Immunic THERAPEUTICS

Immunic Therapeutics

Developing Selective Oral Drugs in Immunology

NASDAQ: IMUX

Ladenburg Thalmann Healthcare Conference

September 24, 2019

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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 to reflect events or circumstances after the date of this presentation.

Our Vision

We are developing new therapies with best-in-class potential for the treatment of chronic inflammatory and autoimmune diseases.

Key Investment Highlights – 3 Oral Drugs in Development

- IMU-838 currently tested in **three phase 2 trials**
- RRMS **phase 2 data** of IMU-838 expected for Q3 2020
- Very promising **data from interim dosing analysis** in UC phase 2
- Three active oral programs in development – each with unique positioning
  - Phase 1 of **IMU-935** started in Sep 2019 – 1st data expected Q1 2020
  - **IMU-856** could be a **disruptive technology** for treating GI diseases like IBS-D and IBD – restoring intestinal barrier function

Immunic Leadership Team

Company is led by an experienced management team

Daniel Vitt, PhD
CEO & President

Andreas Muehler, MD, MBA
CMO

Hella Kohlhof, PhD
CSO

Manfred Groeppel, PhD
COO

Sanjay S. Patel, CFA
CFO

Renowned international board of directors

Duane Nash, MD, JD, MBA
Former Director of
Vital Therapies

Joerg Neermann, PhD
LSP

Vincent Ossipow, PhD, CFA
Omega Funds

Jan Van den Bossche
Fund+

Daniel Vitt, PhD
CEO & President of Immunic

Development Pipeline

			Preclinical	Phase 1	Phase 2	Phase 3
IMU-838	Multiple Sclerosis	DHODH				
	Ulcerative Colitis	DHODH				
	Crohn's Disease	DHODH				
	PSC	DHODH				
IMU-935	Psoriasis	RORγt				
	Orphan AI Diseases	RORγt				
IMU-856	GI	Intestinal Barrier Function				

Investigator-Sponsored Trial performed at Mayo Clinic / NIH

Completed or ongoing

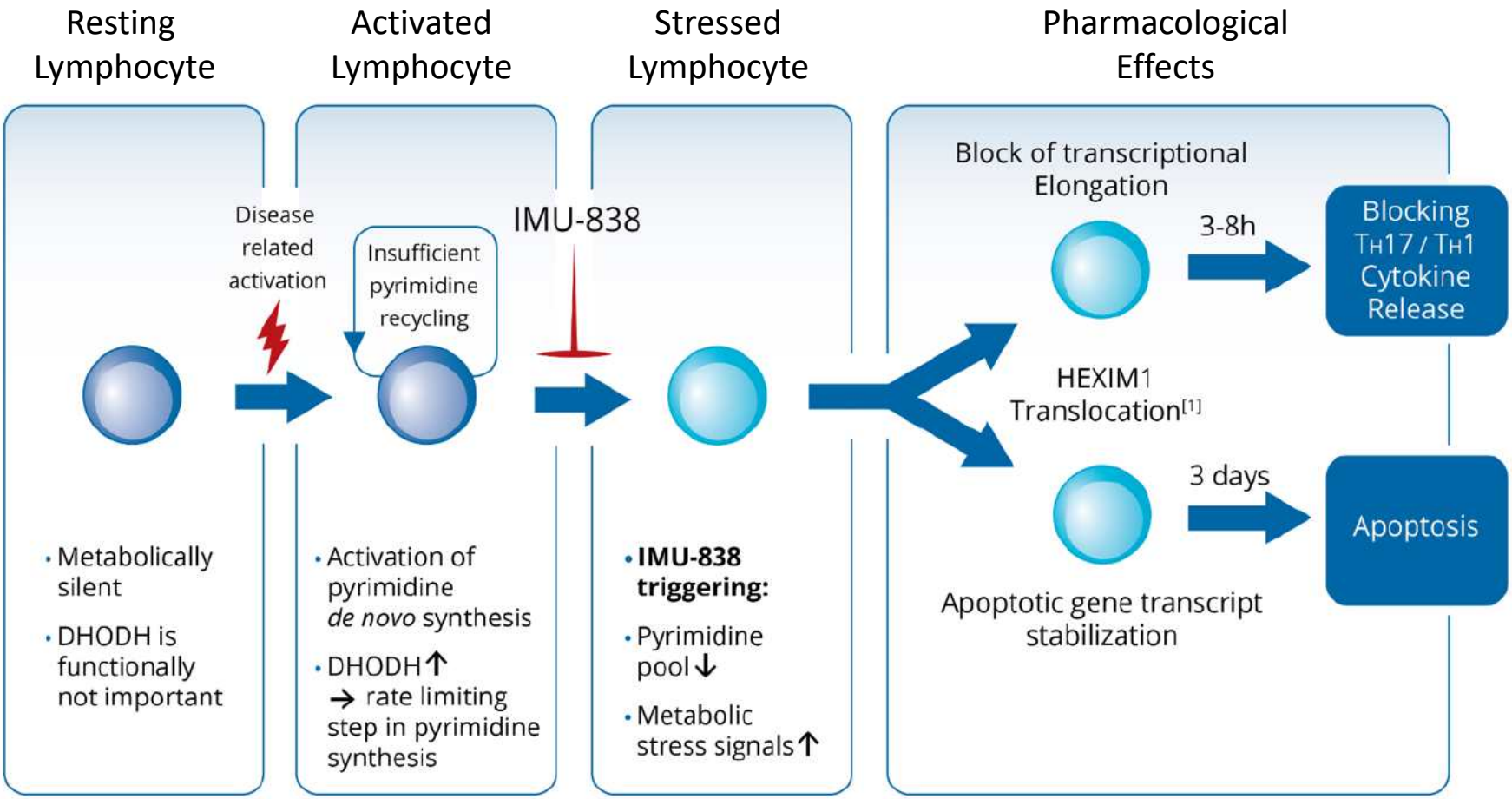
In preparation or planned

Immunic THERAPEUTICS

IMU-838 in Multiple Sclerosis

Mode of Action of IMU-838 Enables Broad Therapeutic Use

Mode of Action: DHODH Targeting Leads to Metabolic Stress in Metabolically Activated Cells



[1] Tan et al., 2016, Molecular Cell 62, 34-46

MS Opportunity

Aubagio® (teriflunomide) is currently the **only approved** DHODH inhibitor for MS

Despite its substantial side effects, Aubagio® **reached sales of around USD 1.8 billion in 2018**[1]

IMU-838 has the potential to be a **best-in-class DHODH inhibitor** and **MS drug** due to improved safety and pharmacokinetics profile

[1] http://hugin.info/152918/R/2233891/878937.PDF Accessed April 3, 2019

IMU-838: Potential Advantages in MS

- Potential advantages of IMU-838 therapy compared with Aubagio® (teriflunomide):
  - Selectivity and sensitivity[1] [2] [3] [4]
  - Pharmacokinetic parameters[5] [6]
  - Safety profile[7] [8] [9] [10]
  - Drug-drug interaction potential[6]

[1] FDA CDER Pharmacological Review Teriflunomide 2012
[2] Merrill JE, et al. J Neurol 256: 89-103, 2009
[3] Büttner R, et al. Blood 130 (suppl 1): 4426 abstract, 2017
[4] Cada DJ, et al. Hosp Pharm 48: 231-240, 2013)
[5] FDA CDER Clinical Pharmacology and Biopharmaceutics Review Teriflunomide 2012
[6] Summary of Product Characteristics Aubagio ®
[7] SmPC Aubagio®
[8] FDA CDER Medical Review Teriflunomide, 2012
[9] O'Connor et al, NEJM 365: 1293-1303, 2011
[10] O'Connor et al, NEJM 365: supplementary appendix, 2011

IMU-838: Phase 2 Clinical Trial in RRMS

- Phase 2 trial in patients with relapsing-remitting multiple sclerosis (RRMS)*
- Study Design
  - Planning to enroll 195 patients in four countries
  - Primary endpoint: cumulative number of combined unique active (CUA) MRI lesions, up to week 24
  - Central reading of MRI
- Timelines
  - Study started in February 2019
  - Currently estimated to deliver top-line data in Q3 2020

* clinicaltrials.gov: NCT03846219

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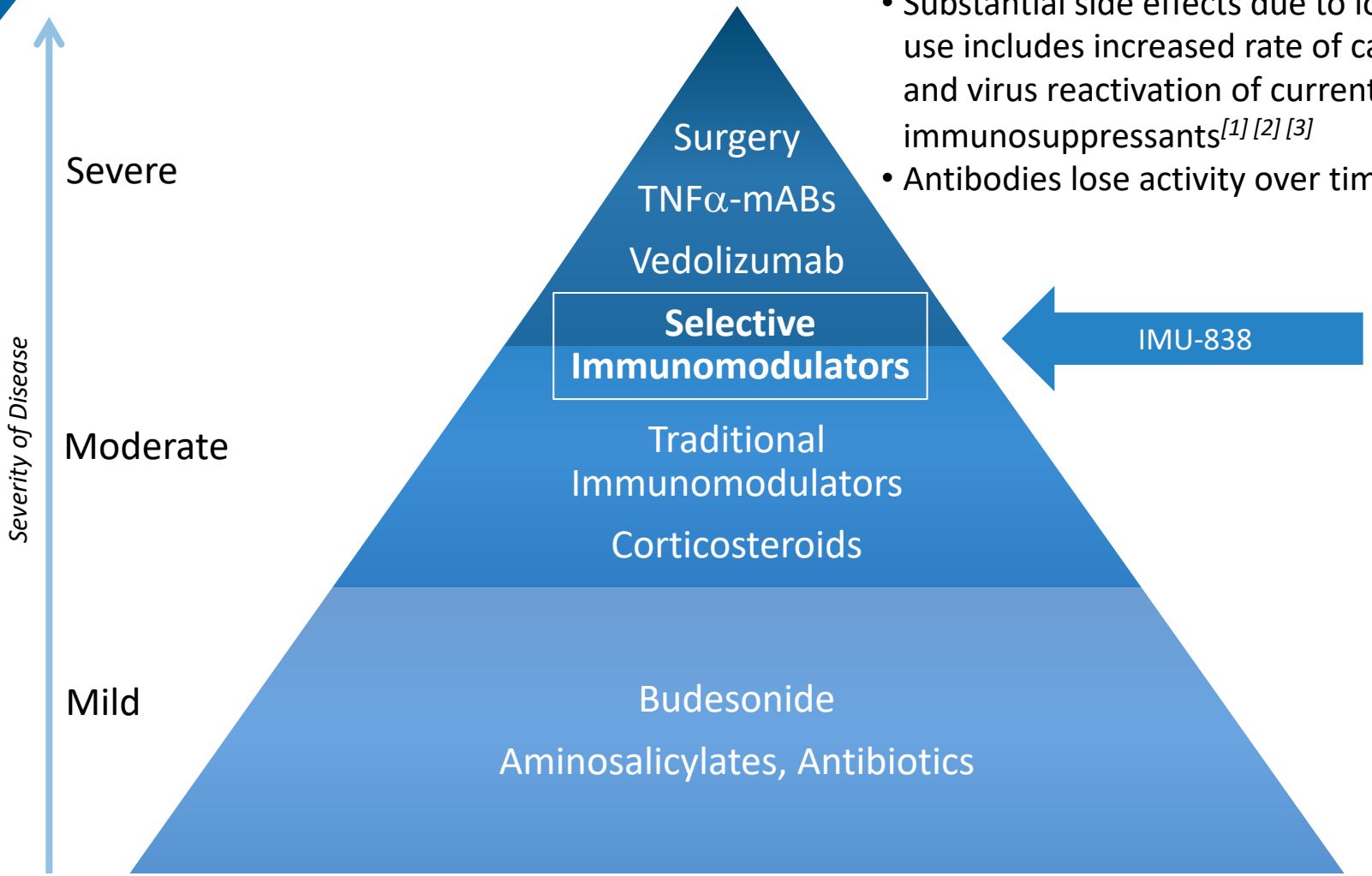
IMU-838 in Inflammatory Bowel Disease (IBD)

New Oral Treatment with Promising Safety Profile

IBD: Therapeutic Pyramid

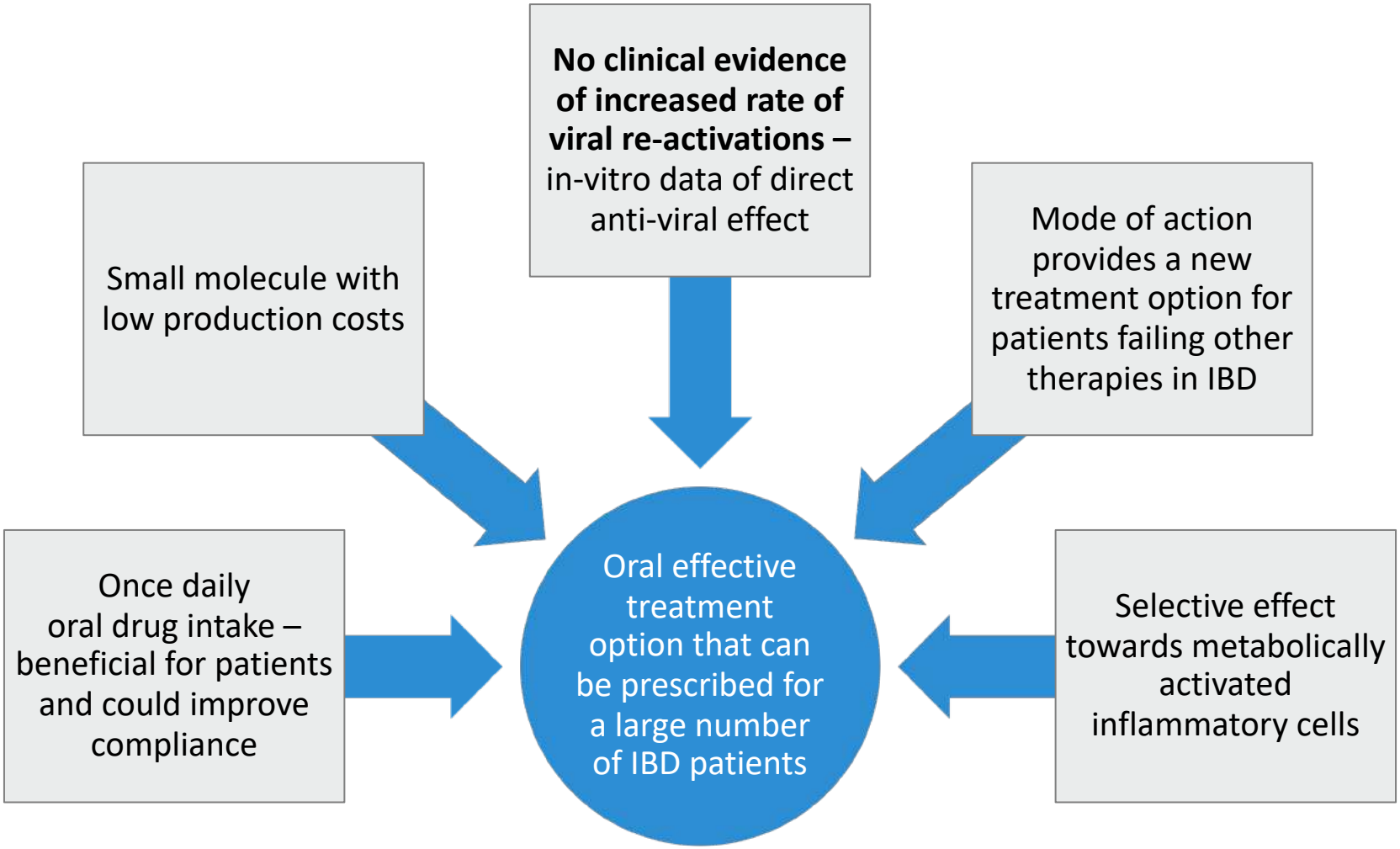


Current solutions have limitations

- Substantial side effects due to long-term use includes increased rate of cancer risk and virus reactivation of currently used immunosuppressants[1] [2] [3]
- Antibodies lose activity over time[4]

[1] Present, Daniel H., et al. *Annals of internal medicine* 1989; 111.8: 641-649.
[2] Dayharsh, Gerald A., et al. *Gastroenterology 2002;* 122.1: 72-77.
[3] Winthrop, Kevin L., et al. *Arthritis & rheumatology* 2014; 66.10: 2675-2684.
[4] Roda, Giulia, et al. *Clinical and translational gastroenterology 2017*; 7.1: e135.

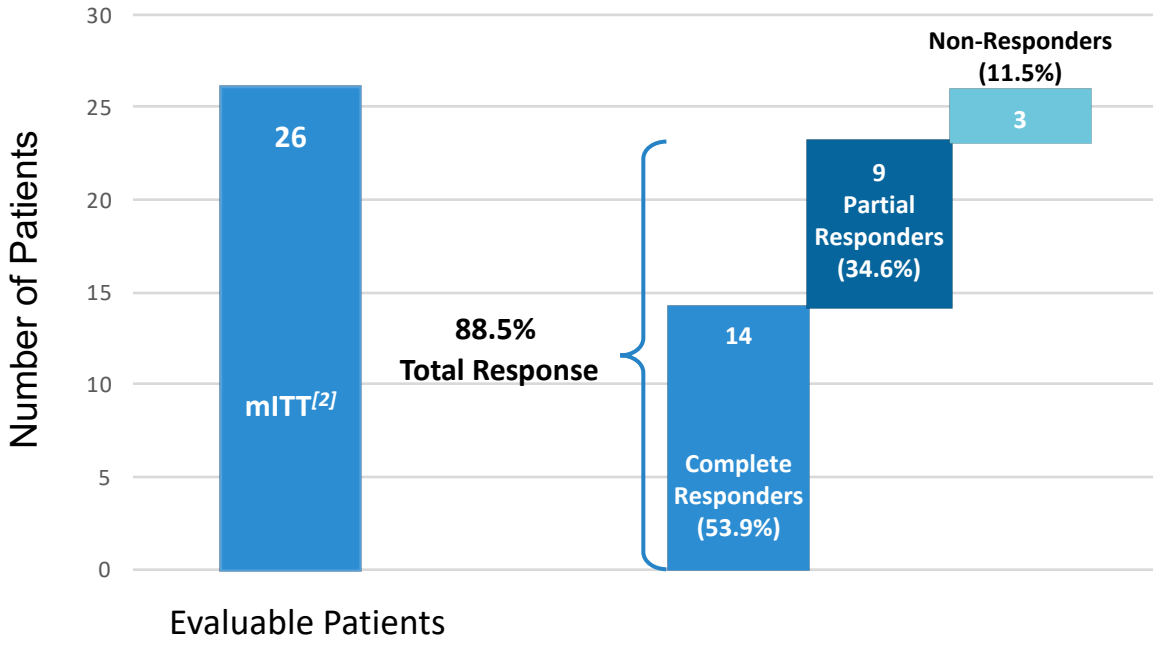
IMU-838: Key Strengths That Address Limitation of Existing Therapies in IBD



IBD Phase 2a ENTRANCE: Primary Efficacy Results

ENTRANCE study:[1]

- Study performed with active moiety vidofludimus
- All patients failed two attempts to taper down steroids
- Open-label
- Primary efficacy endpoint: steroid-free/steroid-reduced remission (week 12)



IMU-838 had response rates of:
85.7% in Crohn's disease
91.7% in ulcerative colitis

[1] Herrlinger et.al., 2011, Gastroenterology *140*:588.
[2] mITT: modified intent to treat

IMU-838: Clinical Phase 2 in UC Ongoing

- Active IND in the US; study started in April 2018
- Study design*
  - Central endoscopy assessment for active disease for study eligibility in order to reduce placebo rate
  - Endpoint measuring proportion of patients with symptomatic remission and endoscopic healing at week 10
- Currently more than 70 active sites in 10 countries
  - USA, Western, Central and Eastern Europe
- Interim dosing analysis performed end of August 2019
  - Performed by an unblinded, independent data review committee
  - Immunic hypothesized 30 mg to be the lowest effective dose and therefore anticipated that the 10 mg dose might be discontinued

    → 10 mg surprisingly also showed hints of activity

    → All three doses are being continued

* clinicaltrials.gov: NCT03341962

IMU-838: Clinical Phase 2 Trial in Crohn's Disease

- Study in preparation
- Considerable operational and financial synergies expected
  - Same systems and service providers used
  - Investigators already familiar with study set-up
  - High-enrolling sites of UC study expected to participate in CD trial
  - Supplemented by additional sites and additional countries
  - Primary endpoint: clinical remission, at week 14;
    Secondary endpoint: endoscopic response

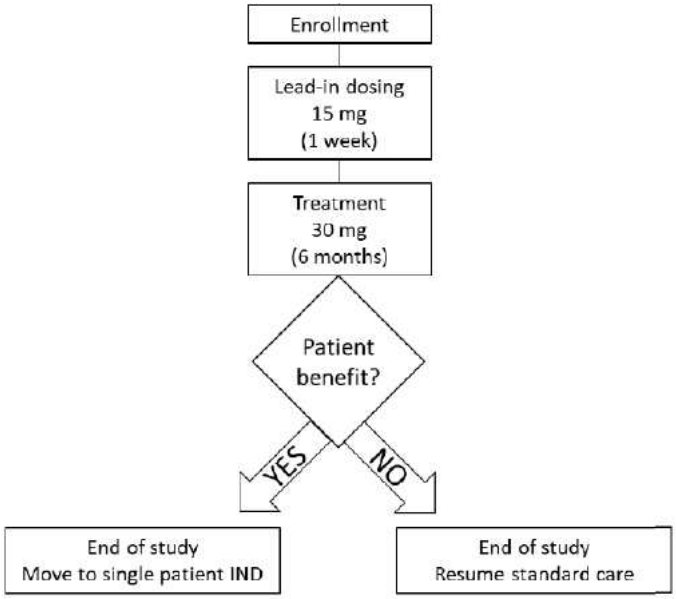
IMU-838: Phase 2 Proof-of-Concept Study in PSC

- Primary Sclerosing Cholangitis (PSC) is a very **rare liver disease** with a prevalence of about 4.15 per 100,000 in the US[1]; estimated time from diagnosis to death or liver transplant has been shown to be less than 15 years[2]
- Investigator-sponsored trial in patients with PSC conducted in collaboration with investigators at **Arizona State University and Mayo Clinic**
  - Prominent hepatologist Keith Lindor, MD, Arizona State University, is Principal Investigator of the study and was awarded a **grant from the National Institutes of Health (NIH)** for the performance of the study
  - Study is sponsored by Elizabeth Carey, MD, Mayo Clinic, who has received Investigator IND approval from the US FDA and IRB approval

[1] Toy et al., BMC Gastroenterology, 2011, 11:83.
[2] Sharma, Kanika/Bittner, Frank/Kamholz, John, Neurology Apr 2018, 90 (15 Supplement) P1.140

IMU-838: Phase 2 Proof-of-Concept Study in PSC

- Single-arm, open-label, exploratory study planning to enroll 30 patients, aged 18 to 75 years*
  - Conducted at two Mayo Clinic sites in Arizona and Minnesota
  - Dosing: 30 mg IMU-838 qd for six months; if benefit received from study, patients can continue in single-patient IND
  - Immunic provides the study medication to clinical sites
  - Primary endpoint: **change in serum alkaline phosphatase (ALP)** at six months compared to baseline
- Study started in August 2019
- Positive data should enable immediate start of a pivotal trial in this orphan indication by Immunic



Study Flow Chart

* clinicaltrials.gov: NCT03722576

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IMU-935

Unique RORγt-Inverse Agonist

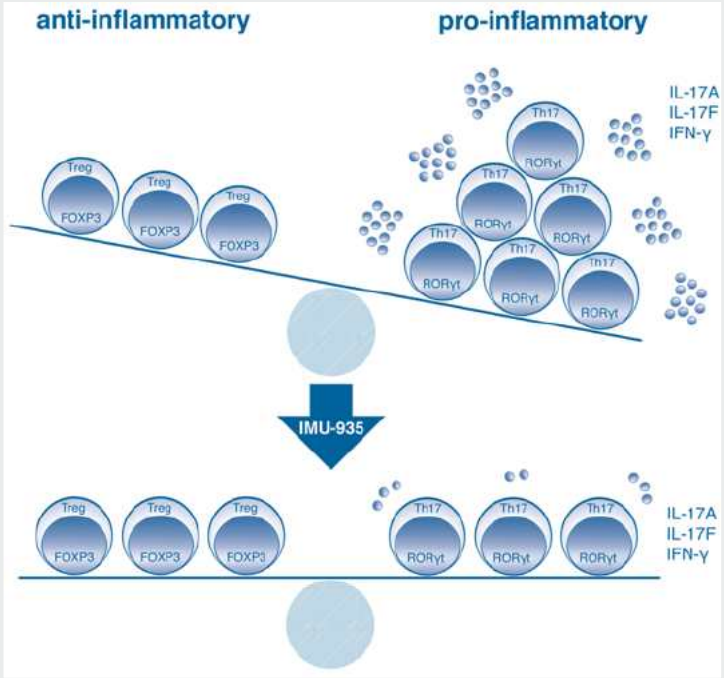
Autoimmune Diseases and IMU-935

Challenge:

- Autoimmune diseases are frequent diseases affecting millions of patients worldwide[1]
- Th17/IL-17/RORγt axis is important in auto immunity related diseases[2]
- Antibodies targeting this axis successfully demonstrated this concept but bear the disadvantage of being a non-oral drug[2]

Solution:

- IMU-935 is a potent small molecule targeting RORγt



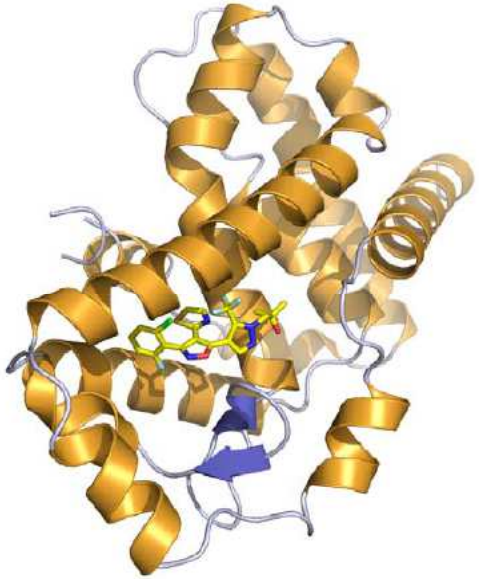
[1] Rose, Noel R. American journal of epidemiology 2016; 183.5: 403-406.
[2] Fasching, Patrizia, et al. *Molecules* 2017 22.1: 134.

IMU-935: Cytokine Inhibition in Low Nanomolar Range

- Effect of the development compound IM105935 (IMU-935) in stimulated human PBMCs
  - Inhibition of RORγ (20 nM) and DHODH (240 nM) leads to synergistical inhibition of cytokines with IC_{50} of 3-5 nM in stimulated human lymphocytes

	IC_{50} (µM)
IL-17A	0.005
IL-17F	0.004
IFNγ	0.003
IL-1a and b	no inhibition
IL-4,5,6,8	no inhibition
RORγ (MST)	0.024
RORγ (cellular, rep.)	0.020
DHODH	0.240
Th17 differentiation	0.150

Read-out: effect on cytokine production after 48 hours in PBMCs



Resolution 2.6 A of a closely related derivative compound binds to hydroxycholesterol binding site of RORγ

IMU-935: Project Status

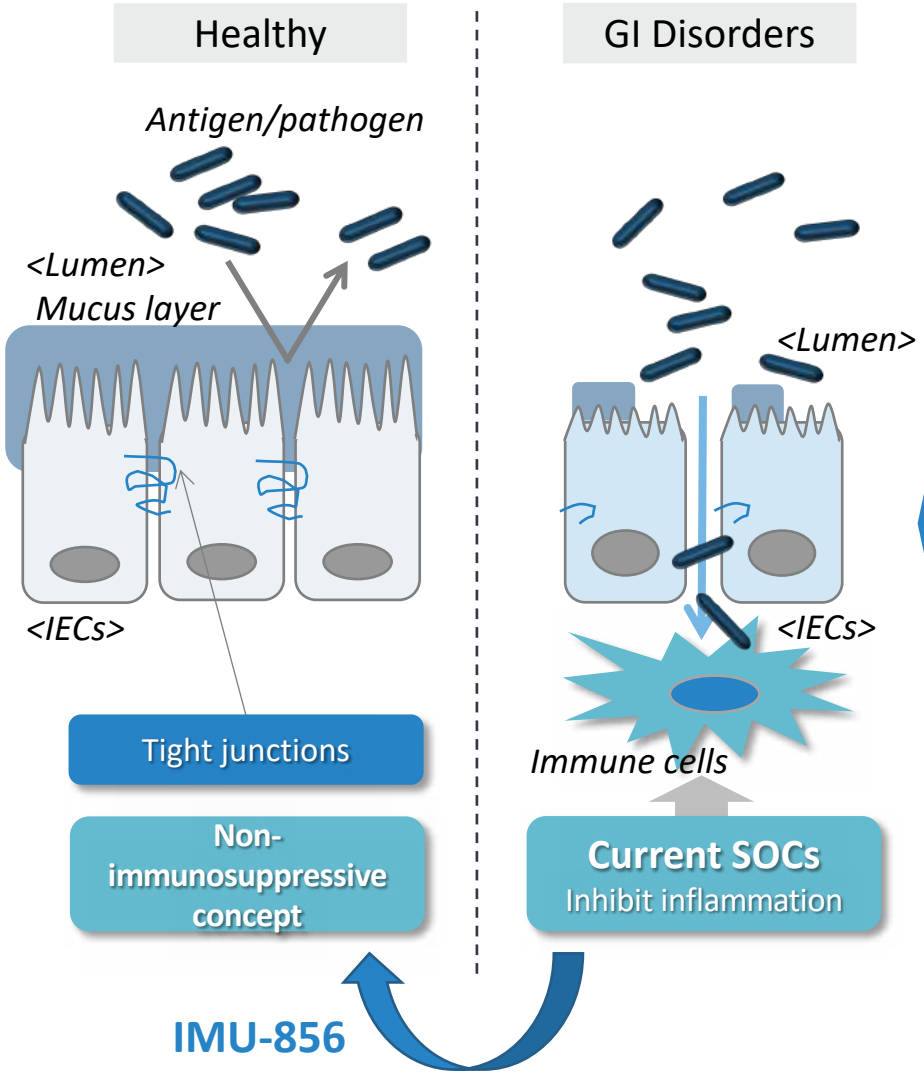
- Clinical phase 1 program, directed by Immunic's Australian subsidiary, started in September 2019
  - Double-blind, placebo-controlled, single and multiple ascending dose trials of IMU-935 in healthy volunteers
  - Extension of these studies to assess safety and mechanism-related biomarkers in patients with mild to moderate psoriasis is planned – would potentially offer early read-out of activity based on four-week treatment
- Identification of suitable orphan indications with high unmet medical need for accelerated development is ongoing

Immunic THERAPEUTICS

IMU-856

Restoring Intestinal Barrier Function

Hypothesis: Bacterial Penetration Through Weakened Cellular Adhesion Causes Immune Overstimulation



IMU-856 modulator concept:
Ameliorates barrier function

- ✓ Accelerates **mucosal healing** with standard of care due to its new mode of action
- ✓ Enhances **maintenance of remission**, that is the highest unmet medical need in GI disorders

Source: Adopted from Daiichi Sankyo Venture Science Labs, November 2018

IMU-856: Targeting Gut Barrier Function

- IMU-856 is a potent inhibitor of a **novel target** which was validated in a knock-out animal model
- Small **orally available** molecule suitable for once daily dosing
- Carefully performed lead compound selection based on exploratory **full safety panel**, including non-GLP 14-day tox studies in rats and monkeys
  - Large therapeutic window expected
  - No critical issues identified in genotoxicity and safety pharmacology studies
- Pharmacological effect is improving intestinal barrier function: shown in-vitro and in-vivo to reverse pathophysiology of IBD
- Optioned from **Daiichi Sankyo Venture Science Labs**
  - Execution of worldwide option after availability of GLP tox data

IMU-856: Development Plan

- Possible GI indications: IBD, IBS-D, ICI
- Clinical development plan:
  - Phase 1 single and multiple ascending dose studies are expected to start in H1 2020
- IMU-856 has substantial potential for the treatment of further diseases outside GI
- Product is covered by a global PCT patent application

Financial Summary

- Nasdaq: **IMUX**
- Headquarters in San Diego – plan to relocate to East Coast in 2019
- Shares outstanding: 10.0 million (as of August 8, 2019)
- Cash position of USD 36.1 million (as of August 8, 2019)
- Cash runway expected to be sufficient beyond important value inflection points into Q3 2020
- Immunic's reverse takeover with Vital Therapies was supported by a committed investor base investing approximately USD 30 million in April 2019

Key Investment Highlights

Three potential best-in-class oral therapies

- IMU-838: Potent DHODH inhibitor currently tested in three phase 2 studies
- IMU-935: High demand target with substantial potential
- IMU-856: Novel target – potentially disease modifying for GI disorders

High value markets

- Autoimmune & immunology with **high unmet medical needs**
- **Large markets** for IBD, MS and psoriasis with multibillion USD sales potential

Strong IP position

- IMU-838: Granted patents **until 2031**, patent application coverage **until 2038**
- IMU-935: **New compound IP** filed in 2017
- IMU-856: Compound patent filed in 2018

Experienced global management team

- Experienced management team with strong track record and over 90 years of leadership experience in the pharmaceutical industry
- Headquartered in the US with R&D operations in Munich, Germany

Strong balance sheet

- Well financed with cash runway to near-term value-driving events
- Cash position: USD 36.1 million (as of August 8, 2019)
- Cash expected to last into Q3 2020


Australia
Melbourne
small
IBD
best-in-class
drug
selective
inhibitors
preclinical
RORγt
NASDAQ
colitis
multiple
ulcerative
psoriasis
Crohn's
IMU-856
programs
chronic
Halle/Saale
MayoClinic
Germany
agonist
inflammatory
USA
development
diseases
IMUX
bowel
biotech
Immunic
Munich
novel
candidates
autoimmune
Martinsried
DaiichiSankyo
oral
healthcare
immunology
clinical
proof-of-concept
inverse
immune
molecule
sclerosis
DHODH
IMU-935
PSC
therapies
intestinal
IMU-838
barrier
functionspecialist

Immunic THERAPEUTICS

Thank You!

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