Immunic Therapeutics

Fourth Quarter and Year End 2023 Financial Results and Corporate Update

NASDAQ: IMUX | February 22, 2024

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

Fourth Quarter and Year End 2023 Financial Results and Corporate Update

01 Fourth Quarter 2023 and Subsequent Highlights

02 Financial and Operating Results

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Fourth Quarter 2023 and Subsequent Highlights

January 2024: Three-Tranche Private Placement of up to $240M, Cash Runway Extended Into Q3/2025 Based on Initial $80M Tranche

Private Investment in Public Equity ("PIPE") financing	▪ **First tranche** was an upfront payment **of $80 million** at $1.43 per share ▪ **Second tranche** is a conditional mandatory purchase **of an additional $80 million** at $1.716 per share – Representing 120% of the first tranche purchase price – Conditioned on the announcement of phase 2b top-line data for the CALLIPER trial of vidofludimus calcium in PMS, volume weighted average share price levels, and minimum trading volumes ▪ **Third tranche** provides for the issuance **of $80 million** of shares at the same price per share as the second tranche – To occur no later than three years after the second tranche – Permits investors to fund their purchase obligations on a "cashless" or net settlement basis – Conditioned on the same volume weighted average share price levels and minimum trading volumes as the second tranche ▪ Any of the conditions in the second or third tranches can be waived by holders of a majority of the outstanding securities, including the lead investor
Total Gross Proceeds	▪ **Up to $240 million**
Participating Investors	▪ Led by BVF Partners ▪ Includes participation from **new and existing investors**, including Avidity Partners, Janus Henderson Investors, Soleus Capital, RTW Investments and Adage Capital Partners
Closing Date	▪ January 8, 2024 for initial $80 million tranche
Lead Placement Agent / Placement Agent / Capital Markets Advisors	▪ Leerink Partners / Ladenburg Thalmann / Piper Sandler, B. Riley Securities, Brookline Capital Markets

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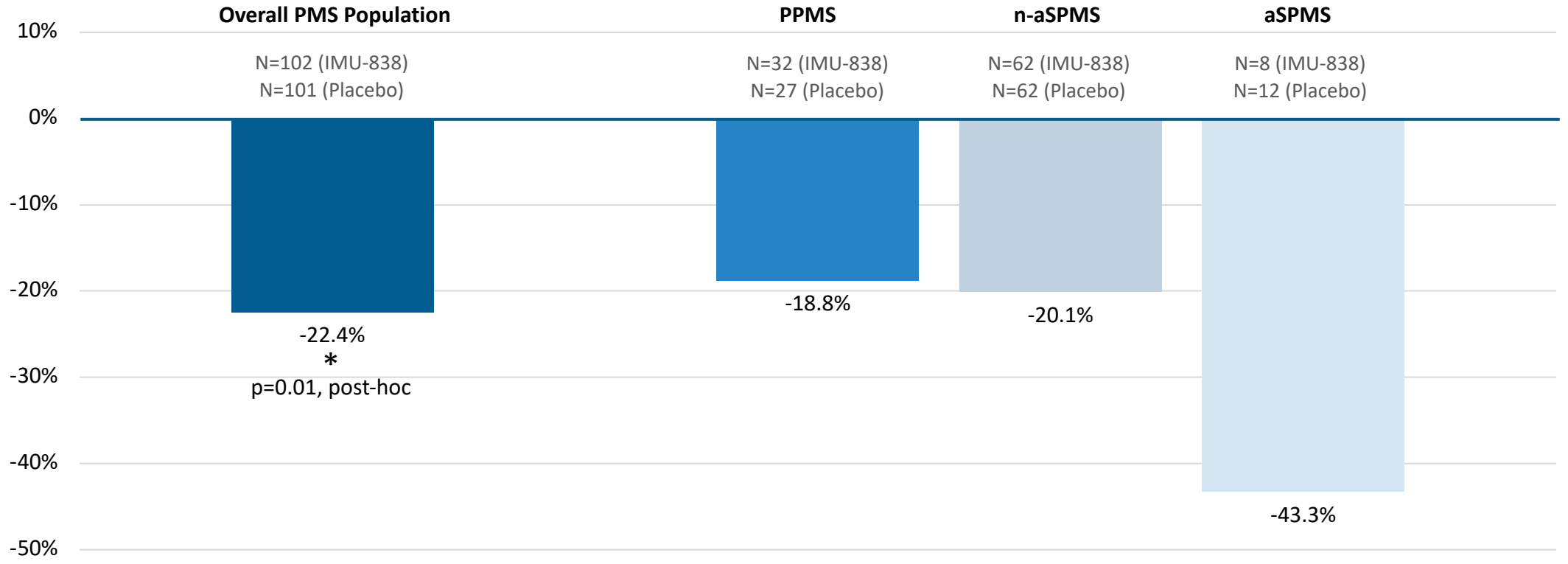
October: Reported Positive Interim Data from Phase 2 CALLIPER Trial of Vidofludimus Calcium in Progressive Multiple Sclerosis

Improvements in Serum NfL for Vidofludimus Calcium Consistent Throughout the Overall PMS Population and All Subtypes

Mean Change to Week 24 as Compared to Placebo in % of Baseline



Standard deviation for change from baseline in % of baseline: CALLIPER week 24: IMU-838 35.7%, PPMS: IMU-838 7.1%, n-aSPMS: IMU-838 14.7%, aSPMS: IMU-838 10.3%, 95% Hodges-Lehmann confidence bound EMPhASIS week 24 for 45mg IMU-838: lower boundary -41.0%, upper boundary -12.0%, includes all randomized patients with available neurofilament data at interim analysis, arithmetic mean value for group averages; aSPMS and n-aSPMS designation as per diagnosis by clinical investigator at study entry

RRMS: relapsing-remitting multiple sclerosis; PPMS: primary progressive multiple sclerosis; SPMS: secondary progressive multiple sclerosis; n-a: non-active; a: active

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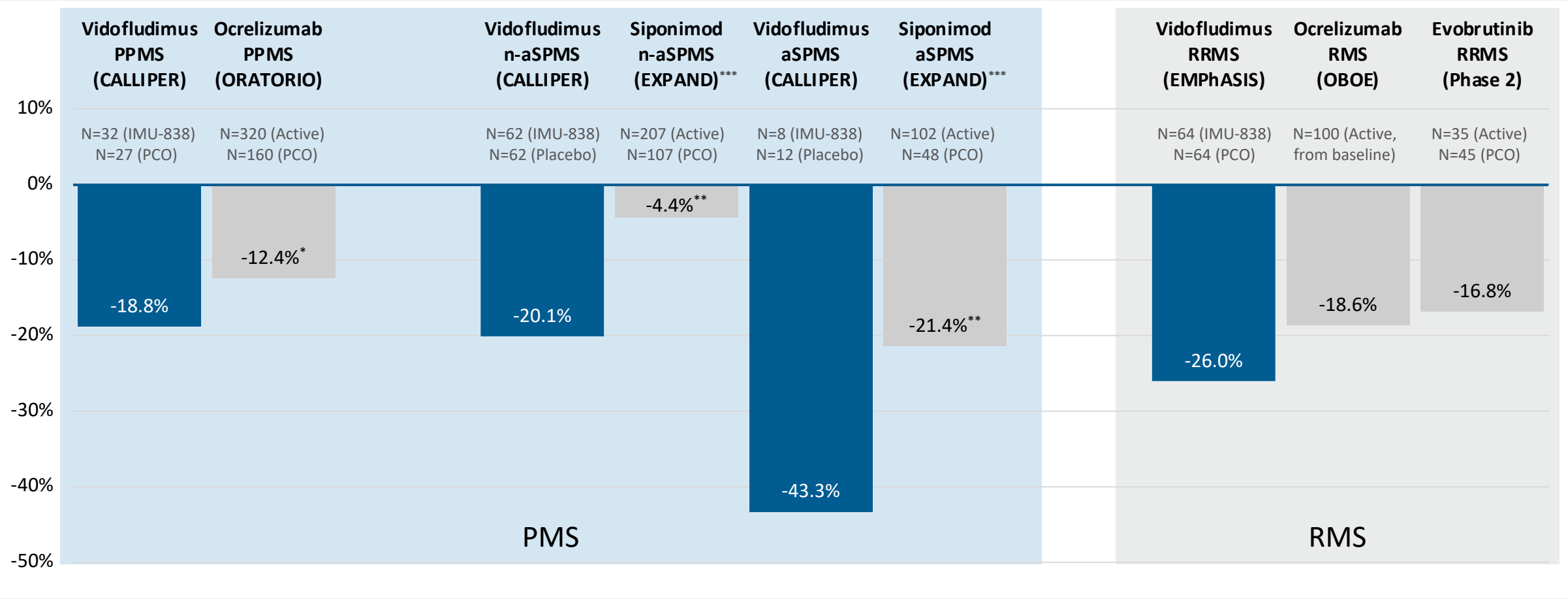
NfL Reduction Compares Favorably with Other MS Therapies

CALLIPER Interim Data Compared to Select Historical Trials



CALLIPER: N = Number of patients in the 45 mg IMU-838 groups, only patients with both baseline and week 24 values considered for change from baseline analysis, arithmetic mean value for group averages; includes all randomized patients with available NfL data at interim analysis
Standard deviation for change from baseline in % of baseline: CALLIPER week 24: IMU-838 35.7%; 95% Hodges-Lehmann confidence bound EMPhASIS week 24 for 45mg IMU-838: lower boundary -41.0%, upper boundary -12.0%
ORATORIO: Bar-Or A. et al., EBioMedicine. 2023 Jul;93:104662; EXPAND: Leppert D., et al., Neurology. 2022 May 24;98(21):e2120-e2131; OBOE: Cross A. et al., Neurology Apr 2019, 92 (15 Supplement) S56.008; evobrutinib: Kuhle J. et al., AAN 2021 Virtual Congress
*plasma NfL levels; ** 12-month data, geometric mean; *** Displayed are data for subpopulation without relapses (n-aSPMS) and with relapses (aSPMS); PCO: placebo; PPMS: primary progressive multiple sclerosis; SPMS: secondary progressive multiple sclerosis; RRMS: relapsing-remitting multiple sclerosis; RMS: relapsing multiple sclerosis; n-a: non-active; a: active

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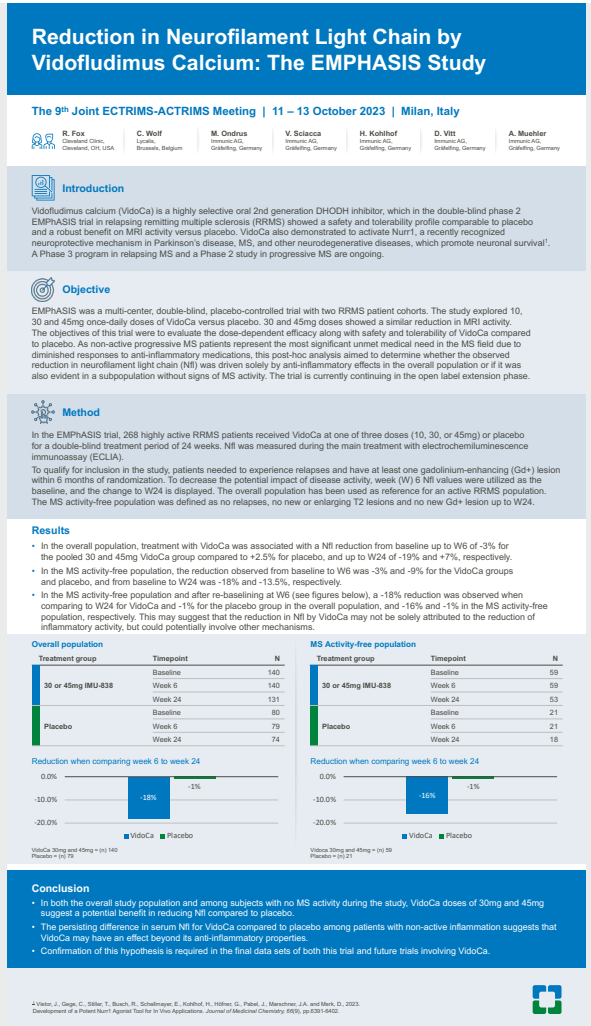
October: Presented Phase 2 EMPhASIS Trial Data of Vidofludimus Calcium in Relapsing-Remitting Multiple Sclerosis at MSMilan2023



Reduction in Neurofilament Light Chain by Vidofludimus Calcium: The EMPHASIS Study

The 9th Joint ECTRIMS-ACTRIMS Meeting | 11 – 13 October 2023 | Milan, Italy

R. Fox, Cleveland Clinic, Cleveland, OH, USA; C. Wolf, Lycaris, Brussels, Belgium; M. Ondrus, Immunic AG, Gräfelfing, Germany; V. Sciacca, Immunic AG, Gräfelfing, Germany; H. Kohlhof, Immunic AG, Gräfelfing, Germany; D. Vitt, Immunic AG, Gräfelfing, Germany; A. Muehler, Immunic AG, Gräfelfing, Germany

Introduction

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) showed a safety and tolerability profile comparable to placebo and a robust benefit on MRI activity versus placebo. VidoCa also demonstrated to activate Nurr1, a recently recognized neuroprotective mechanism in Parkinson's disease, MS, and other neurodegenerative diseases, which promote neuronal survival[1]. A Phase 3 program in relapsing MS and a Phase 2 study in progressive MS are ongoing.

Objective

EMPhASIS was a multi-center, double-blind, placebo-controlled trial with two RRMS patient cohorts. The study explored 10, 30 and 45mg once-daily doses of VidoCa versus placebo. 30 and 45mg doses showed a similar reduction in MRI activity. The objectives of this trial were to evaluate the dose-dependent efficacy along with safety and tolerability of VidoCa compared to placebo. As non-active progressive MS patients represent the most significant unmet medical need in the MS field due to diminished responses to anti-inflammatory medications, this post-hoc analysis aimed to determine whether the observed reduction in neurofilament light chain (Nfl) was driven solely by anti-inflammatory effects in the overall population or if it was also evident in a subpopulation without signs of MS activity. The trial is currently continuing in the open label extension phase.

Method

In the EMPhASIS trial, 268 highly active RRMS patients received VidoCa at one of three doses (10, 30, or 45mg) or placebo for a double-blind treatment period of 24 weeks. Nfl was measured during the main treatment with electrochemiluminescence immunoassay (ECLIA).

To qualify for inclusion in the study, patients needed to experience relapses and have at least one gadolinium-enhancing (Gd+) lesion within 6 months of randomization. To decrease the potential impact of disease activity, week (W) 6 Nfl values were utilized as the baseline, and the change to W24 is displayed. The overall population has been used as reference for an active RRMS population. The MS activity-free population was defined as no relapses, no new or enlarging T2 lesions and no new Gd+ lesion up to W24.

Results

- In the overall population, treatment with VidoCa was associated with a Nfl reduction from baseline up to W6 of -3% for the pooled 30 and 45mg VidoCa group compared to +2.5% for placebo, and up to W24 of -19% and +7%, respectively.
- In the MS activity-free population, the reduction observed from baseline to W6 was -3% and -9% for the VidoCa groups and placebo, and from baseline to W24 was -18% and -13.5%, respectively.
- In the MS activity-free population and after re-baselining at W6 (see figures below), a -18% reduction was observed when comparing to W24 for VidoCa and -1% for the placebo group in the overall population, and -16% and -1% in the MS activity-free population, respectively. This may suggest that the reduction in Nfl by VidoCa may not be solely attributed to the reduction of inflammatory activity, but could potentially involve other mechanisms.

Overall population

Treatment group	Timepoint	N
30 or 45mg IMU-838	Baseline	140
	Week 6	140
	Week 24	131
Placebo	Baseline	80
	Week 6	79
	Week 24	74

Reduction when comparing week 6 to week 24

VidoCa 30mg and 45mg = (n) 140
Placebo = (n) 79

MS Activity-free population

Treatment group	Timepoint	N
30 or 45mg IMU-838	Baseline	59
	Week 6	59
	Week 24	53
Placebo	Baseline	21
	Week 6	21
	Week 24	18

Reduction when comparing week 6 to week 24

VidoCa 30mg and 45mg = (n) 59
Placebo = (n) 21

Conclusion

- In both the overall study population and among subjects with no MS activity during the study, VidoCa doses of 30mg and 45mg suggest a potential benefit in reducing Nfl compared to placebo.
- The persisting difference in serum Nfl for VidoCa compared to placebo among patients with non-active inflammation suggests that VidoCa may have an effect beyond its anti-inflammatory properties.
- Confirmation of this hypothesis is required in the final data sets of both this trial and future trials involving VidoCa.

[1] Vietor, J., Gege, C., Stiller, T., Busch, R., Schallmayer, E., Kohlhof, H., Höfner, G., Pabel, J., Marschner, J.A. and Merk, D., 2023. Development of a Potent Nurr1 Agonist Tool for In Vivo Applications. *Journal of Medicinal Chemistry*, 66(9), pp.6391-6402.

- MSMilan2023: The 9th Joint ECTRIMS-ACTRIMS Meeting
- October 11-13 in Milan, Italy
- Virtual e-poster: Robert J. Fox, M.D., Staff Neurologist, Mellen Center for Multiple Sclerosis, Vice-Chair for Research, Neurological Institute, Cleveland Clinic, Cleveland, Ohio
- Title: Reduction in Neurofilament Light Chain by Vidofludimus Calcium: The EMPhASIS Study
  - Improvement in serum neurofilament light chain (NfL) observed in both treatment arms of vidofludimus calcium over placebo

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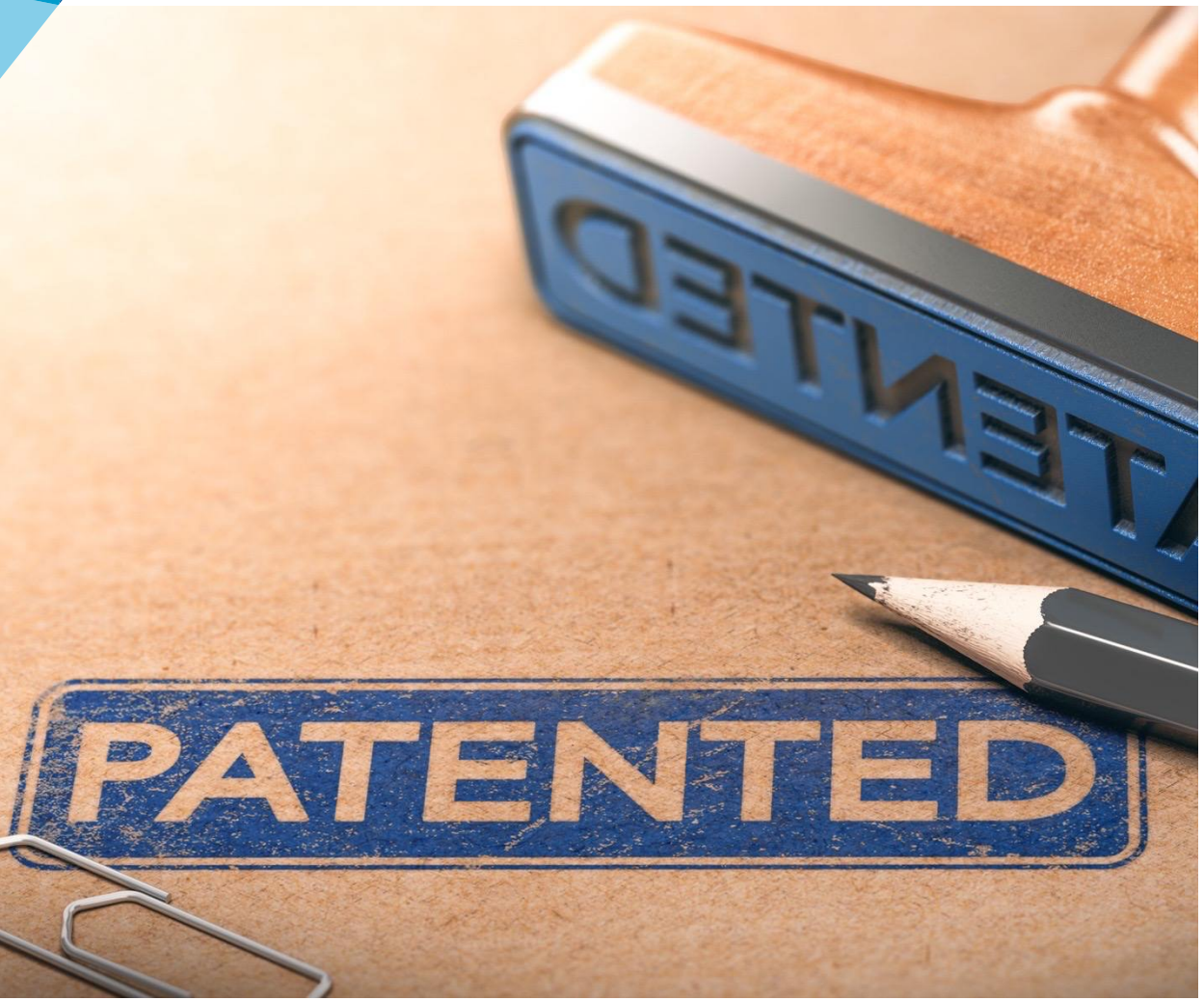
November: Expanded Vidofludimus Calcium Patent Portfolio with Two New Patents Granted in the US, Protection Currently Expected Into 2041 in the US



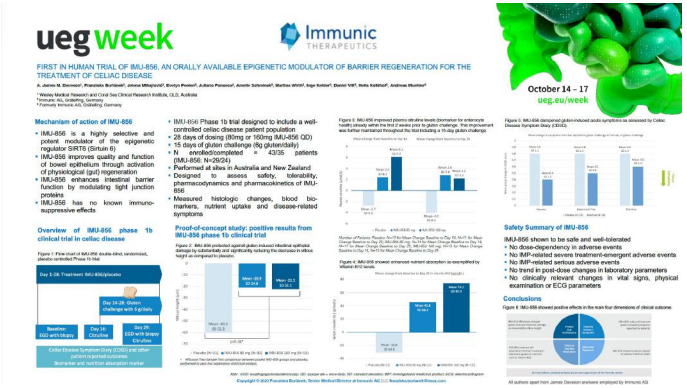
- Notice of Allowance from the USPTO for patent application 17/992,162, **covering the dosing regimens** associated with vidofludimus calcium and other salt as well as free acid forms for the treatment of MS, including all regimens tested in the MS clinical program

- Notice of Allowance from the USPTO for patent application 17/391,442, **covering a daily dose of about 10 to 45 mg** of vidofludimus calcium and other salt as well as free acid forms, including the 30 mg dosage used in the ENSURE trials, for the treatment of RMS

October: Presented Two Abstracts at the UEG (United European Gastroenterology) Week 2023 (October 14-17 in Copenhagen, Denmark)

Positive Phase 1b Data of IMU-856 in Celiac Disease

- Moderated Poster: Franziska Burianek, M.D., Senior Medical Director, Immunic
- Title: First in Human Trial of IMU-856, An Orally Available Epigenetic Modulator of Barrier Regeneration for the Treatment of Celiac Disease



Positive Phase 2 Maintenance Phase Data of Vidofludimus Calcium in UC

- Oral Presentation: Geert R. D'Haens, M.D., Ph.D., Amsterdam University Medical Centers
- Title: Efficacy and Safety of Vidofludimus Calcium (IMU-838) In Patients With Moderately to Severely Active Ulcerative Colitis (UC): Results From the Prospective Placebo-Controlled Phase 2 CALDOSE-1 Trial

November: Presented Phase 1b Data of IMU-856 in Celiac Disease at the AOECS 35th General Assembly Conference 2023

ABSTRACT OF ORIGINAL RESEARCH ON COELIAC DISEASE

FIRST IN HUMAN TRIAL OF IMU-856, AN ORALLY AVAILABLE EPIGENETIC MODULATOR OF BARRIER REGENERATION FOR THE TREATMENT OF CELIAC DISEASE

Submitted by: **Buriánek F[1], Mihajlović M[2], Pröbstl D[1], Peelen E[1], Fonseca J[1], Schreieck A[1], Wirth M[1], Kehler I[1], Vitt D[1], Kohlhof H[1], Muehler A[1]**

[1]*Immunic AG, Germany*
[2]*formerly Immunic AG, Germany*

Introduction

IMU-856 is an orally available, systemically acting and highly selective small molecule modulator that targets SIRT6 (Sirtuin 6), a protein which serves as a transcriptional regulator of intestinal barrier function and regeneration of bowel epithelium. Furthermore, in preclinical studies, the mechanism of IMU-856 has been shown to not affect the status of immune cells. IMU-856´s mechanism of action may present a new approach to treat celiac disease and other intestinal barrier function associated diseases.

Methods

This was a first-in-human, double-blind, randomized, placebo-controlled clinical trial of IMU-856 in healthy volunteers and patients with celiac disease. In the single and multiple ascending dose part of this clinical trial, healthy human subjects were randomized to either placebo or active treatment with different dose levels of IMU-856 or placebo. Phase 1b was designed to assess the safety and tolerability of 28-days of dosing of IMU-856 at two different dose levels (80mg + 160mg once daily) in patients with celiac disease during periods of gluten-free diet and a 15-days gluten challenge (6g gluten/daily). Secondary objectives included pharmacokinetics as well as histology, symptoms, and non-invasive biomarkers.

Results

IMU-856 was safe and well-tolerated with a benign adverse event profile and with pharmacokinetics that allow once-daily dosing.

Treatment with IMU-856 showed positive effects in the four main dimensions of clinical outcome in celiac disease patients:

- Protection against gluten induced intestinal damage.
- Improved enterocyte health and function.
- Enhanced nutrient absorption.
- Reduction of gluten-induced increase in symptom severity.

Conclusions

IMU-856 is a highly selective and potent epigenetic modulator, showing first signals of improving the intestinal barrier integrity in patients with celiac disease undergoing a gluten challenge. IMU-856 was safe and well-tolerated with a benign adverse event profile and with pharmacokinetics that allow once-daily dosing. Phase 1b provided proof of concept data for IMU-856 in patients with celiac disease during periods of gluten-free diet and 15-days gluten challenge, setting stage for a potential first-in-class oral celiac disease therapy.

IMU-856 may offer extensive potential beyond celiac disease in other diseases, both intestinal and systemic, with compromised intestinal barrier integrity.

All authors are/were employed by Immunic AG

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Recommendation letter: German Coeliac Society

AOECS

Deutsche Zöliakie Gesellschaft e.V.

- Association of European Coeliac Societies (AOECS) 35th General Assembly Conference 2023
- November 2-5 in Athens, Greece
- Virtual e-poster: Franziska Burianek, M.D., Senior Medical Director, Immunic
- Title: First In Human Trial of IMU-856, an Orally Available Epigenetic Modulator of Barrier Regeneration For the Treatment of Celiac Disease

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Financial and Operating Results

Consolidated Statements of Operations
(In thousands, except share and per share amounts, unaudited)

	Years Ended December 31,	
	2023	2022
Operating expenses:		
Research and development	$ 83,215	$ 71,255
General and administrative	16,008	15,263
Goodwill impairment	—	32,970
Total operating expenses	99,223	119,488
Loss from operations	(99,223)	(119,488)
Other income (expense):		
Interest income	3,075	1,041
Other income (expense), net	2,536	(1,960)
Total other income (expense), net	5,611	(919)
Net loss	$ (93,612)	$ (120,407)
Net loss per share, basic and diluted	$ (2.11)	$ (3.78)
Weighted-average common shares outstanding, basic and diluted	44,320,050	31,819,006

$46.7 million in cash, cash equivalents and investments as of December 31, 2023 plus the approximately $75.0 million in net proceeds raised in the January 2024 private placement expected to **fund operations into Q3/2025**

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Anticipated Clinical Milestones

Several Clinical Value Inflection Points Ahead

IMU-838 in PMS	▪ Readout phase 2 CALLIPER trial estimated for April 2025
IMU-838 in RMS	▪ Interim futility analysis phase 3 ENSURE program estimated for late 2024 ▪ Readout first phase 3 ENSURE trial estimated for Q2/2026
IMU-856	▪ Phase 2 clinical trial in preparation ▪ Applicable to a multitude of gastrointestinal disorders

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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
Vidofludimus Calcium (IMU-838)	Relapsing Multiple Sclerosis (RMS) – ENSURE Trials			
	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

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Thank You!

Jessica Breu

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