Immunic Therapeutics

Developing Selective Oral Drugs in Immunology

NASDAQ: IMUX | November 17, 2020 | Stifel 2020 Virtual Healthcare Conference

Cautionary Note Regarding Forward-Looking Statements

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 Private Securities Litigation Reform Act of 1995.

Such forward-looking statements are based on our expectations and involve risks and uncertainties; consequently, actual results may differ materially from those expressed or implied in the statements due to a number of factors, including, but not limited to, risks relating to strategy, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives of management. Risks and uncertainties that may cause actual results to differ materially from those expressed or implied in any forward-looking statement include, but are not limited to: Immunic’s plans to develop and commercialize its product candidates, including IMU-838, IMU-935 and IMU-856; the timing of initiation of Immunic’s planned clinical trials; the potential for IMU-838 to safely and effectively target and treat relapsing-remitting multiple sclerosis or infections associated with coronavirus disease 2019 (COVID-19); the impact of future preclinical and clinical data on IMU-838 and the Company’s other product candidates; the availability or efficacy of Immunic’s potential treatment options for patients with relapsing-remitting multiple sclerosis or other conditions, if any, that may be supported by the Company’s phase 2 EMPhASIS trial data discussed herein; expectations regarding potential market size; the timing of the availability of data from Immunic’s clinical trials; the timing of any planned investigational new drug application or new drug application; Immunic’s plans to research, develop and commercialize its current and future product candidates; Immunic’s ability to successfully collaborate with existing collaborators or enter into new collaboration agreements, and to fulfill its obligations under any such collaboration agreements; the clinical utility, potential benefits and market acceptance of Immunic’s product candidates; Immunic’s commercialization, marketing and manufacturing capabilities and strategy; Immunic’s ability to identify additional products or product candidates with significant commercial potential; developments and projections relating to Immunic’s competitors and industry; the impact of government laws and regulations; Immunic’s ability to protect its intellectual property position; Immunic’s listing on The Nasdaq Global Select Market; expectations regarding the capitalization, resources and ownership structure of the company; the executive and board structure of the company; Immunic’s estimates regarding future revenue, expenses, capital requirements and need for additional financing; the nature, strategy and focus of the company; and the other risks set forth in the company’s Annual Report on Form 10-K for the year ended December 31, 2019 and Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, filed with the Securities and Exchange Commission (“SEC”).

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 Vision

We are developing new therapies with best-in-class potential for the treatment of chronic inflammatory and autoimmune diseases.

Immunic THERAPEUTICS

Key Investment Highlights: Broad Value-Generating Pipeline

Lead Program IMU-838

- Successfully **demonstrated robust efficacy and excellent safety/tolerability in RRMS** phase 2 trial
- Phase 2 studies in **three further indications** ongoing: ulcerative colitis, COVID-19, primary sclerosing cholangitis

Three Potential Best-in-Class Oral Therapies

- IMU-935: **Oral IL-17 inhibitor** with substantial potential
- IMU-856: Novel target, **potentially disease modifying** for gastrointestinal disorders

NASDAQ: IMUX

- Experienced global management team
- Headquartered in New York City with R&D operations in Gräfelfing (Munich), Germany

Strong Balance Sheet

- **Raised approx. USD 103.5 million** in August 2020
- **Cash and cash equivalents of approx. USD 133 million** (as of September 30, 2020), expected to fund activities **into the second half of 2022**

Immunic THERAPEUTICS

Leadership Team

Company is Led by an Experienced Management Team

Daniel Vitt, PhD
CEO & President

Duane Nash, MD, JD, MBA
Executive Chairman

Andreas Muehler, MD, MBA
CMO

Hella Kohlhof, PhD
CSO

Manfred Groeppel, PhD
COO

Glenn Whaley, CPA
Vice President Finance, Principal Financial and Accounting Officer

Renowned International Board of Directors

Duane Nash, MD, JD, MBA
Executive Chairman

Daniel Vitt, PhD
CEO & President of Immunic

Tamar Howson, CFA
Independent Director

Barclay "Buck" A. Phillips
Independent Director

Joerg Neermann, PhD
LSP

Vincent Ossipow, PhD, CFA
Omega Funds

Jan Van den Bossche
Fund+

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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	■	■		
	Primary Sclerosing Cholangitis	DHODH	■	■	■	Investigator-Sponsored Trial performed at Mayo Clinic / NIH
	COVID-19*	DHODH	■	■	■	■
IMU-935	Psoriasis	RORγt	■	■		
	Guillain-Barré Syndrome	RORγt	■	■		
IMU-856	Gastrointestinal Diseases	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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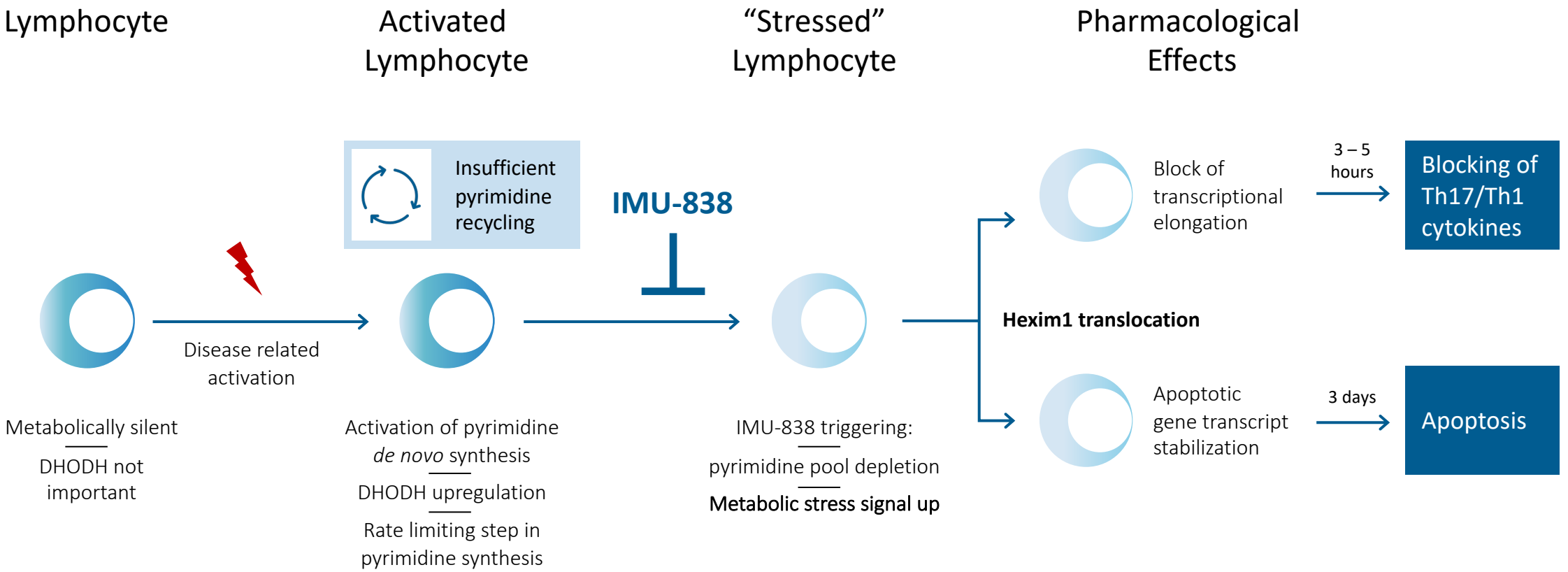
Mode of Action: DHODH Targeting Leads to Metabolic Stress in Metabolically Hyperactivated Cells



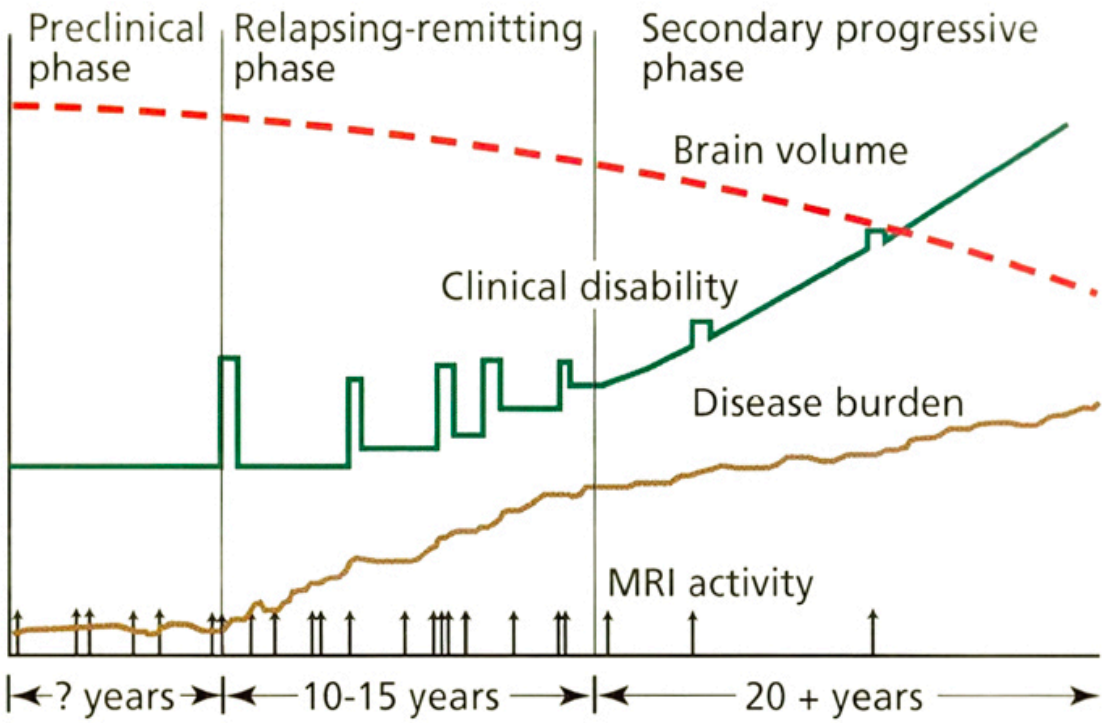
Adapted from Tan et al., 2016, Mol Cell 62

High Unmet Medical Need

IMU-838 in Relapsing-Remitting Multiple Sclerosis (RRMS)

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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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.

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

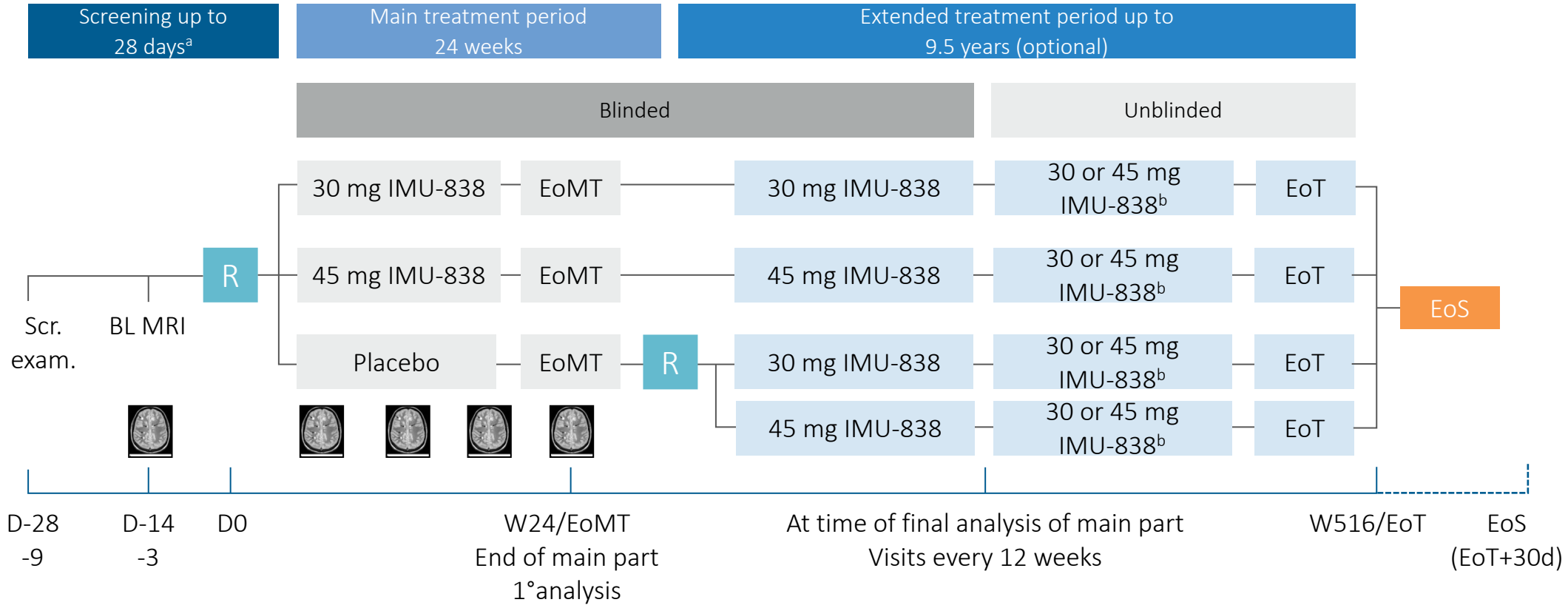
- Parallel group design with placebo control
- Overall blinded treatment period of 24 weeks
- MRI every six weeks

Extended Treatment Period

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

www.clinicaltrials.gov: NCT03846219
EDSS: Expanded Disability Status Scale

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**

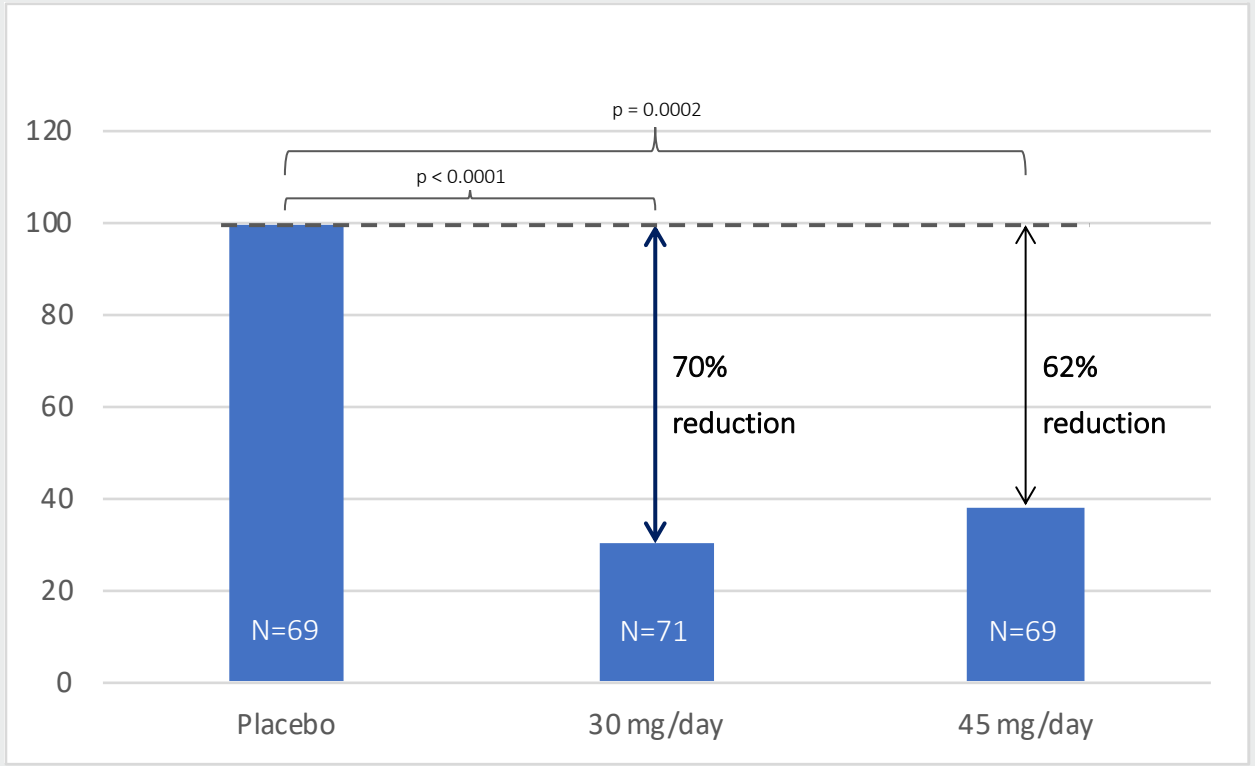
- **Primary endpoint: 45 mg IMU-838 vs. placebo**
- **Key secondary endpoint: 30 mg IMU-838 vs. placebo**

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



Suppression of CUA MRI Lesions
IMU-838 versus Placebo over 24 weeks

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-enhancing lesions on T1-weighted 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 Gadolinium-enhancing 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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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; CUA: combined unique active; Gd: Gadolinium

[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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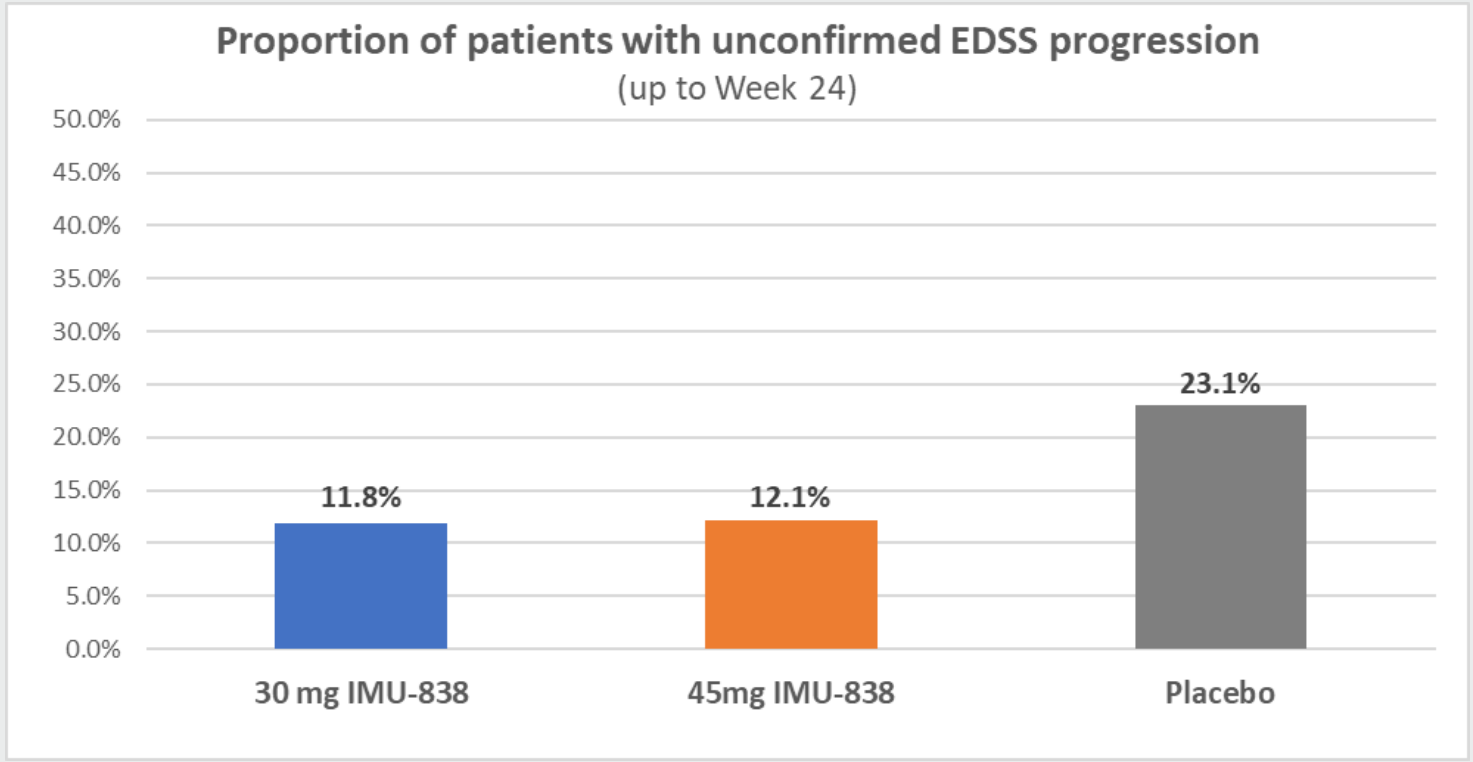
Unconfirmed Disability Progression up to Week 24

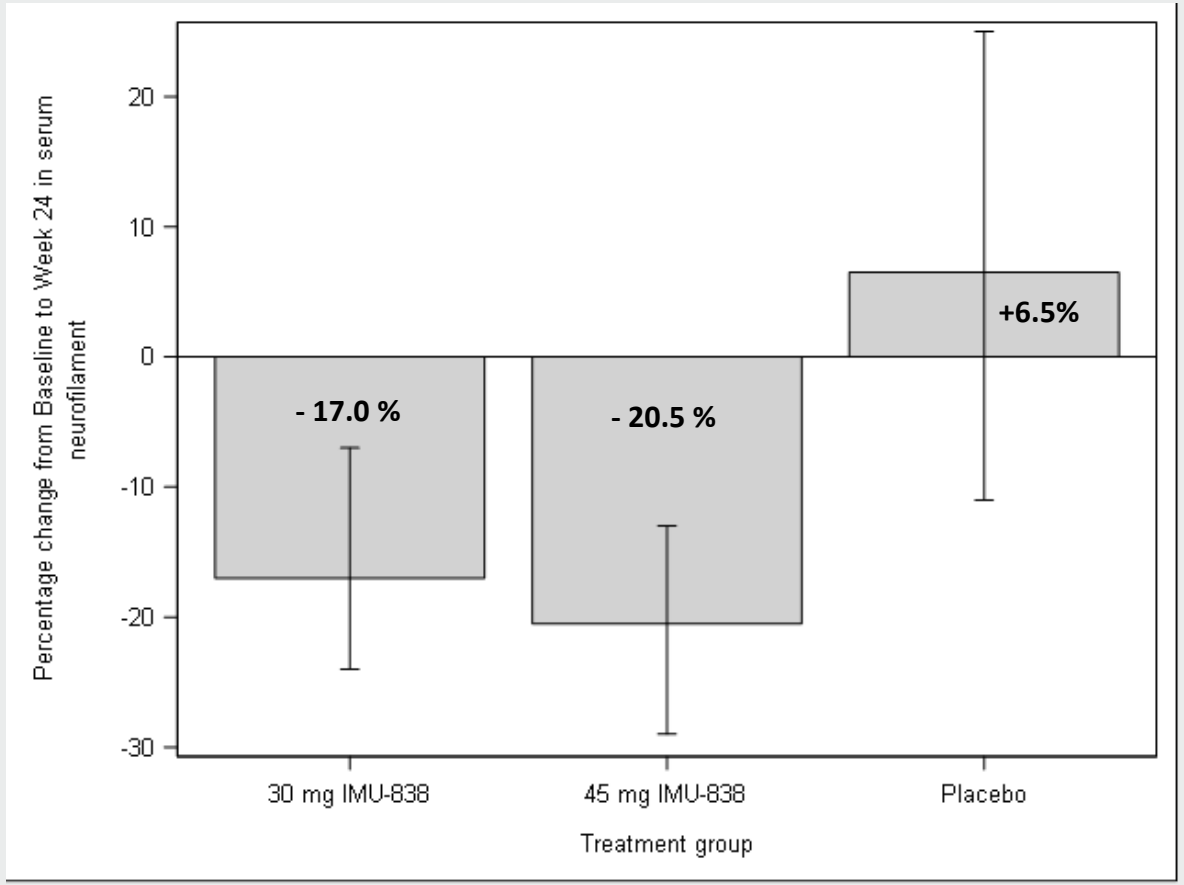


Despite the study's relatively small sample size and short duration of blinded treatment (24 weeks), a positive signal on unconfirmed disability was detected.

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.

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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Phase 2 Data EMPhASIS Trial

Safety

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

[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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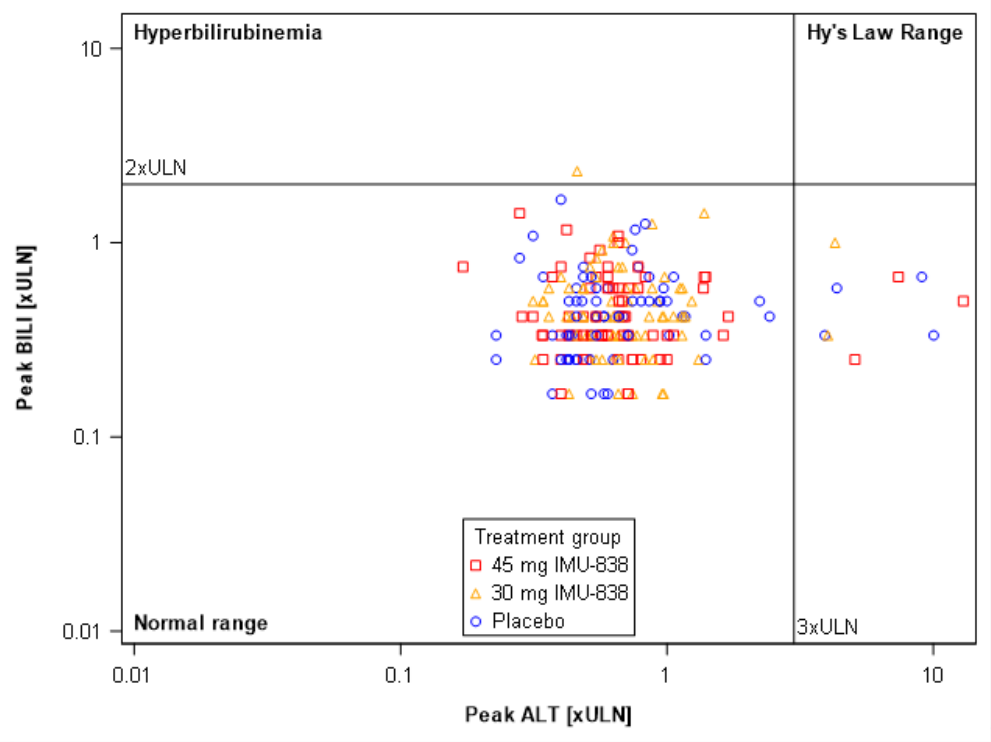
Absence of Hepatotoxicity Signals

Hy's Law Assessment for Drug-Induced Liver Injury

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

Hy's Law Assessment (ALT)



Liver Enzyme Elevations

	IMU-838 (30 mg and 45 mg pooled)	Placebo
Number of Patients	140	69
ALT or AST >5xULN	2.9% (4)	2.9% (2)
ALT or AST >10xULN	0.7% (1)	1.4% (1)
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.

ALT: alanine aminotransferase; AST: aspartate aminotransferase; ULN: upper limit of normal

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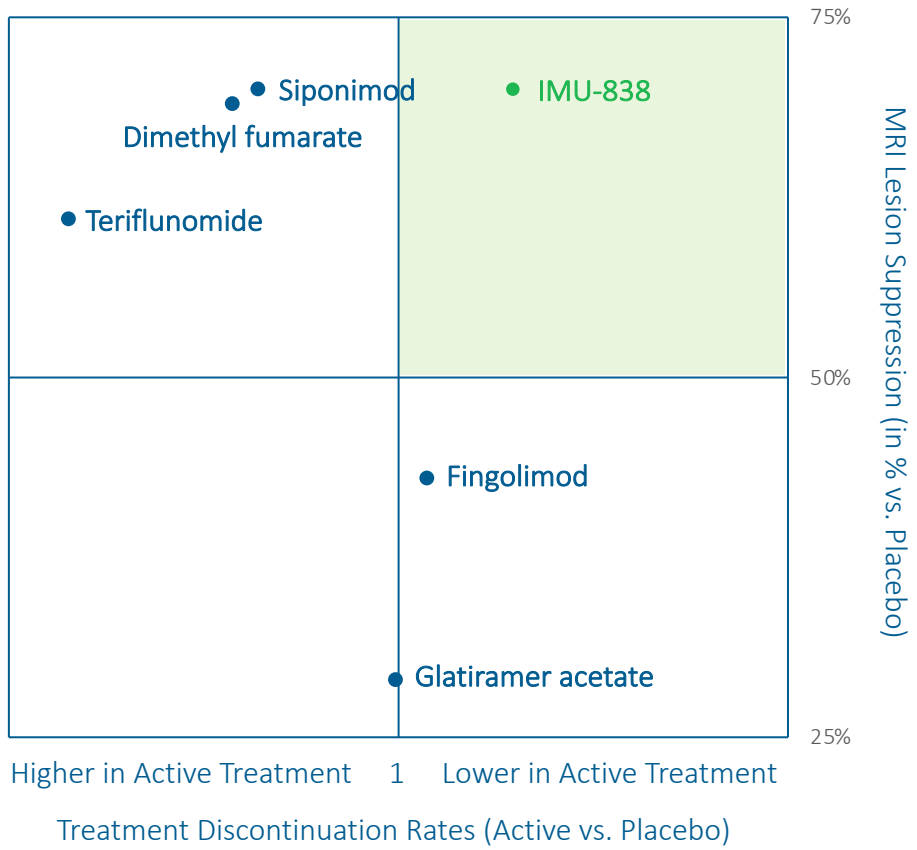
IMU-838 Compared with First-Line and Oral Medications in RRMS



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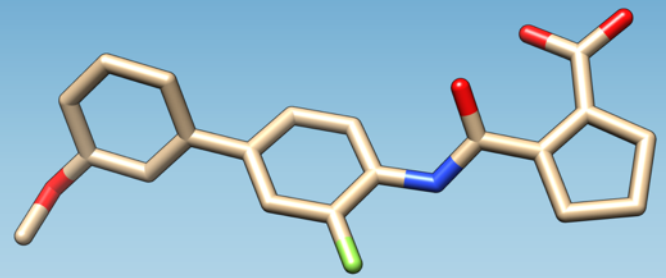
IMU-838 Positioned to be a New Safe and Efficacious Treatment Option for Early RRMS Patients

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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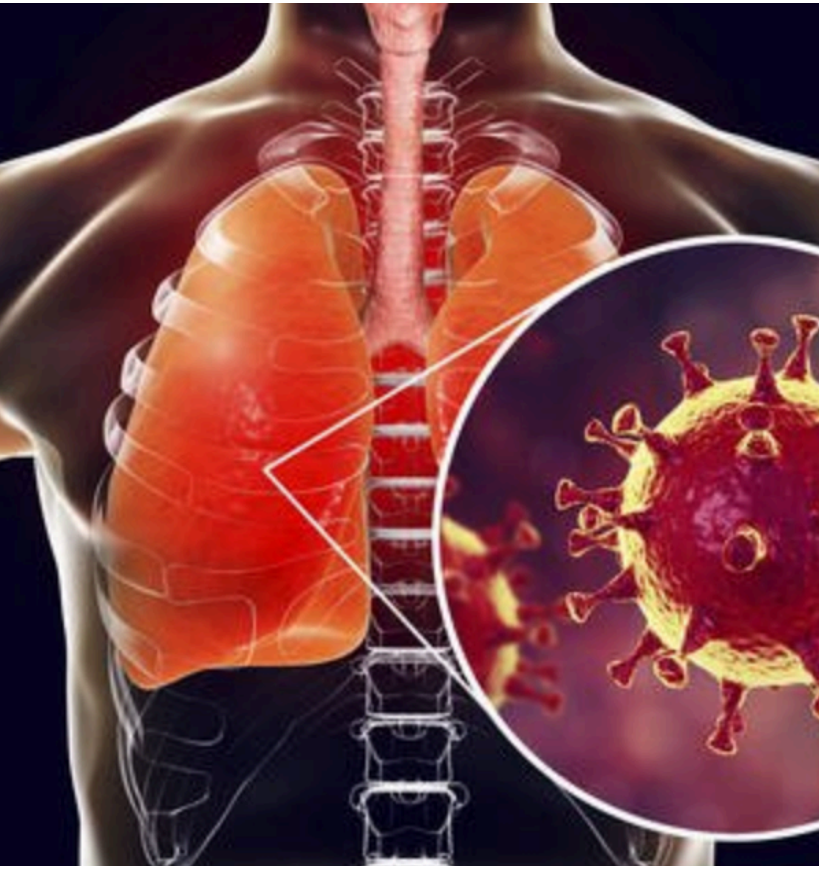
IMU-838 Fighting COVID-19

Leveraging DHODH's Broad-Spectrum Antiviral Activity

IMU-838: Triple Attack on COVID-19

IMU-838 is an Advanced Clinical Drug Candidate With Attractive Pharmacokinetic, Safety and Tolerability Profile With More Than **650 Individuals Exposed to Date**



IMU-838 Attacks COVID-19 Disease by Three Complementary Mechanisms:

1. Inhibition of **virus replication** by depletion of nucleotide pool
2. Insufficient first immune response due to SARS-CoV-2 encoded interferon antagonists. Induction of **innate immune response** by DHODH inhibition independent of interferon signaling
3. Excessive activation of adaptive immune response – “cytokine storm”. Inhibition of “overreacting”, **cytokine high** producing immune cells

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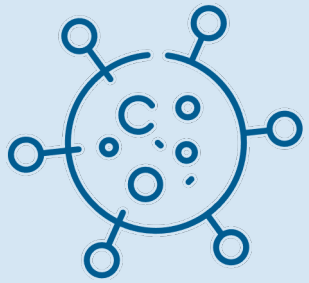
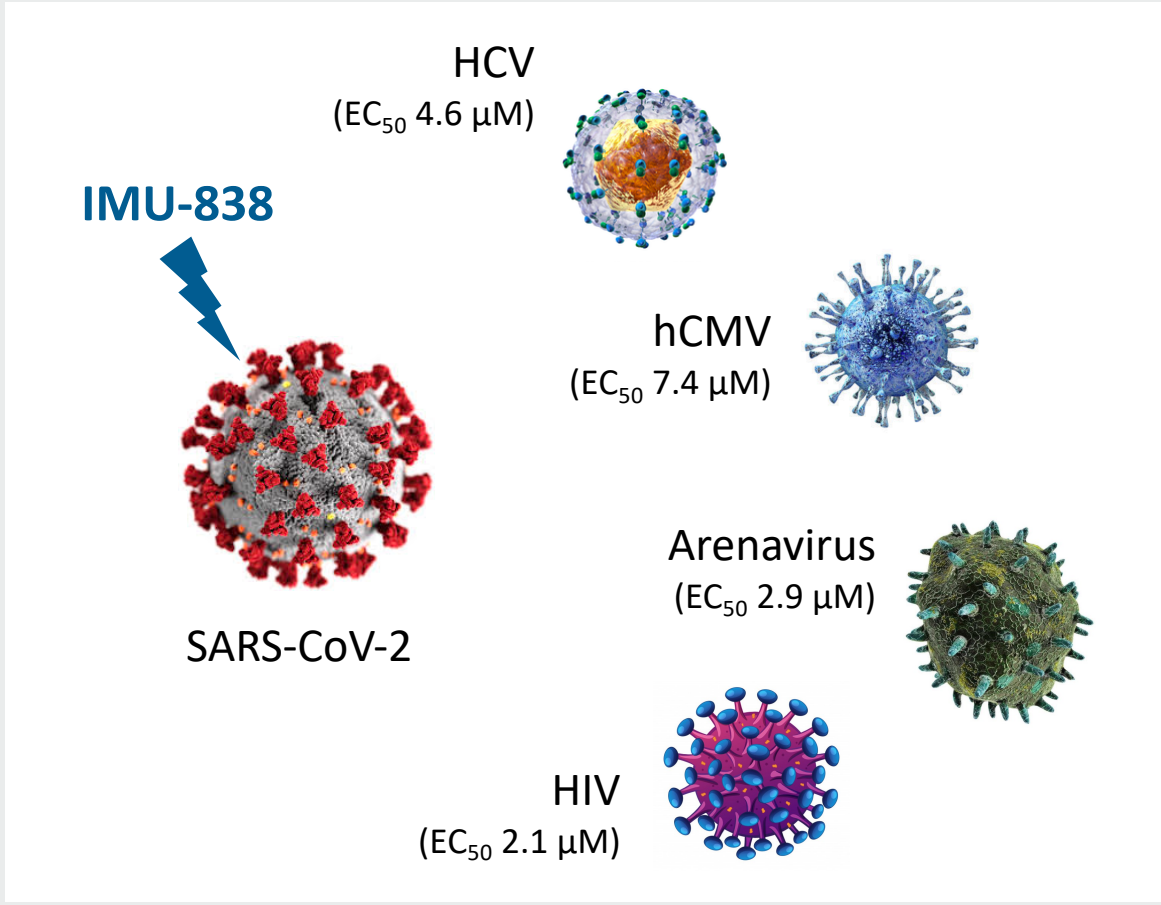
IMU-838 Antiviral Activity Against SARS-CoV-2 and Other Viruses



- IMU-838 is active against SARS-CoV-2
- IMU-838 has shown broad-spectrum antiviral activity against different pathogenic viruses with EC_{50} values in single digit µM range



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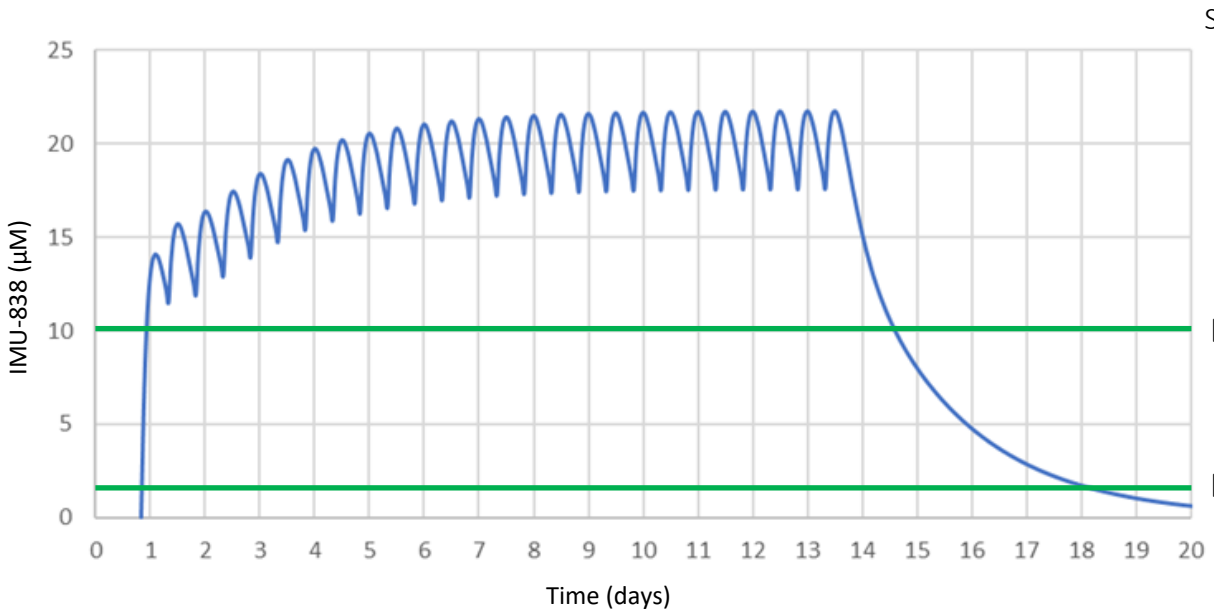
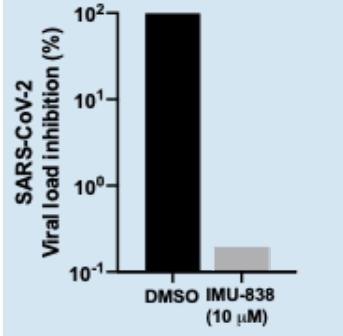
Anticipated Pharmacokinetic Profile 22.5 mg BID 14-day Treatment in Phase 2 IMU-838 in COVID-19 Patients



SARS-CoV-2

A549-ACE2



Proposed dosing regimen ensures that therapeutic levels of IMU-838 are reached starting from first dose.

Based on Population Pharmacokinetic Model for IMU-838 as described in the following publication: Muehler et al. Eur J Drug Metab Pharmacokinet. 2020 May 2. doi: 10.1007/s13318-020-00623-7
BID: bis in die = two times daily

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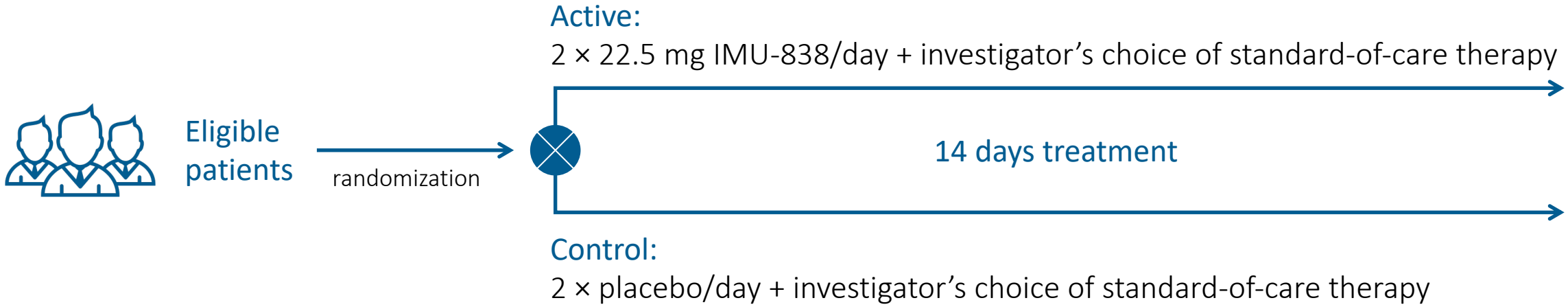
CALVID-1: Phase 2 Clinical Trial Design in COVID-19

Prospective, multicenter, randomized, placebo-controlled, double-blind phase 2 clinical trial



- n=230 patients
- About 25 clinical sites in the United States and Europe

- Top-line data from main phase 2 efficacy analysis expected to be available in Q1/2021
- USD 29 million EIB venture loan available for further phase 2/3 development

www.clinicaltrials.gov: NCT04379271

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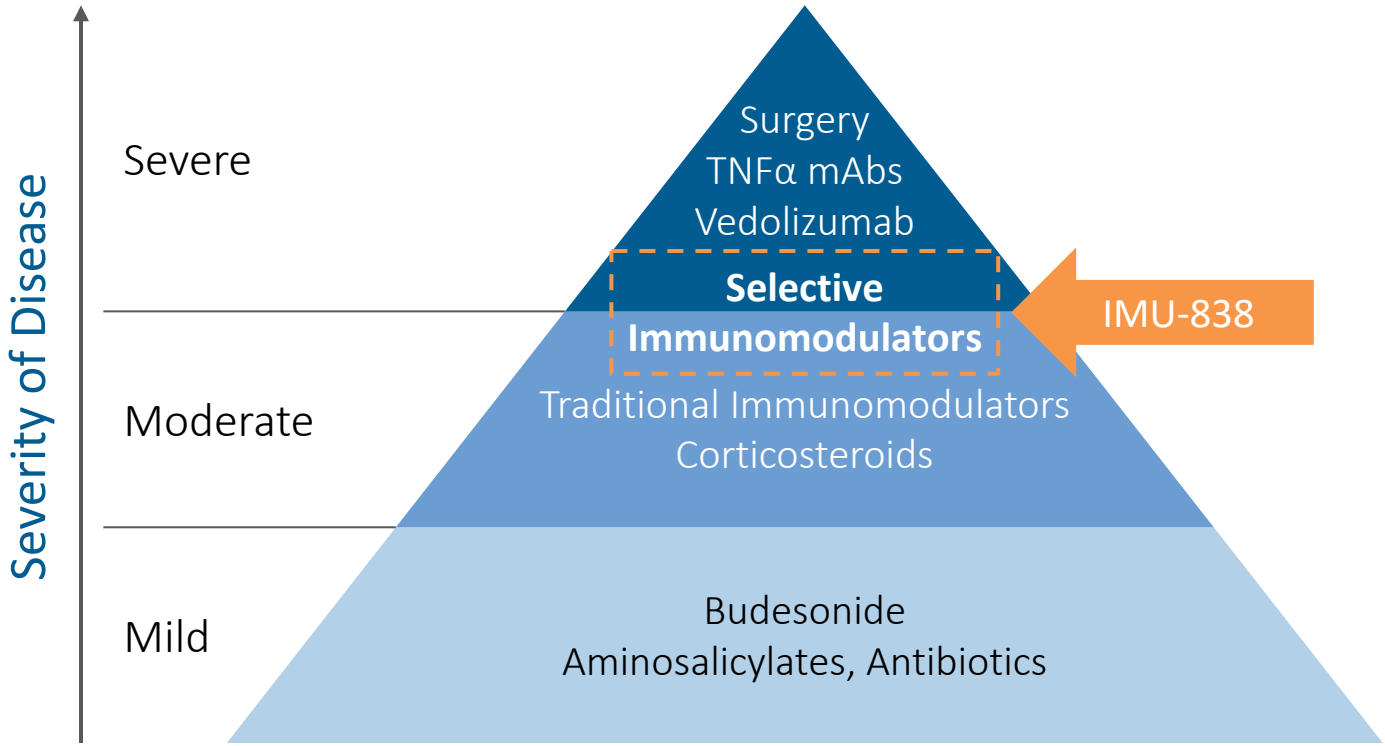
IMU-838 in Inflammatory Bowel Disease (IBD)

New Oral Treatment Option with Promising Safety Profile

IBD: Therapeutic Pyramid

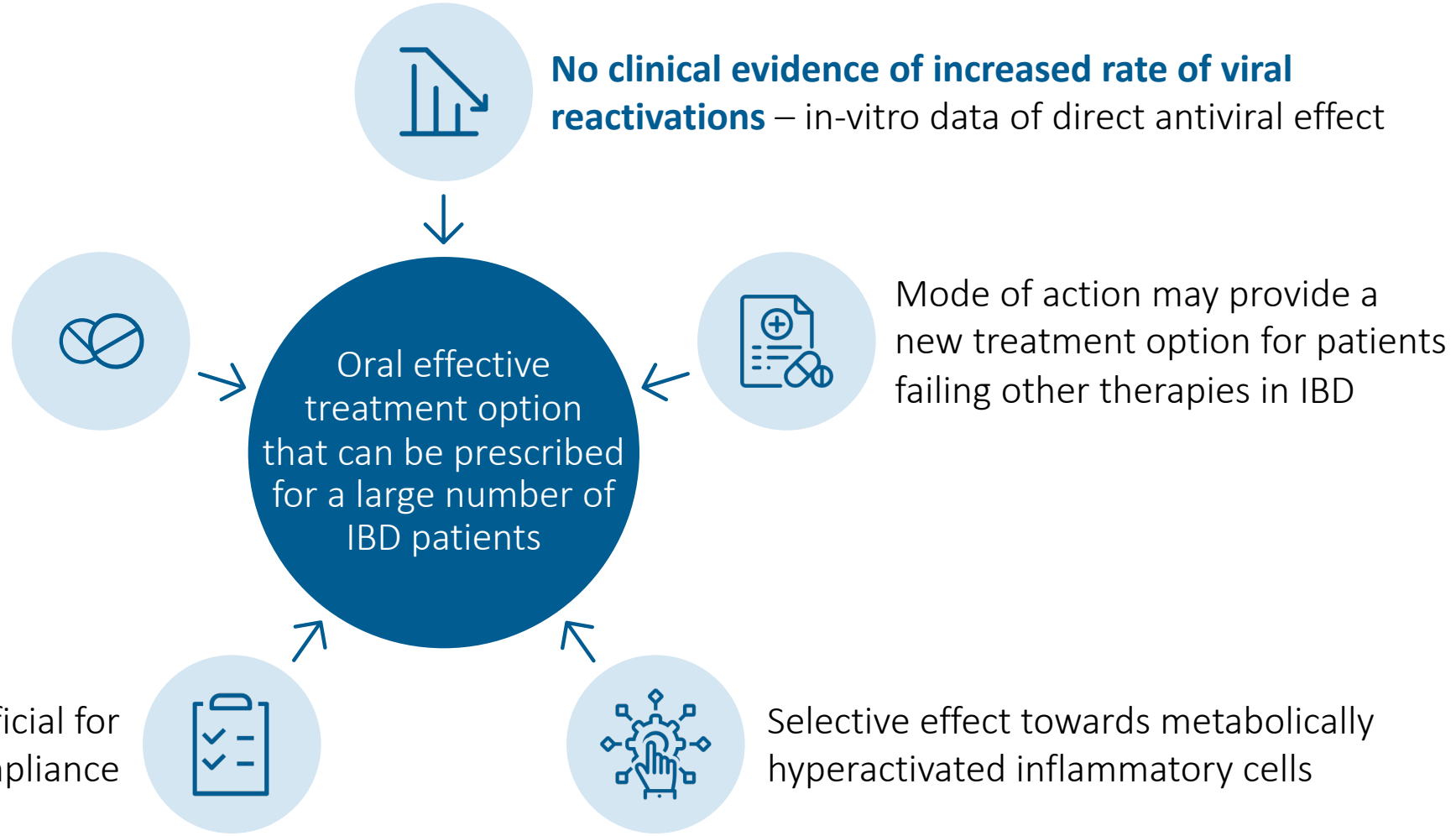


Current Solutions Have Limitations

- Substantial side effects due to long-term use includes increased rate of cancer risk and virus reactivation of currently used immunosuppressants[1] [2] [3]
- Antibodies lose activity over time[4]

[1] Present, Daniel H., et al. Annals of internal medicine 1989; 111.8: 641-649 [2] Dayharsh, Gerald A., et al. Gastroenterology 2002; 122.1: 72-77
[3] Winthrop, Kevin L., et al. Arthritis & rheumatology 2014; 66.10: 2675-2684 [4] Roda, Giulia, et al. Clinical and translational gastroenterology 2017; 7.1: e135
TNF: tumor necrosis factor; mAb: monoclonal antibody

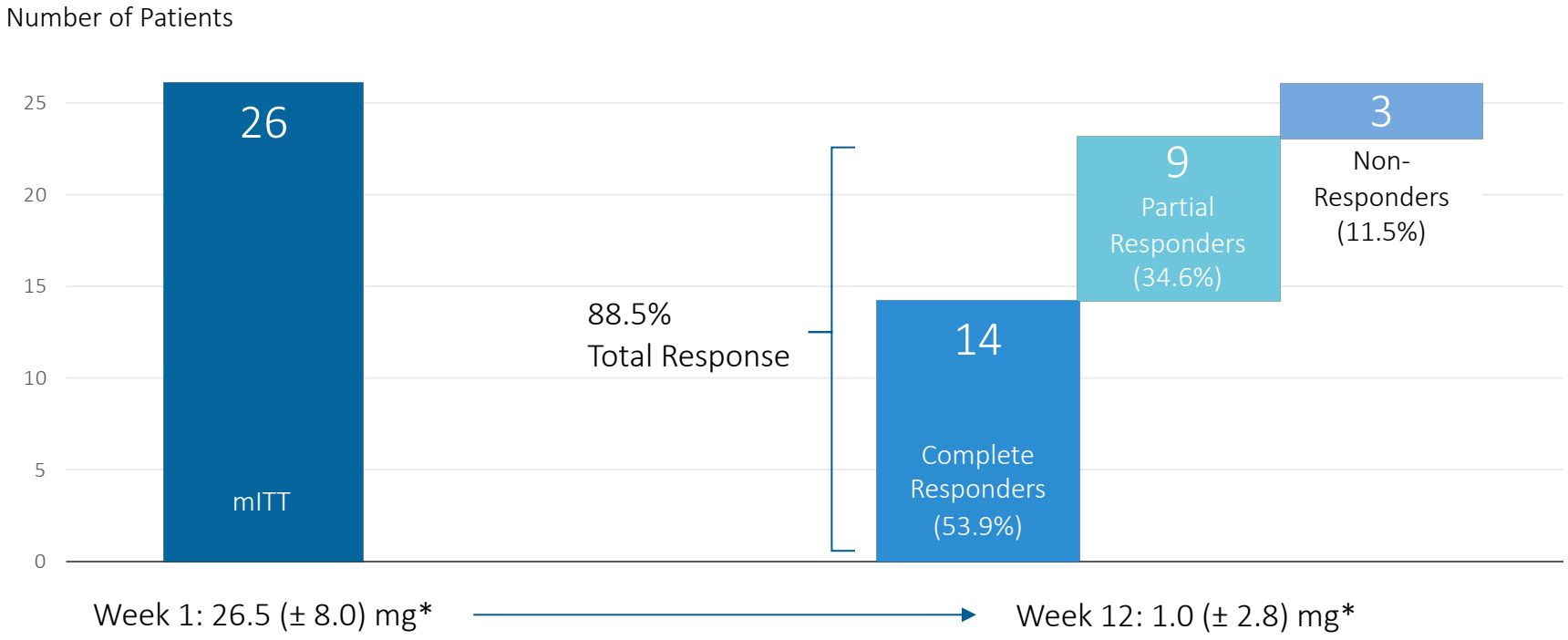
IMU-838: Key Strengths That Address Limitation of Existing Therapies in IBD



ENTRANCE Study: Primary Efficacy Results

ENTRANCE Study:

- Study performed with active moiety vidofludimus
- All patients failed two attempts to taper down steroids
- Open-label, dosing of 35 mg vidofludimus qd
- Primary efficacy endpoint: steroid-free/steroid-reduced remission (week 12)



IMU-838 had response rates of:

85.7 % in Crohn's disease

91.7 % in ulcerative colitis

Herrlinger et.al., 2011, Gastroenterology 140:588

*Mean dose of steroid equivalent in mg per day; mITT: modified intent to treat

Immunic THERAPEUTICS

CALDOSE-1: Clinical Phase 2 in UC Ongoing

Coordinating Investigator:
Dr. Geert d'Haens
(AMC Amsterdam)

Active IND in the United States

Overall Number of Patients:
240

Currently More Than 90 Active Sites in 13 Countries:
USA, Western, Central and Eastern Europe

Patient Population:

- Male and female patients, aged 18 to 80 years
- Previous treatment failure with immuno-modulators, steroids or biologicals
- Active symptoms defined as a Mayo stool frequency score of ≥2 and a modified Mayo endoscopy subscore of ≥2 at the screening flexible sigmoidoscopy (independent central reader)

Primary Endpoint:
Proportion of patients with symptomatic remission and endoscopic healing at week 10

Timelines:
Study started in April 2018
Currently estimated to deliver top-line data in H1/2022

www.clinicaltrials.gov: NCT03341962
IND: investigational new drug

CALDOSE-1: Interim Analysis Established Potentially Broad Effective Dose Range

- Performed by an unblinded data review committee (DRC) in August 2019
- Analysis based on all available clinical, endoscopic, biomarker, PD, and safety data

1 Main Treatment Period

- Doses of 10 to 45 mg may be effective in UC

2 Interim Analysis Confirmed the Good Safety Profile

- No intolerable dose identified
- No safety signal observed

The interim analysis supported that IMU-838 is a safe oral medication in patients with UC with a broad therapeutic index.

Immunic THERAPEUTICS

IMU-838 in Primary Sclerosing Cholangitis (PSC)

Investigator-Sponsored Trial Performed at the Mayo Clinic

IMU-838: Phase 2 Proof-of-Concept Study in PSC

Principal Investigator

Elizabeth Carey, MD (Mayo Clinic)

Timelines

- Study Started in August 2019
- Read-out of 18 patients who were enrolled prior to the COVID-19 pandemic expected during Q4/2020
- If successful, this indication may allow an accelerated path to regulatory approval

Rare Progressive Liver Disease Without Approved Pharmaceutical Treatments

Investigator-Sponsored Trial in Patients with PSC

- Single-arm, open-label, exploratory study planning to enroll 30 patients, aged 18 to 75 years
- Conducted at two Mayo Clinic sites in Arizona and Minnesota
- Supported by NIH grant
- Immunic provides the study medication to clinical sites
- Dosing: 30 mg IMU-838 qd for up to six months
- Primary endpoint: **change in serum alkaline phosphatase (ALP) at six months compared to baseline**

www.clinicaltrials.gov: NCT03722576

Immunic THERAPEUTICS

IMU-935

Unique RORγt Inverse Agonist

Autoimmune Diseases and IMU-935

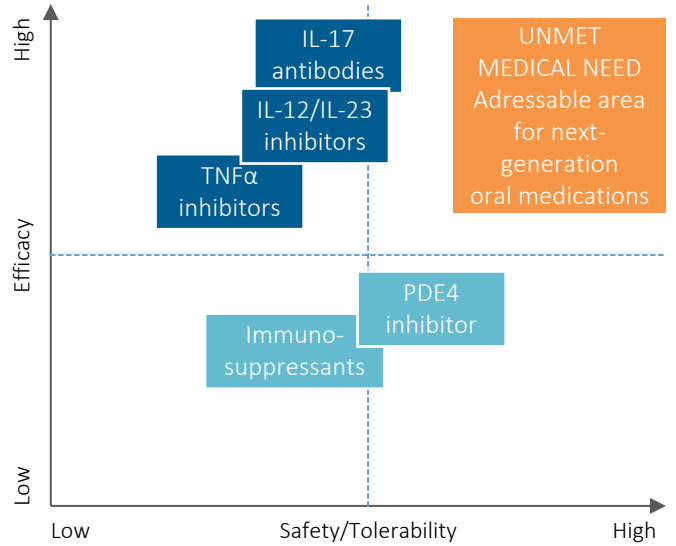
IL-17 in Autoimmune Diseases

- Autoimmune diseases are frequent diseases affecting millions of patients worldwide[1]
- Th17/IL-17/RORγt axis is important in auto immunity related diseases[2]
- Antibodies targeting this axis successfully demonstrated this concept but bear the disadvantage of being a non-oral drug[2]

Goal

- Develop an orally available and potent IL-17 inhibitor for the safe and efficacious treatment of autoimmune diseases
- Small molecule inhibitor of RORγt functions in autoimmune disease state without affecting physiological functions of RORγt

Unmet Need in Psoriasis Care



Strong Medical Need for Oral IL-17 Pathway Inhibitors such as IMU-935

[1] Rose, Noel R. American journal of epidemiology 2016; 183.5: 403-406
[2] Fasching, Patrizia, et al. Molecules 2017 22.1: 134

IMU-935: Selective Cytokine Inhibition in Low Nanomolar Range

Effect of the Development Compound IM105935 (IMU-935) in Stimulated Human PBMC

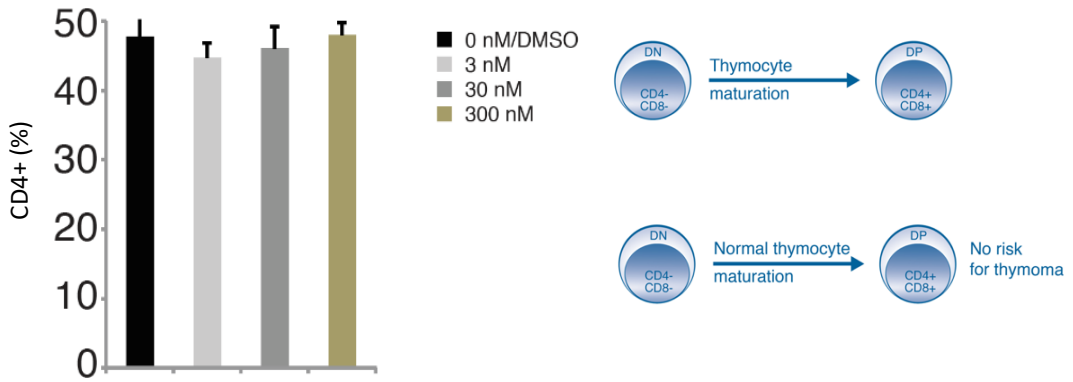
Inhibition of RORγ (20 nM) and DHODH (240 nM) leads to synergistical inhibition of cytokines with IC_{50} of 3-5 nM in stimulated human lymphocytes

	IC_{50} (µM)
IL-17A	0.005
IL-17F	0.004
IFNγ	0.003
IL-1a and b	no inhibition
IL-4,5,6,8	no inhibition
RORγ (MST)	0.024
RORγ (cellular, reporter assay)	0.020
DHODH	0.240
Th17 differentiation (murine)	150 nM

Read-out: effect on cytokine production after 48 hours in PBMC

PBMC: Peripheral Blood Mononuclear Cells

IMU-935 Maintains Normal Thymocyte Maturation and Retains Basal Activity of RORγt



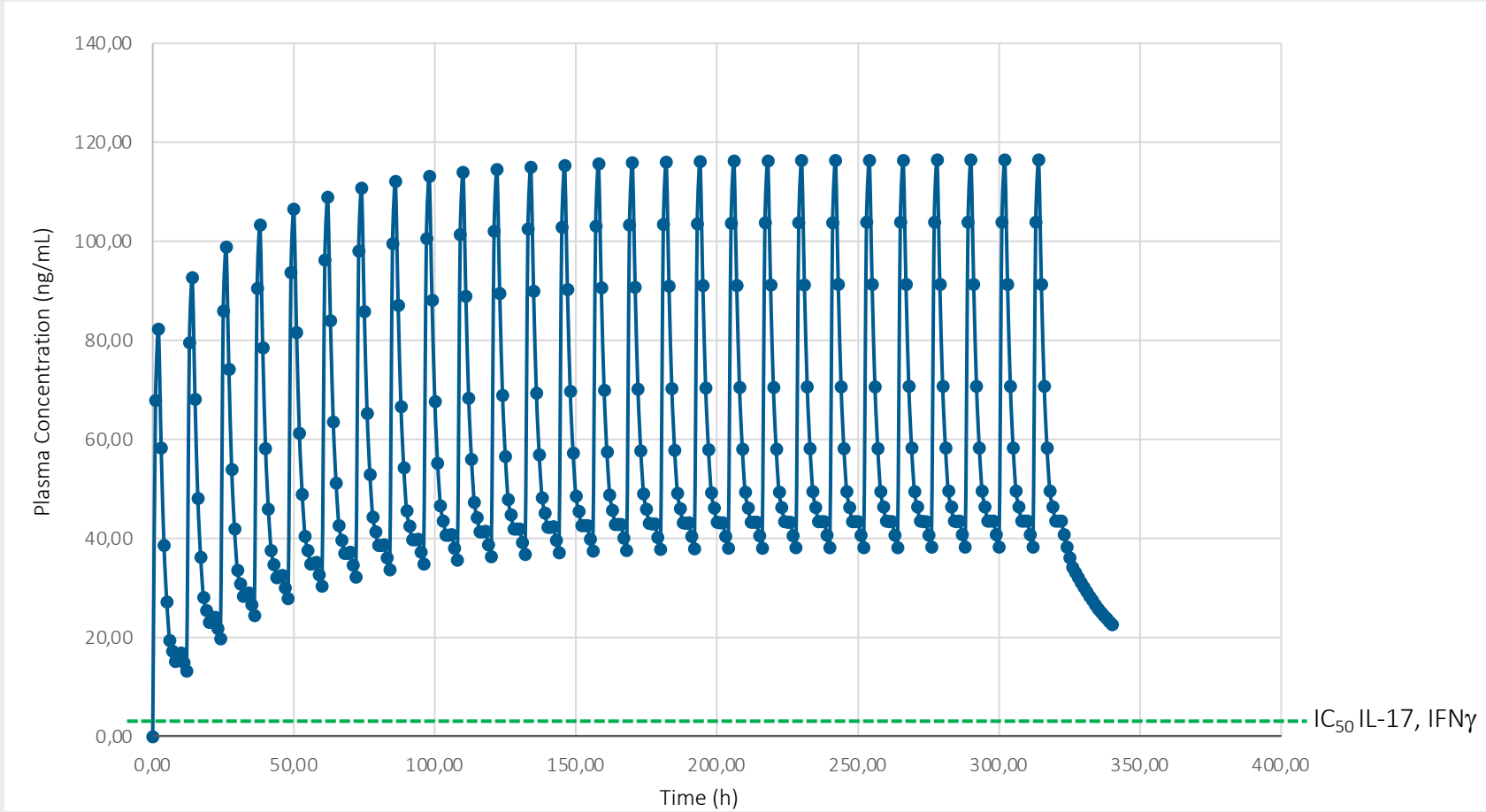
IMU-935 allows normal thymocyte maturation from murine DN towards matured CD4+ thymocytes (CD4+ and CD4+/CD8+)

Immunic THERAPEUTICS

IMU-935: Pharmacokinetic Modeling of Multiple Dose

Prediction of multiple dose pharmacokinetics (75 mg IMU-935 BID)

Estimated accumulation factor for multiple dosing 1.22



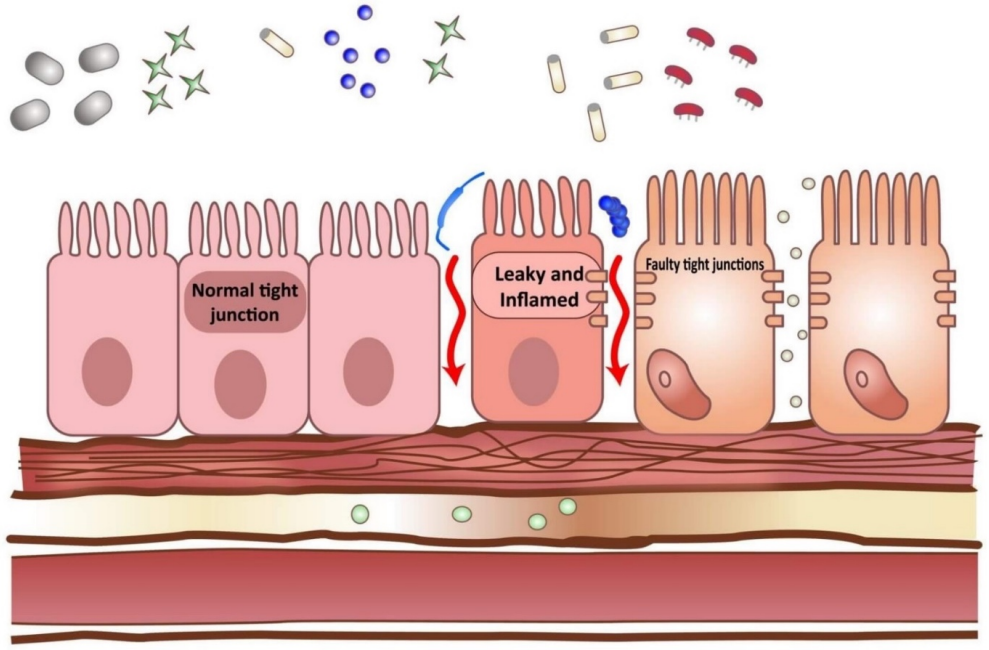
BID: bis in die = two times daily

IMU-856

Restoring Intestinal Barrier Function

Concept of IMU-856: Restoring the Intestinal Barrier Function Without Impairing the Immune System

Increased Bowel Permeability Connects the Microbiome and the Immune System

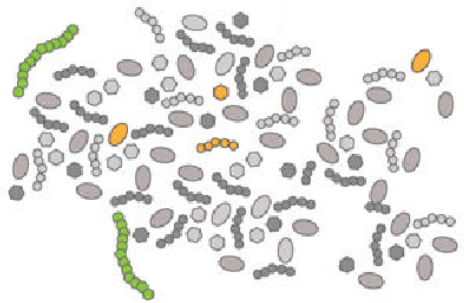


Picture taken from https://vibrantblueoils.com/essential-oils-to-heal-and-seal-the-gut/

IMU-856: Hypothesis of Therapeutic Approach

Compartmentalize Microbiome and Immune System by Strengthening the Bowel Barrier Function

Microbiota

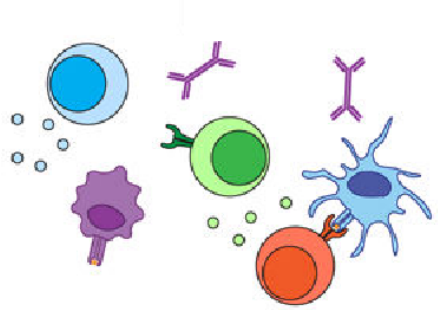


Influencing the Microbiome

- Changes in nutrition are driving the increase in disease rates
- Diversity of microbiome is good, but data on pathogenicity of particular species is often inconsistent
- Effects of probiotics on disease have been shown (supportive)

Gut wall

Immune System



Focus on Immunosuppression

- Stimulation of the immune system by the microbiome cannot be prevented
- Suppression of the secondary inflammatory process
- Usually has unintended consequences in terms of adverse event (infections, malignancies, inability to vaccinate)

Immunic THERAPEUTICS

IMU-856: Development Concept

- Double-blind, randomized, placebo-controlled clinical phase 1 study performed by Immunic subsidiary in Australia started in August 2020
- Phase 1 study includes patient population for confirmation of pharmacodynamic activity:
  - Safety and pharmacokinetics in healthy volunteers (Part A: SAD, Part B: MAD)
  - In Part C, patients with IBS-D and IBD will be included
  - 2-sugar test performed for bowel permeability to monitor IMU-856 therapy effects

Immunic Therapeutics

Summary

Summary and Highlights

Advanced and well-balanced pipeline:
Three products in clinical development

More phase 2 data read-outs ahead:
Several clinical phase 2 trials with IMU-838 expected to read-out in the next couple of months

Excellent phase 2 data in RRMS:
IMU-838 met all statistical endpoints and underlined favorable safety and tolerability profile

Shares outstanding: 20,718,340 (as of October 31, 2020)

Cash and cash equivalents of approx. USD 133 million and additional USD 29 million EIB venture loan
(as of September 30, 2020)

Phase 3 program in RRMS expected to start after end-of-phase 2 meetings with regulatory authorities, which are anticipated in May 2021

Raised approx. USD 103.5 million in August 2020, substantially extending cash runway beyond important value inflection points

Thank You!

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