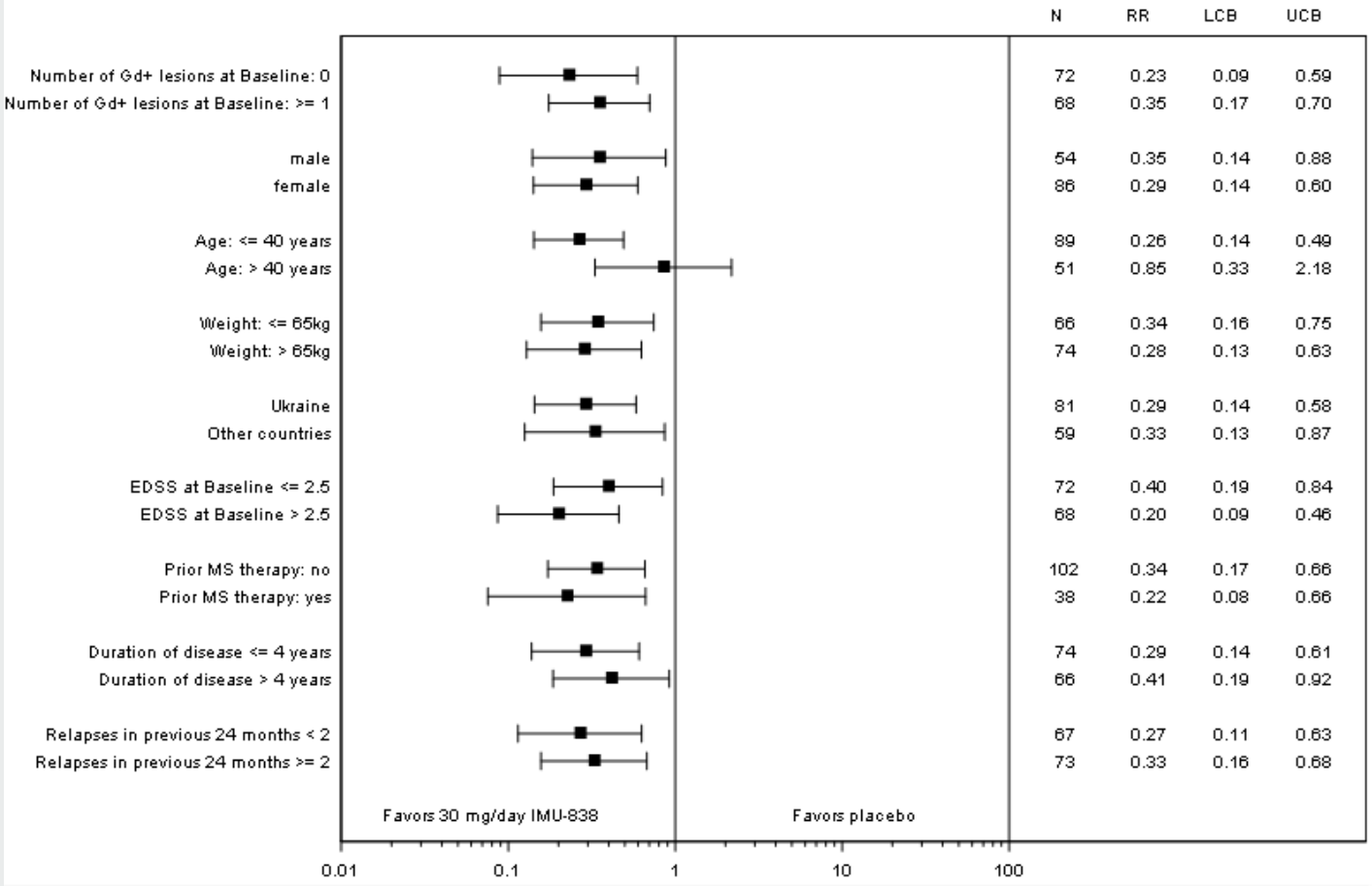
Subgroup Analysis CUA MRI Lesions 30mg IMU-838

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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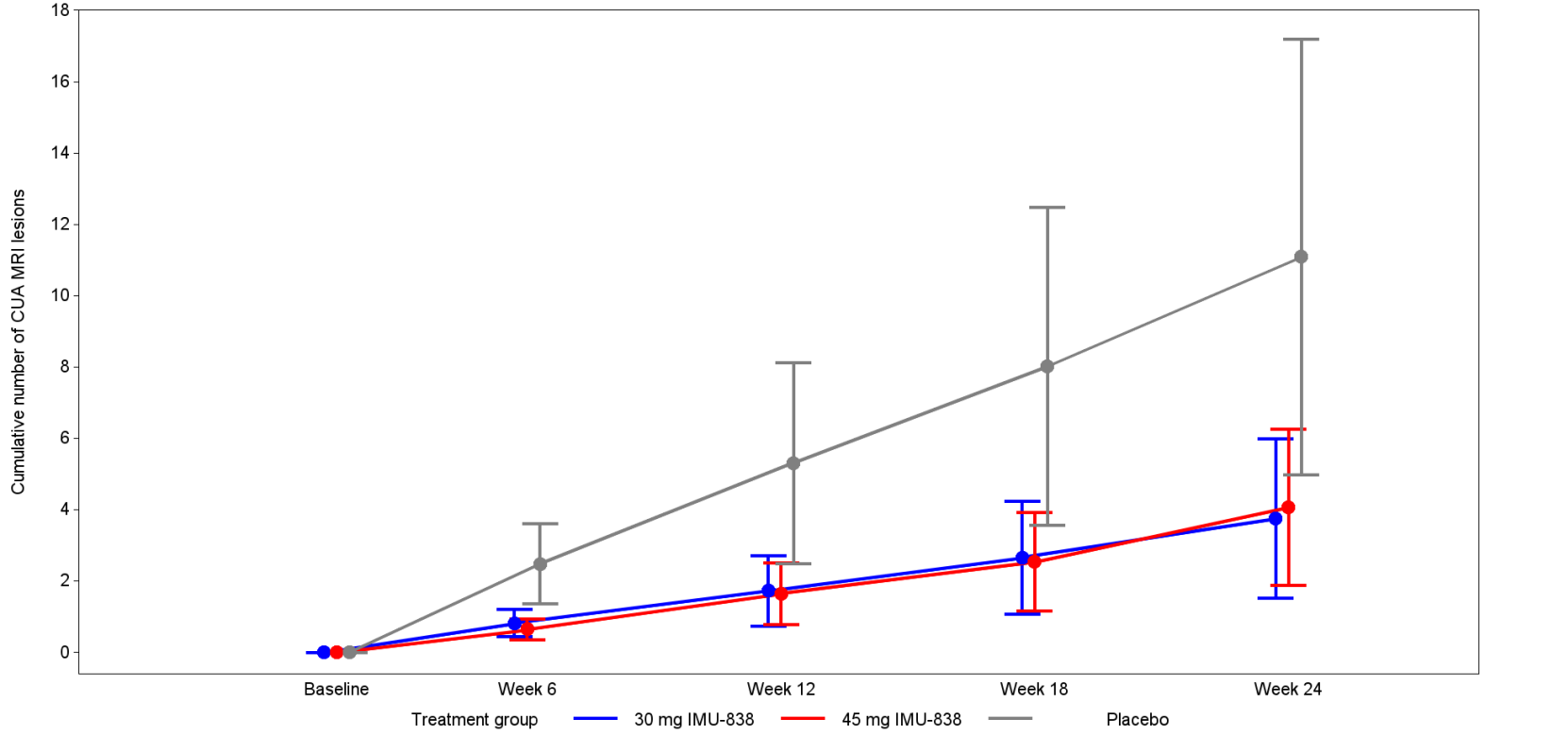
MRI: Cumulative Number of CUA MRI Lesions

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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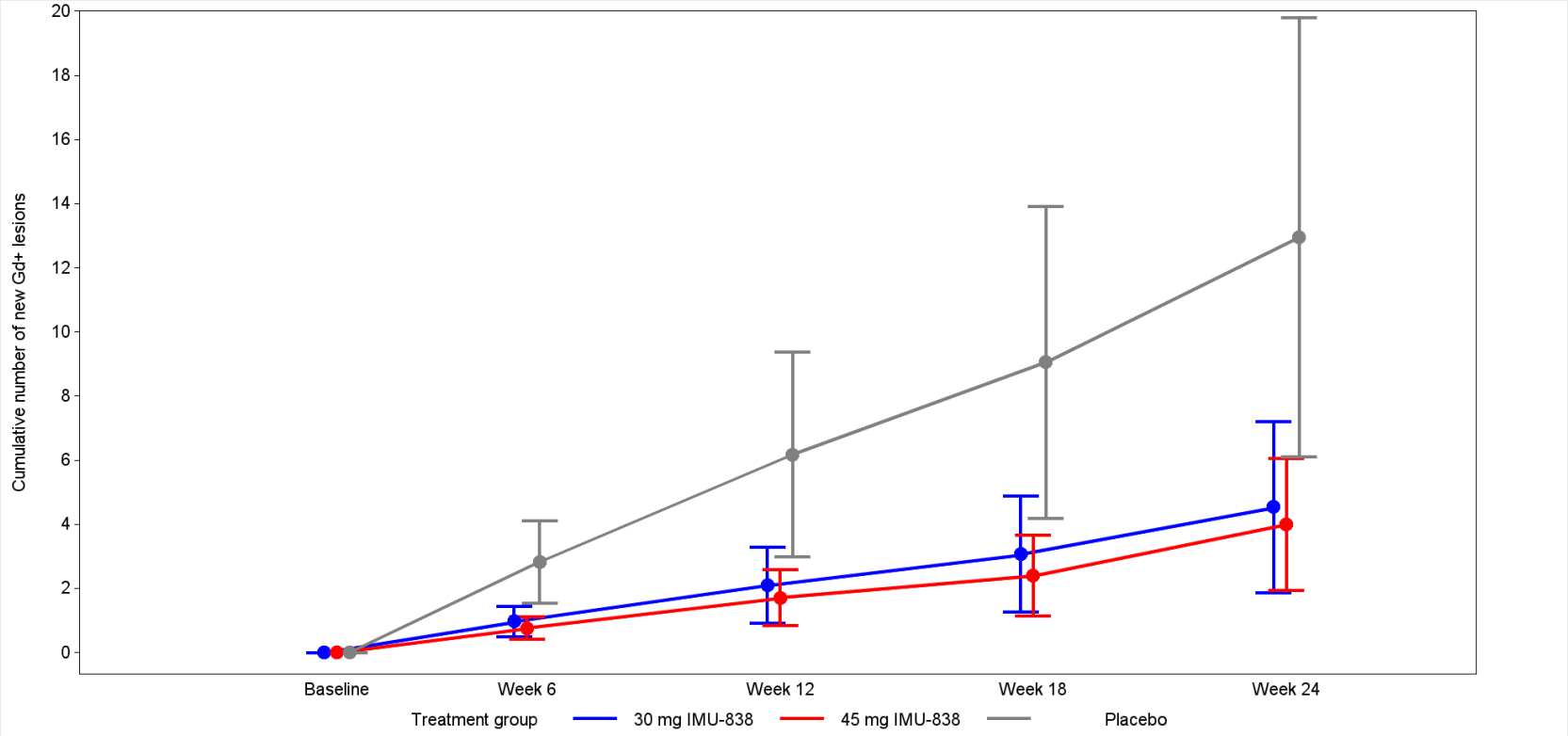
MRI: Cumulative Number of New Gd-Enhancing MRI Lesions

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: New Gadolinium-Enhancing MRI Lesions

Number of Patients Without Any Gadolinium MRI Lesions Over Entire 24-Week Treatment Period*

Treatment Group	Number of Patients Without Any Gadolinium MRI Lesions Over Entire 24-Week Treatment Period	
	(N)	(%)
30 mg IMU-838	42/71	59.2%
45 mg IMU-838	34/69	49.3%
Placebo	26/69	37.7%

IMU-838 also substantially increases the number of patients without any Gd+ lesions throughout the entire study.

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Secondary Endpoints: Relapse-Related Endpoints

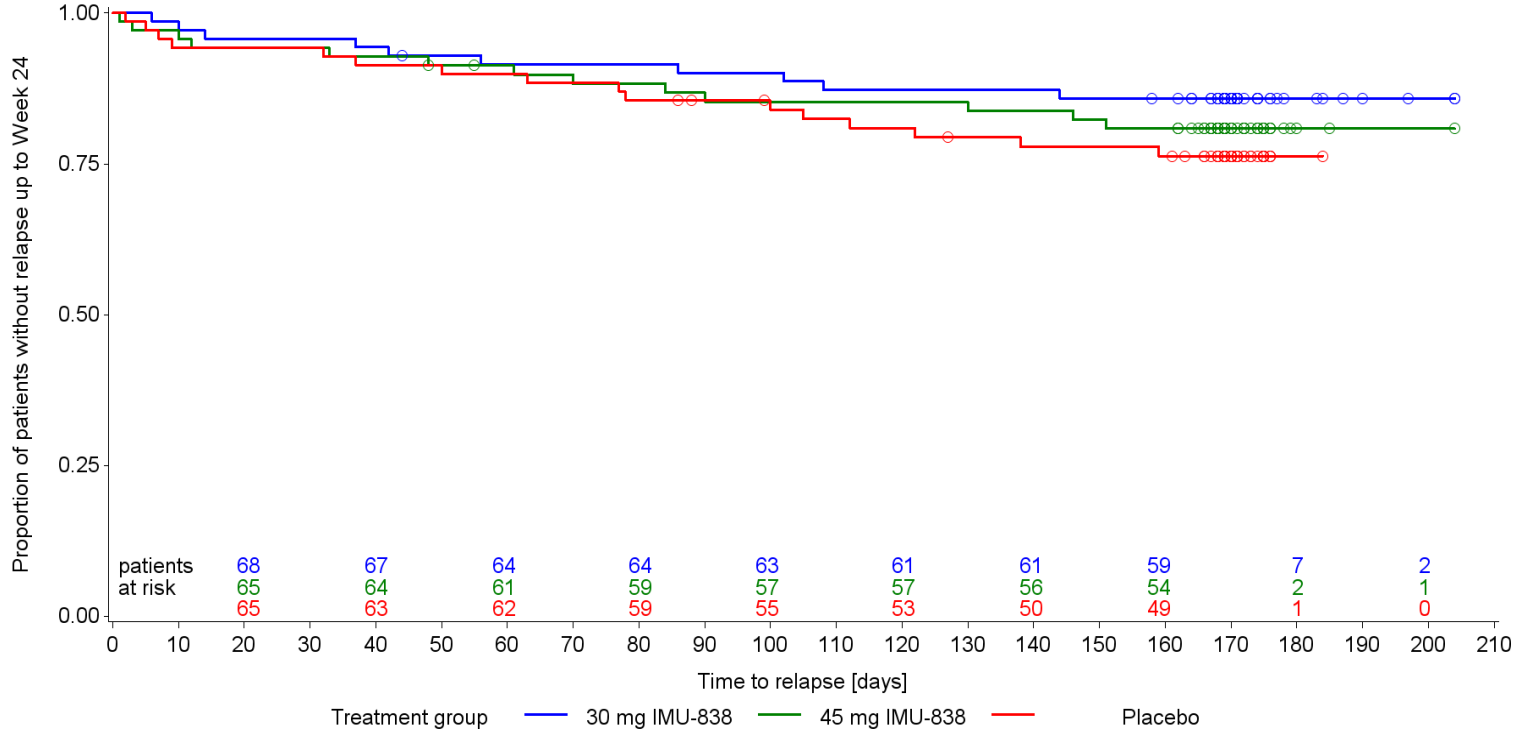
Effect on Annualized Relapse Rate (ARR)

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).

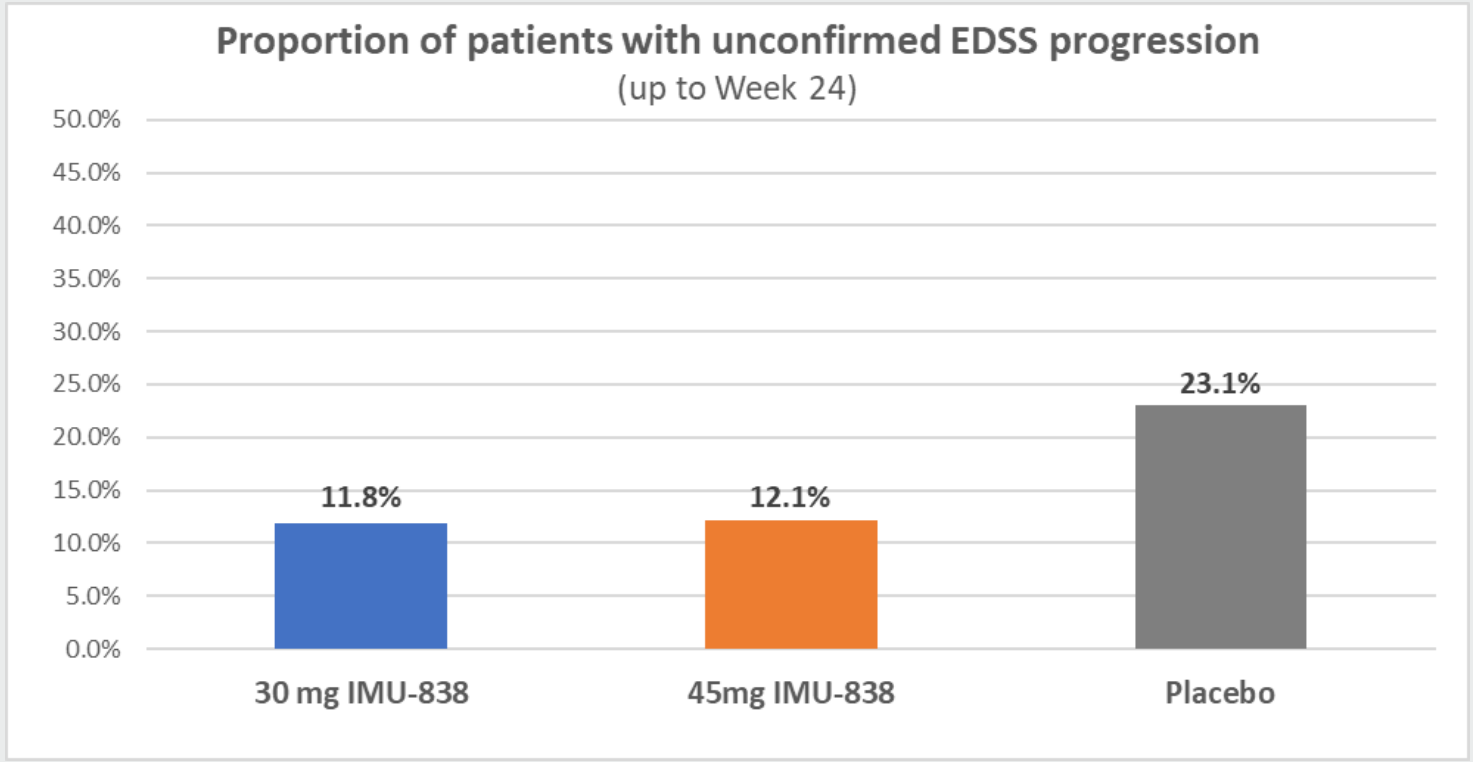
Time to Relapse
Kaplan Meier Analysis



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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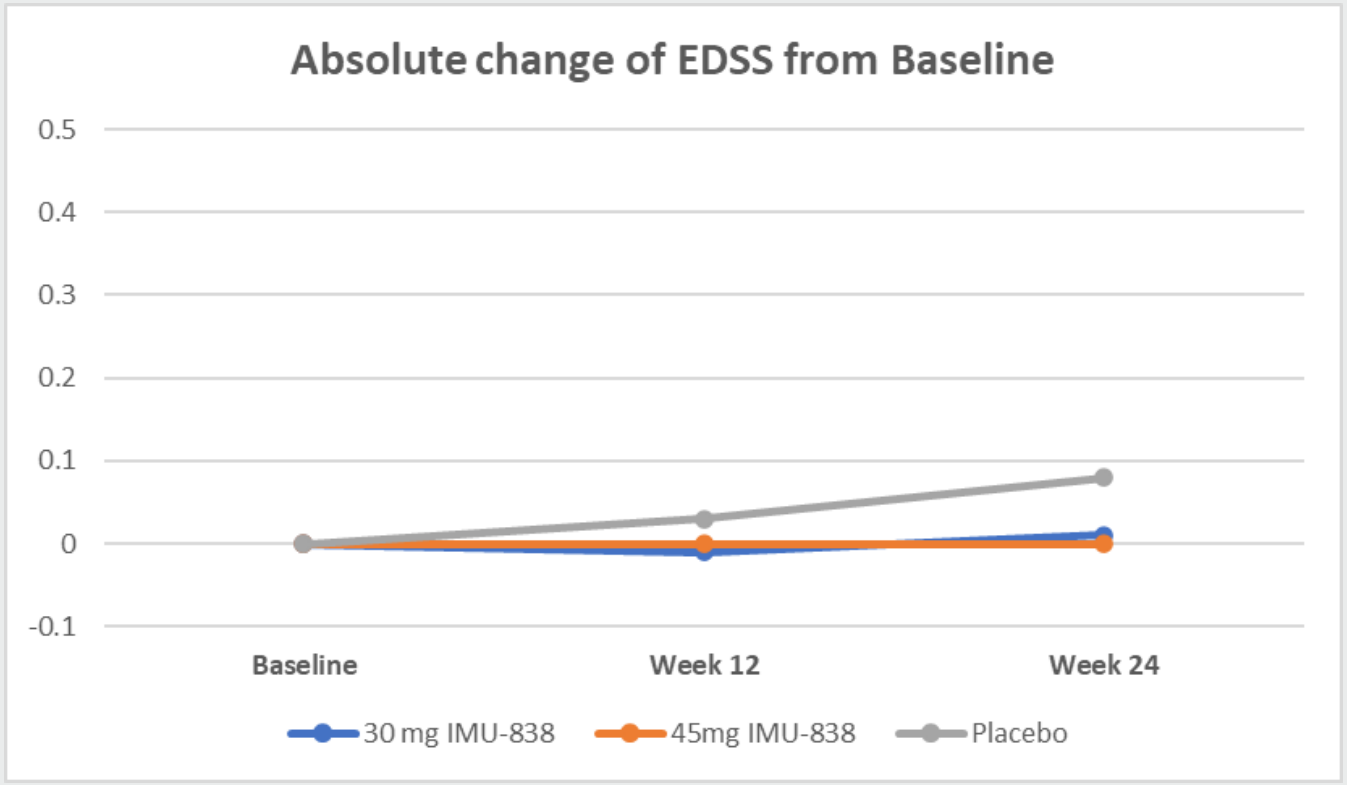
Expanded Disability Status Scale (EDSS)
Change from Baseline to Week 24



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

Displayed are mean values

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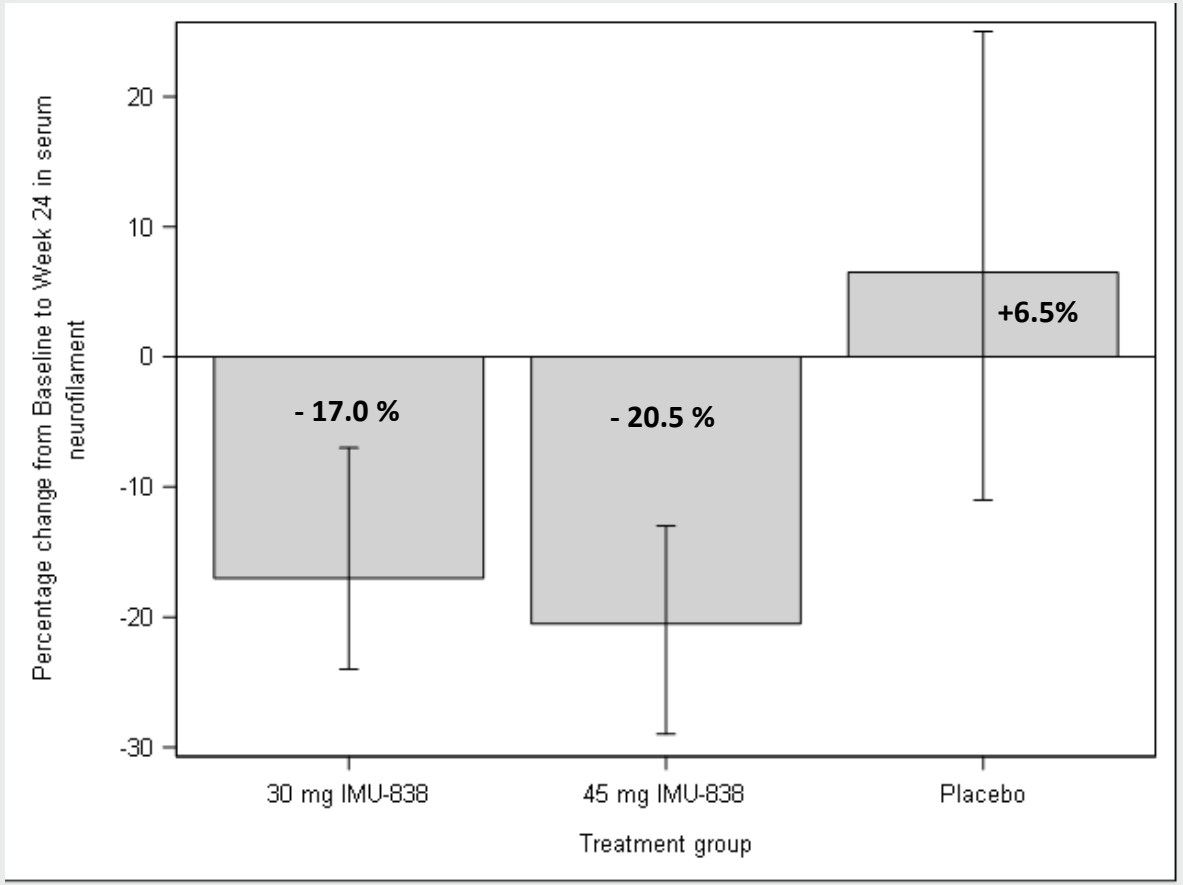
Neurofilament Light Chain in Serum

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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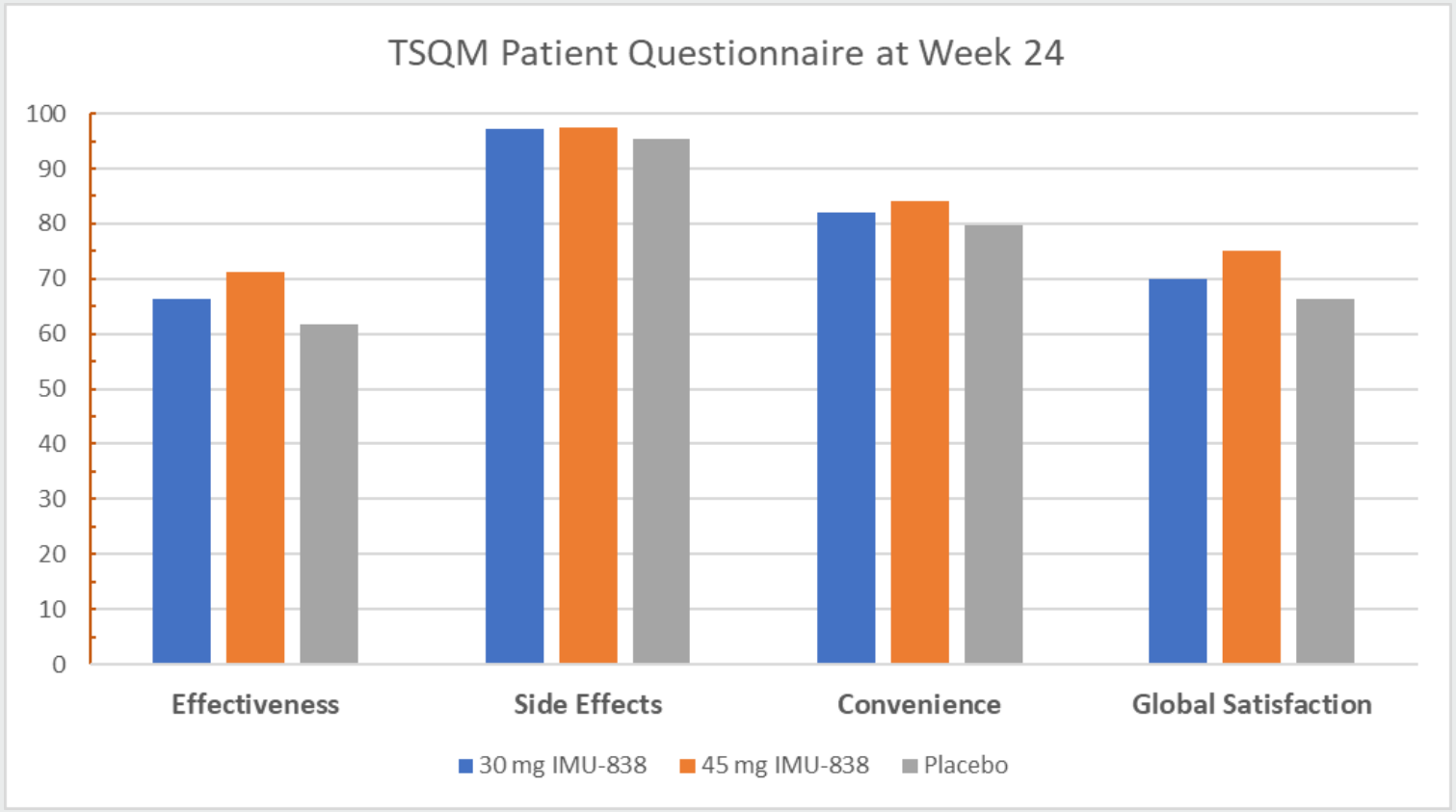
Patient Reported Outcome

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, unconfirmed disability, and EDSS detected, 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**

5

Phase 2 Data EMPhASIS Trial

Safety

IMU-838 is Safe and Well-Tolerated

Administration of IMU-838 in this clinical trial was observed to be well-tolerated, thereby also providing further evidence of a favorable safety profile of IMU-838 in the RRMS patient population

- In general, safety profile is similar to placebo

Very low rate of treatment discontinuations

- IMU-838 discontinuation rate compares favorably to many other medications in RRMS suggesting a good overall tolerance profile

Favorable safety profile of IMU-838 observed

- No increase in liver and renal events, as compared to placebo
- No signal for any hepatotoxicity or elevations of liver enzymes

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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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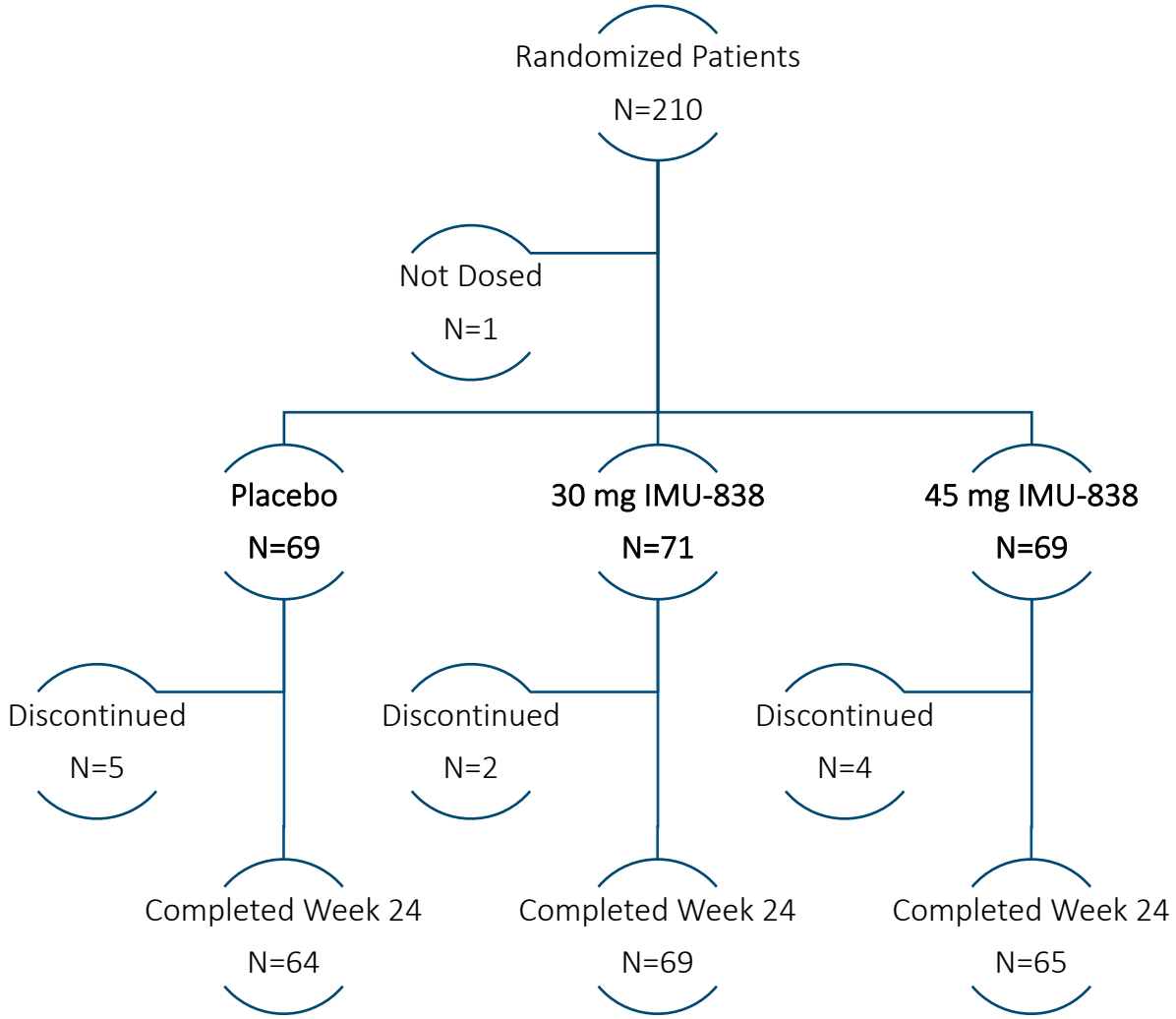
Phase 2 Data EMPhASIS Trial

Safety: Treatment Discontinuations

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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Treatment Discontinuations due to Adverse Events

Treatment Discontinuations Due to Adverse Events Before Week 24	Placebo (N=69)	30 mg IMU-838 (N=71)	45 mg IMU-838 (N=69)
Number of Patients Discontinued Treatment Related to Adverse Events (investigator decision due to AE, or fulfilling study stopping rules for hepatic events)	N=3	N=0	N=2
Number of Events Leading to Discontinuations	4	N/A	3

Treatment discontinuations due to adverse events were as prevalent in placebo as in IMU-838 treatment arms.

Adverse events leading to treatment discontinuations:

Placebo
- N=2 liver enzyme elevations
- N=1 cervix carcinoma
- N=1 hematuria

30 mg IMU-838
- No events

45 mg IMU-838
- N=2 liver enzyme elevations
- N=1 rash

Stopping rules for liver enzyme elevations were: ALT or AST >8 x ULN, or ALT or AST >5 x ULN for more than 2 weeks

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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EMPhASIS Trial: Liver Events

Liver Enzyme Elevations

Liver Enzyme Elevations

	30 mg IMU-838	45 mg IMU-838	Placebo
Number of Patients Evaluated	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%)

Liver enzyme elevations above certain thresholds were as prevalent in placebo as in IMU-838 treatment arms.

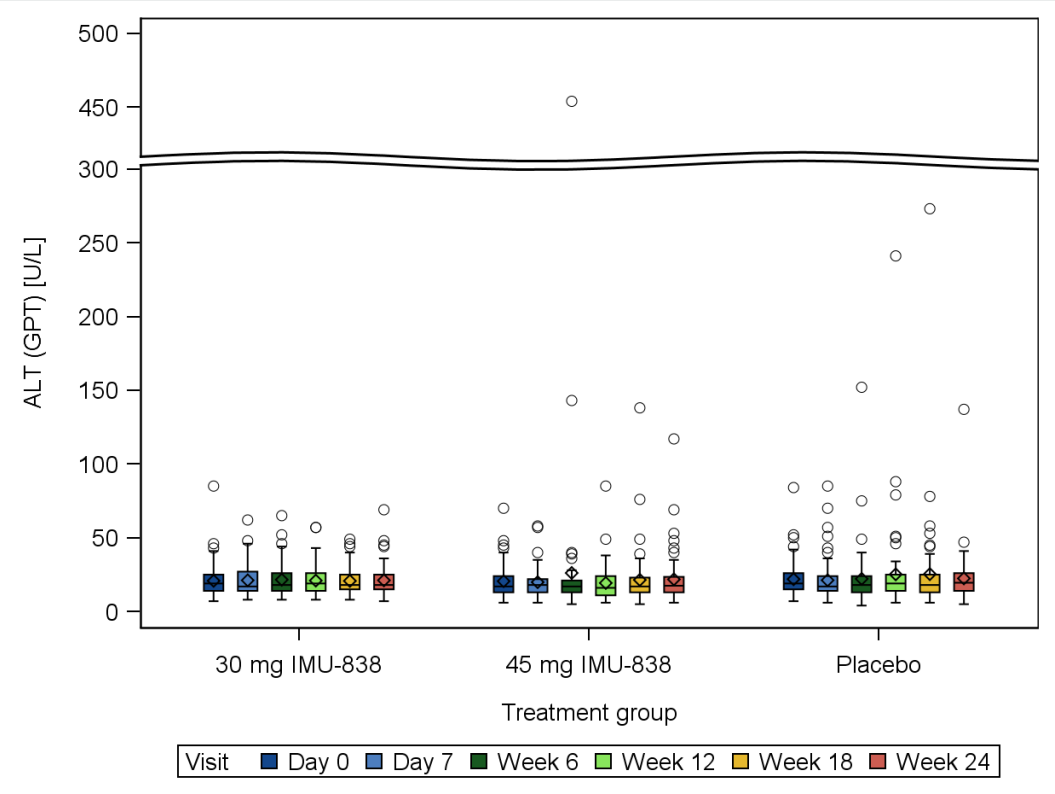
Very few cases of increases of alanine aminotransferase increases (ALT) or aspartate aminotransferase (AST) above the different thresholds of upper limit of normal (ULN)

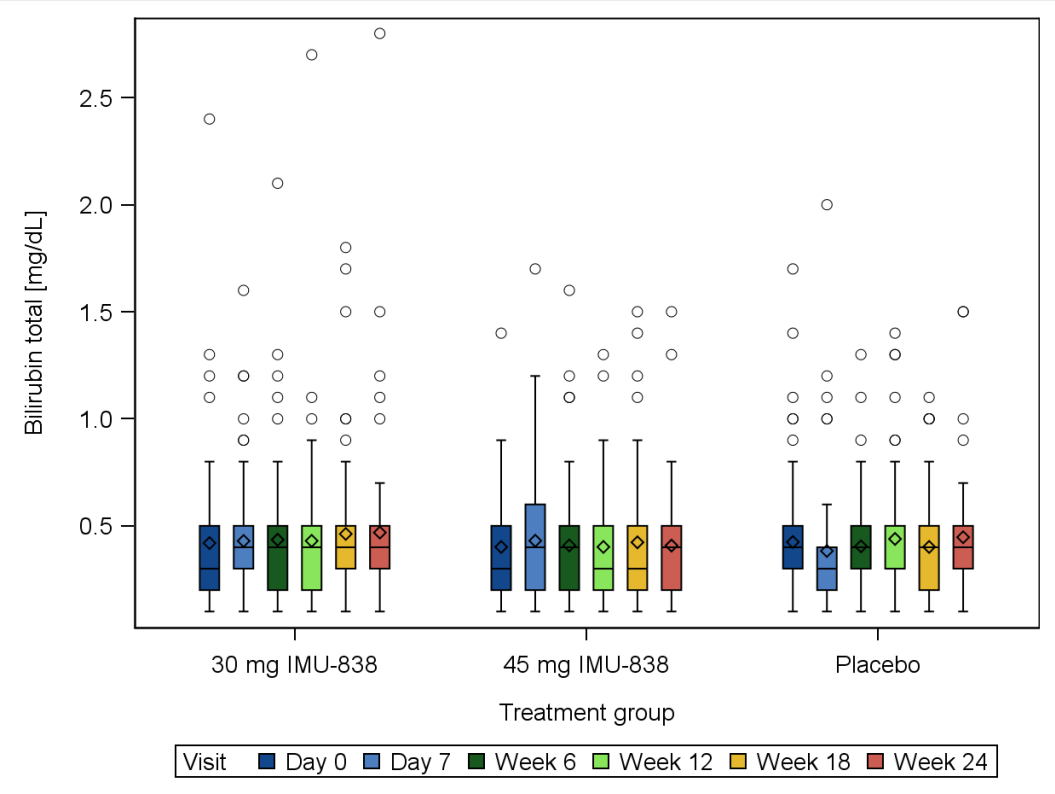
- Such cases are comparable between IMU-838 treatments arms and placebo

ULN: upper limit normal

Liver Investigations

No Generalized Effect on ALT or Total Bilirubin





Liver enzymes as well as bilirubin did not show a trend for changes during IMU-838 treatment.

The bottom and top edges of the box indicate the interquartile range (IQR; range of values between the first and third quartile). The mean value is indicated by a marker inside the box, the median value by a line. Endpoints of whiskers display minimum and maximum without any outliers. Circles show outliers which are 1.5*IQR beyond the bottom and top edges of the box.
If for a clinical laboratory value no exact numerical value is given (as value is e.g. below the lower limit of quantification [e.g. < 0.5]), the value without sign [e.g. 0.5] was used for boxplots.

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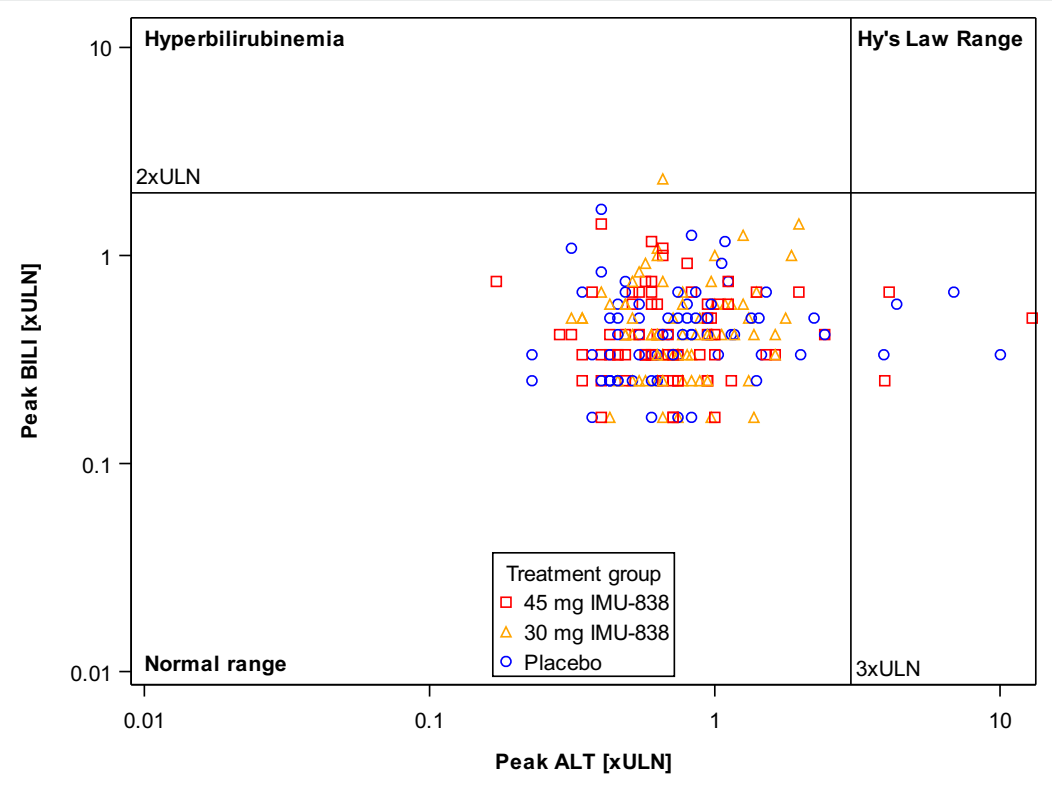
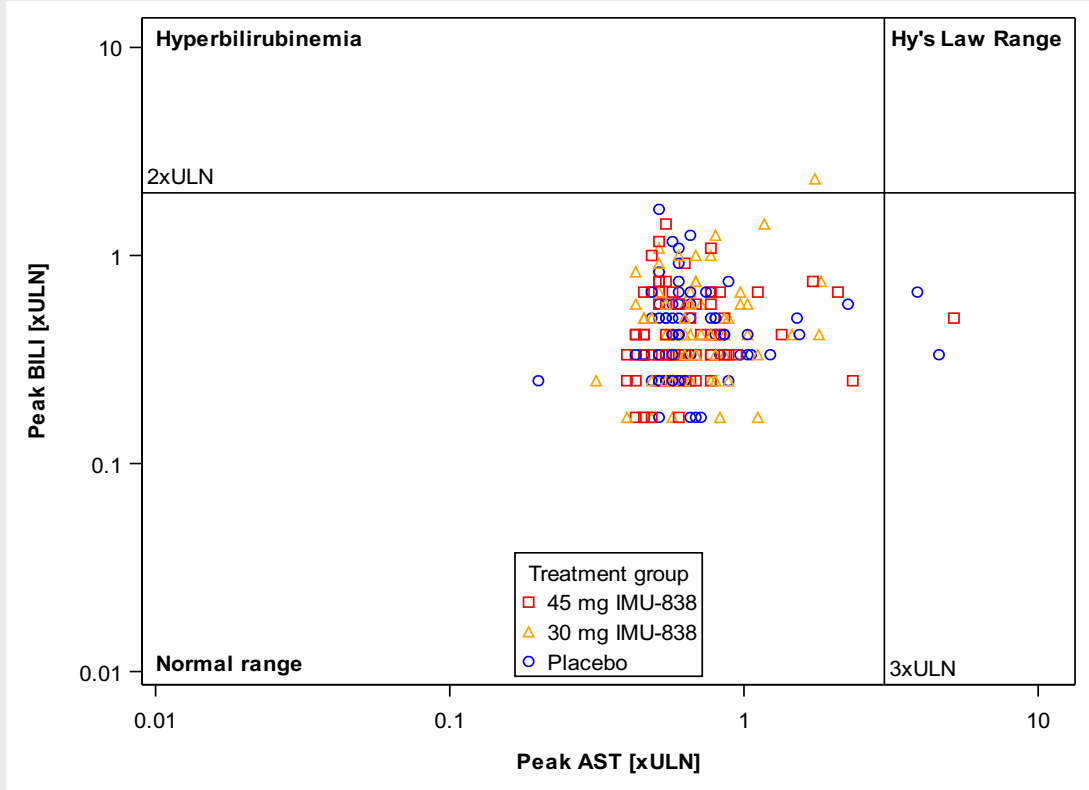
Hy's Law Assessment for Drug-Induced Liver Injury

No Hy's Law Cases for Either ALT or AST





There are no Hy's Law cases with concurrent increases of ALT and BILI (there are no such cases in the entire IMU-838 development program).

ALT: alanine aminotransferase. AST: aspartate aminotransferase
The peak AST/ALT and peak total Bilirubin (BILI) values are calculated from Day 7 to Week 24 and are normalized by ULN (upper limit normal).
The X- and Y-axis are on log scale.

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Phase 2 Data EMPhASIS Trial

Safety: Adverse Events of Interest

Adverse Events of Interest

		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 (%)
Blood and Lymphatic System Disorders	Neutropenia	0	0	0	0	0	0	1	1	1.4	1	1	0.5
	Leukopenia	0	0	0	0	0	0	1	1	1.4	1	1	0.5
	Lymphopenia	0	0	0	0	0	0	0	0	0	0	0	0
Sub-Total		0	0	0	0	0	0	2	1	1.4	2	1	0.5
Skin and Subcutaneous Tissues Disorders	Alopecia	3	3*	4.2	1	1	1.4	0	0	0	4	4	1.9
Sub-Total		3	3*	4.2	1	1	1.4	0	0	0	4	4	1.9
Gastrointestinal Disorders	Diarrhea	0	0	0	0	0	0	0	0	0	0	0	0
Sub-Total		0	0	0	0	0	0	0	0	0	0	0	0

Adverse events indicating general immuno-suppressive or general antiproliferative effects were not present or were rare during IMU-838 treatment.

* All three patients with mild alopecia came from the same clinical site.

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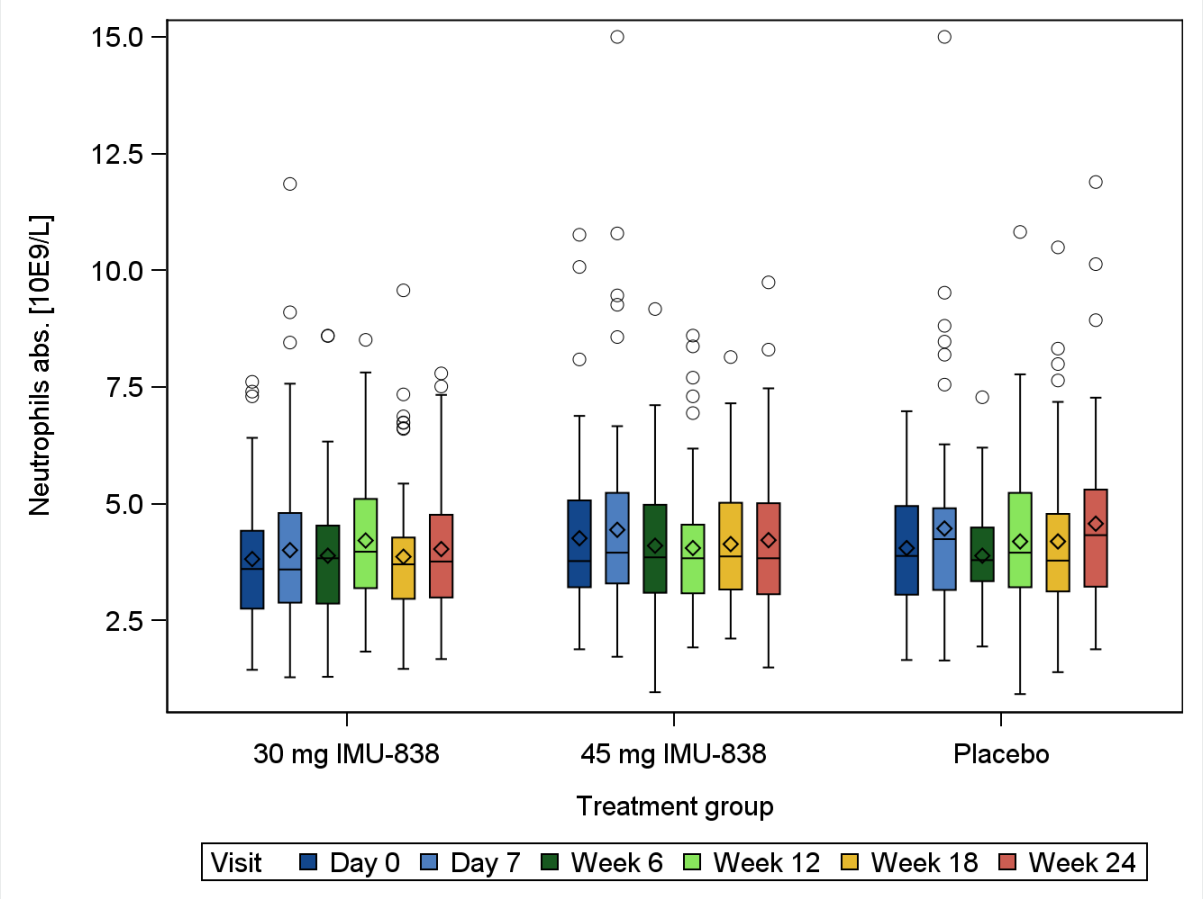
Hematology Analysis

No Generalized Effect on Neutrophils Count



IMU-838 treatment does not have a generalized effect on hematology laboratory values, as exemplified by neutrophils.

The bottom and top edges of the box indicate the interquartile range (IQR; range of values between the first and third quartile). The mean value is indicated by a marker inside the box, the median value by a line. Endpoints of whiskers display minimum and maximum without any outliers. Circles show outliers which are 1.5*IQR beyond the bottom and top edges of the box.
If for a clinical laboratory value no exact numerical value is given (as value is e.g. below the lower limit of quantification [e.g. < 0.5]), the value without sign [e.g. 0.5] was used for boxplots.

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Phase 2 Data EMPhASIS Trial

Safety: Renal Events

Overall Rate of Renal Events

There Was No Increase in Renal 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 renal event
IMU-838	2.1% (3/140)
Placebo	1.4% (1/69)

Renal events, including both clinical adverse events and clinically significant renal 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'.

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Treatment-Emergent Adverse Events: Renal Events

Renal Events	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 (%)
Blood Creatinine Increased	1	1	1.4	0	0	0.0	0	0	0.0	1	1	0.5
Chromaturia	0	0	0.0	1	1	1.4	0	0	0.0	1	1	0.5
Hematuria	0	0	0.0	0	0	0.0	1	1	1.4	1	1	0.5
Hydronephrosis	1	1	1.4	0	0	0.0	0	0	0.0	1	1	0.5
Ureterolithiasis	1	1	1.4	0	0	0.0	0	0	0.0	1	1	0.5
Total	4	**2**	2.8	1	**1**	1.4	1	**1**	1.4	6	**4**	1.9

Hematuria was defined as:

- ≥5 RBCs per HPF were found in at least 2 consecutive, properly collected urine sediment specimens (according to AUA Guidelines) and/or
- the finding of RBC urine positive had diagnostic or therapeutic consequences.

Treatment-emergent adverse events (TEAE) are as coded by MedDRA version 22.0. The preferred term is displayed in this table.
TEAE are AE starting at or after the day of the first study drug administration or AE already present that worsen in either intensity or frequency following exposure to the IMP.
Only TEAE with predetermined PTs related to renal function from SOC='Renal and urinary disorder' or SOC='Investigations' are displayed.
Each patient is counted at most once for the line total.

Adverse events related to kidney are not more prevalent in IMU-838 treatment as in placebo.

Immunic THERAPEUTICS

Adverse Events of Special Interest

Adverse Events of Special Interest	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 (%)
Hematuria	0	0	0.0	0	0	0.0	1	1	1.4	1	1	0.5
Ureterolithiasis	1	1	1.4	0	0	0.0	0	0	0.0	1	1	0.5
Total	1	**1**	1.4	0	**0**	0.0	1	**1**	1.4	2	**2**	1.0

Hematuria was defined as:

- ≥5 RBCs per HPF were found in at least 2 consecutive, properly collected urine sediment specimens (according to AUA Guidelines) and/or
- the finding of RBC urine positive had diagnostic or therapeutic consequences.

Treatment-emergent adverse events (TEAE) are as coded by MedDRA version 22.0. The preferred term is displayed in this table.
TEAE are AE starting at or after the day of the first study drug administration or AE already present that worsen in either intensity or frequency following exposure to the IMP.
Adverse events of special interest were defined as either: red blood cells in urine positive, at least of moderate intensity, hematuria, or retroperitoneal colicky pain with suspected or confirmed nephrolithiasis.
Each patient is counted at most once for the line total.

Adverse events of special interest (related to uric acid metabolism) were as prevalent in placebo as in IMU-838 treatment arms.

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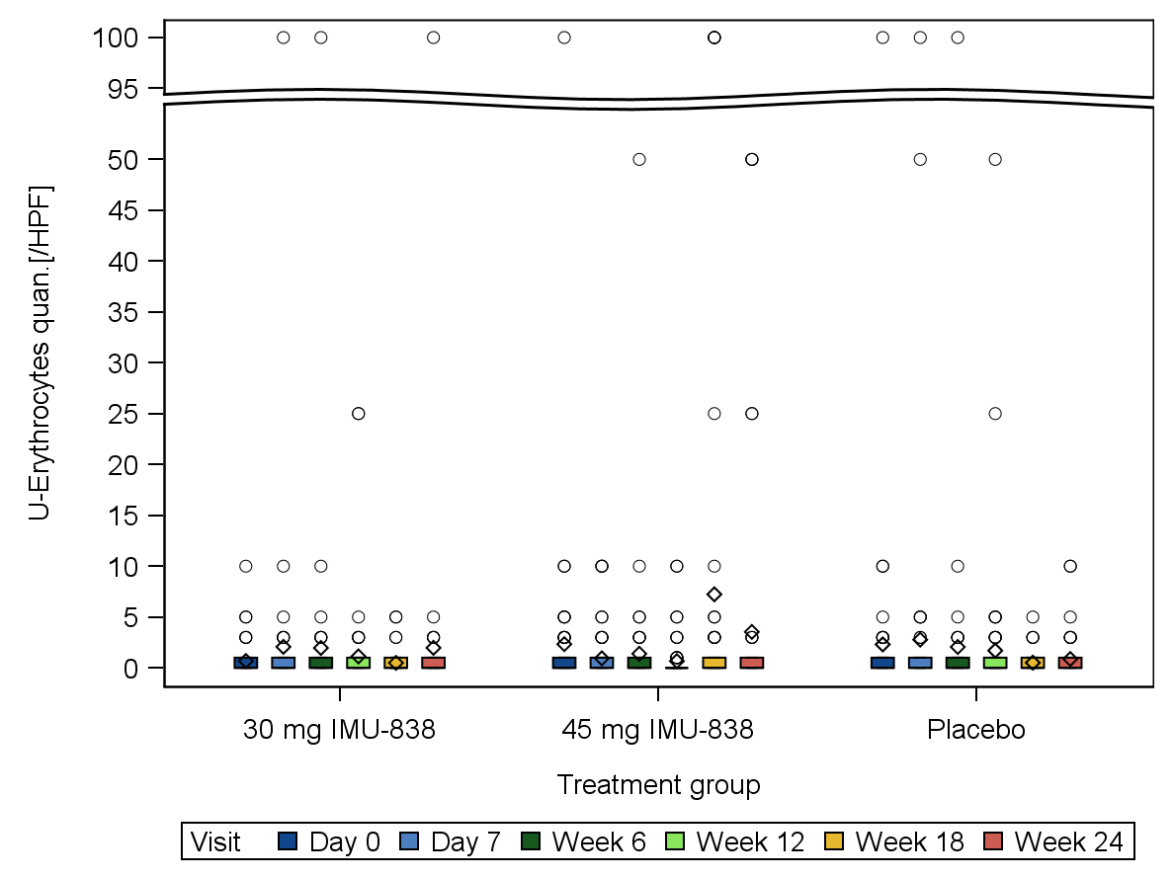
Urine Sediment Analysis

No Generalized Effect Regarding Hematuria



There is no trend for hematuria (as measured in urine sediment) to be increased during IMU-838 treatment versus placebo.

The bottom and top edges of the box indicate the interquartile range (IQR; range of values between the first and third quartile). The mean value is indicated by a marker inside the box, the median value by a line. Endpoints of whiskers display minimum and maximum without any outliers. Circles show outliers which are 1.5*IQR beyond the bottom and top edges of the box.
If for a clinical laboratory value no exact numerical value is given (as value is e.g. below the lower limit of quantification [e.g. < 0.5]), the value without sign [e.g. 0.5] was used for boxplots.

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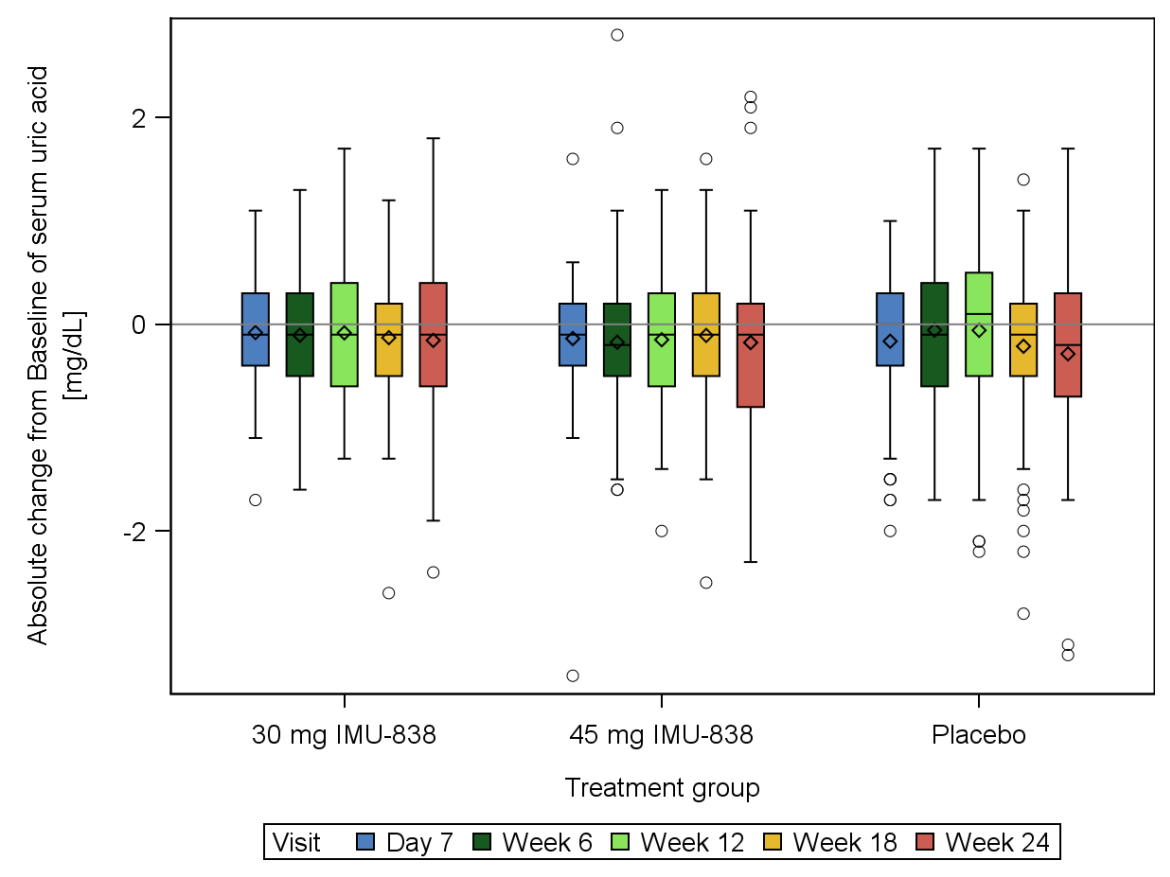
Serum Uric Acid

No Generalized Change from Baseline



There is no generalized effect on serum uric acid during IMU-838 treatment.

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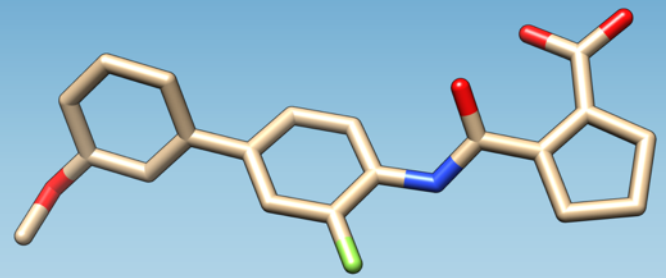
Conclusions Regarding Safety

- 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 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!

Immunic, Inc.
1200 Avenue of the Americas
New York City, NY 10036
USA

Immunic AG
Gräfelfing near Munich
Germany

Immunic Research GmbH
Weinberg Campus
Halle (Saale)
Germany

Immunic Australia Pty. Ltd.
Melbourne
Australia

Immunic, Inc.

1200 Avenue of the Americas, Suite 200
New York, NY 10036, USA

www.imux.com

Jessica Breu

Head of IR & Communications

Phone: +49 89 2080 477 09

Email: ir@imux.com