Immunic Therapeutics

Top-Line Data Phase 2 CALDOSE-1 Trial in Ulcerative Colitis and Corporate Update

NASDAQ: IMUX | June 2, 2022

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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 Private Securities Litigation Reform Act of 1995.

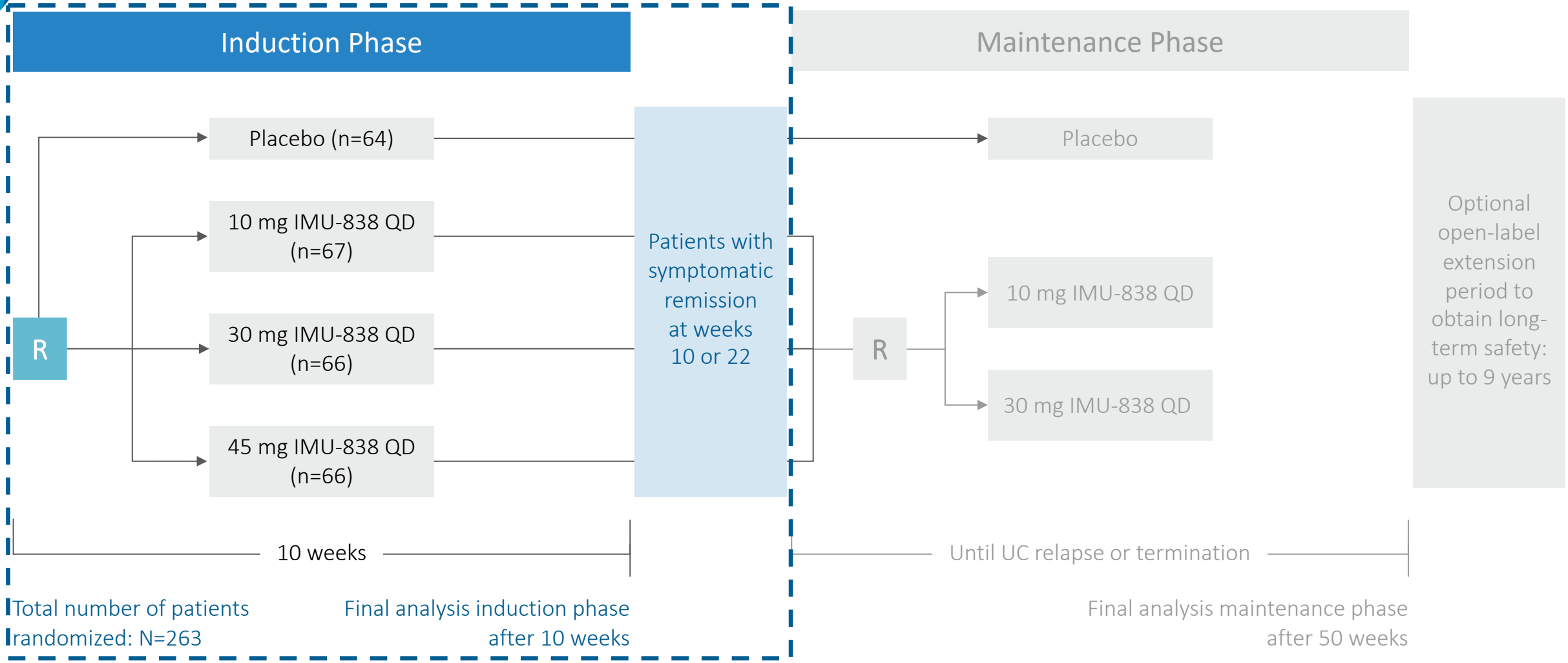
Such forward-looking statements are based on our expectations and involve risks and uncertainties; consequently, actual results may differ materially from those expressed or implied in the statements due to a number of factors, including, but not limited to, risks relating to strategy, future operations, 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 and the Company’s other product candidates to safely and effectively target and treat the diseases mentioned herein; 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 that may be supported by 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 fiscal year ended December 31, 2021, filed with the Securities and Exchange Commission.

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.

Top-Line Data Phase 2 CALDOSE-1 Trial in Ulcerative Colitis (UC)

CALDOSE-1: Readout of Induction Phase Data

Phase 2 Trial Design in Moderate-to-Severe UC, NCT03341962



R: randomization; QD: quaque die = once-daily

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CALDOSE-1: Clinical Phase 2 Trial in UC
NCT03341962

Coordinating investigator:
Dr. Geert D'Haens
(AMC Amsterdam)

Conducted with active IND in the United States

Total number of patients randomized: 263

More than 100 sites in 19 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 disease was defined as Mayo stool frequency score of ≥2, Mayo rectal bleeding score of ≥1 and a modified Mayo endoscopy subscore of ≥2 at the screening flexible sigmoidoscopy (independent central reader)

Primary endpoint:
Proportion of patients with clinical remission (symptomatic remission and endoscopic remission) at week 10

Primary statistical analysis:
Clinical remission of pooled 30 and 45 mg active dose groups versus placebo group

IND: investigational new drug

CALDOSE-1: Demographics

Stratification at Randomization for Prior Biologics and Concurrent Corticosteroid Use

		Treatment Groups								Total	
		10 mg IMU-838		30 mg IMU-838		45 mg IMU-838		Placebo			
		N	%	N	%	N	%	N	%	N	%
Concurrent Use of Corticosteroids											
No	Biologic-Naïve Patients	28	41.8	26	38.8	26	39.4	26	41.3	106	40.3
Yes	Biologic-Naïve Patients	25	37.3	30	44.8	29	43.9	26	41.3	110	41.8
Total	Biologic-Naïve Patients	53	79.1	56	83.6	55	83.3	52	82.5	216	**82.1**
No	Biologic-Experienced Patients	5	7.5	6	9.0	4	6.1	5	7.9	20	7.6
Yes	Biologic-Experienced Patients	9	13.4	5	7.5	7	10.6	6	9.5	27	10.3
Total	Biologic-Experienced Patients	14	20.9	11	16.4	11	16.7	11	17.5	47	**17.9**
No		33	49.3	32	47.8	30	45.5	31	49.2	126	47.9
Yes	**Total**	**34**	**50.7**	**35**	**52.2**	**36**	**54.5**	**32**	**50.8**	**137**	**52.1**
Total		67	100.0	67	100.0	66	100.0	63	100.0	263	100.0

The table provides the demographic information for prior biologics use and concurrent use of corticosteroids, as used as stratification factor for randomization as provided by the investigator. The actual rate of concurrent corticosteroid use is slightly different than these strata information, however, there is no substantial difference to actual corticosteroid use.

Allowed concurrent corticosteroid use per protocol: Use of oral systemic corticosteroids (≤20 mg/day prednisolone equivalent), including beclomethasone dipropionate (at ≤5 mg/day) and budesonide (MMX at ≤9 mg/day) unless they have been used for at least four weeks before first randomization, and at a stable dose for at least two weeks before first randomization. Concurrent use of corticosteroids used as stratification factor at randomization (ensures equivalent distribution to all treatment groups). Doses of corticosteroids were required to be stable and could not be changed throughout the induction phase.

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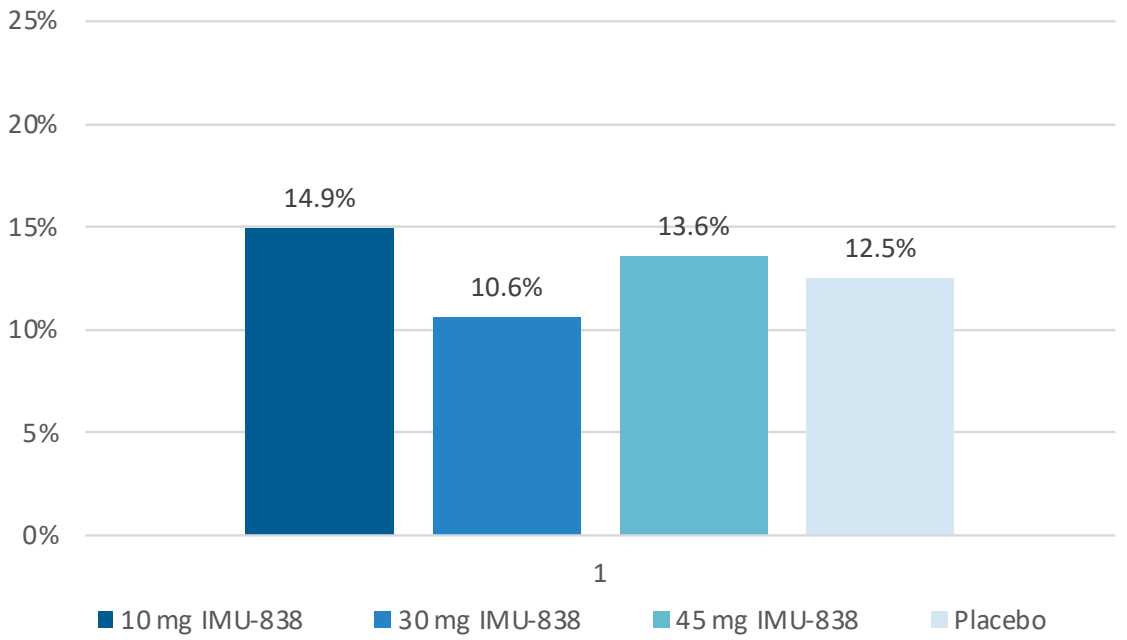
CALDOSE-1: Clinical Remission
Primary Endpoint Not Achieved*

ITT Data Set	10 mg IMU-838	30 mg IMU-838	45 mg IMU-838	Placebo
Number of Randomized Patients	67	66	66	64
Number of Patients Meeting Primary Endpoint	10	7	9	8
Clinical Remission Rate at Week 10	**14.9%**	**10.6%**	**13.6%**	**12.5%**

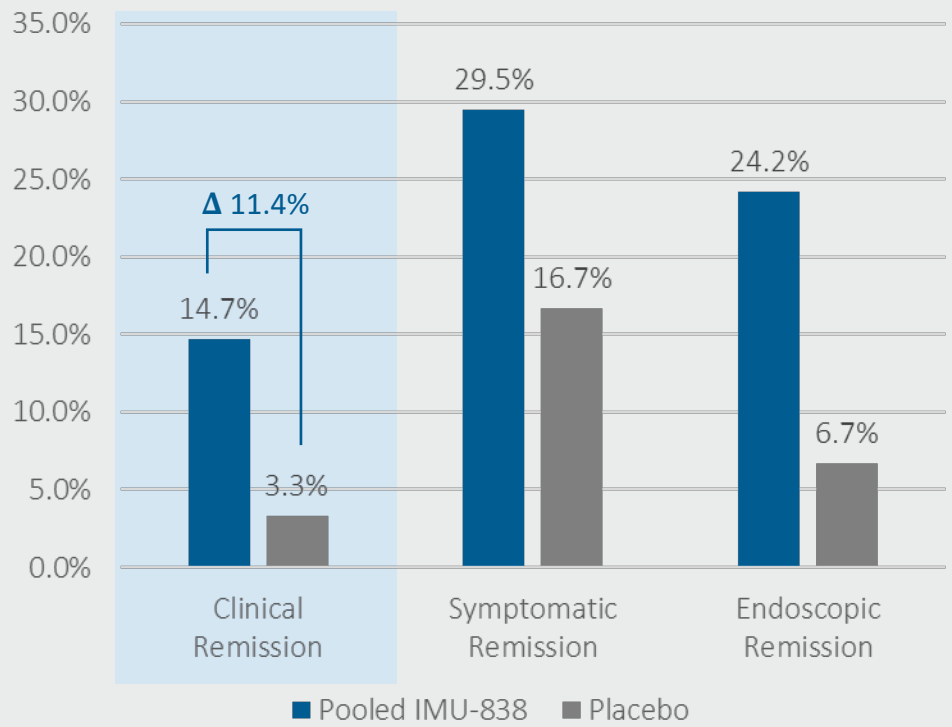
The primary endpoint of clinical remission at week 10 included a composite of patient-reported symptomatic remission (stool frequency Mayo subscore of 0 or 1, rectal bleeding Mayo score of 0) and modified Mayo endoscopy subscore of 0 or 1

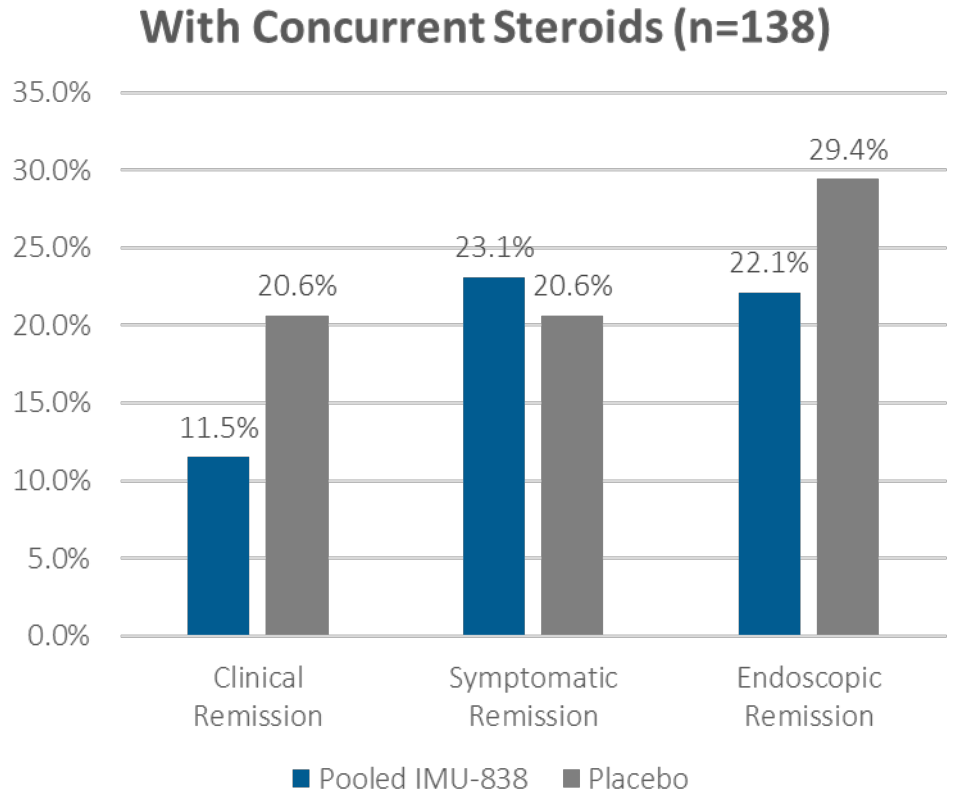
Clinical Remission at Week 10 (ITT Data Set)



*Primary endpoint was based on the Full Analysis Set: Pooled 30 and 45 mg IMU-838 data: 13.8%; 16/116 (n=16 missing data at week 10), placebo: 14.0%; 8/49 (n=16 missing data at week10), not statistically significant
ITT: intent-to-treat

Interference Between Vidofludimus Calcium and Concurrent Use of Corticosteroids





The graphs use the concurrent use of corticosteroids, as used as stratification factor for randomization provided by the investigator, not actual use of concurrent corticosteroids. However, actual steroid use does not differ substantially.
Data display ITT population of both biologic-naïve and -experienced patients. Pooled vidofludimus calcium data contain all data from 10 mg (no steroids n=33, steroids n=34), 30 mg (no steroids n=32, steroids n=34), 45 mg IMU-838 (no steroids n=30, steroids n=36). Placebo data: no steroids n=30, steroids n=34.
Clinical Remission: achieving both symptomatic remission and endoscopic remission, as defined below
Symptomatic Remission: Mayo rectal bleeding subscore of 0, and Mayo stool frequency subscore of 0 or 1
Endoscopic Remission: Modified Mayo endoscopy subscore of 0 or 1

Safety and Tolerability Profile of Vidofludimus Calcium in Line with Previous Investigations in Other Patient Populations

The Safety and Tolerability Profile of Vidofludimus Calcium in the CALDOSE-1 Trial Was in Line with Previous Trials

- No increase in infections or infestations as compared to placebo
- No elevated rate of liver events or liver enzyme elevations as compared to placebo
- No elevated rate on hematology changes as compared to placebo
- Most common treatment-emergent adverse events in this trial were:
  - Anemia in 15/263 patients (5.7%)
  - Headache in 9/263 (3.4%)
  - COVID-19 in 7/263 (2.7%)
  - Abdominal pain, nausea, nasopharyngitis, respiratory tract infection viral and hematuria in 5/263 (1.9%) each
  - Hypertension, vomiting, backpain in 4/263 (1.5%) each
- Discontinuation rate until week 10: pooled vidofludimus calcium treatment arms: 17.0%, placebo: 15.9%
- Most adverse events were mild in nature
- No new safety signals observed

Treatment-emergent adverse events (TEAEs) are defined as any event not present prior to the first intake of study medication or any event already present that worsens in either intensity or frequency following exposure to study medication.

Summary of Clinical Trial Results
Phase 2 CALDOSE-1 Trial of Vidofludimus Calcium in UC

- Primary endpoint was not achieved as a **result of an unexpected interference between vidofludimus calcium and concurrent use of corticosteroids**:
  - Patient population without concurrent use of corticosteroids (about half of the randomized patients) show evidence of activity of vidofludimus calcium in UC patients, thereby confirming the known anti-inflammatory effects observed in other patient populations (including relapsing-remitting multiple sclerosis)
  - Explanation for interference is not yet available and will be explored
  - Steroid tapering should overcome this issue in any future trial
  - No interference observed or expected in the multiple sclerosis program
- Safety and tolerability profile of vidofludimus calcium in UC in line with previous trials in other patient populations

- Given the wealth of compelling opportunities across the clinical development portfolio, Immunic does not intend to move forward with phase 3 development of vidofludimus calcium in UC without a partner, despite the activity observed in patients without concurrent corticosteroid therapy in the CALDOSE-1 trial.
- The company however intends to further discuss the data with clinical experts and potential partners to enhance our understanding of the strategic implications.

Corporate Update

Strategic Conclusions

Multiple Advanced Clinical-Stage Programs with Upcoming Value Inflection Points

Immunic will take this opportunity to sharpen its focus
R&D personnel and financial resources can be focused on its other promising programs

Vidofludimus Calcium Development Program in Neurology is Advancing

- Patient enrollment in both the phase 3 ENSURE program in patients with relapsing multiple sclerosis and the phase 2 CALLIPER trial in patients with progressive multiple sclerosis is progressing

IMU-935 in Psoriasis

- Proof-of-clinical-activity data of up to 40 psoriasis patients expected in H2/2022
  - Double-blind, placebo-controlled phase 1b clinical trial
  - Evaluating safety, tolerability, pharmacodynamics and exploratory efficacy (PASI reduction) in moderate-to-severe psoriasis patients
  - High-dose cohort is currently being started

IMU-856 in Celiac Disease

- Safety, tolerability and pharmacokinetic data in healthy human subjects expected in Q3/2022
- Proof-of-clinical-activity trial of up to 42 celiac disease patients started recently
  - Double-blind, randomized, placebo-controlled phase 1b clinical trial
  - Evaluating response to acute (evaluation of serum IL-2) and chronic gluten challenge (protection of intestinal architecture) in well-controlled celiac disease patients on gluten-free diet

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Multiple Clinical Data Readouts Expected Throughout 2022

Program	Target	Preclinical	Phase 1	Phase 2	Phase 3	Key Milestones
Vidofludimus Calcium (IMU-838)	DHODH	Relapsing Multiple Sclerosis (RMS) – ENSURE Trials				▪ RMS interim analysis planned after approx. half of the events occurred ▪ PMS interim analysis planned after half of the patients completed 24 weeks of treatment
		Progressive Multiple Sclerosis (PMS) – CALLIPER Trial				
		Ulcerative Colitis (UC) – CALDOSE-1 Trial				
		Crohn's Disease (CD)				
		Primary Sclerosing Cholangitis (PSC)				
IMU-935	IL-17 / RORγt	Psoriasis				▪ H2/2022: initial psoriasis data expected
		Castration-Resistant Prostate Cancer (CRPC)				▪ Q3/2022: initial CRPC safety data expected
IMU-856	Intestinal Barrier Function	Celiac Disease				▪ Q3/2022: SAD/MAD safety data expected

■ Completed or ongoing ■ In preparation or planned

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EMPhASIS Trial: Strong Reduction of MRI Lesion Activity

Pooled Cohorts 1 & 2

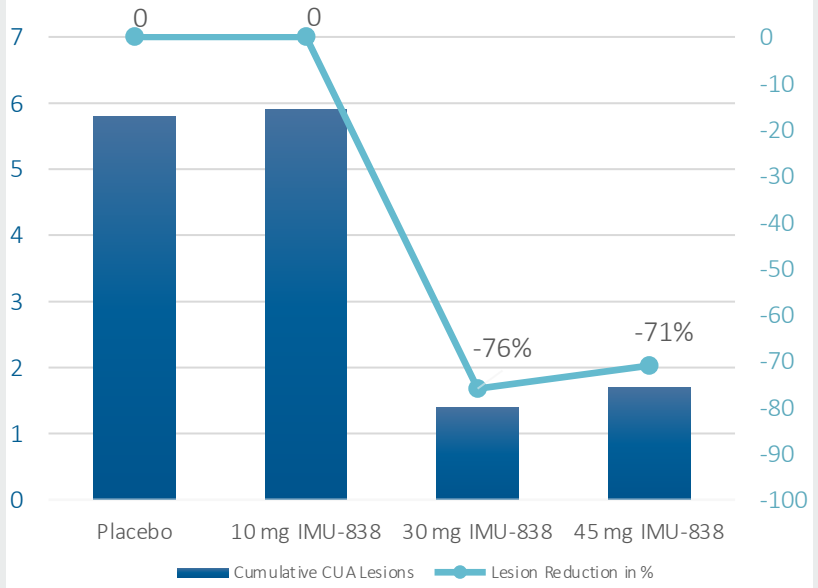
Double-Blind, Placebo-Controlled, Randomized, Parallel-Group Phase 2 Trial in RRMS

- Blinded main treatment period of 24 weeks
- Randomized 268 patients in 36 centers across four European countries
- Cohort 1: 30 and 45 mg or placebo
- Cohort 2: 10 mg or placebo
- Extended treatment period of up to 9.5 years to observe long-term safety

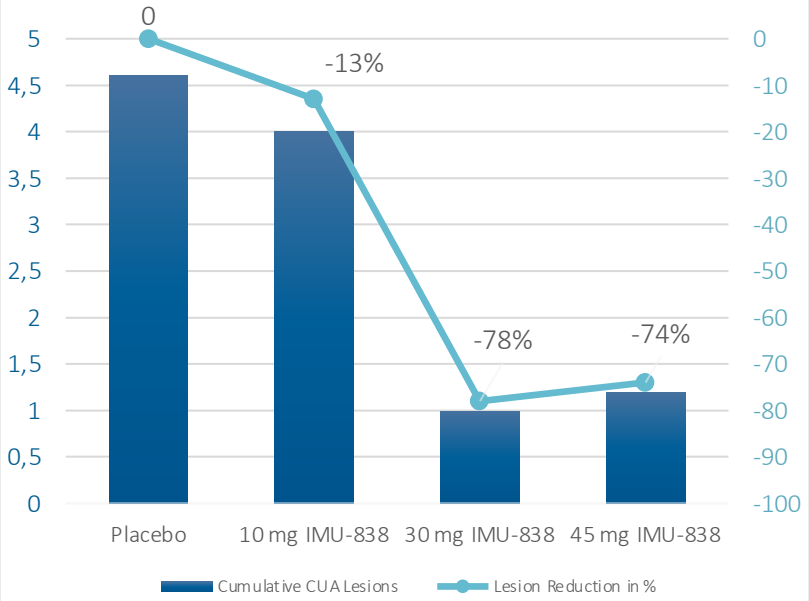
Efficacy Endpoints

- Cumulative number of new CUA and Gd+ MRI lesions up to week 24
- Primary endpoint: Difference in CUA MRI lesions between 45 mg/day vidofludimus calcium and placebo
- Primary and key secondary endpoints met with high statistical significance (primary: p = 0.0002 / key secondary: p < 0.0001)

Reduction in Cumulative CUA Lesions up to Week 24



Reduction in Gd+ Lesions up to Week 24



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

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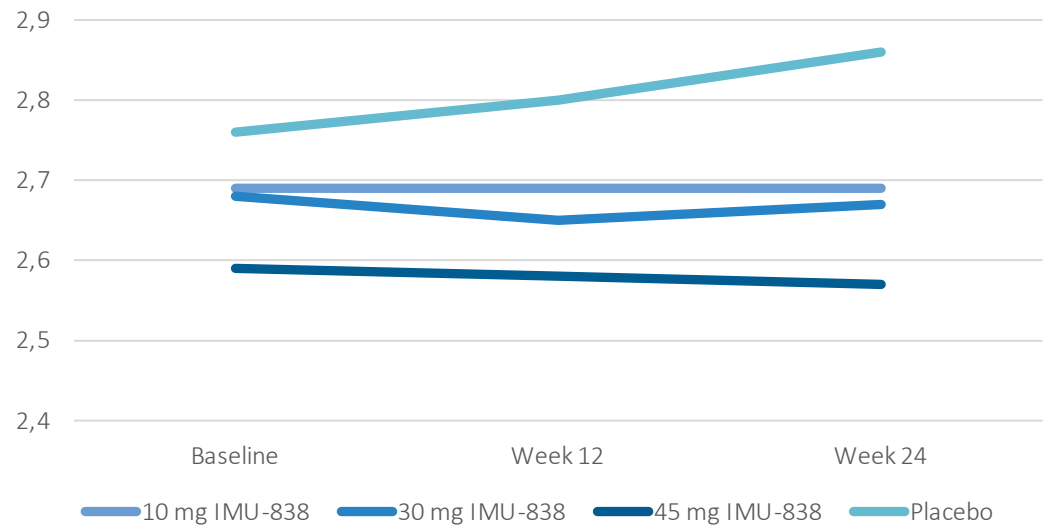
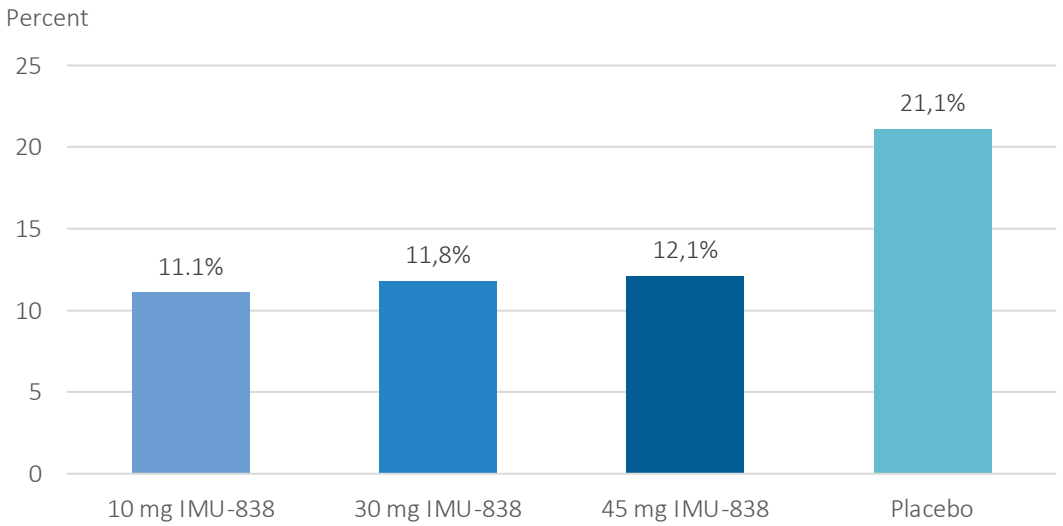
EMPhASIS Trial: Encouraging Signals of Neuroprotective Effects

Based on EDSS Assessments, Pooled Cohorts 1 & 2

Change of EDSS from Baseline to Week 24



Proportion of Patients With Unconfirmed EDSS Progression up to Week 24



Displayed are mean values, combined data for Cohort 1 and 2 patients
EDSS: Expanded Disability Status Scale

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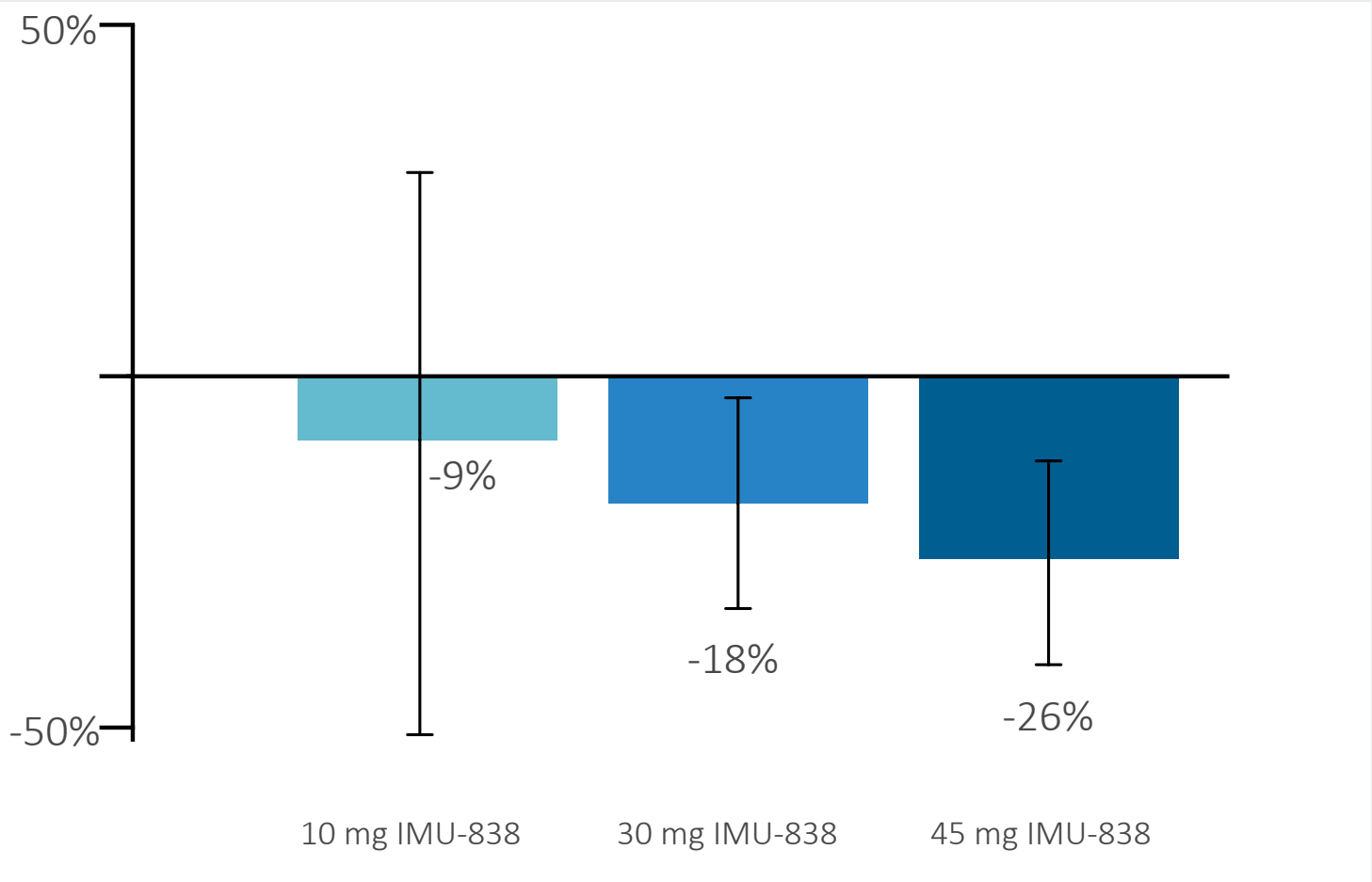
EMPhASIS Trial: Relative Change of Serum NfL Concentrations

Versus Placebo After 24 Weeks, Pooled Cohorts 1 & 2



The relative change of serum neurofilament light chain versus placebo is proportional to vidofludimus calcium dose.

- May reflect increasing trough levels and related improved effects of vidofludimus calcium
- Should favor higher doses when neuroprotective effects are more important

Displayed are median values of differences between percentage change of serum neurofilament light chain concentration (Hodges-Lehmann estimation), treatment vs. placebo, combined data for Cohort 1 and 2 patients
NfL: neurofilament

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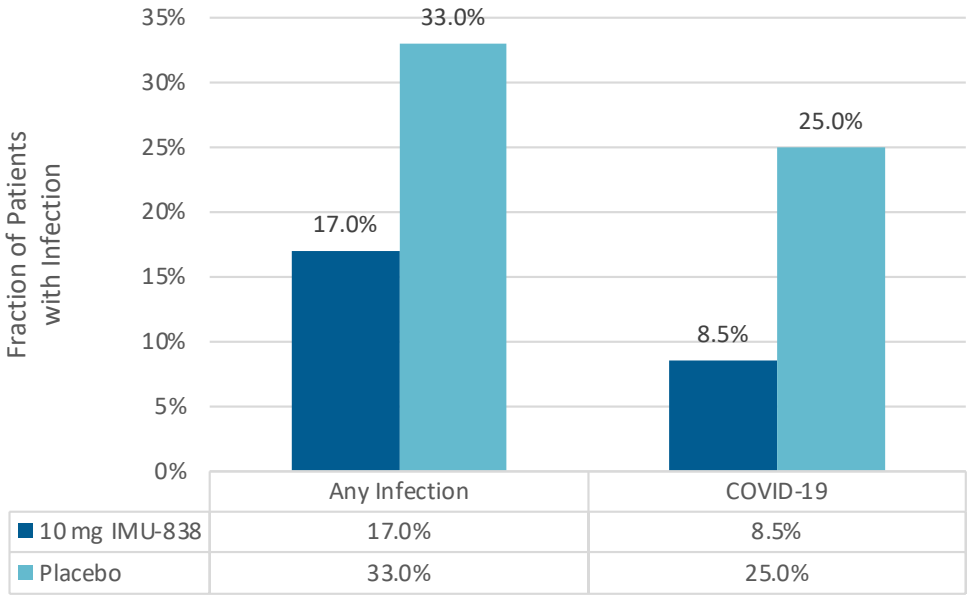
Vidofludimus Calcium Showed Interesting Hints for Clinical Anti-Infection and Anti-SARS-CoV-2 Activity

Treatment Corresponds with Decreased Number of Opportunistic COVID-19 Infections



Phase 2 EMPhASIS Trial in RRMS

Number of reported COVID-19 infections in Cohort 2

Treatment Does Not Interfere With Antibody Development During SARS-CoV-2 Infection

	Day 6		Day 14		Day 28	
	IgA	IgG	IgA	IgG	IgA	IgG
Placebo	84%	88%	94%	94%	97%	99%
Vidofludimus Calcium	86%	93%	97%	97%	95%	100%

Phase 2 CALVID-1 Trial in COVID-19

Proportion of patients with anti-SARS-CoV-2 IgA or IgG antibodies

COVID-19: coronavirus disease 2019; SARS-CoV-2: severe acute respiratory syndrome coronavirus; RRMS: relapsing-remitting multiple sclerosis; QD: quaque die = once-daily; IgA: immunoglobulin A; IgG: immunoglobulin G

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IMU-935 Phase 1 Clinical Trial

Trial Design and Current Status

PART A ✓

Evaluation of
single ascending doses (SAD)

—

Healthy human subjects randomized to receive single dose of IMU-935 or placebo

- Dose escalation completed: 100, 200, 300 and 400 mg of IMU-935
- Final PK analysis ongoing
- 79 subjects enrolled
- IMU-935 was well-tolerated and showed dose-linear PK

PART B ✓

Evaluation of
multiple ascending doses (MAD)

—

Healthy human subjects randomized to receive 14-day treatment of IMU-935 or placebo

- Dose escalation completed: 150 mg QD and 150 mg BID of IMU-935
- Final PK analysis ongoing
- 15 subjects enrolled
- IMU-935 was well-tolerated and steady-state was achieved after 3-6 days of dosing

PART C

Evaluation of
moderate-to-severe psoriasis patients receiving 28-day treatment of
IMU-935 or placebo

- 150 mg QD and 150 mg BID of IMU-935
- Approximately 40 patients planned to be enrolled
- Initial results expected to be available in H2/2022

PK: pharmacokinetic; QD: quaque die = once-daily; BID: bis in die = two times daily

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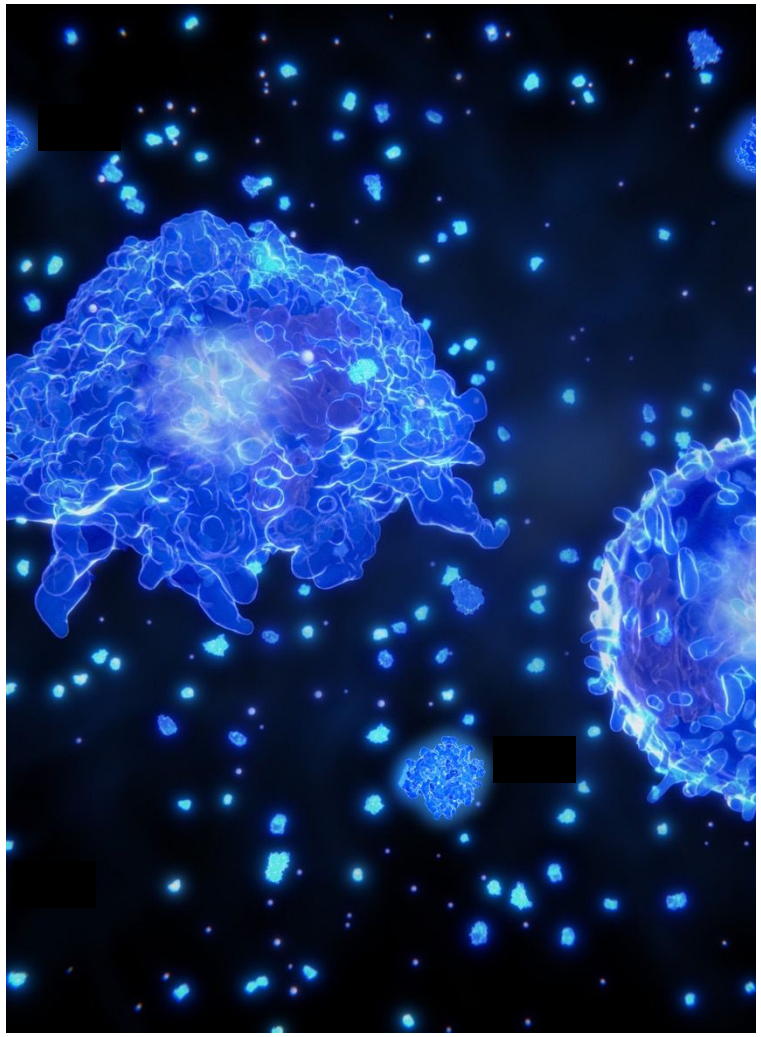
IMU-935 Phase 1 Clinical Trial

Part C in Moderate-to-Severe Psoriasis Patients



Detecting Therapeutic Activity of IMU-935 in Moderate-to-Severe Psoriasis Patients

- Double-blind, placebo-controlled dose escalation study to evaluate safety, tolerability, pharmacodynamics and exploratory efficacy of IMU-935 in patients with moderate-to-severe psoriasis
- Psoriasis patients receive **28 days** of daily treatment in two cohorts:
  - First cohort of up to 16 patients receive a low dose of IMU-935 (150 mg QD) or placebo at a ratio of 3:1
    - Low dose cohort ongoing in Australia and New Zealand
  - Second cohort of up to 24 patients receive a high dose of IMU-935 (150 mg BID) or placebo at a ratio of 3:1
    - **Received regulatory approval** this week to proceed with the trial in Europe, high-dose cohort is **currently being started**
- Initial results from part C are expected to be available **in H2/2022**

QD: quaque die = once-daily; BID: bis in die = two times daily

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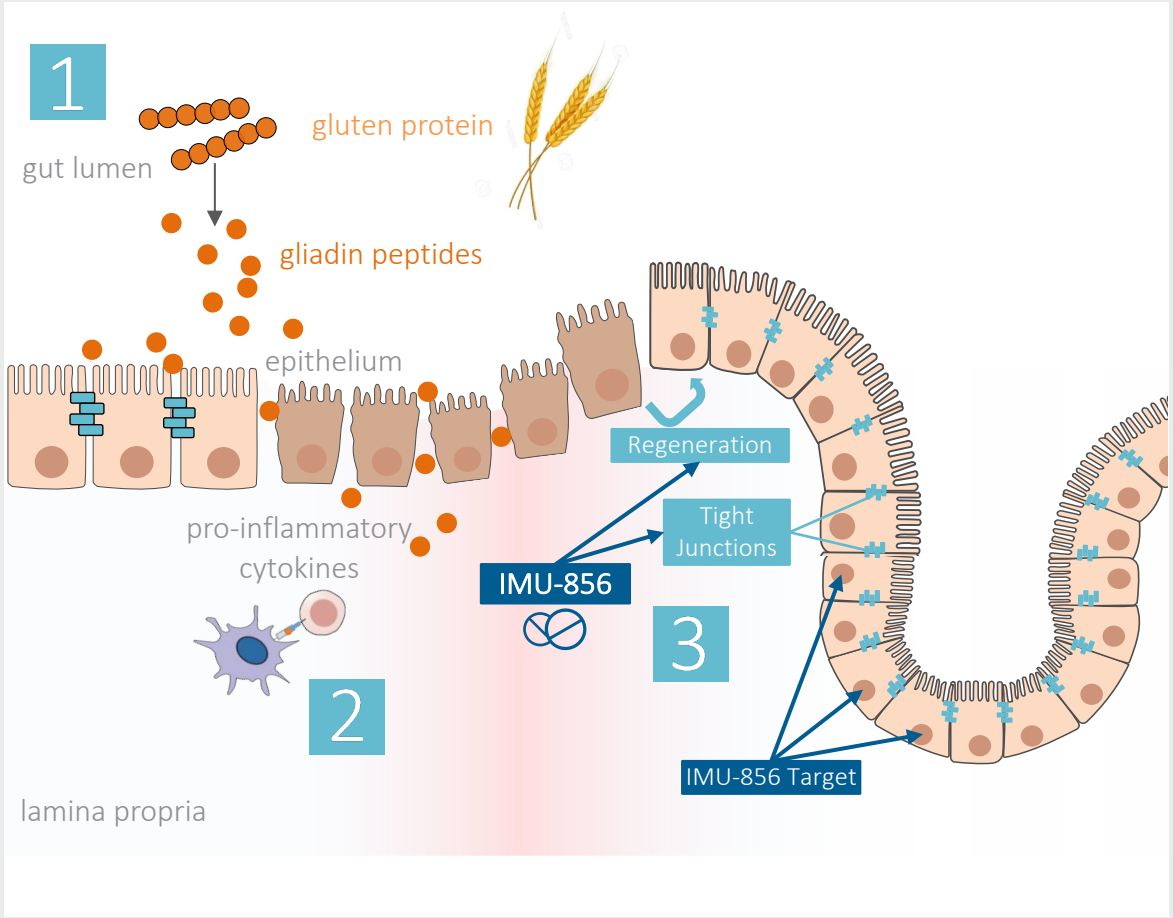
Celiac Disease is a Serious Autoimmune Disease



Celiac disease is a multifactorial, complex autoimmune disease caused by an immune reaction against a degradation product of gluten and is strongly associated with specific HLA class II gene variants (HLA-DQ2 and -DQ8)[1]

1
- Gluten is degraded into gliadin peptides which are taken up by the bowel epithelium (trans- or paracellular)

2
- In patients with a specific HLA receptor (DQ2 and DQ8) composition, deaminated gliadin (by TG2) is recognized and can trigger an immune response which leads upon continued gliadin uptake to
  - Increased intestinal permeability
  - Epithelial and mucosal damage with negative changes of the gut architecture, including villous atrophy leading to malabsorption of nutrients

3
- Hypothesis for IMU-856's mode of action:
  - Improves intestinal barrier function and restores permeability
  - Restores villous architecture by triggering regenerative processes of the epithelial lining

HLA: human leukocyte antigen; TG2: tissue transglutaminase 2
Picture: self-drawn; [1] Caio et al. BMC Medicine (2019) 17:142

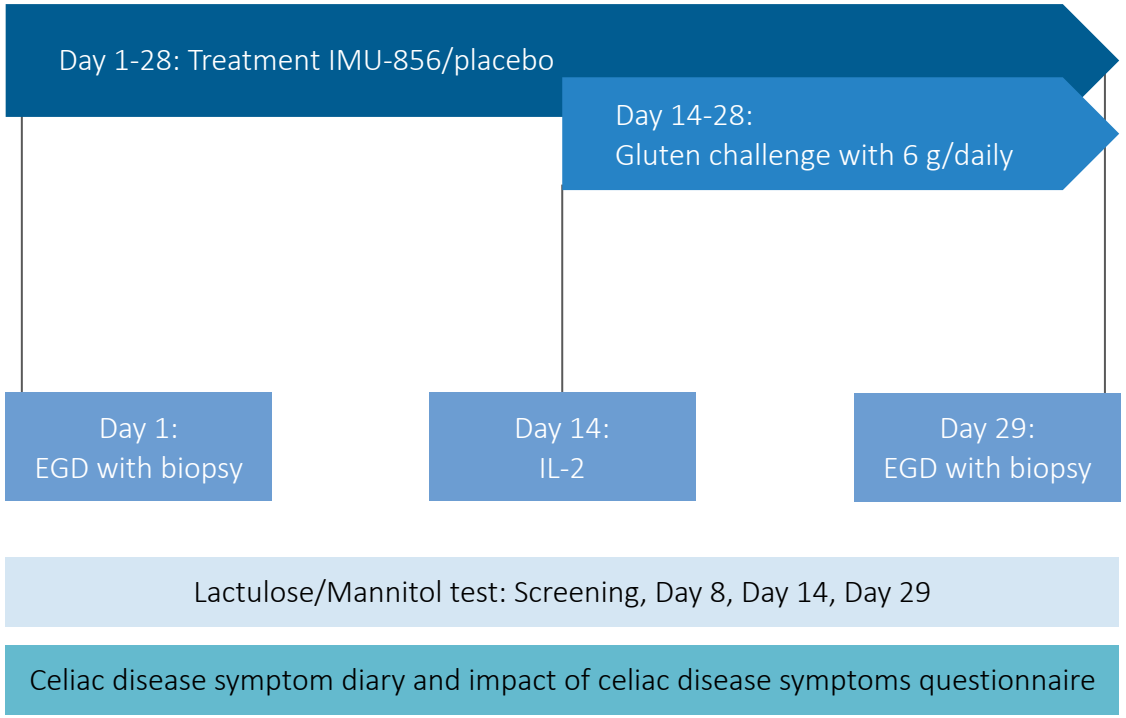
IMU-856: Three-Part, Double-Blind, Randomized, Placebo-Controlled Phase 1 Clinical Trial

Performed at Approx. 10 Sites in Australia and New Zealand

- Conducted in three parts:
  - Safety and pharmacokinetics in healthy human subjects (Part A: single ascending doses, Part B: multiple ascending doses)
  - Part C includes a celiac disease patient population, designed to assess safety and tolerability of IMU-856 as well as pharmacokinetics and acute (serum IL-2) and chronic (VH:CrD) disease markers

Safety data from the single and multiple ascending dose parts expected to be available in Q3/2022

Flow Chart of Part C in Celiac Disease



EGD: esophagogastroduodenoscopy, VH:CrD: villous hight to crypt depth ratio, one of the main histological assessments of small bowel architecture, IL-2: interleukin-2

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Multiple Clinical Data Readouts Expected Throughout 2022

Advanced clinical pipeline:
three differentiated investigational medicines in various phases of clinical development

Oral IL-17 inhibitor IMU-935:
proof-of-concept data in psoriasis expected in H2/2022; further development in CRPC

RMS phase 3 program of vidofludimus calcium ongoing, intended to provide a straightforward path towards regulatory approval

IMU-856 for intestinal barrier function:
unblinded phase 1 safety data expected in Q3/2022; proof-of-concept trial in celiac disease ongoing

PMS phase 2 trial of vidofludimus calcium ongoing, designed to corroborate vidofludimus calcium's neuroprotective potential

Cash runway into Q4/2023
Cash position: USD 93.1 million (as of May 31, 2022)
Shares outstanding: 30,540,383 (as of May 2, 2022)

Q&A Session

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Immunic currently has three investigational medicines in active clinical trials from phase 1 to phase 3 with multiple important data readouts ahead in H2/2022

- Discussions planned with clinical experts and potential partners to enhance the understanding of the strategic implications of the CALDOSE-1 trial
- Company to focus on efficacy read-out of IMU-935 in psoriasis, expected to be available in H2/2022

Thank You!

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