



Immunic
THERAPEUTICS

Immunic Therapeutics

First Quarter 2023 Financial Results and Corporate Update

NASDAQ: IMUX | May 11, 2023

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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.



Agenda

First Quarter 2023 Financial Results and Corporate Update

01 First Quarter 2023 and Subsequent Highlights

02 Financial and Operating Results

03 Anticipated Clinical Milestones

04 Q&A Session

05 Summary and Highlights



01

First Quarter 2023 and Subsequent Highlights

Treatment of Celiac Disease



Current Pathways for Drug Development & Persistent Disease Activity Despite Gluten-Free Diet as the Unmet Medical Need

AGENDA

11:00 – 11:05: Welcome and Introductions
11:05 – 11:20: Introduction to Celiac Disease
11:20 – 11:30: Celiac Disease Treatment Landscape
11:30 – 11:35: Interleukin-2 Response Following Gluten Ingestion
11:35 – 11:55: Expert Presentation: Joseph A. Murray, MD
11:55 – 12:05: Mechanism of Action and Preclinical Data for IMU-856
12:05 – 12:25: Expert Presentation: Michael Schumann, MD
12:25 – 12:35: Q&A With the Two Experts
12:35 – 12:45: Clinical Overview for IMU-856
12:45 – 13:00: Q&A Session and Closing

FEATURED KEY OPINION LEADERS



Joseph A. Murray, MD

Professor of Medicine
Director, Celiac Disease Research
John and Shirley Berry Professor
of Gastrointestinal Sciences
Division of Gastroenterology
and Hepatology, Department of
Internal Medicine
Mayo Clinic, Rochester, MN



Michael Schumann, MD

Attending Physician in
Internal Medicine and
Gastroenterology
Department of
Gastroenterology, Infectious
Diseases and Rheumatology
Campus Benjamin Franklin
Charité – Universitätsmedizin
Berlin

Immunic's Celiac
Disease R&D Webcast
Thursday, February 9, 2023
11:00am - 1:00pm Eastern Time

Register Now

The Celiac Disease R&D webcast will be held virtually via Zoom. To participate, please register in advance at:
https://jimux.zoom.us/webinar/register/WN_wi-01YeJSbe4XRTEQ1PLQw
Registrants will receive a confirmation email containing a link for online participation or a telephone number for dial in access.

IMMUNIC SPEAKERS



Daniel Vitt, PhD

Chief Executive
Officer & President



Hella Kohlhof, PhD

Chief Scientific Officer



Andreas Muehler, MD

Chief Medical Officer

February: Hosted Virtual Celiac Disease R&D Webcast



Current Pathways for Drug Development & Persistent Disease Activity Despite Gluten-Free Diet as the Unmet Medical Need

- Featured key opinion leaders:
 - Joseph A. Murray, MD, Mayo Clinic, Rochester, MN
 - Michael Schumann, MD, Charité – Universitätsmedizin Berlin
- Immunic speakers:
 - Daniel Vitt, PhD, CEO & President
 - Hella Kohlhof, PhD, CSO
 - Andreas Muehler, MD, CMO
- Recording: <https://www.youtube.com/watch?v=xsPJQHpw-BI>

February: Presented Data From Phase 2 EMPHASIS Trial at ACTRIMS Forum 2023

Assessment of effect of vidofludimus calcium on confirmed disability worsening in the blinded treatment and open-label extension periods of the phase 2 study (EMPhASIS) in relapsing-remitting multiple sclerosis

The eighth annual Americas Committee for Treatment and Research in Multiple Sclerosis Forum 2023



R. Fox
Cleveland Clinic,
Cleveland, OH, USA

C. Wolf
Lycalis,
Brussels, Belgium

V. Sciarra
Immunic AG,
Grafelfing, Germany

M. Ondrus
Immunic AG,
Grafelfing, Germany

A. Muehler
Immunic AG,
Grafelfing, Germany

Background

Vidofludimus calcium (VidoCa) is a highly selective oral 2nd generation DHODH inhibitor, which in the double-blind phase 2 EMPHASIS trial in relapsing-remitting multiple sclerosis (RRMS) has shown a robust activity against placebo and a safety and tolerability profile comparable to placebo, presumably due to lack of off-target effects on kinases. This summary describes the first interim analysis of the ongoing long-term open-label extension period focusing on disability worsening during the continued treatment with VidoCa in RRMS patients.

Objective

EMPHASIS was a randomized, placebo-controlled phase 2 trial in RRMS, assessing efficacy and safety of 10, 30 and 45mg of VidoCa as compared to placebo for a period of 24-weeks. Upon completion of the double-blind treatment period, the study participants could enter the long-term open-label extension (OLE) period with further monitoring of safety, tolerability, and selected efficacy parameters (such as EDSS). Herein we report the long-term activity of VidoCa on confirmed disability worsening events in RRMS patients.

Methods

In the EMPHASIS trial, 268 patients with RRMS received study medication with either 10, 30, or 45 mg VidoCa or placebo for a double-blind treatment of 24 weeks. Upon completion of the double-blind period, 254 patients continued in the OLE period. The patients originally randomized to VidoCa 30 and 45 mg continued with the same dose, while the patients originally assigned to placebo or VidoCa 10mg were randomly assigned to either 30 or 45mg of VidoCa. The original treatment allocation was disclosed only after the last patient completed the main treatment period. Subsequently, a transition of all patients in OLE period to 30 mg VidoCa was initiated.

CDW: confirmed disability worsening; EDSS: Expanded Disability Status Scale

*Only disability worsening with a trigger point during the 24-week blinded treatment period are considered. The EDSS increases during the blinded treatment phase were subsequently confirmed during open-label extension phase of the trial. Patients at risk in this analysis are 187 for vidofludimus calcium (pooling 10, 30 and 45 mg) and 81 for placebo. The trigger event is an EDSS progression defined as an increase in the EDSS compared to baseline of at least 1.5 points if Baseline EDSS = 0, of at least 1.0 points if Baseline EDSS of 1-4, or of at least 0.5 points if Baseline EDSS ≥ 5. 12-week CDW: The confirmation event is at least 77 days after the trigger event. At the confirmation event and each assessment between trigger event and possible confirmation event, EDSS must be at least as high as at the trigger event. 24-week CDW is defined analogously, the only difference being the time interval between trigger event and confirmation visit, which is at least 161 days. Full analyses set pooled cohorts: 1&2 (N10 = 47, N30 = 71, N45 = 69), NPRO C1 = 69, NPRO C2 = 12)

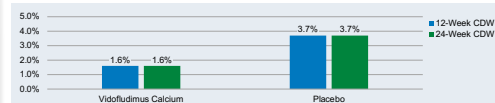


Results

- As of October 2022, 209 patients remained on OLE treatment with VidoCa, with some patients having received more than 180 weeks of active treatment (roughly 3.5 years).
- For the initial 24-week double-blind treatment period, 12-week Confirmed Disability Worsening (12wCDW) and 24-week Confirmed Disability Worsening (24wCDW) events occurred in 1.6% of subjects in the combined VidoCa treatments arms as compared to 3.7% in the placebo group.
- In the OLE period, the proportion of patients free from 12wCDW was 97.2% after 48 weeks and 94.2% after 96 weeks of VidoCa treatment. Similar results were seen for 24wCDW and sustained CDW (i.e. CDW persisting through last assessment).
- Among VidoCa patients in the OLE period of the trial, 3% experienced one or more relapses within the first year and 6.2% within the first two years.

Confirmed Disability Worsening Events

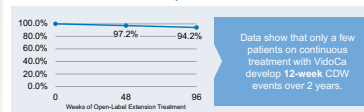
End during the initial 24-week blinded treatment period



Data suggest a possible benefit of VidoCa on 12-week and 24-week confirmed disability worsening* events as compared to placebo. Confirmatory data will be obtained in the ongoing phase 3 ENSURE clinical program.

Interim analysis regarding 12wCDW events

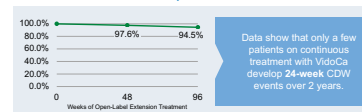
Patients free of 12-week CDW after 1 & 2 years of OLE VidoCa Treatment



Data show that only a few patients on continuous treatment with VidoCa develop 12-week CDW events over 2 years.

Interim analysis regarding 24wCDW events

Patients free of 24-week CDW after 1 & 2 years of OLE VidoCa Treatment



Data show that only a few patients on continuous treatment with VidoCa develop 24-week CDW events over 2 years.

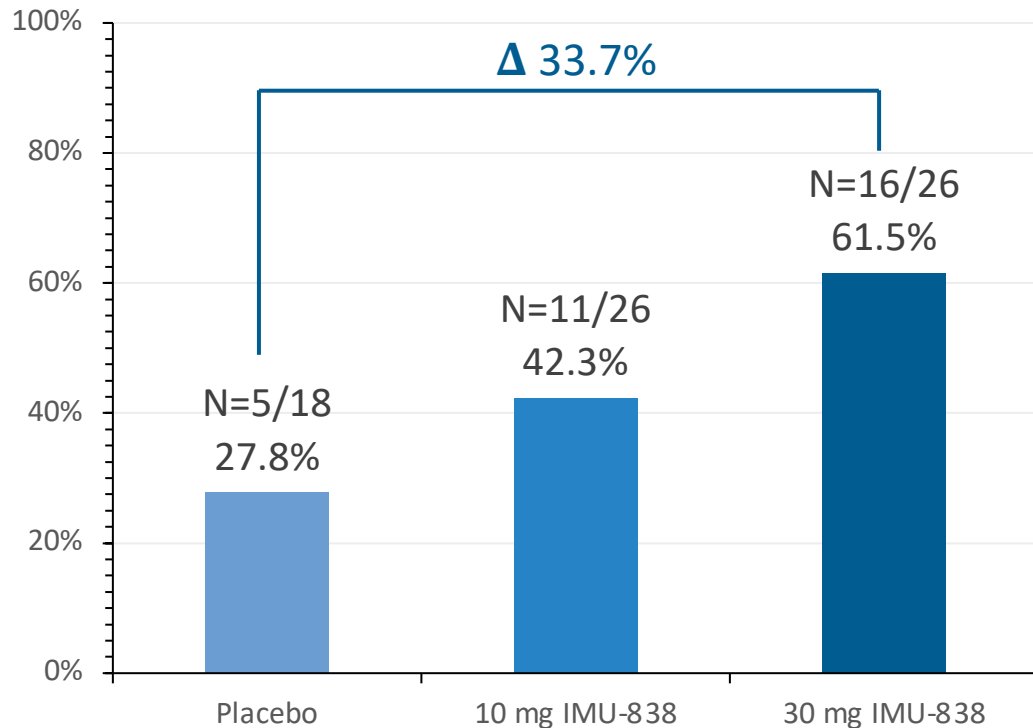
Conclusion

Over the 24 weeks of blinded treatment and the open-label extension period, rates of CDW in VidoCa-treated patients were low. These findings provide an initial signal for VidoCa preventing or slowing confirmed disability progression in RRMS.

- Eighth annual Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum 2023
- February 23-25 in San Diego, California
- Poster Presentation: Robert J. Fox, M.D., Staff Neurologist, Mellen Center for Multiple Sclerosis, Vice-Chair for Research, Neurologic Institute, Cleveland Clinic, Cleveland, Ohio
- Data from the blinded and open-label extension parts of Immunic's phase 2 EMPHASIS trial of vidofludimus calcium in RRMS

April: Positive Maintenance Phase Data of Phase 2 CALDOSE-1 Trial of Vidofludimus Calcium in Moderate-to-Severe Ulcerative Colitis

Clinical Remission at Week 50



30 mg of vidofludimus calcium found to be statistically superior to achieve clinical remission during maintenance treatment at week 50 as compared to placebo

Planned treatment	Clinical remission at week 50	Number of patients (N)	Proportion of patients (%)	Statistical output (t-test)
30 mg IMU-838	Yes	16	61.5%	p-value (two-sided) p=0.0358
	No	10	38.5%	
Placebo	Yes	5	27.8%	odds ratio (30 mg IMU-838 / placebo) 4.1600
	No	13	72.8%	

Clinical remission: 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

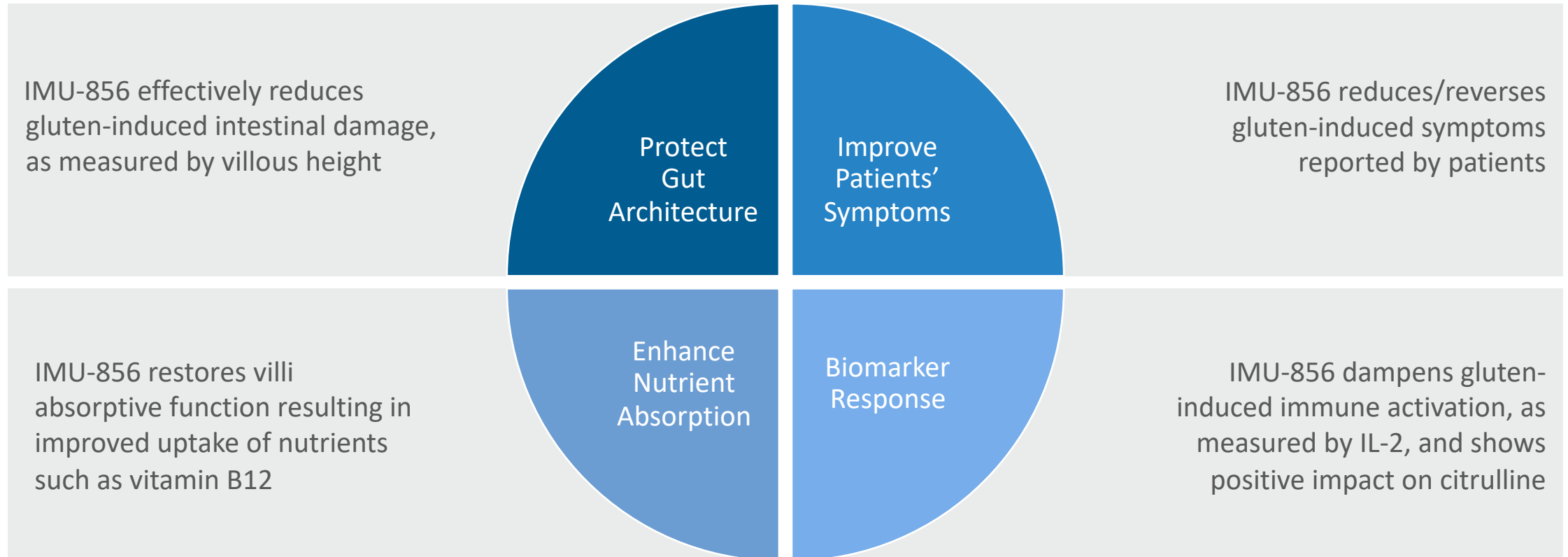
Full Analysis Set of Maintenance Phase (N10 = 45, N30 = 40, NPBO = 27), Post-Hoc Unplanned Analysis: Two-sided Pearson's chi-square test (significance level alpha=0.05) for achieving clinical remission at week 50 between 30 mg IMU-838 and placebo

April: Appointed Richard Rudick, M.D. to Board of Directors



- Thought-leader in multiple sclerosis with decades of experience in the clinic, academia and industry
- Effective April 26, 2023

May: Positive Results From Phase 1b Trial of IMU-856 in Celiac Disease, Positive Effects in Main Four Dimensions of Clinical Outcome



All these effects achieved without any known suppression of the immune system
IMU-856 shown to be safe and well-tolerated

May: Presented Clinical and Preclinical Data for IMU-856 at Digestive Disease Week 2023

FIRST-IN-HUMAN TRIAL OF IMU-856, AN ORALLY AVAILABLE REGULATOR OF BARRIER FUNCTION FOR THE TREATMENT OF CELIAC DISEASE

Franziska Buriánek¹, Thomas Polasek², Jelena Mihajlović¹, Evelyn Peelen¹, Juliano Fonseca¹, Martina Wirth¹, Inge Kehler¹, Daniel Vitt¹, Hella Kohlhorf¹, Andreas Muehler¹

¹ Immunic AG, Gräfelfing, Germany
² Certara LP, Princeton, NJ, United States

Introduction

IMU-856 is an orally available and systemically acting small molecule modulator that targets SIRT6 (Sirtuin 6), a protein which serves as a transcriptional regulator of intestinal barrier function and regulation of bowel architecture. IMU-856 has been shown in preclinical investigations to abate suppression of immune cells. It may therefore restore immune surveillance for patients during therapy. An impact of activated immune cells on barrier function is discussed in the following section.

Mechanism of action of IMU-856

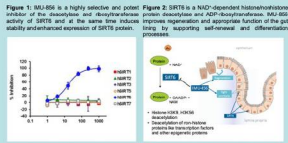


Figure 1: IMU-856 is a highly selective and potent inhibitor of SIRT6. Figure 2: SIRT6 is a NAD-dependent histone deacetylase (HDAC) in the intestine which serves as a transcriptional regulator of intestinal barrier function and regulation of bowel architecture. IMU-856 has been shown in preclinical investigations to abate suppression of immune cells. It may therefore restore immune surveillance for patients during therapy. An impact of activated immune cells on barrier function is discussed in the following section.



Figure 3: Increase of damaged gut architecture is driven by barrier function of intestinal cells. Intestinal cells differentiate into enterocytes and specialized cells such as, e.g., mucus producing goblet cells. SIRT6 is highly expressed in intestinal epithelial cells in the jejunum, and it was shown that IMU-856 treatment in a transgenic setting in a DSS model prevents normal gut architecture and improves regeneration of the gut lining which can be required by a lower % of drug cycles.

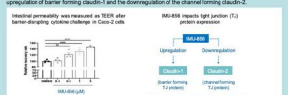


Figure 4: Strong interaction between epithelial cells lining the gut wall provides a well-controlled intestinal healthy barrier. It could be shown appropriate transport of nutrients by providing essential permeability due to proper intercellular junctions with the immune systems. IMU-856 treatment induces a dose dependent tightening of the intestinal barrier, measured as a TEER (transendothelial electrical resistance) assay performed with fully differentiated Caco-2 cells. This response is triggered by IMU-856 could be further partially attributed to the upregulation of barrier forming junctions and the downregulation of the barrier forming junctions.

Methods

This is a first-in-human, double-blind, randomized, placebo-controlled clinical trial comprised of three parts. In the single ascending dose (SAD) part of the phase 1 clinical trial, healthy human subjects were randomized (ratio 3:1) in a double-blind manner to either placebo or active treatment with single doses of IMU-856 at 10, 20, 40, 80, 160 and 320 mg in the multiple ascending dose (MAD) part of the clinical trial. Healthy human subjects were dosed for 14 consecutive days with 40, 80 or 160 mg once-daily of IMU-856 or placebo in a double-blind manner (ratio 3:1).

The ongoing Part C includes a double-blind, randomized, placebo-controlled trial designed to assess the safety and tolerability of IMU-856 in patients with celiac disease during periods of gluten-free diet and gluten challenge. A total of approximately 42 patients are planned to be enrolled in three consecutive cohorts with 80 mg and 160 mg of IMU-856 or placebo given once-daily over 28 days. Secondary objectives include pharmacokinetics as well as acute and chronic disease markers, including immunologic (IgA and IgG) and those measuring gastrointestinal architecture and inflammation.

Results

IMU-856 showed linear pharmacokinetics in healthy human subjects following single and multiple ascending doses with a mean accumulation factor of 1.5 for C_{max} and 1.5 for AUC_{0-24} . T_{max} was similar across all cohorts (2-4 hours), half-life in steady state ranging from 17.7 to 21.5 hours and C_{ss} and AUC showed a dose proportionate increase across the investigated doses. Steady-state plasma concentrations of IMU-856 were reached after 4.7 days. Mean plasma trough concentrations in steady state were substantially above IC_{50} and EC_{50} of target inhibition (linker, kinase, residual, enzymatic) function in cellular test system. EC_{50} : half-maximal effective concentration, EC_{90} : 90% maximal effective concentration.

Parameter (Day 1)	Cohort 7 (40 mg)	Cohort 8 (80 mg)	Cohort 9 (160 mg)	Cohort 7 (80 mg)	Cohort 8 (160 mg)
C_{max} (ng/mL)	131	269	603	184	400
T_{max} (h)	2.40	2.20	1.83	3.00	2.85
$T_{1/2}$ (h)	10.8	13.5	8.9	21.5	17.7
AUC ₀₋₂₄ (ng·h/mL)	1300	3368	6190	2067	4809

Abbreviations: C_{max} : maximum plasma drug concentration; T_{max} : time to reach maximum plasma concentration; $T_{1/2}$: terminal elimination half-life; AUC_{0-24} : area under the drug concentration-time curve from time 0 to 24 hours.

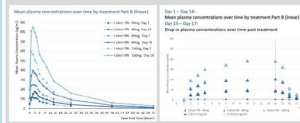


Figure 5: IMU-856 mean plasma trough concentration by treatment (Part B)

Safety

Most of the related treatment-emergent adverse events (TEAE) were mild in severity with no dose dependency. There were no systematic clinically important findings relative to safety and tolerability, as assessed by physical examination, clinical laboratory tests, vital signs, and 12-lead electrocardiograms (ECG).

Part A: Single doses of IMU-856 were safe and well-tolerated with catheter site irritation and catheter site pain being the most common TEAEs following oral tablet administration. Catheter insertion itself was necessary to enable blood sampling. Therefore these TEAEs are not thought to be related to the drug itself. Abdominal pain and diarrhea were the most common non-investigational medical product-related TEAEs, however, they occurred in less than 10% of patients, were only mild in severity, and were comparable to the incidence in the placebo group. There were no other clinically meaningful findings relative to safety and tolerability, as assessed by clinical laboratory tests, vital signs, and 12-lead ECGs following study treatment. No serious adverse events occurred.

MedDRA Preferred Term	Cohort 7 (40 mg)	Cohort 8 (80 mg)	Cohort 9 (160 mg)	Placebo (n=11)
Catheter site irritation	1 (17%)	2 (23%)	1 (17%)	0 (0)
Catheter site pain	1 (17%)	3 (35%)	1 (17%)	0 (0)
Abdominal pain	1 (17%)	1 (11%)	2 (29%)	1 (9%)
Diarrhea	1 (17%)	1 (11%)	2 (29%)	1 (9%)
Headache	1 (17%)	1 (11%)	2 (29%)	1 (9%)

Table 2: IMU-856 most common treatment-emergent adverse events (TEAEs) - Part A

MedDRA Preferred Term	Cohort 7 (40 mg)	Cohort 8 (80 mg)	Cohort 9 (160 mg)	Placebo (n=11)
Headache	3 (38%)	2 (23%)	1 (15%)	2 (18%)
Catheter site pain	2 (24%)	1 (11%)	3 (42%)	3 (27%)
Diarrhea	1 (12%)	2 (23%)	1 (15%)	4 (36%)
Abdominal pain	1 (12%)	1 (11%)	1 (15%)	1 (9%)

Table 3: IMU-856 most common treatment-emergent adverse events (TEAEs) - Part B

Overview ongoing Part C:

The ongoing Part C is designed to assess the safety and tolerability of IMU-856 in patients with celiac disease during periods of gluten-free diet and gluten challenge. A total of approximately 42 patients are planned to be enrolled in two consecutive cohorts with 80 mg and 160 mg of IMU-856 or placebo given once-daily over 28 days. Secondary objectives include pharmacokinetics as well as acute and chronic disease markers, including immunologic (IgA and IgG) and those measuring gastrointestinal architecture and inflammation. Sites in Austria and New Zealand are participating in Part C.



MedDRA Preferred Term	Cohort 1 (80 mg)	Cohort 2 (160 mg)
Catheter site irritation	1 (12%)	2 (25%)
Catheter site pain	1 (12%)	3 (37%)
Abdominal pain	1 (12%)	2 (25%)
Diarrhea	1 (12%)	2 (25%)
Headache	1 (12%)	2 (25%)

Table 4: IMU-856 most common treatment-emergent adverse events (TEAEs) - Part C

MedDRA Preferred Term	Cohort 1 (80 mg)	Cohort 2 (160 mg)
Headache	3 (38%)	2 (25%)
Catheter site pain	2 (24%)	3 (37%)
Diarrhea	1 (12%)	2 (25%)
Abdominal pain	1 (12%)	2 (25%)

Table 5: IMU-856 most common treatment-emergent adverse events (TEAEs) - Part C

- May 6-9 in Chicago
- Virtual e-poster: Franziska Buriánek, M.D., Senior Medical Director at Immunic
 - Data from the single and multiple ascending dose portions of the phase 1 clinical trial of IMU-856 in healthy human subjects
 - Preclinical data on IMU-856, including its mode of action as a highly selective and potent small molecule modulator of SIRT6





02

Financial and Operating Results

Condensed Consolidated Statements of Operations

(In thousands, except share and per share amounts, unaudited)

	Three Months Ended March 31,	
	2023	2022
Operating expenses:		
Research and development	\$ 22,963	\$ 17,445
General and administrative	4,288	3,990
Total operating expenses	27,251	21,435
Loss from operations	(27,251)	(21,435)
Other income (expense):		
Interest income	800	7
Other income (expense), net	1,179	620
Total other income	1,979	627
Net loss	\$ (25,272)	\$ (20,808)
Net loss per share, basic and diluted	\$ (0.58)	\$ (0.74)
Weighted-average common shares outstanding, basic and diluted	43,664,783	28,127,288

\$97.1 million in cash, cash equivalents and investments as of March 31, 2023 are expected to fund operations into the fourth quarter of 2024



03

Anticipated Clinical Milestones

Several Clinical Value Inflection Points Expected



IMU-838 in PMS

- Interim analysis phase 2 CALLIPER trial estimated for H2/2023
- Readout phase 2 CALLIPER trial estimated for end of 2024

IMU-838 in RMS

- Interim analysis phase 3 ENSURE program estimated for late 2024
- Readout phase 3 ENSURE-1 trial estimated for end of 2025

IMU-856

- Phase 2b clinical trial in preparation
- Also applicable for other gastrointestinal disorders



04

Q&A Session



05

Summary and Highlights

Advanced Clinical Pipeline

Well Differentiated Programs in Various Phases of Clinical Development

Program	Preclinical	Phase 1	Phase 2	Phase 3	Key Milestones
Vidofludimus Calcium (IMU-838)		Relapsing Multiple Sclerosis (RMS) – ENSURE Trials			<ul style="list-style-type: none"> Interim analysis of CALLIPER trial in PMS planned after half of the patients completed 24 weeks of treatment, estimated for H2/2023 CALLIPER trial estimated to readout end of 2024 Interim analysis of first ENSURE trial in RMS planned after approximately half of the events occurred, estimated for late 2024 ENSURE-1 trial estimated to readout end of 2025, ENSURE-2 soon thereafter
		Progressive Multiple Sclerosis (PMS) – CALLIPER Trial			
		Ulcerative Colitis (UC) – CALDOSE-1 Trial			
IMU-856		Celiac Disease			
IMU-381		Gastrointestinal Diseases			

■ Completed or ongoing ■ In preparation or planned

Thank You!



Jessica Breu

Head of IR & Communications

Phone: +49-89-2080477-09

Email: ir@imux.com

Web: www.imux.com

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

Immunic AG
Lochhamer Schlag 21
82166 Gräfelfing (Munich)
Germany

Immunic Australia Pty. Ltd.
Melbourne
Australia

