Immunic Therapeutics

First Quarter 2023 Financial Results and Corporate Update

NASDAQ: IMUX | May 11, 2023

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 development programs and the targeted diseases; the potential for Immunic’s development programs to safely and effectively target and treat the diseases mentioned herein; preclinical and clinical data for Immunic’s development programs; the impact of future preclinical and clinical data on Immunic’s product candidates; the timing of the availability of data from Immunic’s clinical trials; the availability or efficacy of Immunic’s potential treatment options that may be supported by trial data discussed herein; the timing of current and future clinical trials and anticipated clinical milestones; Immunic’s ability to protect its intellectual property position; Immunic’s plans to research, develop and commercialize its current and future product candidates; the timing of any planned investigational new drug application or new drug application; the development and commercial potential of any product candidates of the company; expectations regarding potential market size; developments and projections relating to Immunic’s competitors and industry; 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 successfully collaborate with existing collaborators or enter into new collaboration agreements, and to fulfill its obligations under any such collaboration agreements; Immunic’s ability to identify additional products or product candidates with significant commercial potential; the impact of government laws and regulations; COVID-19 and the armed conflict in Ukraine; 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 further updates with respect thereto; and the other risks set forth in the company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2022, 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.

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

Immunic THERAPEUTICS

01

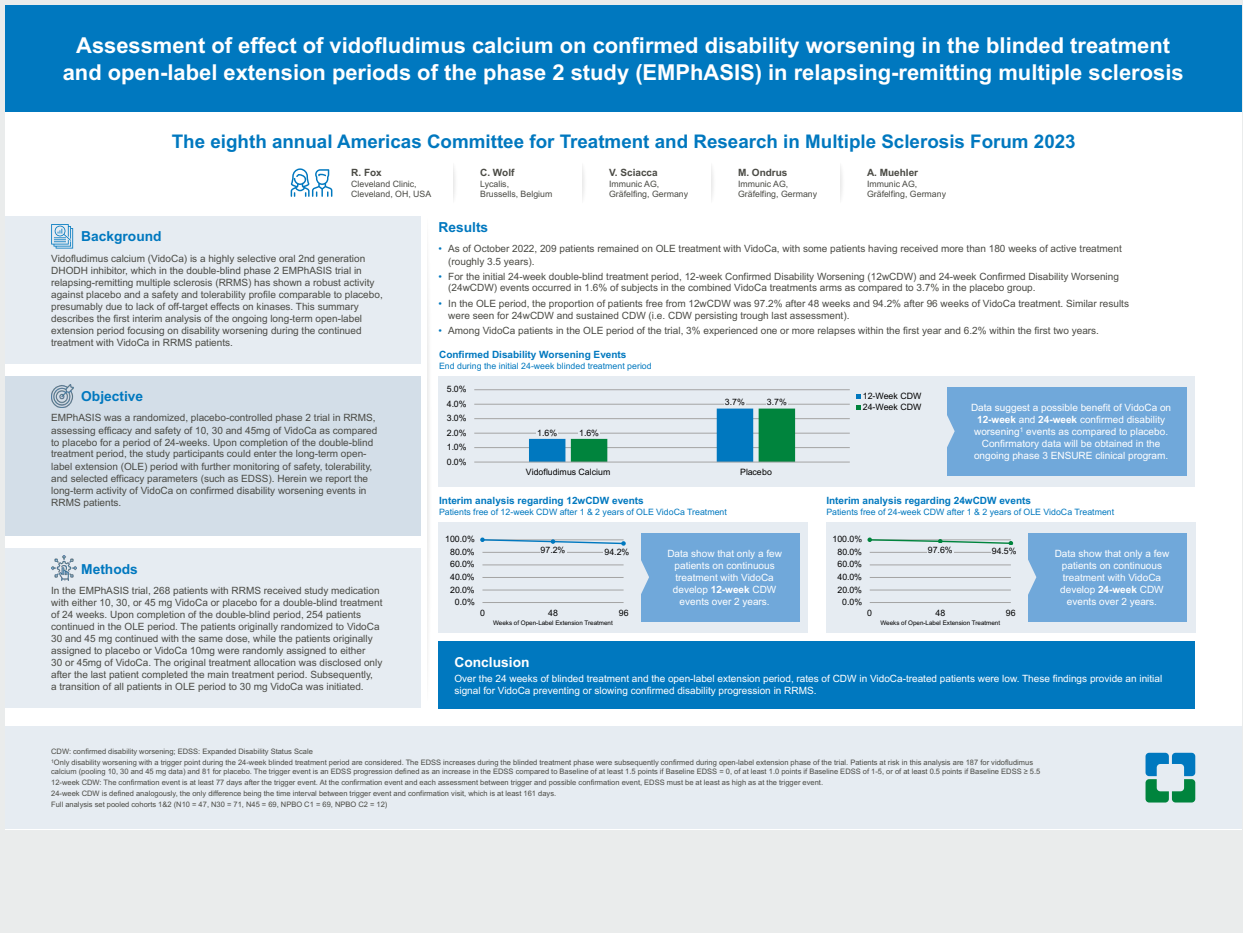
First Quarter 2023 and Subsequent Highlights

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, Brussells, Belgium
V. Sciacca, Immunic AG, Gräfelfing, Germany
M. Ondrus, Immunic AG, Gräfelfing, Germany
A. Muehler, Immunic AG, Gräfelfing, 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.

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 trough 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[1] 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

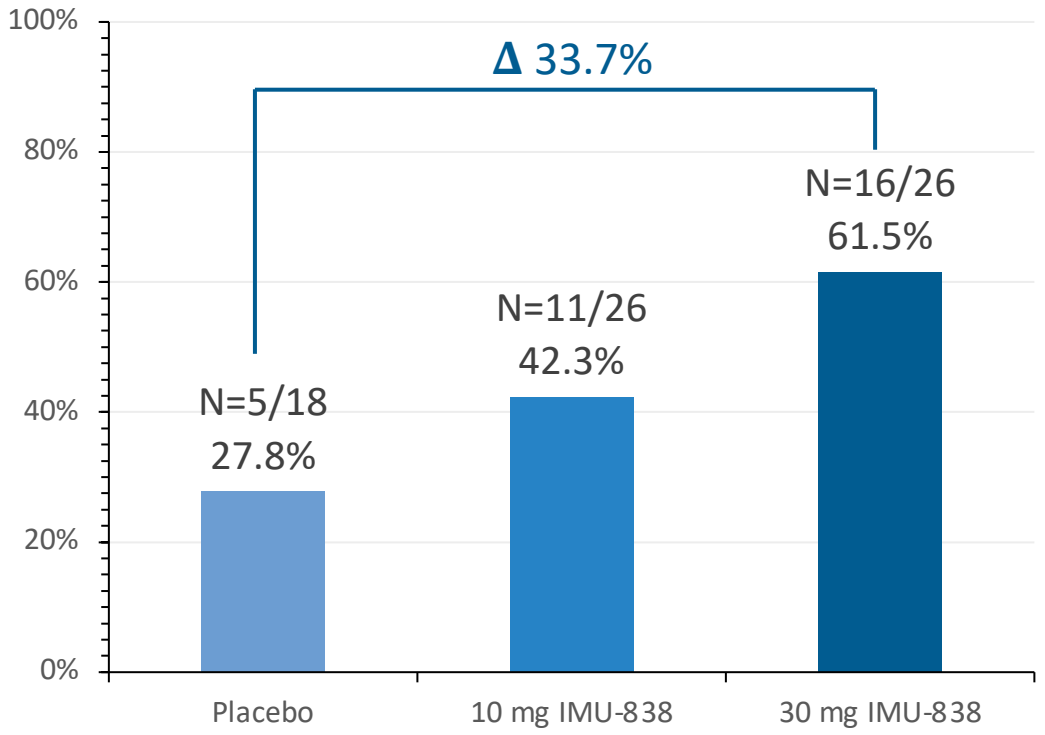
Over the 24 weeks of blinded treatment and the open-label extension period, rates of CDW in VidoCa-treated patients were low. These findings provide an initial signal for VidoCa preventing or slowing confirmed disability progression in RRMS.

CDW: confirmed disability worsening; EDSS: Expanded Disability Status Scale
[1]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 data) 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 1-5, or of at least 0.5 points if Baseline EDSS ≥ 5.5
12-week CDW: The confirmation event is at least 77 days after the trigger event. At the confirmation event and each assessment between trigger 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 analysis set pooled cohorts 1&2 (N10 = 47, N30 = 71, N45 = 69, NPBO C1 = 69, NPBO C2 = 12)

- 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** odds ratio (30 mg IMU-838 / placebo) 4.1600
	No	10	38.5%	
Placebo	Yes	5	27.8%	
	No	13	72.8%	

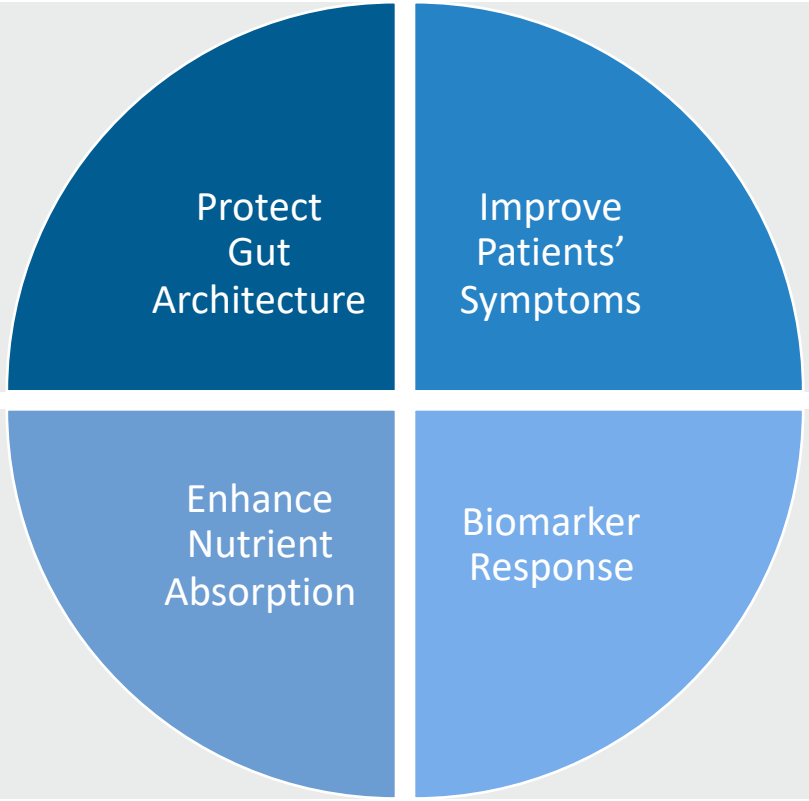
Clinical remission: composite of patient-reported symptomatic remission (stool frequency Mayo subscore of 0 or 1, rectal bleeding Mayo score of 0) and modified Mayo endoscopy subscore of 0 or 1
Full Analysis Set of Maintenance Phase (N10 = 45, N30 = 40, NPBO = 27), Post-Hoc Unplanned Analysis: Two-sided 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

IMU-856 effectively reduces gluten-induced intestinal damage, as measured by villous height



IMU-856 reduces/reverses gluten-induced symptoms reported by patients

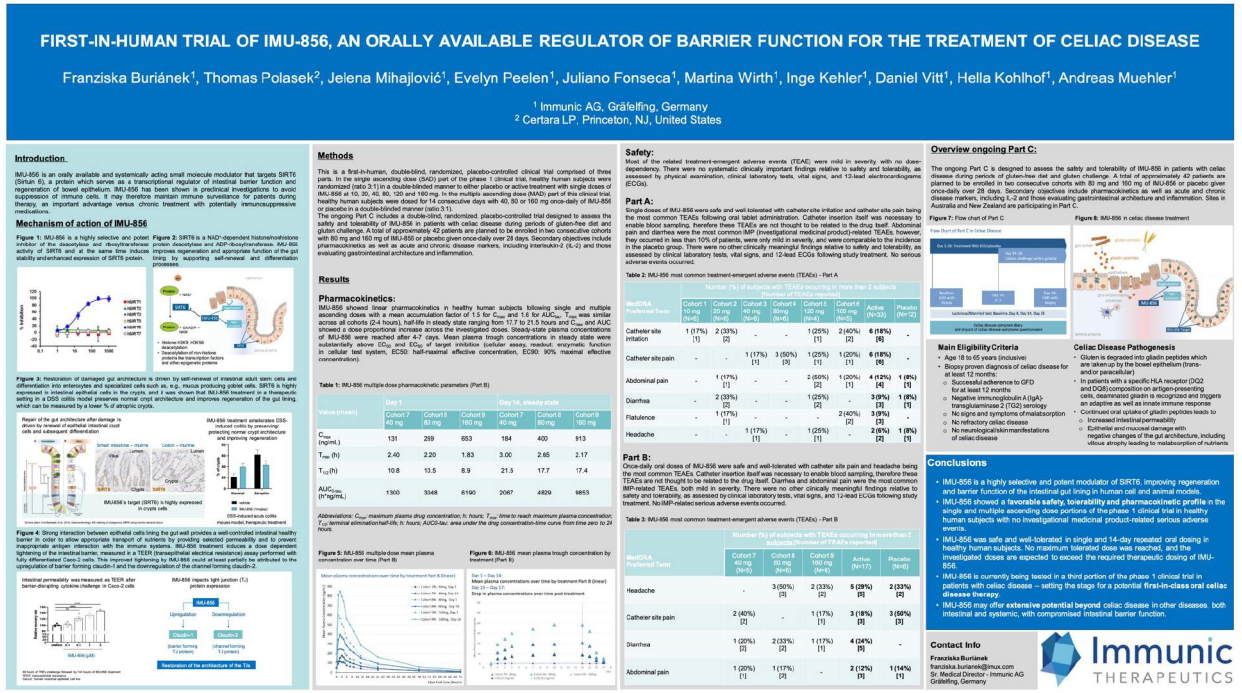
IMU-856 restores villi absorptive function resulting in improved uptake of nutrients such as vitamin B12

IMU-856 dampens gluten-induced immune activation, as measured by IL-2, and shows positive impact on citrulline

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

Immunic THERAPEUTICS

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 Buriánek[1], Thomas Polasek[2], Jelena Mihajlović[1], Evelyn Peelen[1], Juliano Fonseca[1], Martina Wirth[1], Inge Kehler[1], Daniel Vitt[1], Hella Kohlhof[1], Andreas Muehler[1]

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

- 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

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**

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

Immunic THERAPEUTICS

Q&A Session

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 Progressive Multiple Sclerosis (PMS) – CALLIPER Trial Ulcerative Colitis (UC) – CALDOSE-1 Trial				▪ 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
IMU-856	Celiac Disease				
IMU-381	Gastrointestinal Diseases				

■ Completed or ongoing ■ In preparation or planned

Immunic THERAPEUTICS

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