Immunic Therapeutics

Fourth Quarter and Year-End 2021 Financial Results and Corporate Update

NASDAQ: IMUX | February 24, 2022

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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05 Summary and Highlights

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Multiple Clinical Data Readouts for All Three Development Programs 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 ▪ June 2022: top-line UC data expected
		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	Gastrointestinal Diseases				▪ Q3/2022: SAD/MAD safety data expected

■ Completed or ongoing ■ In preparation or planned

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01

Fourth Quarter 2021 and Subsequent Highlights

October: Appointed Patrick Walsh to the Newly Created Role of Chief Business Officer

Mr. Walsh is responsible for business development, including strategic partnering opportunities, and has become part of the executive management team of Immunic.

- Mr. Walsh joined Immunic from Akebia Therapeutics, Inc., where he served as Vice President of Business Development and completed an array of strategic transactions, including multiple partnerships, in-licenses, non-dilutive financings, and a merger. Mr. Walsh was previously in Corporate Development at AVEO Oncology, during which time he worked on all aspects of business development. Earlier in his career, he was a consultant to life science companies with Capgemini SE and was on the healthcare investment banking team at Leerink Partners (now SVB Leerink).
- Mr. Walsh holds both an M.S. in molecular, cellular and developmental biology and an MBA from the University of Michigan and a B.A. in biology and economics from Colby College.

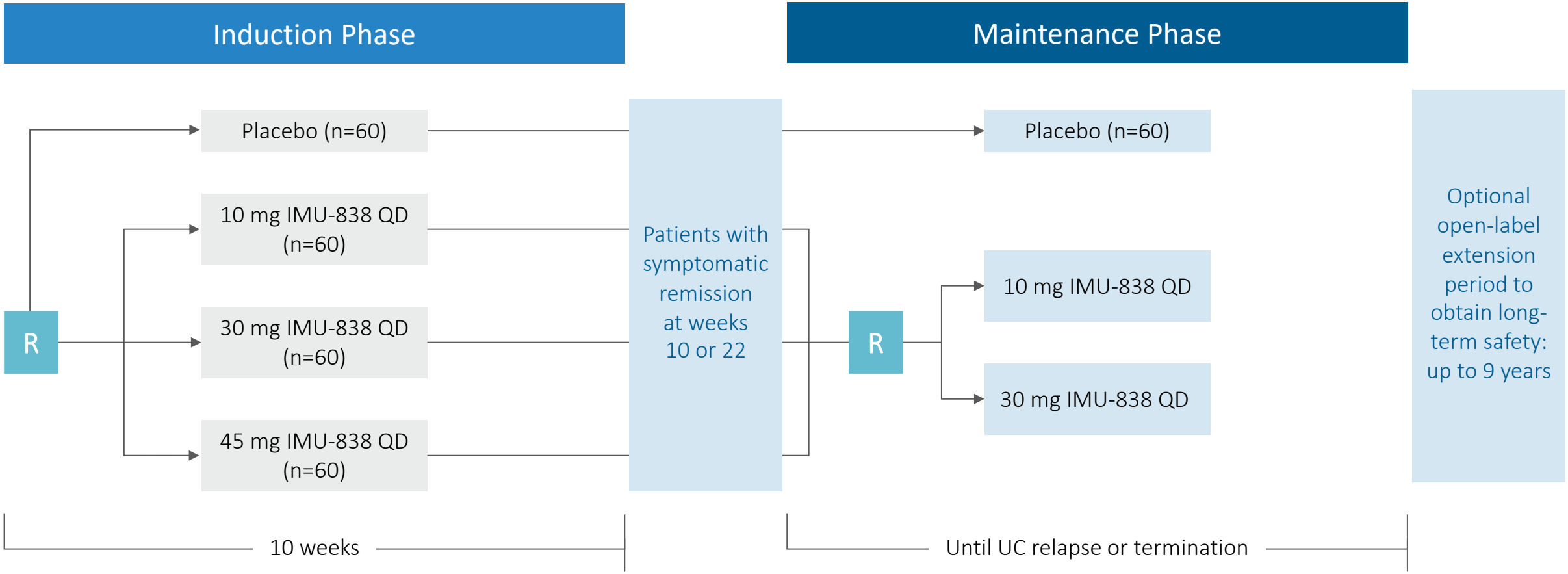
October: Dosed the First Patient With Moderate-to-Severe Psoriasis in Part C of the Ongoing Phase 1 Trial of IMU-935

Phase 1 Clinical Trial: Actively Enrolling Psoriasis Patients in Part C

- 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 will receive 28 days of daily treatment in 2 cohorts:
  - First cohort will receive a low dose of IMU-935 (150 mg QD) or placebo at a ratio of 3:1
  - Second cohort will receive a high dose of IMU-935 (150 mg BID) or placebo at a ratio of 3:1
- Initial results from part C are now expected to be available in H2/2022
  - To enable a rapid conduction of the trial, despite COVID-19-related limitations in Australia and New Zealand, where the trial is exclusively performed so far, Immunic has early initiated measures to randomize patients faster. This includes a potential expansion of the trial to European countries.

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

October: Randomized the Last Patient in the Phase 2 CALDOSE-1 Trial of Vidofludimus Calcium in Patients With Ulcerative Colitis*



Total number of patients randomized: N=263

Final analysis induction phase after 10 weeks

Final analysis maintenance phase after 50 weeks

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

* NCT03341962

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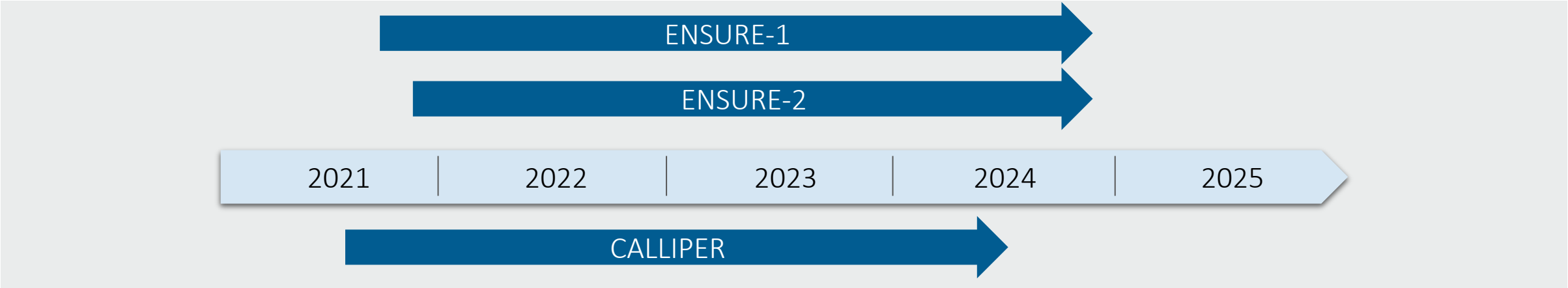
November: Enrolled the First Patient in the Phase 3 ENSURE Program of Vidofludimus Calcium in RMS

Phase 3 ENSURE Program in RMS

- Two identical pivotal trials in RMS patients
- Goal: Regulatory approval of vidofludimus calcium
- Dosage: 30 mg vidofludimus calcium QD
- ClinicalTrials.gov: NCT05134441 & NCT05201638

Phase 2 CALLIPER Trial in PMS

- Phase 2 trial in PMS patients
- Goal: Demonstrate vidofludimus calcium's potential for neuroprotective activity
- Dosage: 45 mg vidofludimus calcium QD
- ClinicalTrials.gov: NCT05054140



QD: quaque die = once-daily

December: Enrolled the First Patient in the Open-Label Phase 1 Clinical Trial of IMU-935 in mCRPC

Study Design

- Open-label dose escalation trial to evaluate safety, tolerability, anti-tumor activity, and pharmacokinetics of IMU-935 in patients with progressive, metastatic castration-resistant prostate cancer
- Main treatment will be single agent IMU-935 for 3 cycles of 28 days each
- Dose escalation follows a Bayesian optimal interval (BOIN) design
- An expansion cohort can be added at a therapeutically active dose level
- Patients who benefit can receive extended treatment
- At each dose level:
  - A safety analysis after 28 days will be performed to consider start of next dose
  - An interim activity analysis after 3 months of treatment will be performed
  - A main cohort analysis will be performed when the last patient in treatment reaches the 6 months follow-up visit

Principal Investigator

Johann Sebastian de Bono, M.D., Ph.D.

Regius Professor of Cancer Research and Professor in Experimental Cancer Medicine

The Institute of Cancer Research and The Royal Marsden NHS Foundation Trust

London, United Kingdom

* NCT05124795

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December: Reported Positive Unblinded Safety, Tolerability and PK Results of Phase 1 Clinical Trial of IMU-935 in Healthy Human Subjects

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 52 patients planned to be enrolled
- Initial data 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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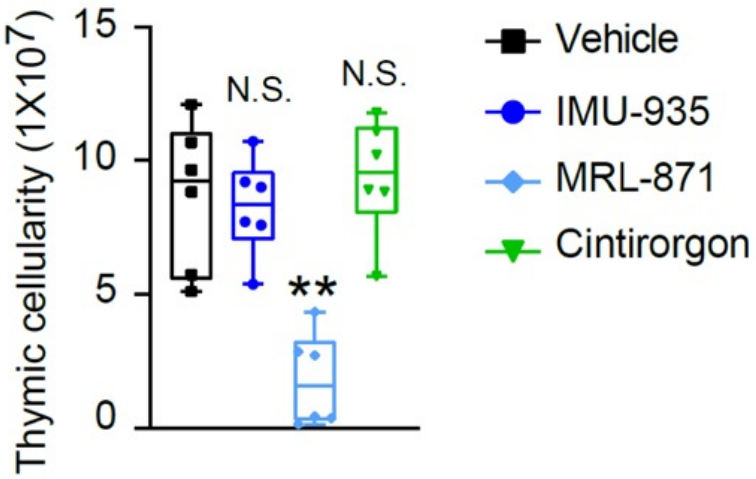
December: Announced Newly Available *In Vivo* Data for IMU-935

Maintains Normal Thymocyte Maturation in Relevant Acute and Chronic Mouse Models

Acute Model, 3 Days of Treatment



- Newly obtained *in vivo* data from acute and chronic treatment of mice further corroborated previously published *in vitro* data showing that, compared to two known RORγt inhibitors, exposure to IMU-935 allows normal thymocyte maturation.
- With these *in vivo* data, Immunic believes that the company may have the first clinical-stage RORγt inverse agonist which circumvents thymocyte maturation issues.

Guo et al., 2016, Cell Reports (MRL-871), Guntermann et al., 2017, JCI Insight (Cpd1), Mahalingam et al., 2019, Clin Cancer Res. (Cintirorgon)
Sun, Zuoming. City of Hope, 2021, unpublished

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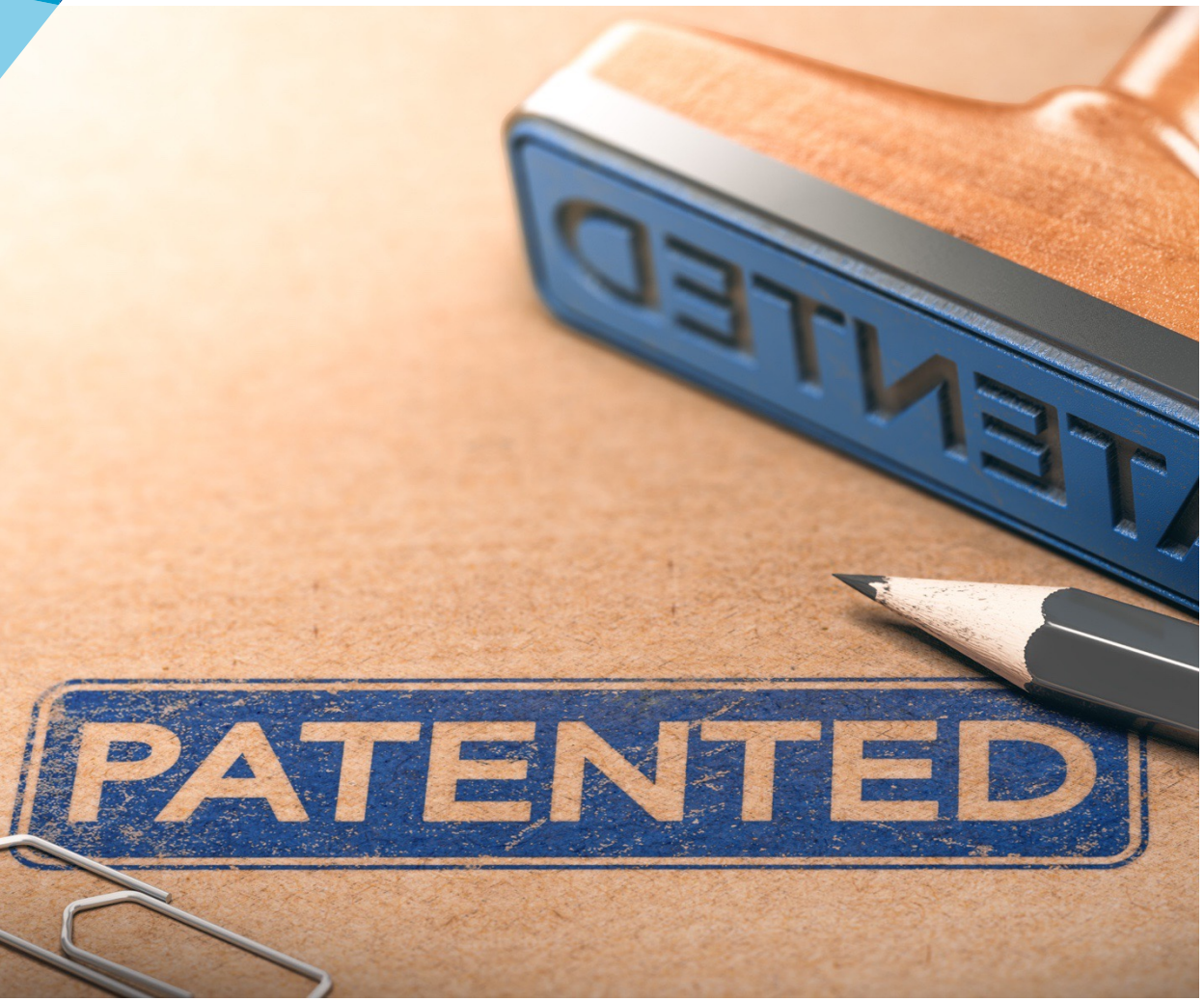
February 2022: Received Notice of Allowances for Composition-of-Matter Patents for IMU-935



- Received Notice of Allowance from the U.S. Patent and Trademark Office for patent application 16/644581, entitled, “IL-17 and IFN-gamma inhibition for the treatment of autoimmune diseases and chronic inflammation”.
- Also received notice of allowance of patent application EP18762111.5 in Europe, and notice of grant of patent application 2018330633 in Australia.
- All three patents cover composition-of-matter of IMU-935 and related formulations, and are expected to provide protection into at least 2038.

February 2022: Presented Preclinical Data for Vidofludimus Calcium at the 17th Congress of European Crohn's and Colitis Organization

European Crohn's and Colitis Organisation

Highlights Include:

- Vidofludimus calcium reduces proinflammatory immune cell responses by inducing regulatory macrophages, reducing pro-inflammatory cytokine secretion and reducing T cell proliferation.
- Vidofludimus calcium shows an additive to synergistic effect with anti-TNF antibodies.
- DHODH is important in cells that receive a strong immune stimulus and are highly metabolically active.

TNF: tumor necrosis factor

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February 2022: Announced Blinded Baseline Characteristics of Phase 2 CALDOSE-1 Trial of Vidofludimus Calcium in UC

The Main Blinded Baseline Characteristics of the CALDOSE-1 Trial Include:

- 263 moderate-to-severe UC patients were enrolled in 78 study sites
- 83% were biologically naïve and 17% were biologically experienced
- Baseline characteristics for patient-reported outcomes were:
  - The baseline Mayo stool frequency scores were: (i) score of 3 for 59% of patients, (ii) score of 2 for 36% of patients and (iii) score of 1 for 5% of patients.
  - The Mayo rectal bleeding scores were: (i) score of 3 in 10% of patients, (ii) score of 2 for 54% of patients and (iii) score of 1 for 31% of patients.
  - The average value for fecal calprotectin at baseline was approximately 1,320 µg/g for currently available, yet incomplete data.
- The trial employed a central independent reader to evaluate the endoscopic eligibility criteria and the following modified Mayo endoscopic scores were assessed at baseline:
  - 55% of patients with a score of 3; and
  - 45% of patients with a score of 2.
- At week 10, an adjudication procedure was used for endoscopy assessments. In the case of disagreement between two independent readers, a third independent reader was used for adjudication.

Immunic believes that these blinded baseline characteristics of randomized patients and the methodology regarding endoscopic assessments contributes to ensuring an optimized study read-out.

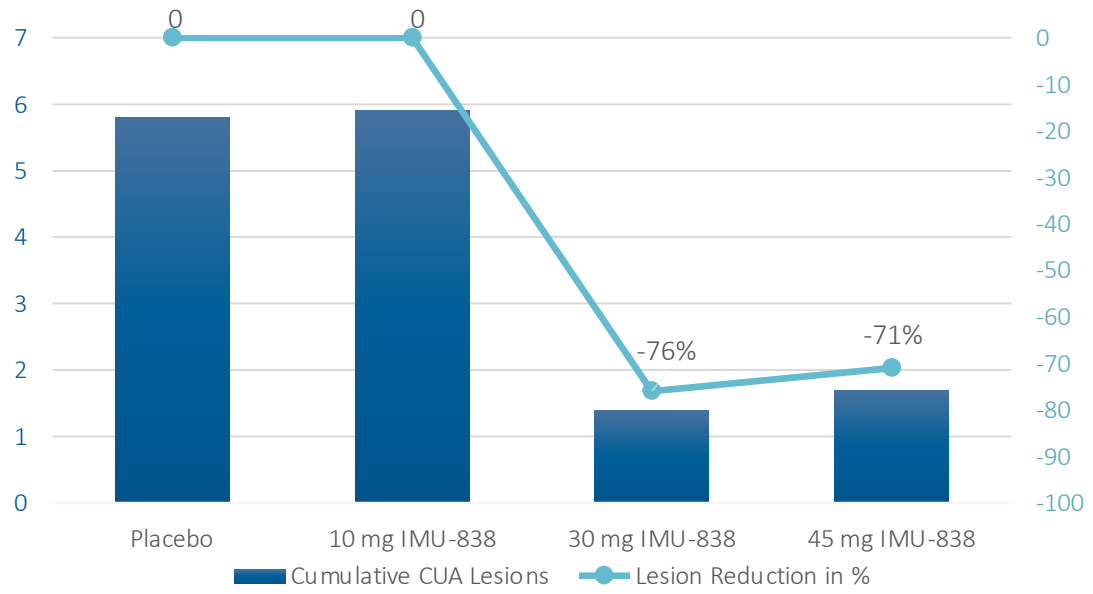
Phase 2 EMPhASIS Trial of Vidofludimus Calcium in RRMS

Final Cohort 2 Data Now Available

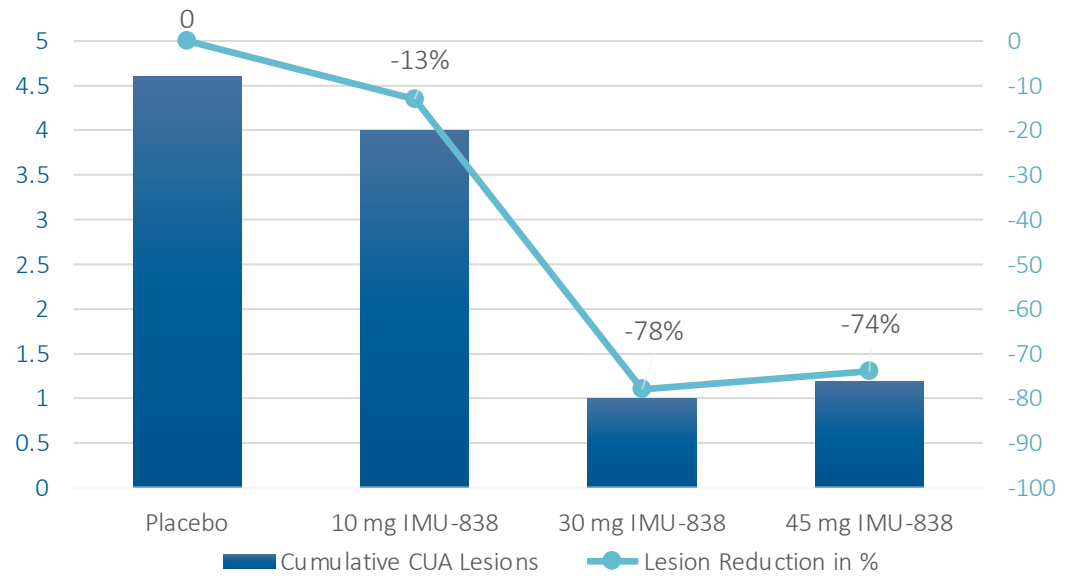
Vidofludimus Calcium Phase 2 EMPhASIS Trial in RRMS

Reduction of MRI Lesion Activity (Pooled Cohorts 1 & 2)

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 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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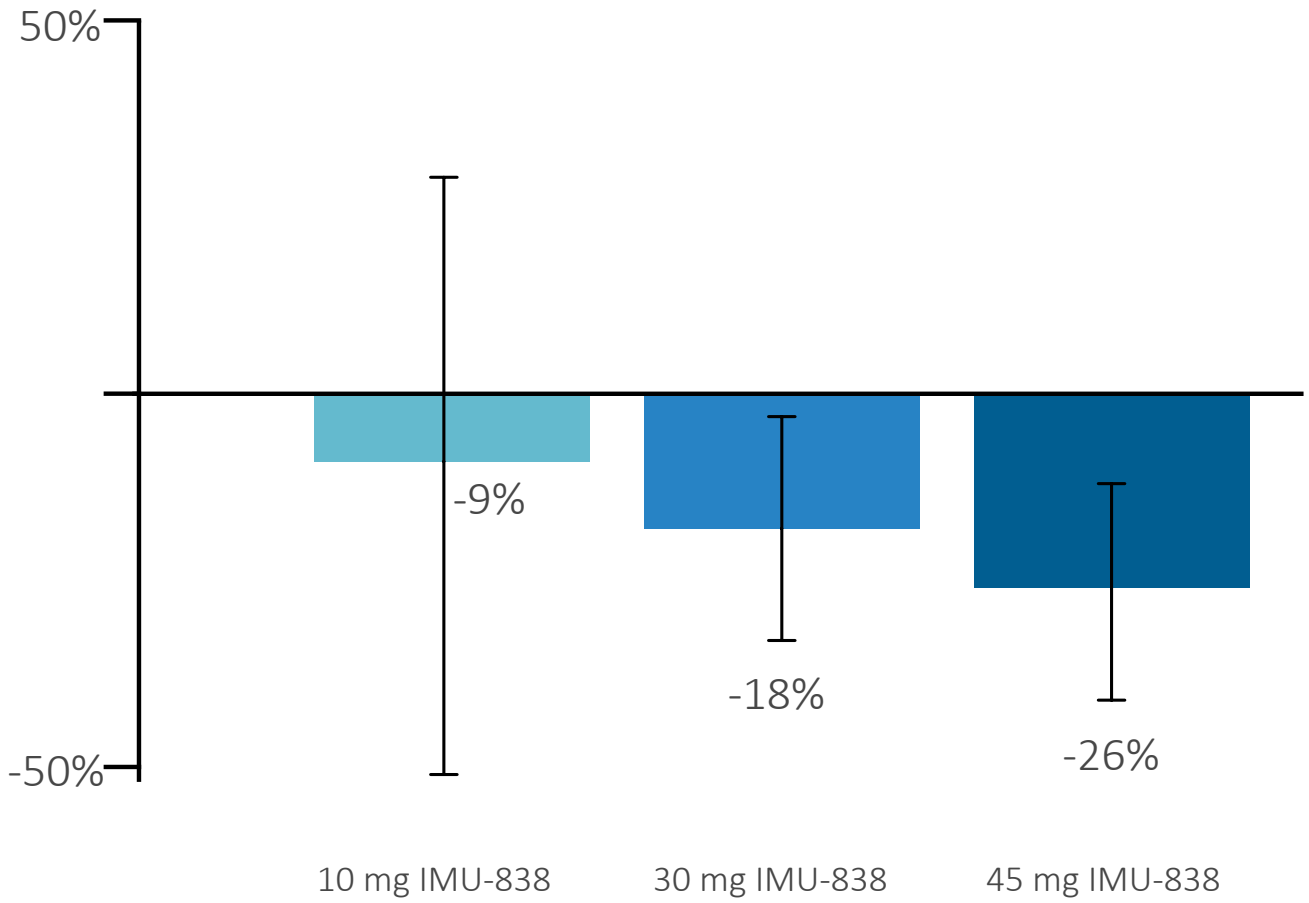
Vidofludimus Calcium Phase 2 EMPhASIS Trial in RRMS

Relative Change of Serum NfL Concentrations Versus Placebo After 24 Weeks (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
RRMS: relapsing-remitting multiple sclerosis; NfL: neurofilament

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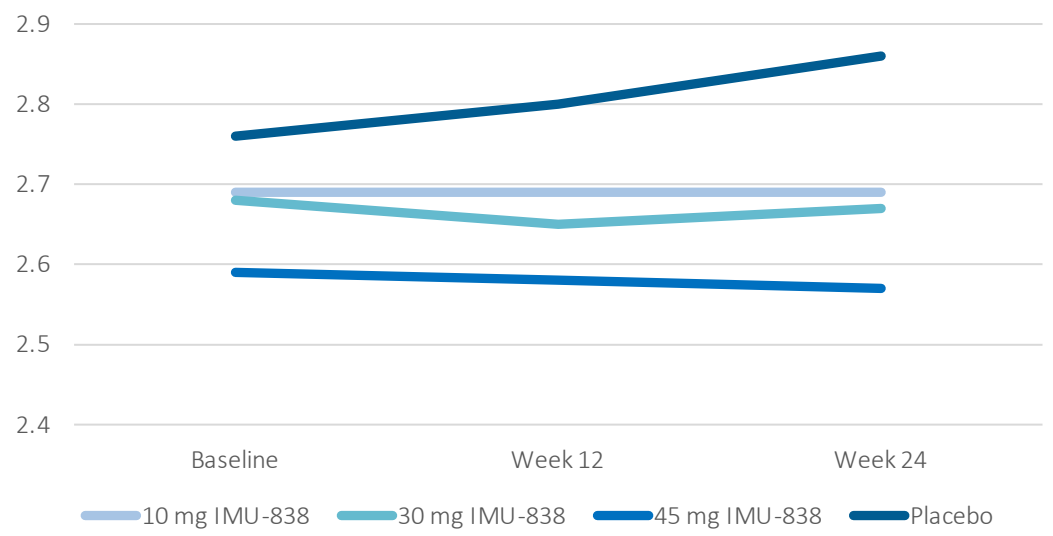
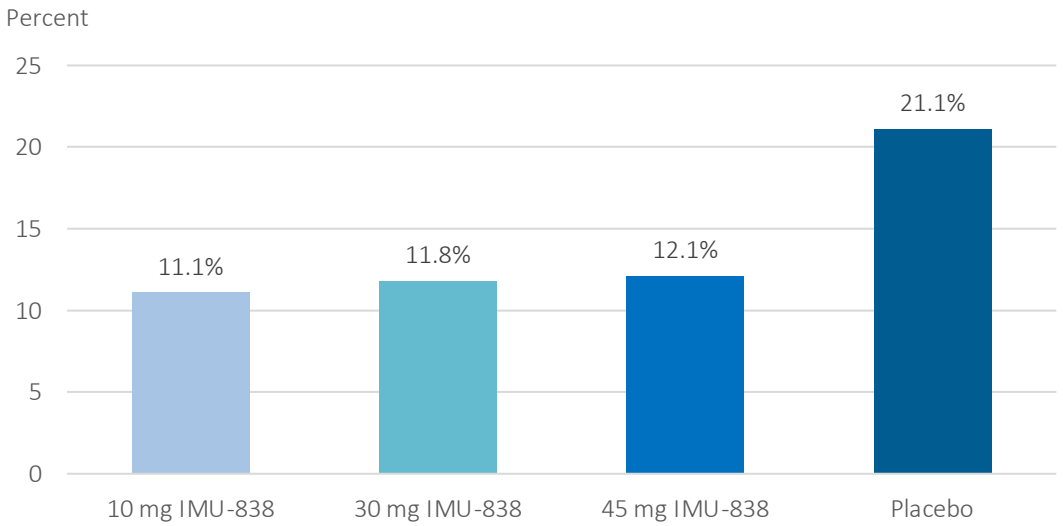
Vidofludimus Calcium Phase 2 EMPhASIS Trial in RRMS

Encouraging Signals of Neuroprotective Effects Based on EDSS Assessments (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
RRMS: relapsing-remitting multiple sclerosis; EDSS: Expanded Disability Status Scale

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Clinical Data of Vidofludimus Calcium in the COVID-19 Context

Treatment Tends to Decrease the Number of Opportunistic COVID-19 Infections

	IMU-838 (10 mg QD)	Placebo
Any Infection	17% (8/47)	33% (4/12)
COVID-19	**8.5%** (4/47)	**25%** (3/12)

Phase 2 Trial in RRMS (EMPhASIS)

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 Trial in COVID-19 (CALVID-1)

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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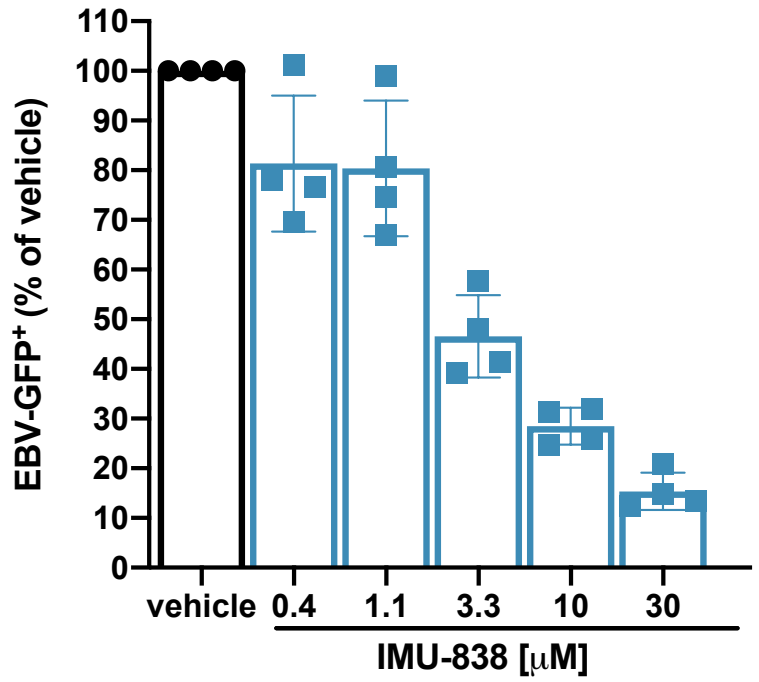
Vidofludimus Calcium: Potent Anti-EBV Activity Demonstrated in Cell-Culture-Based Systems

Anti-Akata-BX1-EBV-GFP stimulated with hIgG



Vidofludimus calcium showed concentration-dependent anti-EBV activity at concentrations of 3.3-30 µM in Raji and B95-8 cells in a superinfection assay.

Prof. M. Marschall, Institute for Clinical and Molecular Virology, Friedrich-Alexander University of Erlangen-Nürnberg, Germany. TPA: 12-O-tetradecanoylphorbol-13-acetate, Zta: an immediate early EBV antigen
EBV: Epstein–Barr virus

CNS Penetration of Vidofludimus* in Rats

Targeted Quantification in Cerebrospinal Fluid (CSF) via LC-MS

Vidofludimus Mean Concentration (Rat) (ng/mL; n=3/time point)	1.5 Hours Post-Dose	8.0 Hours Post-Dose
Blood Serum	9,737	8,792
CSF	2,591	1,175
Relationship of Vidofludimus Concentration CSF Versus Blood Plasma	26.6%	13.4%

Sample extraction followed by LC-MS/MS analysis (N=3 per time point and sample matrix)
Blood brain barrier in females Wistar Han rats: targeted quantitation of vidofludimus (parent) by LC/MS after single oral dose of 2.5 mg/kg
Internal Immunic data

Comparison BTKi SAR442168
@ 2.0 hours post dose (humans)

~ 20 ng/mL

1.87 ng/mL

~ 10%

Results of human phase 1 clinical trial
Lumbar puncture performed 2 hours post oral administration
Presented at ACTRIMS Forum 2019

CNS: central nervous system; BTKi: Bruton's tyrosine kinases inhibitor
* Vidofludimus is the active moiety of vidofludimus calcium (IMU-838)

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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,		
	2021		2020
Operating expenses:			
Research and development	$ 61,115		$ 38,637
General and administrative	13,300		10,334
4SC Royalty Settlement	17,250		—
Total operating expenses	91,665		48,971
Loss from operations	(91,665)		(48,971)
Other income (expense):			
Interest income	66		58
Other income (expense), net	(1,346)		4,896
Total other income (expense)	(1,280)		4,954
Net loss	$ (92,945)		$ (44,017)
Net loss per share, basic and diluted	$ (3.93)		$ (2.81)
Weighted-average common shares outstanding, basic and diluted	23,652,779		15,663,826

$86.9 million in cash and cash equivalents as of December 31, 2021, plus approximately $16.2 million raised under the company's at-the-market sales agreement in Q1/2022 are **expected to fund operations through the first quarter of 2023**

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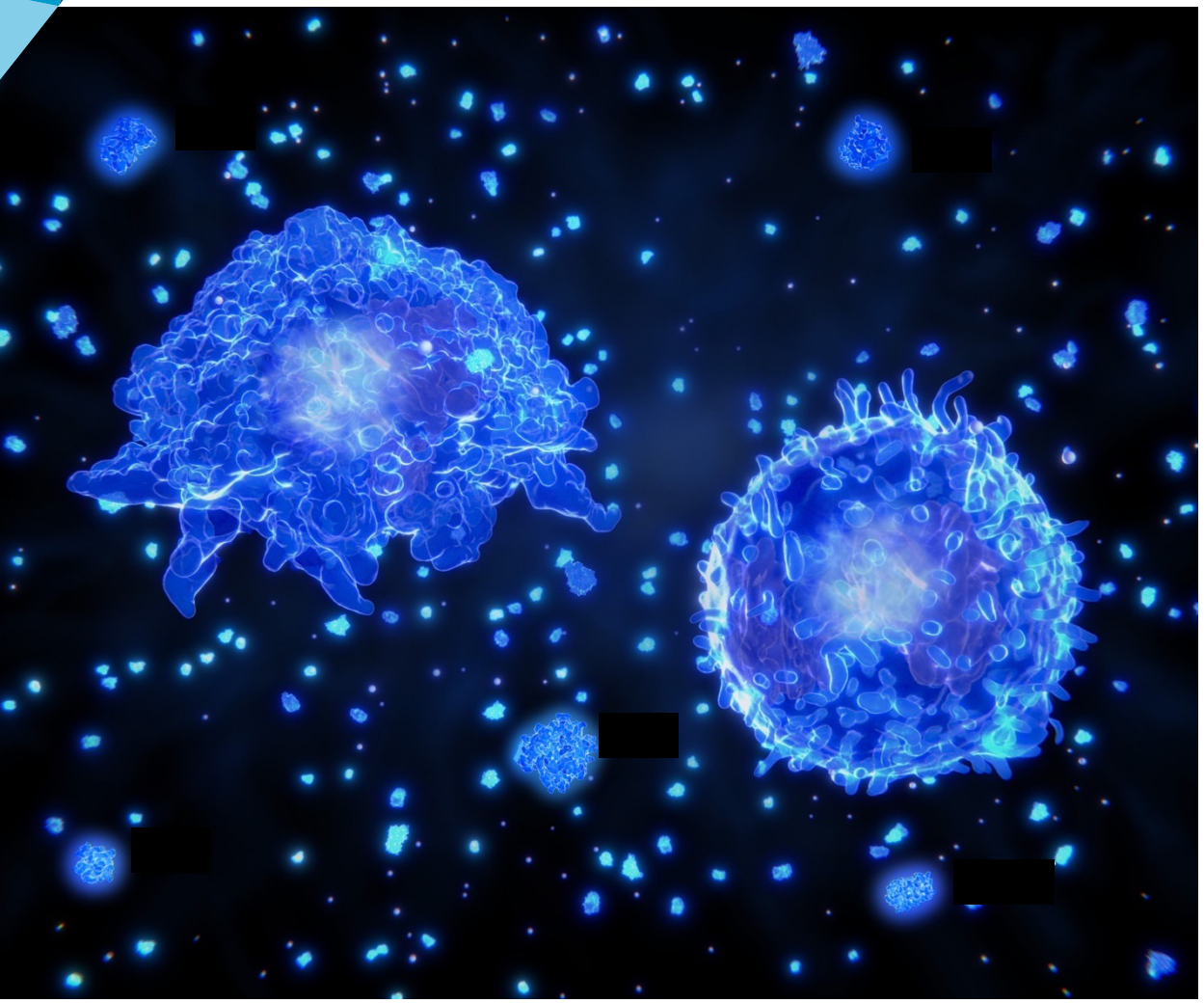
Anticipated Clinical Milestones

Vidofludimus Calcium in Ulcerative Colitis

Top-line data of the induction phase of the phase 2 CALDOSE-1 trial of vidofludimus calcium in moderate-to-severe UC are expected to be available in June of 2022.

IMU-935 Phase 1 Program: Part C in Psoriasis



Initial results from the third portion of the phase 1 clinical trial of IMU-935 in patients with moderate-to-severe psoriasis are expected to be available in H2/2022.

IMU-935 Phase 1 Trial in CRPC

Principal Investigator

Johann Sebastian de Bono, M.D., Ph.D.

Regius Professor of Cancer Research and Professor in Experimental Cancer Medicine

The Institute of Cancer Research and The Royal Marsden NHS Foundation Trust

London, United Kingdom

Initial clinical safety data from the open-label phase 1 dose escalation trial of IMU-935 in patients with progressive metastatic CRPC are expected to be available in Q3/2022.

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IMU-856 Phase 1 Program

The SAD part of the ongoing phase 1 clinical trial of IMU-856 has been completed. Based on the favorable data available so far, the Ethics Committee in Australia has agreed to proceed to the MAD part which is currently being dosed.

Unblinded safety data from the SAD and MAD parts of IMU-856 in healthy human subjects are expected to be available in Q3/2022.

Initiation of the third portion of the phase 1 clinical trial of IMU-856 in patients is expected in H1/2022.

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Q&A Session

Summary and Highlights

Multiple Clinical Data Readouts for All Three Development Programs Expected Throughout 2022

Advanced clinical pipeline:
three differentiated products 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, to be supported by neuroprotective data from PMS phase 2 trial

IMU-856 for intestinal barrier function:
unblinded phase 1 safety data expected in Q3/2022

UC phase 2 data of vidofludimus calcium expected in June of 2022

Cash runway through Q1/2023

Shares outstanding: 27,906,942 (as of February 18, 2022)

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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
Gräfelfing (Munich)
Germany

Immunic Research GmbH
Weinberg Campus
Halle (Saale)
Germany

Immunic Australia Pty. Ltd.
Melbourne
Australia