



**Immunic**  
THERAPEUTICS

# Immunic Therapeutics

Second Quarter 2022 Financial Results and Corporate Update

NASDAQ: IMUX | August 4, 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

## Second Quarter 2022 Financial Results and Corporate Update

01 Second Quarter 2022 and Subsequent Highlights

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02 Clinical Updates

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03 Financial and Operating Results

04 Anticipated Clinical Milestones

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05 Q&A Session

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06 Summary and Highlights



01

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## Second Quarter 2022 and Subsequent Highlights

# May: Announced Start of Celiac Disease Cohorts in Ongoing Phase 1 Clinical Trial of IMU-856



- Double-blind, randomized, placebo-controlled phase 1 study performed in three parts:
  - Safety and pharmacokinetics in healthy human subjects (Part A: single ascending dose, Part B: multiple ascending dose)
  - Part C includes a celiac disease patient population, designed to assess safety and tolerability of IMU-856 as well as pharmacokinetics and disease markers
- On May 5, 2022, Immunic announced the start of the celiac disease patient cohorts, representing the first time patients will be treated with the orally available small molecule modulator targeting restoration of intestinal barrier function and regeneration of bowel epithelium
- Exclusive global rights to commercialization of IMU-856 in all countries obtained through option and licensing agreement with Daiichi Sankyo



## June: Reported Top-Line Data from Phase 2 CALDOSE-1 Trial of Vidofludimus Calcium in Patients with Moderate-to-Severe UC

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- Revealed a previously unknown interaction with chronic concurrent steroid use, resulting in missing the trial's primary endpoint
- Announced that the company's development programs in the inflammatory bowel disease indications will not be continued without a partner

# June: Announced Publication of Data from Phase 2 EMPHASIS Trial of Vidofludimus Calcium in RRMS in Peer Reviewed Journal



RESEARCH ARTICLE

## **A double-blind, randomized, placebo-controlled phase 2 trial evaluating the selective dihydroorotate dehydrogenase inhibitor vidofludimus calcium in relapsing-remitting multiple sclerosis**

Robert J. Fox<sup>1</sup>, Heinz Wiendl<sup>2</sup>, Christian Wolf<sup>3</sup>, Nicola De Stefano<sup>4</sup>, Johann Sellner<sup>5</sup>, Viktoriia Gryb<sup>6</sup>, Konrad Rejdak<sup>7</sup>, Plamen Stoyanov Bozhinov<sup>8</sup>, Nataliya Tomakh<sup>9</sup>, Iryna Skrypchenko<sup>10</sup> & Andreas R. Muehler<sup>11</sup>

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<sup>10</sup>Kharkiv Regional Clinical Hospital Department of Neurology, Kharkiv, Ukraine

<sup>11</sup>Immunic AG, Lochhamer Schlage 21, 82166, Gräfelfing, Germany

- Published in the peer reviewed journal, *Annals of Clinical and Translational Neurology*
- Authored by coordinating investigator Robert J. Fox, M.D., Staff Neurologist, Mellen Center for Multiple Sclerosis, Vice-Chair for Research, Neurologic Institute, Cleveland Clinic, Cleveland, Ohio

# July: Announced Appointment of Maria Törnsén to Board of Directors



- Industry executive with 20 years of global commercial experience in U.S. and ex-U.S. markets
- Jan Van den Bossche resigned from the Board
- Both effective July 5, 2022



02

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## Clinical Updates

# EMPhASIS Trial: Post-Hoc Analysis Shows That Concomitant Corticosteroids Treatment in RRMS Patients is Rare and Short



## Concomitant Corticosteroids Treatment Was Rare

- Overall, few patients required concurrent corticosteroid treatment and, when needed, only one or very few courses were required
- A total of only N= 52/268 (19 %) patients had any use of corticosteroid during the main treatment period with an average duration of only 4.4 days

N of Corticosteroid Courses Given	0	1	2	>2
N of Patients	216 (80 %)	43 (16 %)	6 (2 %)	3 (0.7 %)



## Concomitant Corticosteroids Treatment Was Short

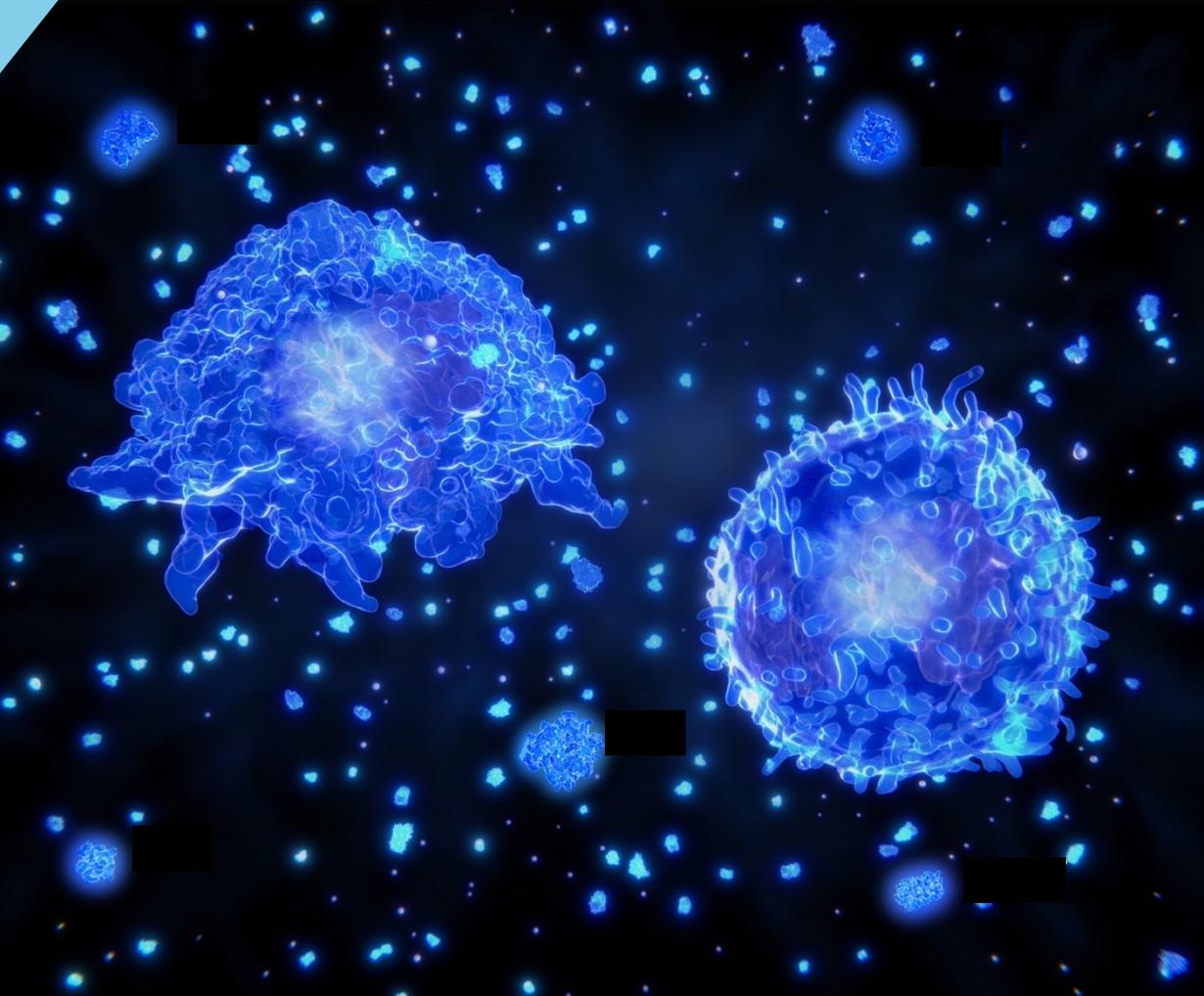
Corticosteroids were used only as short-term concomitant medication for:

- MS relapse (N=48)
- COVID-19 infection (N=1)
- Eczema (N=1)
- Acute bronchitis (N=1)
- Contact urticaria (N=1)

Average Duration of Each Corticosteroid Treatment Course (Pooled Cohorts 1+2)	4.4 days
Minimum	1 day
Maximum	10 days

Total number of patients Cohort 1 + Cohort 2 EMPhASIS: 268. 10 mg N=47, 30 mg N=71, 45 mg N= 69, Placebo N=81

# Exploratory Phase 1 Drug-Drug Interaction (DDI) Study of IMU-935 Raised No Concerns



- Exploratory phase 1 study completed in 15 evaluable healthy human subjects to assess the DDI potential of IMU-935
- No relevant signals for DDI potential observed
- Treatment was safe and well-tolerated

# Update on Phase 1 Clinical Trial of IMU-935 in mCRPC

## Initial Safety Data Available



Initial safety data available so far show a promising safety profile of IMU-935 in metastatic castration-resistant prostate cancer (mCRPC).

- 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
  - First two dose cohorts fully recruited, 6 patients enrolled in the 300 mg cohort and 6 patients in the 600 mg cohort
  - Of these patients, all have completed initial 28-day safety study part without reaching dose limiting toxicity (DLT)
  - Third, 900 mg cohort expected to start dosing soon
- Initial safety data available so far show a promising safety profile of IMU-935 in mCRPC, with only benign adverse events and no dose limiting toxicities.
- Immunic plans to provide a more comprehensive update on safety and also on potential signs of anti-tumor activity of IMU-935 in this trial as soon as data from the planned dose expansion part are available.



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



03

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## Financial and Operating Results

# Consolidated Statements of Operations

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	\$ 16,538	\$ 15,738	\$ 33,983	\$ 27,257
General and administrative	4,072	3,432	8,062	7,050
4SC royalty settlement	—	—	—	17,250
Total operating expenses	20,610	19,170	42,045	51,557
Loss from operations	(20,610)	(19,170)	(42,045)	(51,557)
Other income (expense):				
Interest income	106	13	113	41
Other income (expense), net	(1,397)	1,223	(777)	(952)
Total other income (expense)	(1,291)	1,236	(664)	(911)
Net loss	\$ (21,901)	\$ (17,934)	\$ (42,709)	\$ (52,468)
Net loss per share, basic and diluted	\$ (0.72)	\$ (0.82)	\$ (1.49)	\$ (2.44)
Weighted-average common shares outstanding, basic and diluted	30,248,767	21,749,439	28,686,910	21,463,656

\$88.1 million in cash and cash equivalents as of June 30, 2022 are expected to **fund operations into the fourth quarter of 2023**



04

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## Anticipated Clinical Milestones

# Vidofludimus Calcium in Multiple Sclerosis

## Executive Summary

**Phase 3 program** of vidofludimus calcium in RMS ongoing based on **excellent clinical data** package

New third-party data clearly highlights the unmet need of **preventing disability progression**, which is seen across the spectrum of patients with MS

Vidofludimus calcium selectively manages all three components needed to **quell smoldering MS**

**Large market opportunity** exists for a therapy that can holistically and sustainably address patients' needs

- Demonstrated effect on all relevant endpoints in 268 RRMS patients, including anti-inflammatory & neuroprotective effects
- Unrivaled safety to date, with over 1,100 individuals treated

- The understanding of MS has evolved, with evidence showing a smoldering disease that is connected to Epstein-Barr virus and subsequent inflammation & neurodegeneration

- Anti-viral effect
- Anti-inflammatory effect
- Neuroprotective impacts

- Even current market leaders only optimize for one feature
- Most treatment options have series of risks / downsides



# Vidofludimus Calcium in Multiple Sclerosis

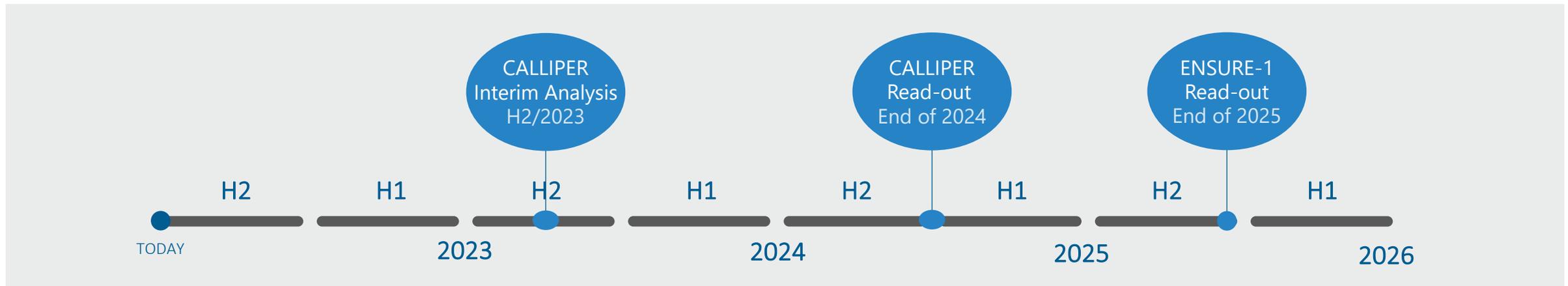
## Straightforward Approval Strategy

### Phase 3 ENSURE Program in RMS<sup>[1]</sup>

- Two identical pivotal trials in RMS patients
- Goal: Low risk clinical program for regulatory approval of vidofludimus calcium
- Dosage: 30 mg vidofludimus calcium QD

### Phase 2 CALLIPER Trial in PMS<sup>[2]</sup>

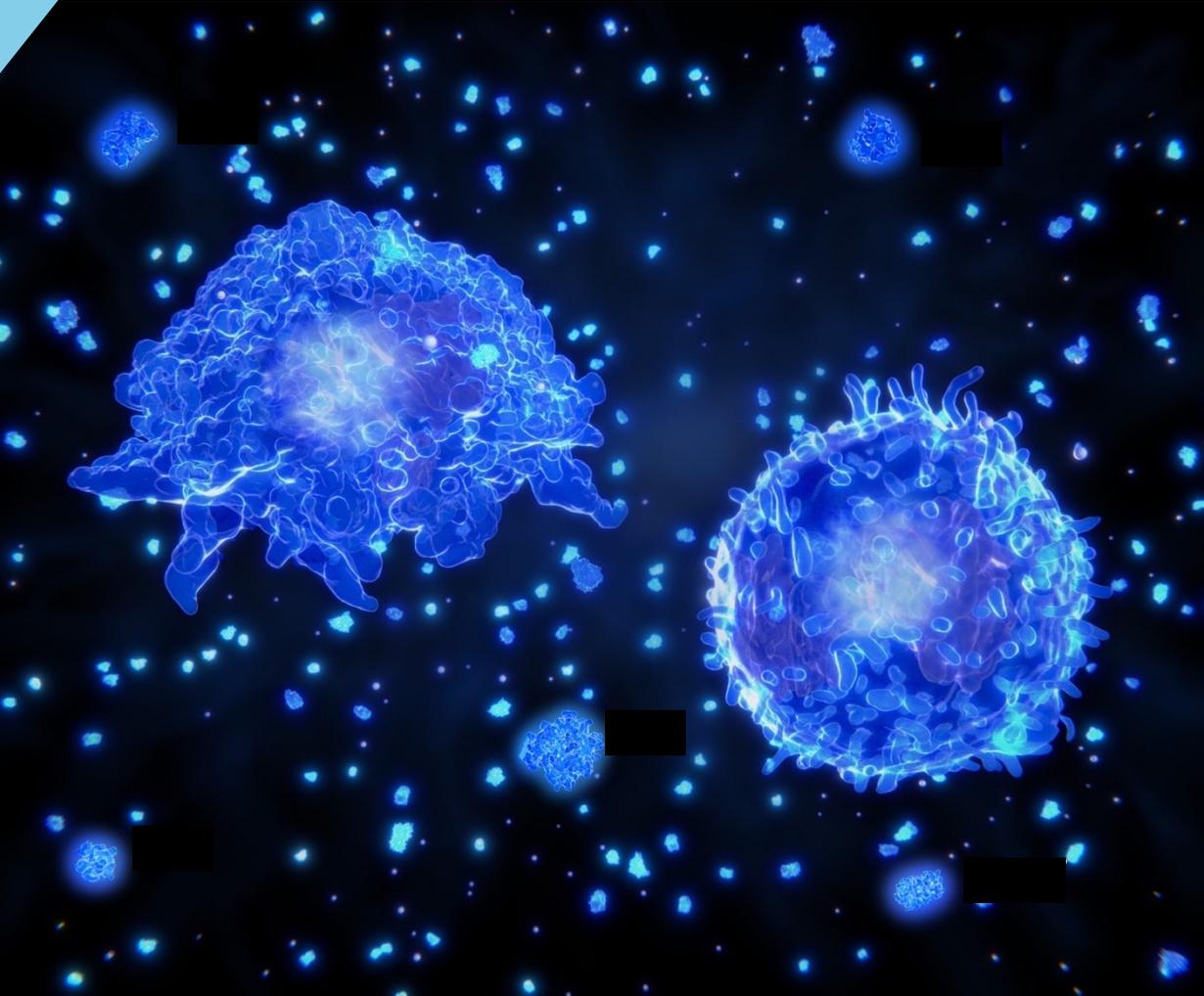
- Phase 2 trial in PMS patients
- Goal: Demonstrate vidofludimus calcium's potential for neuroprotective activity in a non-relapse setting
- Dosage: 45 mg vidofludimus calcium QD



[1] ClinicalTrials.gov: NCT05134441 & NCT05201638; [2] ClinicalTrials.gov: NCT05054140  
RMS: relapsing multiple sclerosis; PMS: progressive multiple sclerosis; QD: quaque die = once-daily

# IMU-935 Phase 1 Clinical Trial

## Part C in Moderate-to-Severe Psoriasis Patients



Recruitment is ongoing in Australia, New Zealand and Bulgaria.

Initial clinical activity results are expected to be available in Q4/2022.

# IMU-856 Phase 1 Clinical Trial



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



05

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Q&A Session



06

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## Summary and Highlights

# Advanced Clinical Pipeline

## Three Differentiated Programs in Various Phases of Clinical Development

Program	Target	Preclinical	Phase 1	Phase 2	Phase 3	Key Milestones
Vidofludimus Calcium (IMU-838)	DHODH	Relapsing Multiple Sclerosis (RMS) – ENSURE Trials				<ul style="list-style-type: none"> <li>RMS interim analysis planned after approx. half of the events occurred</li> <li>PMS interim analysis planned after half of the patients completed 24 weeks of treatment</li> </ul>
		Progressive Multiple Sclerosis (PMS) – CALLIPER Trial				
		Primary Sclerosing Cholangitis (PSC)				
IMU-935	IL-17 / RORγt	Psoriasis				<ul style="list-style-type: none"> <li>Q4/2022: initial psoriasis data expected</li> </ul>
		Castration-Resistant Prostate Cancer (CRPC)				
IMU-856	Intestinal Barrier Function	Celiac Disease				<ul style="list-style-type: none"> <li>Q3/2022: SAD/MAD safety data expected</li> </ul>

■ Completed or ongoing    ■ In preparation or planned

# Thank You!



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