



Immunic
THERAPEUTICS

Immunic Therapeutics

Second Quarter 2023 Financial Results and Corporate Update

NASDAQ: IMUX | August 3, 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.

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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

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04 Q&A Session

05 Summary and Highlights

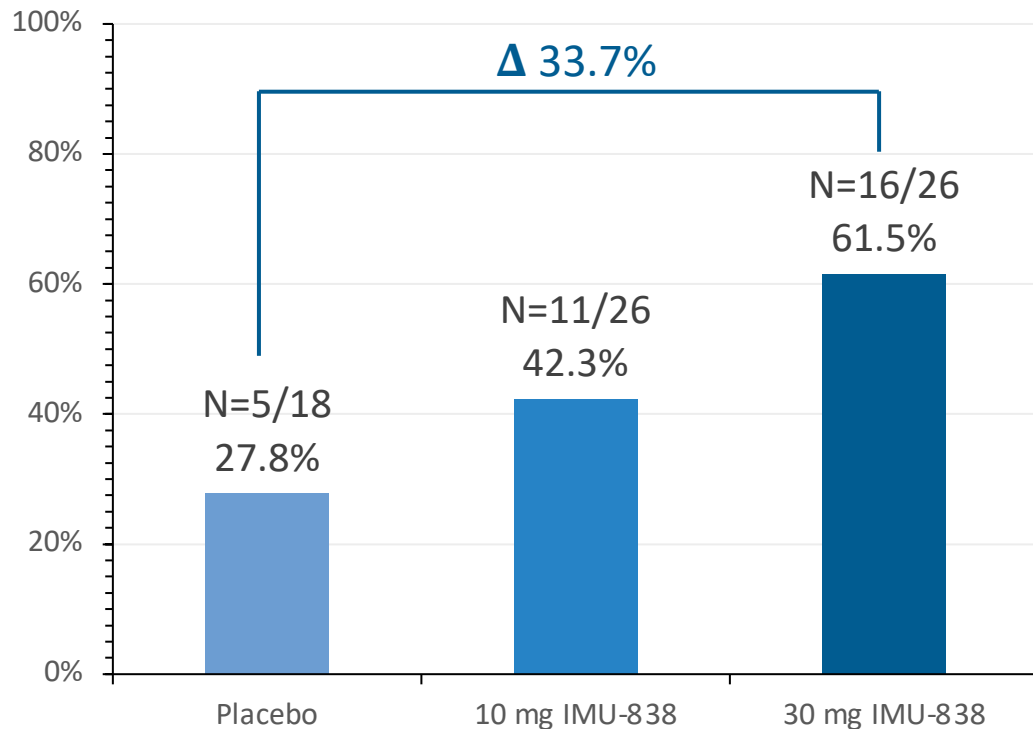


01

Second Quarter 2023 and Subsequent Highlights

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

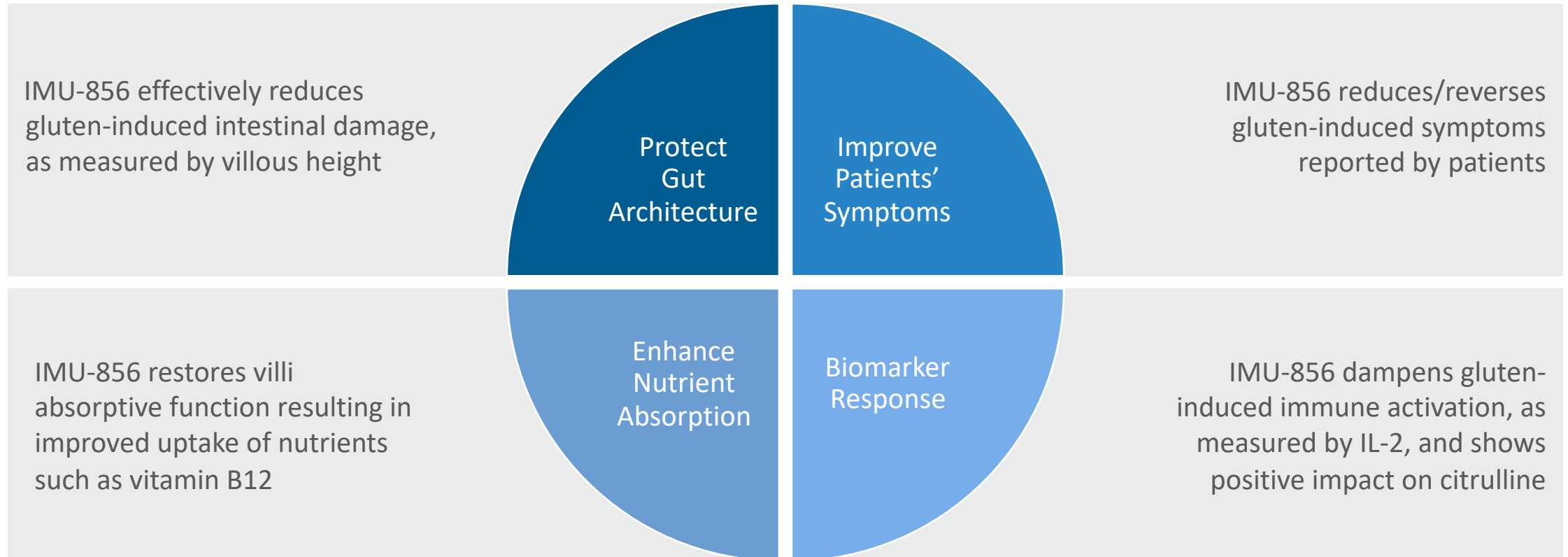
Full Analysis Set of Maintenance Phase (N10 = 45, N30 = 40, NPBO = 27), Post-Hoc Unplanned Analysis: Two-sided Pearson's chi-square test (significance level alpha=0.05) for achieving clinical remission at week 50 between 30 mg IMU-838 and placebo

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

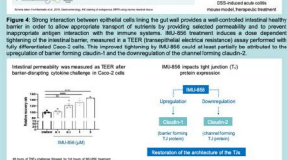
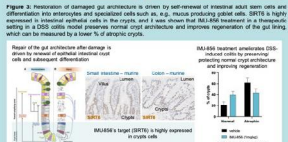
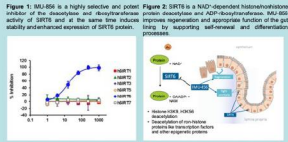
Franziska Buriánek¹, Thomas Polasek², Jelena Mihajlović¹, Evelyn Peelen¹, Juliano Fonseca¹, Martina Wirth¹, Inge Kehler¹, Daniel Vitt¹, Hella Kohlhorf¹, Andreas Muehler¹

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 lower epithelium. IMU-856 has been shown in preclinical investigations to induce upregulation of immune cells. It may therefore increase immune surveillance for patients during therapy. An important advantage versus chronic treatment with potentially immunosuppressive medications.

Mechanism of action of IMU-856



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 (1:1) to a double-blind regimen 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 1:1).

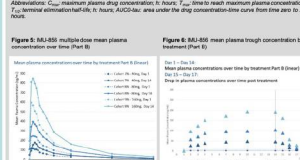
The ongoing Part C includes a double-blind, randomized, placebo-controlled trial designed to assess the safety and tolerability of IMU-856 in patients with celiac disease during periods of gluten-free diet and gluten challenge. A total of approximately 42 patients are planned to be enrolled in three consecutive cohorts with 10, 20 mg and 40 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 AUC₀₋₂₄. T_{1/2} was similar across all cohorts (24 hours), half-life in steady state ranging from 17.7 to 21.5 hours and C_{max} and AUC showed a dose proportional 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 C₅₀ and C₉₀ at target inhibition (lukiferase, mesalazine, mycophenolate) function in cellular test system. EC50: half-maximal effective concentration, EC90: 90% maximal effective concentration.

Table 1: IMU-856 multiple-dose pharmacokinetic parameters (Part B)

| Parameter (Day 1) | Cohort 7 (10 mg) | Cohort 8 (20 mg) | Cohort 9 (40 mg) | Cohort 10 (80 mg) | Cohort 11 (160 mg) |
|-------------------------------|------------------|------------------|------------------|-------------------|--------------------|
| C _{max} (ng/mL) | 131 | 269 | 603 | 184 | 400 |
| T _{1/2} (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 | 3348 | 4190 | 2067 | 4009 |



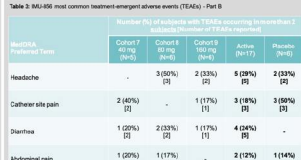
Safety

Most of the related treatment-emergent adverse events (TEAE) were mild to severe 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).

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 three consecutive cohorts with 10, 20 mg and 40 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.

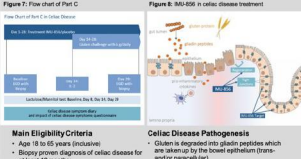
Table 2: IMU-856 most common treatment-emergent adverse events (TEAE) - Part A

| Adverse Event | Cohort 7 (10 mg) | Cohort 8 (20 mg) | Cohort 9 (40 mg) | Cohort 10 (80 mg) | Cohort 11 (160 mg) | Placebo (N=12) |
|--------------------------|------------------|------------------|------------------|-------------------|--------------------|----------------|
| Catheter site irritation | 1 (17%) | 2 (33%) | - | 1 (25%) | 2 (40%) | 0 (0%) |
| Catheter site pain | - | 1 (17%) | 3 (50%) | 1 (25%) | 1 (20%) | 0 (0%) |
| Abdominal pain | - | 1 (17%) | - | 2 (50%) | 1 (20%) | 4 (33%) |
| Diarrhea | - | 2 (33%) | - | 1 (25%) | - | 1 (8%) |
| Flatulence | - | 1 (17%) | - | 2 (50%) | 3 (60%) | 0 (0%) |
| Headache | - | 1 (17%) | - | 1 (25%) | - | 1 (8%) |



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 three consecutive cohorts with 10, 20 mg and 40 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.



Main Eligibility Criteria

- Age 18 to 55 years (inclusive)
- Biopsy proven diagnosis of celiac disease for at least 12 months
- Successful adherence to GFD for at least 12 months
- Specific IgA and IgG anti-tissue transglutaminase (tTG) serology
- No signs and symptoms of malabsorption
- No inflammatory bowel disease
- No neurologic/immunomodulators of celiac disease

Conclusions

- IMU-856 is a highly selective and potent modulator of SIRT6, improving regeneration and barrier function of the intestinal gut lining in human cells and animal models.
- IMU-856 showed a favorable safety, tolerability and pharmacokinetic profile in the single and multiple ascending dose portions of the phase 1 clinical trial in healthy human subjects with no investigational medical product-related serious adverse events.
- IMU-856 was safe and well-tolerated in single and 14-day repeated oral dosing in healthy human subjects. No maximum tolerated dose was reached, and the investigated doses are expected to exceed the required therapeutic dosing of IMU-856.
- IMU-856 is currently being tested in a third portion of the phase 1 clinical trial in patients with celiac disease - setting the stage for a potential first-in-class oral cellular disease therapy.
- IMU-856 may offer extensive potential beyond celiac disease in other diseases, both intestinal and systemic, with compromised intestinal barrier function.

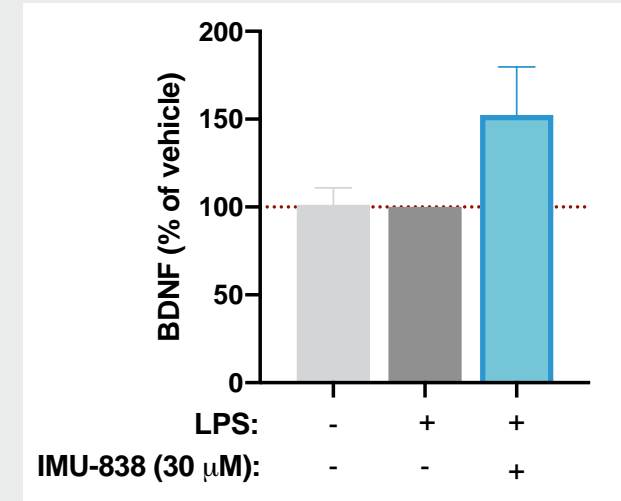
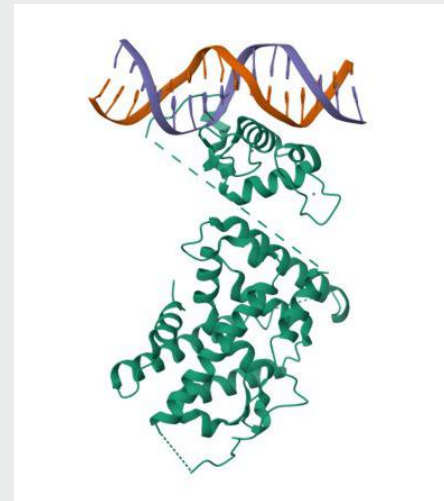
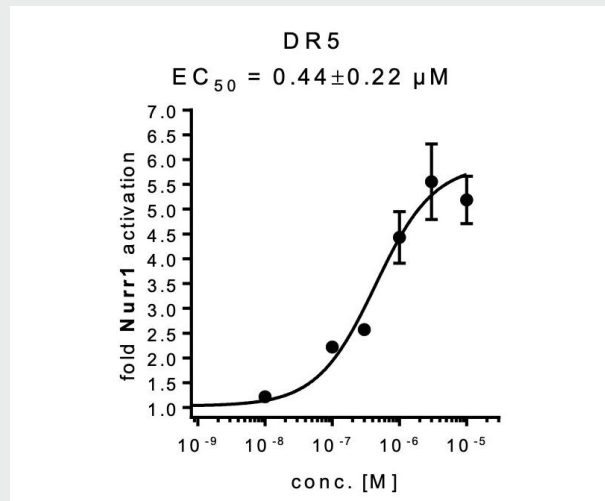
Contact Info
 Franziska Buriánek
 franziska.burienek@immunic.com
 Sr. Medical Director - Immunic AG
 Gräfelfing, Germany



- 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

May: Published Preclinical Data Confirming That Vidofludimus Calcium Acts as a Potent Nurr1 Activator

- Vidofludimus calcium induces a 5-fold activation, with an EC₅₀ of 440 nM concentration
- Nurr1 is a transcription factor binding to DNA
- Vidofludimus calcium enhances production of the Nurr1 target BDNF, positively impacting neuronal survival and myelination



Vidofludimus Calcium



binds and activates

Nurr1



activates

Neuronal Survival

Vietor et al., Journal of Medicinal Chemistry 2023 66 (9), 6391-6402; Structure: Zhao, M. et.al. (2022) Proc Natl Acad Sci USA 119; Nurr1: nuclear receptor related 1; DNA: deoxyribonucleic acid; BDNF: brain-derived neurotrophic factor
The related research project was funded by the German Federal Ministry of Education and Research under the grant number 03INT607AA.

Ongoing Active Celiac Disease and Its High Unmet Medical Need for New Treatment Options

Immunic's Virtual Celiac Disease KOL Roundtable
Thursday, July 20, 2023, 8:00 - 9:00 am Eastern Time

FEATURED EXPERTS



Ciarán P. Kelly, MD

J Thomas LaMont Professor of Gastroenterology
Director Celiac Center
Beth Israel Deaconess Medical Center
Professor of Medicine
Harvard Medical School
Boston, MA



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

Register Now

The Celiac Disease Roundtable will be held virtually via Zoom. To participate, please register in advance at:

https://imux.zoom.us/webinar/register/WN_m-d7ddH1SDqFWc7alkSika

Registrants will receive a confirmation email containing a link for online participation or a telephone number for dial in access.



Marilyn G. Geller

Chief Executive
Celiac Disease Foundation
Los Angeles, CA



Andreas Muehler, MD

Co-Founder & Chief Medical Officer
Immunic Therapeutics
New York, NY / Gräfelfing, Germany

July: Hosted Virtual Celiac Disease Roundtable



Ongoing Active Celiac Disease and Its High Unmet Medical Need for New Treatment Options

- Featured experts included:
 - Ciarán P. Kelly, M.D., Harvard Medical School, Boston, MA
 - Joseph A. Murray, M.D., Mayo Clinic, Rochester, MN
 - Marilyn G. Geller, Celiac Disease Foundation, Los Angeles, CA
 - Andreas Muehler, M.D., Immunic Therapeutics
- Recording: <https://www.youtube.com/watch?v=g8tFGNgqRoE>



02

Financial and Operating Results

Condensed Consolidated Statements of Operations

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|--|--------------------------------|-------------|------------------------------|-------------|
| | 2023 | 2022 | 2023 | 2022 |
| Operating expenses: | | | | |
| Research and development | \$ 21,172 | \$ 16,538 | \$ 44,135 | \$ 33,983 |
| General and administrative | 3,849 | 4,072 | 8,137 | 8,062 |
| Total operating expenses | 25,021 | 20,610 | 52,272 | 42,045 |
| Loss from operations | (25,021) | (20,610) | (52,272) | (42,045) |
| Other income (expense): | | | | |
| Interest income | 968 | 106 | 1,768 | 113 |
| Other income (expense), net | 54 | (1,397) | 1,233 | (777) |
| Total other income (expense) | 1,022 | (1,291) | 3,001 | (664) |
| Net loss | \$ (23,999) | \$ (21,901) | \$ (49,271) | \$ (42,709) |
| Net loss per share, basic and diluted | \$ (0.54) | \$ (0.72) | \$ (1.12) | \$ (1.49) |
| Weighted-average common shares outstanding, basic and diluted | 44,432,955 | 30,248,767 | 44,036,352 | 28,686,910 |

→ \$77.3 million in cash, cash equivalents and investments as of June 30, 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 fall 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 of first phase 3 ENSURE trial estimated for end of 2025

IMU-856

- Phase 2 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 fall 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

