



# Immunic Therapeutics

## Developing Selective Oral Drugs in Immunology



Company Overview  
2019 BIO CEO & Investor Conference



# Cautionary Note Regarding Forward-Looking Statements

- Certain statements contained in this presentation regarding matters that are not historical facts, are forward-looking statements within the meaning of Section 21E of the Securities and Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, known as the PSLRA. 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. Vital Therapies and Immunic undertake 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 PSLRA.
- Such forward-looking statements are based on our expectations and involve risks and uncertainties; consequently, actual results may differ materially from those expressed or implied in the statements due to a number of factors, including, but not limited to, risks relating to the completion of the transaction, including the need for Vital Therapies stockholder approval and the satisfaction of closing conditions; the anticipated financing to be completed concurrently with the closing of the transaction; the cash balance of the company following the closing of the transaction and the financing, and the expectations with respect thereto; the business and prospects of the company following the transaction; and the ability of Vital Therapies to remain listed on the Nasdaq Capital Market. Risks and uncertainties related to Immunic that may cause actual results to differ materially from those expressed or implied in any forward-looking statement include, but are not limited to: Immunic's plans to develop and commercialize its product candidates, including IMU-838, IMU-935 and IMU-856; the timing of initiation of Immunic's planned clinical trials; expectations regarding potential market size; the timing of the availability of data from Immunic's clinical trials; the timing of any planned investigational new drug application or new drug application; Immunic's plans to research, develop and commercialize its current and future product candidates; Immunic's ability to successfully collaborate with existing collaborators or enter into new collaborations, and to fulfill its obligations under any such collaboration agreements; the clinical utility, potential benefits and market acceptance of Immunic's product candidates; Immunic's commercialization, marketing and manufacturing capabilities and strategy; Immunic's ability to identify additional products or product candidates with significant commercial potential; developments and projections relating to Immunic's competitors and industry; the impact of government laws and regulations; Immunic's ability to protect its intellectual property position; and Immunic's estimates regarding future revenue, expenses, capital requirements and need for additional financing following the proposed transaction.
- These risks, as well as other risks associated with the transaction, will be more fully discussed in the proxy statement/prospectus that will be included in the registration statement that will be filed by Vital Therapies with the SEC in connection with the proposed transaction. Additional risks and uncertainties are identified and discussed in the "Risk Factors" section of Vital Therapies' Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and other documents filed from time to time with the SEC. Forward-looking statements included in this presentation are based on information available to Vital Therapies and Immunic as of the date of this presentation. Neither Vital Therapies nor Immunic undertakes any obligation to update such forward-looking statements to reflect events or circumstances after the date of this presentation.



# Additional Information and Where You Can Find It

## Additional Information About the Proposed Transaction and Where to Find it

- This communication is being made in respect of a proposed transaction involving Immunic AG and Vital Therapies, Inc. Vital Therapies intends to file a registration statement on Form S-4 with the U.S. Securities and Exchange Commission (the “SEC”), which will contain a proxy statement/prospectus and other relevant materials, and Vital Therapies has filed with the SEC a registration statement on Form S-4 that contains a preliminary proxy statement/prospectus. The information in the preliminary proxy statement/prospectus is not complete and may be changed. The final proxy statement/prospectus will be sent to the stockholders of Vital Therapies in connection with the Vital Therapies special meeting of stockholders to be held to vote on matters relating to the proposed transaction. STOCKHOLDERS ARE URGED TO READ THE FINAL PROXY STATEMENT/PROSPECTUS (INCLUDING ANY AMENDMENTS OR SUPPLEMENTS THERETO) AND OTHER DOCUMENTS FILED WITH THE SEC CAREFULLY IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE, AS THEY WILL CONTAIN IMPORTANT INFORMATION THAT STOCKHOLDERS OF VITAL THERAPIES SHOULD CONSIDER BEFORE MAKING A DECISION ABOUT THE PROPOSED TRANSACTION AND RELATED MATTERS. In addition to receiving the proxy statement/prospectus and proxy card by mail, Vital Therapies stockholders will also be able to obtain the proxy statement/prospectus, as well as other filings containing information about Vital Therapies, without charge, from the SEC’s website (<http://www.sec.gov>) or, without charge, by directing a written request to: Vital Therapies, Inc., 15222-B Avenue of Science, San Diego, CA 92128, Attention: Investor Relations.

## No Offer or Solicitation

- This communication is not intended to and does not constitute an offer to sell or the solicitation of an offer to subscribe for or buy or an invitation to purchase or subscribe for any securities or the solicitation of any vote or approval in any jurisdiction in connection with the proposed transaction or otherwise, nor shall there be any sale, issuance or transfer of securities in any jurisdiction in contravention of applicable law. No offer of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

## Participants in Solicitation

- Vital Therapies and its executive officers and directors may be deemed to be participants in the solicitation of proxies from Vital Therapies’ stockholders with respect to the matters relating to the proposed transaction. Immunic may also be deemed a participant in such solicitation. Information regarding Vital Therapies’ executive officers and directors is available in Vital Therapies’ proxy statement on Schedule 14A for its 2018 Annual Meeting of stockholders, filed with the SEC on April 12, 2018. Information regarding any interest that Vital Therapies, Immunic or any of the executive officers or directors of Vital Therapies or Immunic may have in the transaction with Immunic is set forth in the preliminary proxy statement/prospectus that Vital Therapies has filed with the SEC in connection with its stockholder vote on matters relating to the proposed transaction.



# Vital Therapies – Immunic Combination

- Follows Vital Therapies' **extensive review of strategic alternatives**
- **All-stock transaction:** Vital Therapies to acquire all outstanding shares of Immunic in exchange for newly issued shares of Vital Therapies common stock; Immunic AG will become a wholly-owned subsidiary of Vital Therapies
- **Vital Therapies stockholders** are expected to own approximately **11%** and **Immunic stockholders** approximately **89%** of the company upon completion of the proposed transaction
- Current shareholders of Immunic committed to **invest 26 million EUR** at closing of the transaction
- Transaction has been **approved by the boards of directors** of both companies and by Immunic stockholders
- Expected **to close in Q2 2019**, subject to the approval of the stockholders of Vital Therapies and other closing conditions



## Our Vision

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

# Key Investment Highlights

## Three potential best-in-class therapies

- Deep and diversified product pipeline, orally available and potent drugs
- IMU-838: Potent DHODH inhibitor well-tolerated in prior clinical studies
- IMU-935: High demand target with substantial deal potential
- IMU-856: Novel target – potentially disease modifying for IBD

## Strong IP position

- IMU-838: Patent application coverage until 2038
- IMU-935: New compound IP filed in 2017
- IMU-856: Compound patent filed in 2018

## High value markets

- Autoimmune & immunology with high unmet medical needs
- Large markets for IBD, MS and psoriasis with multibillion USD sales potential
- Well financed with cash runway to near-term value-driving events

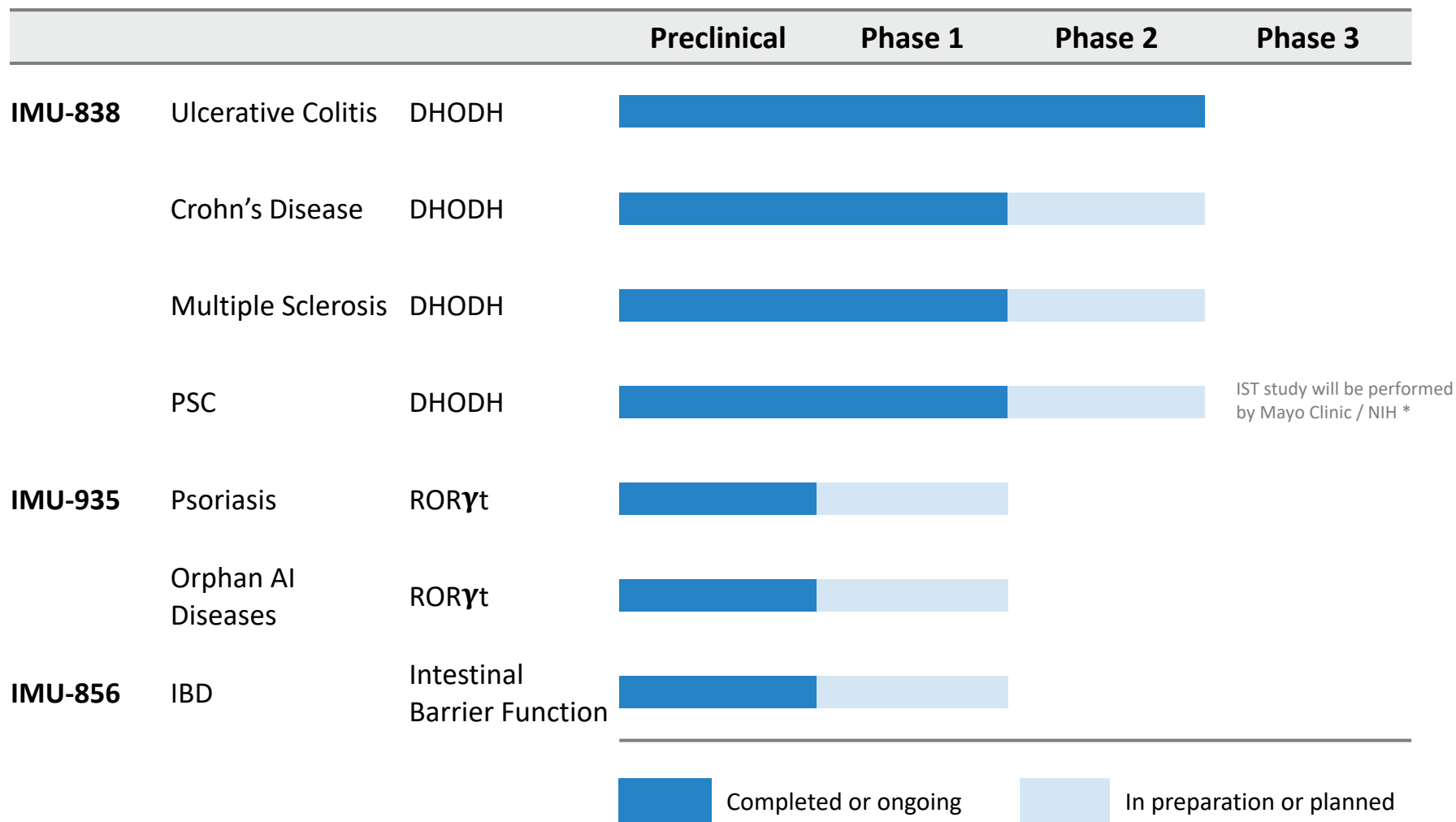
## Experienced management team

- Experienced management team with strong track record and over 70 years of leadership experience in the pharmaceutical industry
- Focused on efficient use of capital to maximize investor return

## Supported by experienced life science investors

- Strong support of sophisticated board members and life science investors
- Life Sciences Partners as lead investor
- Additional investors include: Omega Funds, Fund+, LifeCare Partners, High-Tech Gründerfonds, Bayern Kapital and IBG

# Development Pipeline



# Proven Leadership in Drug Development & Licensing

## Dr. Daniel Vitt, CEO

- PhD in Chemistry from University of Würzburg
- 19 years track record as biotech entrepreneur
- Developed start-up into successful IPO

## Dr. Andreas Muehler, CMO

- MD degree (Charité Berlin) + MBA Duke University
- 25+ years experience in the life science industry
- Medical expertise in the field of IBD with experience in several IBD product launches



## Dr. Hella Kohlhof, CSO

- PhD in Biology from LMU Munich
- More than 10 years experience in Biotech R&D and Immunology
- Track-record in clinical project management

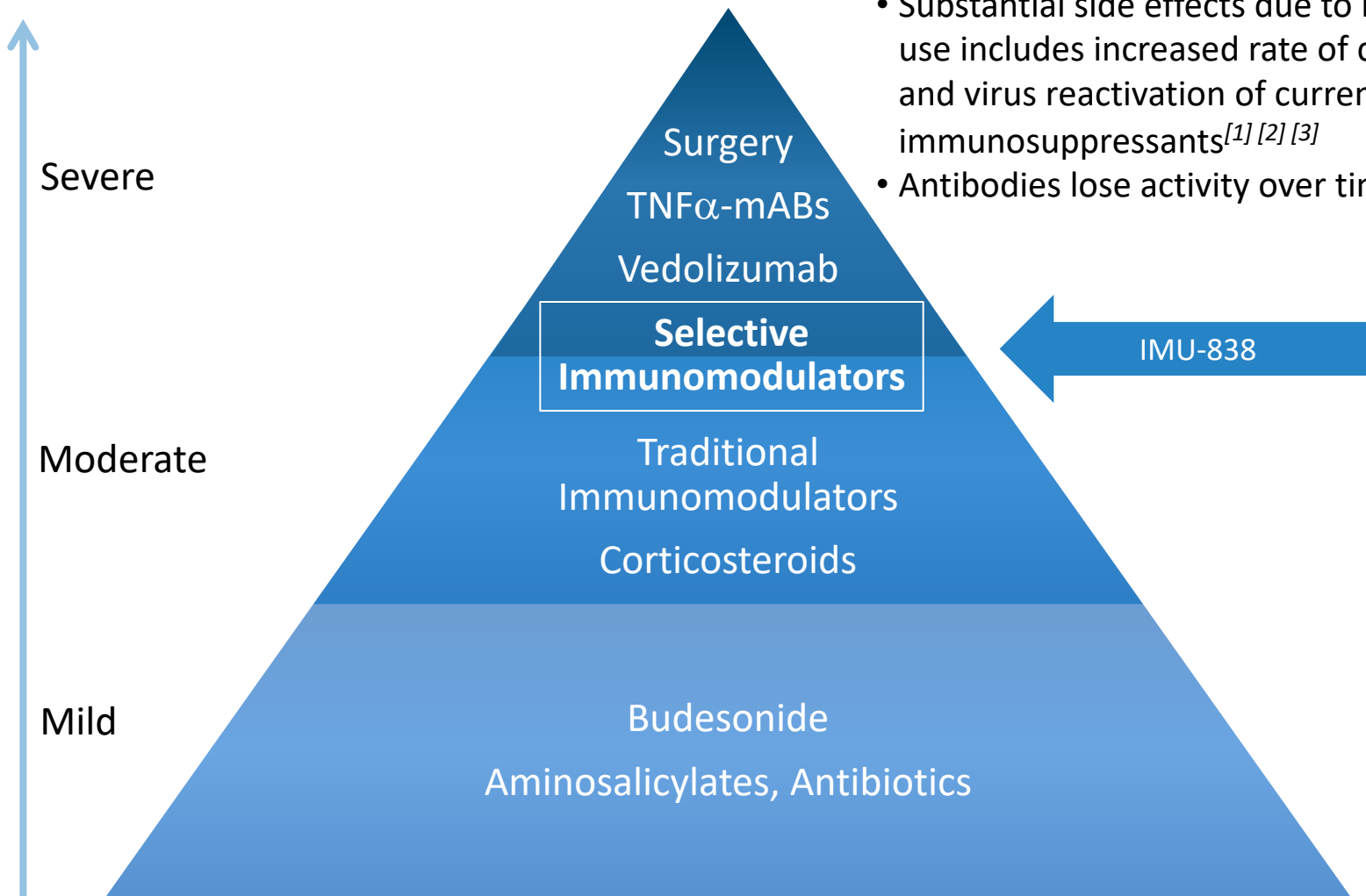
## Dr. Manfred Groeppel, COO

- PhD in Chemistry from University of Erlangen
- 18 years industry experience with US and German biotech companies
- Project leader and member of the vidofludimus development at 4SC

# 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<sup>[1] [2] [3]</sup>
- Antibodies lose activity over time<sup>[4]</sup>

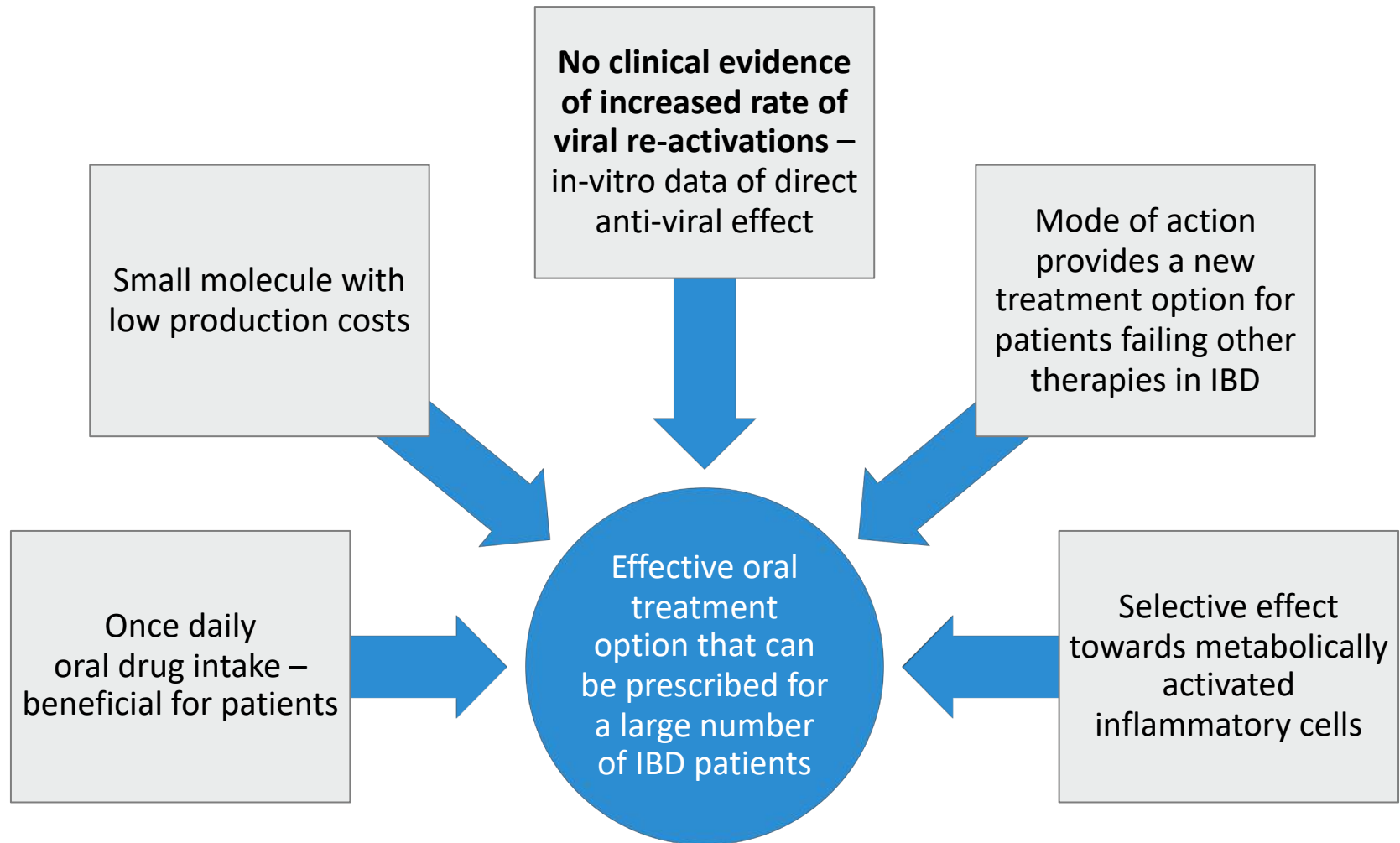
[1] Present, Daniel H., et al. *Annals of internal medicine* 1989; 111.8: 641-649.

[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.

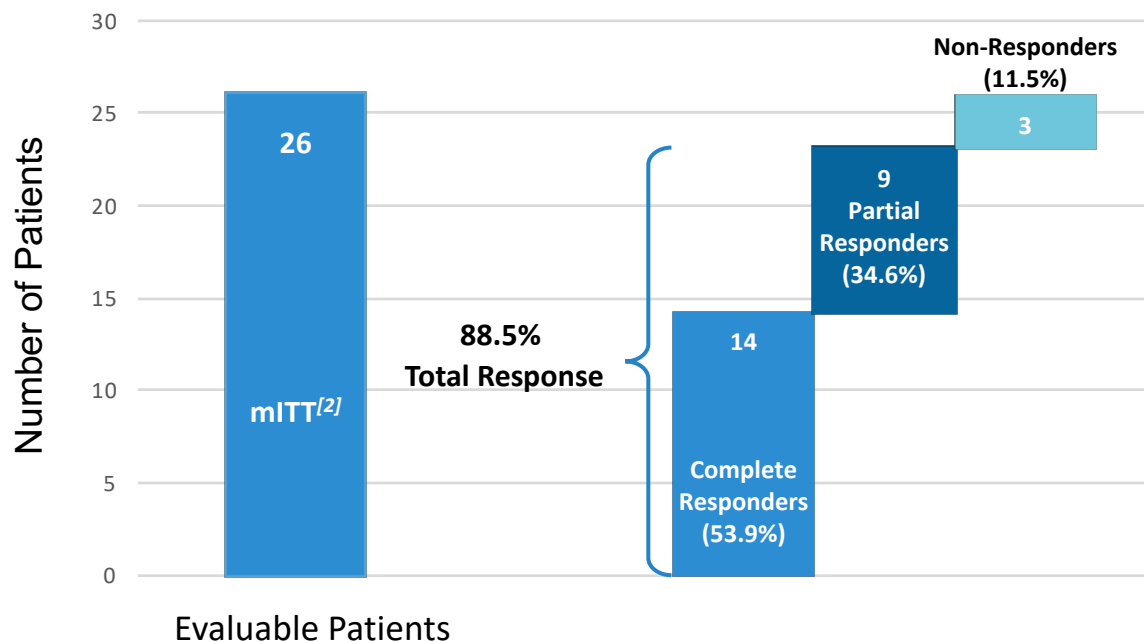
# IMU-838: Key Strengths That Address Limitation of Existing Therapies



# IBD Phase 2a ENTRANCE: Primary Efficacy Results

## ENTRANCE study:<sup>[1]</sup>

- Study performed with vidofludimus, the active moiety of IMU-838
- Patients with steroid-dependent IBD disease
- Open-label
- Primary efficacy endpoint: steroid-free/steroid-reduced remission (Week 12)



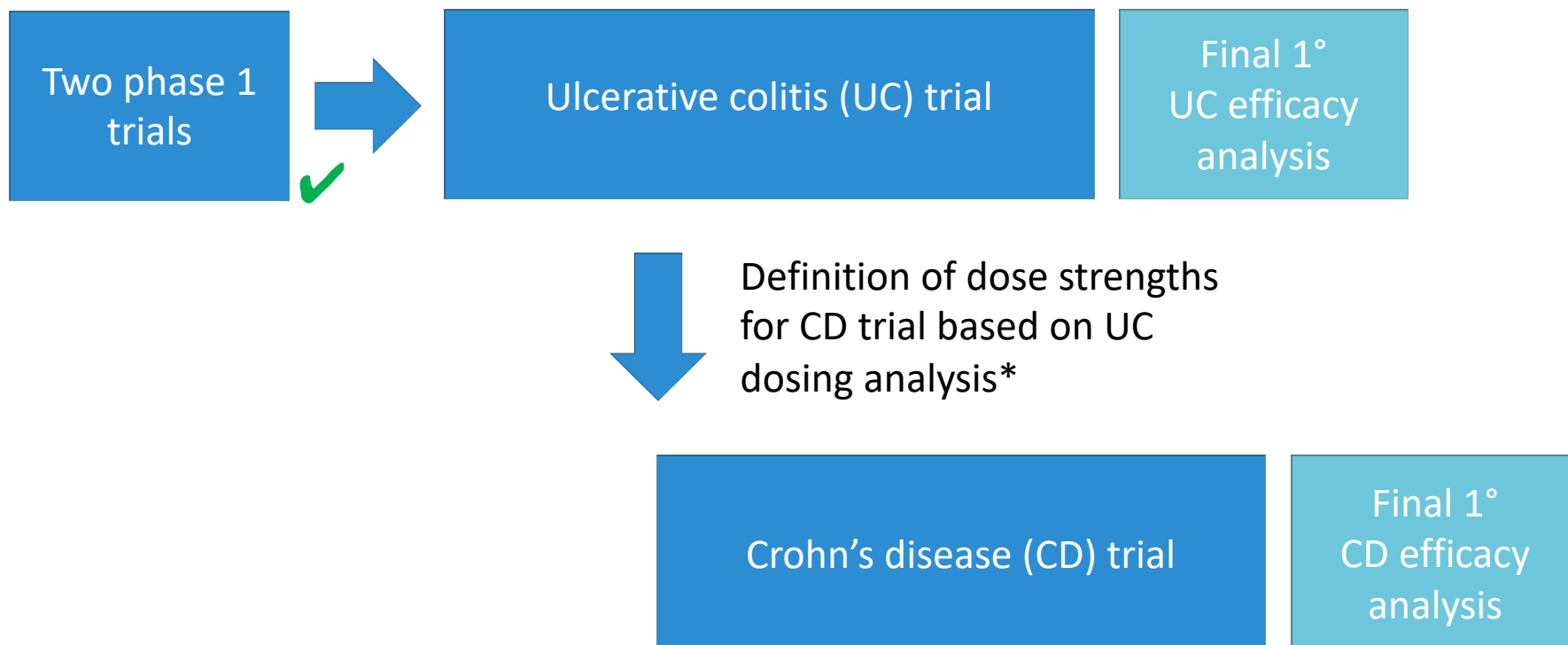
IMU-838 had response rates of:  
85.7% in Crohn's disease  
91.7% in ulcerative colitis



## IMU-838: Clinical Phase 2 in UC Ongoing

- Active IND in the US
- Currently more than 60 active sites in 8 countries
  - USA, Western, Central and Eastern Europe
- Study design
  - Central endoscopy assessment for active disease for study eligibility in order to reduce placebo rate
- Despite competitive study landscape in IBD
  - Study is approximately 33% enrolled and on track
  - Targeted to end enrollment in early 2020

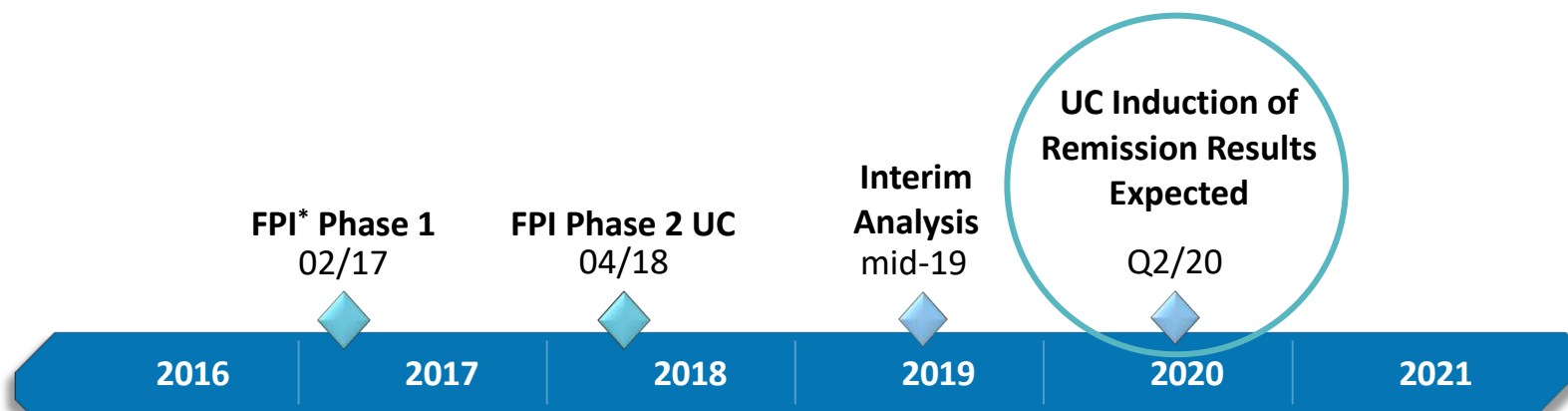
# IBD: Overall Study Program



# IMU-838: Clinical Development Plan

Phase 1 (SAD\* and MAD\*) 02/17 - 11/17

Phase 2 Ulcerative Colitis Q1/18 - Q2/20



Phase 2 Multiple Sclerosis Start of phase 2 study in MS expected

Phase 2 Primary Sclerosing Cholangitis Start of phase 2 study in PSC anticipated

Phase 2 Crohn's Disease Start of phase 2 study in CD expected

# IMU-935: Unique ROR $\gamma$ t Inverse Agonist

- ROR $\gamma$ t is an important regulator of auto immunity related diseases<sup>[1]</sup>

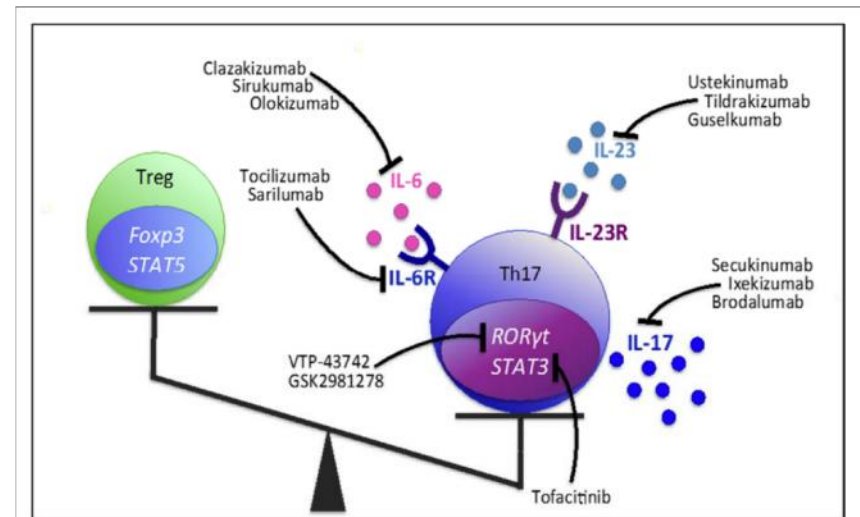
- IMU-935 (IM105935) is a small molecule immune modulator

- Inverse agonist of ROR $\gamma$ t
- Inhibitor of DHODH
- Potent inhibitor of
  - IL17A, IL17F and IFN $\gamma$  production
  - Th17 differentiation

- Target indications

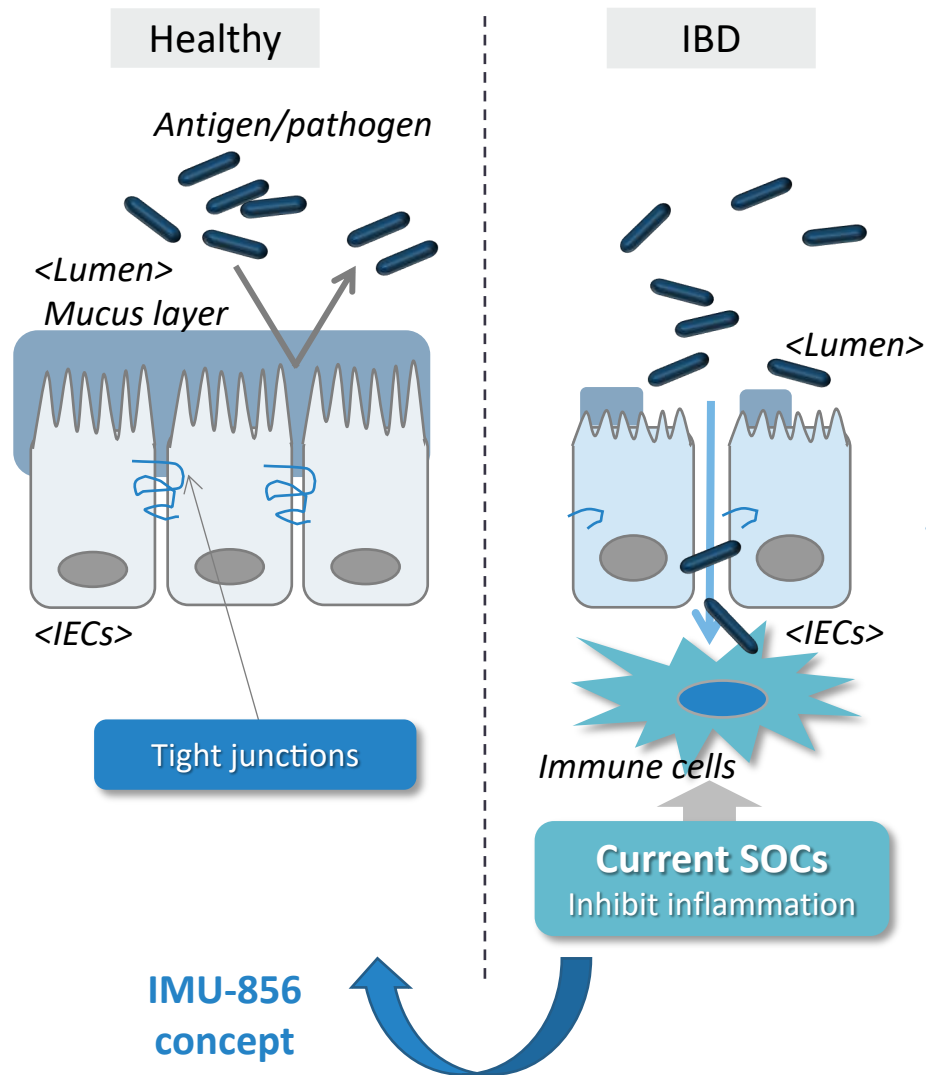
- Psoriasis
- Autoimmune and chronic inflammatory diseases with dysregulated Th17 and Th1 response

- Phase 1 clinical development expected to start mid-2019



Source: Fasching, Patrizia, et al. *Molecules* 2017; 22.1: 134.

# Hypothesis: Bacterial Penetration Through Weakened Cellular Adhesion Causes Immune Overstimulation



**IMU-856 inhibitor 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 IBD

# Summary



# Key Investment Highlights

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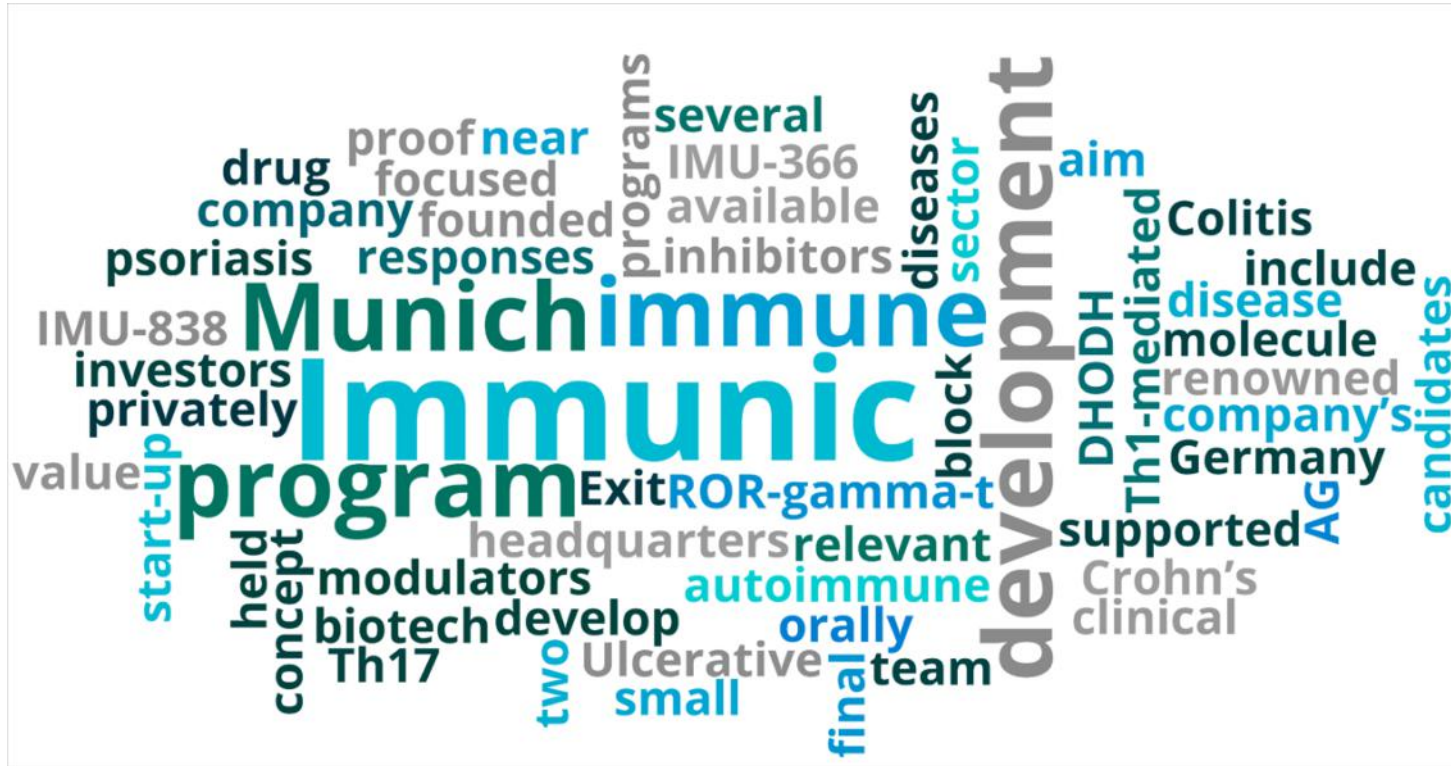
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- Life Sciences Partners as lead investor
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# Appendix





# Vital Therapies – Immunic Combination (Cont'd)

- NASDAQ-listed company focused on the development of oral therapies for chronic inflammatory and autoimmune diseases
  - Three drug development programs (IMU-838, IMU-935, IMU-856), with IMU-838, a potentially best-in-class DHODH inhibitor, already in phase 2b
  - Multiple near-term read-outs expect to provide multiple value inflection points
    - Phase 2 trials in UC, CD, MS and PSC for IMU-838 ongoing or planned
    - Clinical safety and proof-of-concept studies for IMU-935 and IMU-856 planned
- Lead asset, IMU-838, is a new oral treatment option for diseases such as ulcerative colitis (UC), Crohn's disease (CD) and multiple sclerosis (MS)
  - Mode of action commercially proven with IMU-838 having the potential for best-in-class DHODH inhibitor safety profile
  - IMU-838 advanced into phase 2b studies in UC; 350+ patients treated with active moiety overall
  - Easy, once daily oral administration
- Complementary portfolio of selective oral therapies in immunology
  - IMU-935 is a unique inverse agonist of the nuclear receptor ROR $\gamma$ t inverse agonist and DHODH inhibitor currently in preclinical stage. Phase 1 is expected to start mid-2019
  - IMU-856 is a newly developed and orally available small molecule targeting improvement in intestinal barrier function and currently in preclinical testing. Phase 1 is expected to start in H1 2020
- Management team experienced in executing and rapidly advancing drug development
- Cash balance expected to be sufficient to fund development into Q3 2020 and through IMU-838 phase 2b data read-out

# Vital Therapies – Immunic Leadership

- Company will be led by an experienced management team



**Daniel Vitt, PhD**  
CEO



**Andreas Muehler, MD, MBA**  
CMO



**Hella Kohlhof, PhD**  
CSO



**Manfred Groeppel, PhD**  
COO

- Board to be comprised of 5 directors, 4 from Immunic and 1 from Vital Therapies



**Daniel Vitt, PhD**  
CEO of Immunic



**Joerg Neermann, PhD**  
Life Science Partners



**Vincent Ossipow, PhD, CFA**  
Omega Funds



**Jan van den Bossche**  
Fund+



**Duane Nash, MD, JD, MBA**  
CEO of Vital Therapies

- Corporate HQ will be located in Boston, MA with R&D site based in Munich, Germany

# Further Information

## IMU-838

# IBD: Two Indications with High Unmet Medical Need

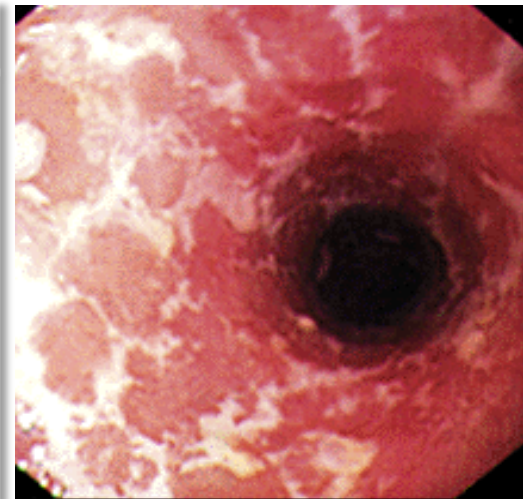
## Crohn's Disease (CD)

- A patchy, transmural inflammation involving the entire bowel wall
- May affect any part of the gastro intestinal tract from the mouth to the anus
- Most commonly, CD affects the lower part of the small intestine and colon
- Symptoms include: abdominal pain, diarrhea, and weight loss
- Structural problem (like e.g. fistulas, abscesses) are common



## Ulcerative Colitis (UC)

- Diffuse mucosal inflammation limited to the colon (involving only the upper layer of the bowel wall)
- 95% of UC cases affect the rectum
- UC may extend in a symmetrical, circumferential and uninterrupted pattern to affect parts or all of the large intestine
- Symptoms include: bloody diarrhea, colic, abdominal pain, cramping, urgency and a constant feeling of needing to empty the bowel



# Large Market Opportunity

- Global market for IBD in 2023 **estimated to be approximately 7.6 billion USD<sup>[1]</sup>**
- **11.2 million patients** affected by UC or CD worldwide in 2015<sup>[2]</sup>
- Patient numbers continue to grow

	Europe <sup>[3]</sup>	USA <sup>[4]</sup>	Canada <sup>[5]</sup>
<b>IBD Total</b>	2,600,000	1,300,000	233,000
<b>UC</b>	1,500,000	700,000	104,000
<b>CD</b>	1,100,000	600,000	129,000

<sup>[1]</sup> Global IBD Market Forecast 2018.

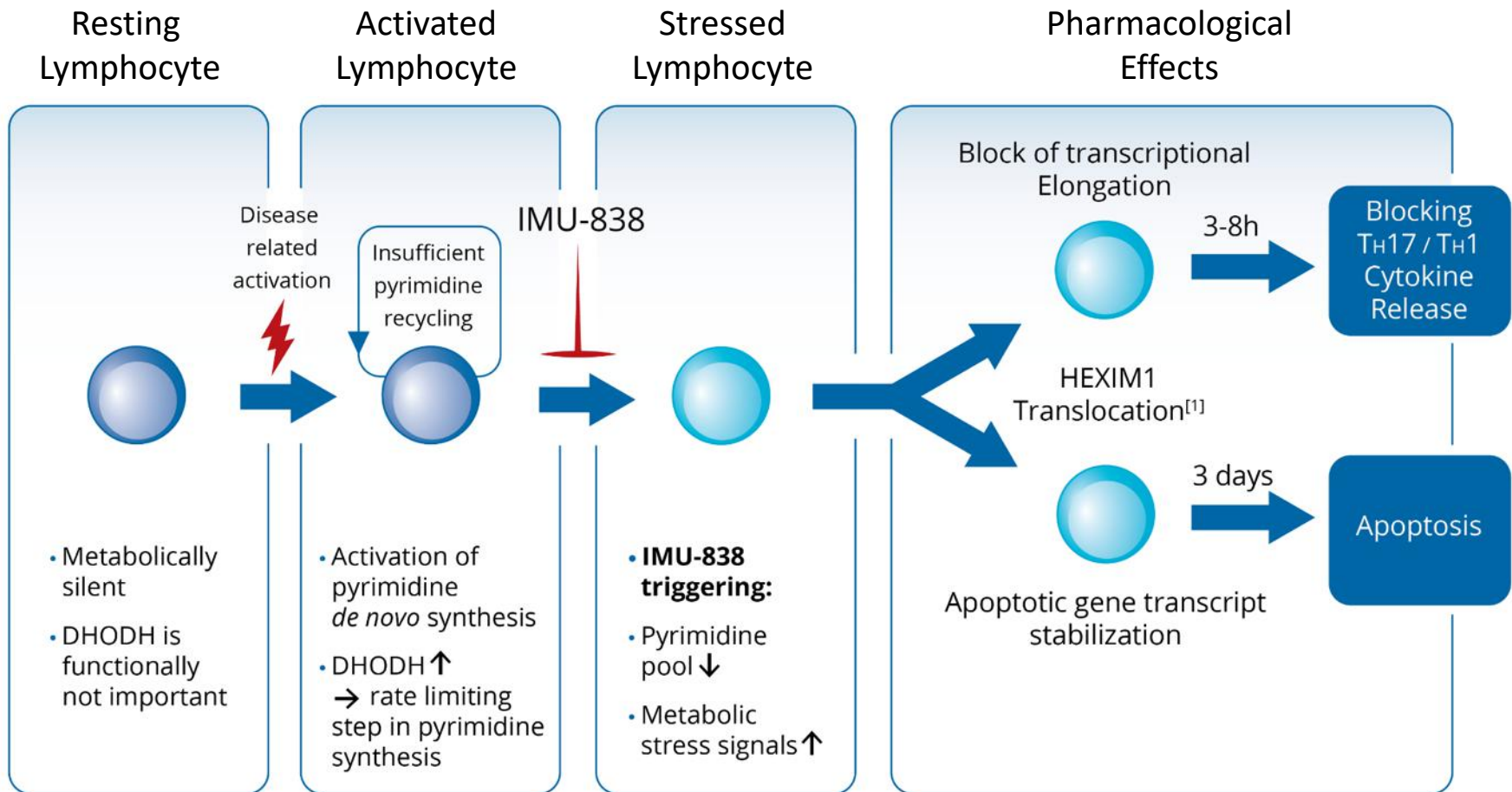
<sup>[2]</sup> GBD 2015 Lancet. 388 (10053): 1545–1602.

<sup>[3]</sup> Burisch et al. Journal of Crohn's and Colitis 2013 7, 322–337

<sup>[4]</sup> Hanauer S. 2006;12:S3-9 (Suppl 1), Kappelman MD et al, Clin Gastroenterol Hepatol. 2007; 5:1424-9.

<sup>[5]</sup> The Burden of IBD in Canada. www.ccfc.ca. Accessed 16 May 2014

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



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



# IMU-838: Compelling Safety and Efficacy Data

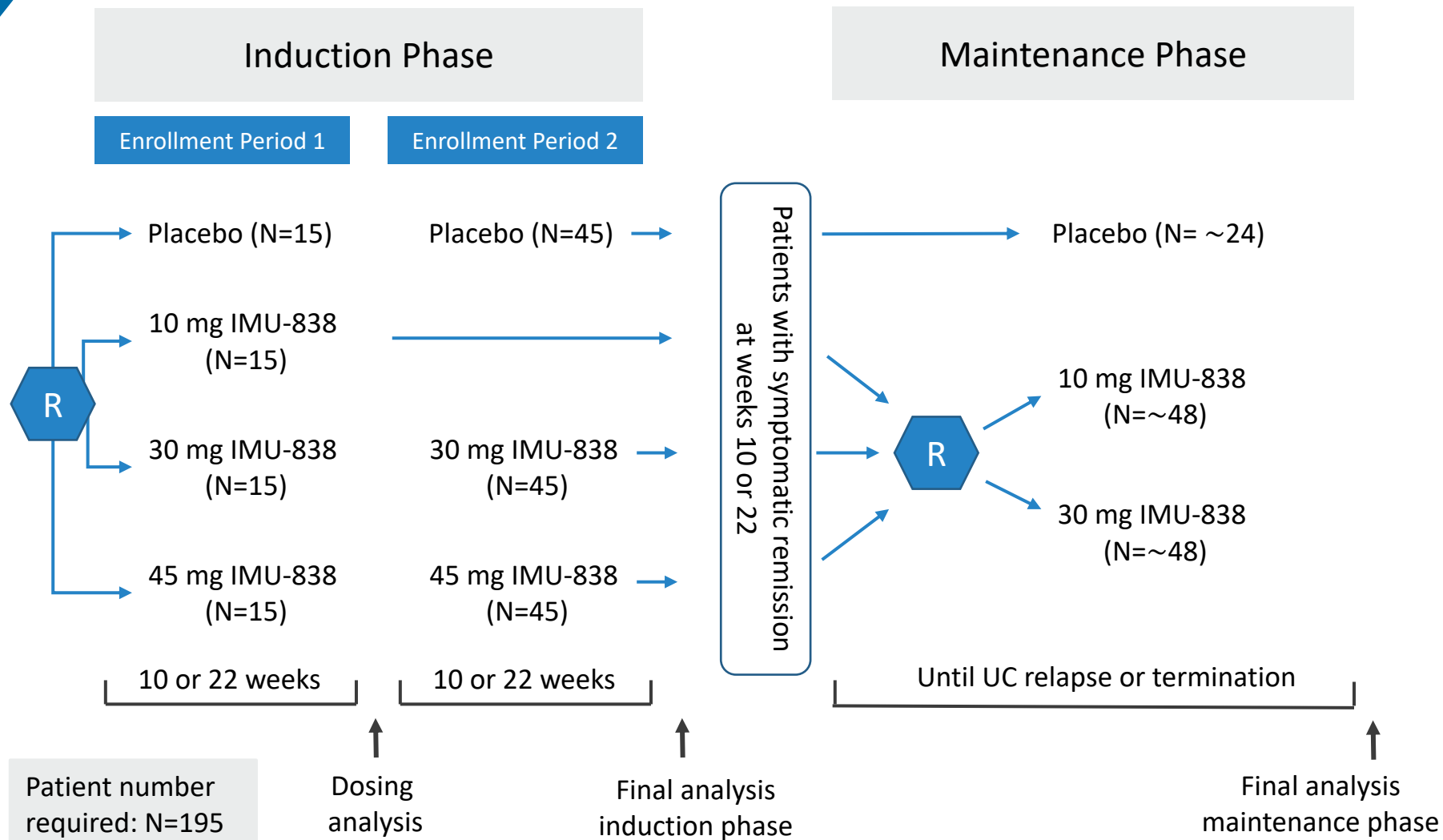
- Safety

- Animal and in-vitro data show **selective effect** on activated immune cells and **no general detrimental effect** on bone marrow
- Already more than **350 individuals treated** with active moiety of IMU-838
- Two phase 1 trials of IMU-838 formulation established its safety up to **daily doses of 50 mg**
- Safety profile **similar to placebo** at therapeutically used doses
- **No increased rate of infections and infestations** compared with placebo in clinical trials

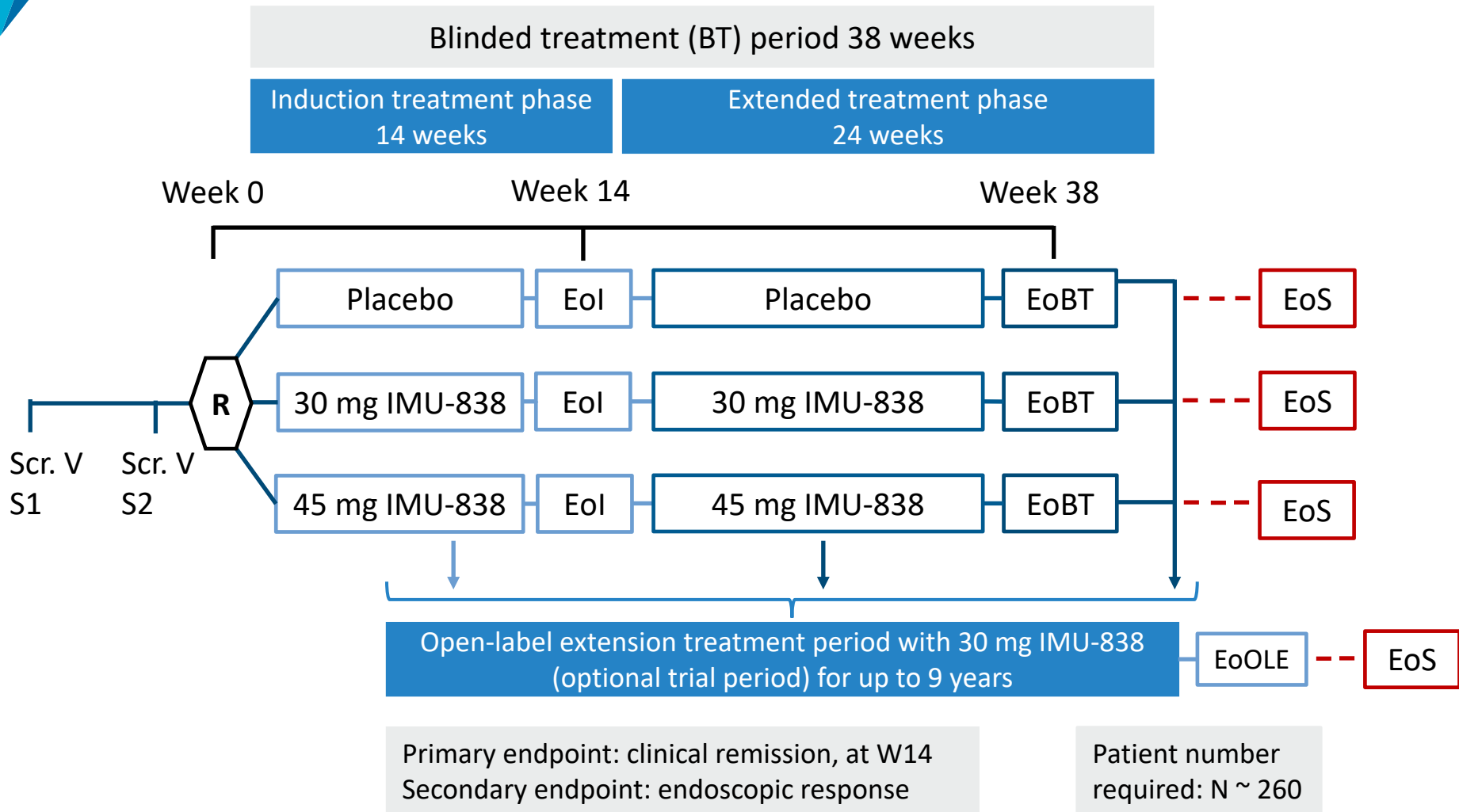
- Efficacy

- Mechanism of DHODH inhibition already established successfully in rheumatoid arthritis and multiple sclerosis
- Investigator trials with other DHODH inhibitors have shown positive effects on Crohn's disease patients
- **Proof-of-concept** trial using IMU-838 active moiety (ENTRANCE trial) provided initial efficacy results in steroid-dependent IBD patients

# General Phase 2 Trial Design in UC



# General Phase 2 Trial Design in CD





## IMU-838: Phase 2 Study in PSC

- Immunic is collaborating with a prominent hepatologist in the US and two Mayo Clinic locations
  - PI received a grant approval letter from the NIH for performance of an investigator sponsored trial with IMU-838 in patients with primary sclerosing cholangitis (PSC)
  - Single-arm, exploratory study
  - Primary endpoint: change in serum alkaline phosphatase (ALP) at 6 months vs. baseline
  - Dosing: 30 mg IMU-838, (Clinicaltrials.gov: NCT03722576)
  - Investigator IND for IMU-838 and IRB approval already established
- Immunic to provide clinical trial material for the patients to clinical sites
- Assumed start of enrollment in Q1 2019
- Positive data should enable immediate start of a pivotal trial in this orphan indication by Immunic

# MS Opportunity

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

Despite its substantial side effects, Aubagio® **reached sales of around 1.8 billion USD in 2017<sup>[1]</sup>**

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

# IMU-838: Potential Advantages in MS

- Potential advantages of IMU-838 therapy compared with Aubagio® (teriflunomide):
  - Selectivity and sensitivity<sup>[1] [2] [3] [4]</sup>
  - Pharmacokinetic parameters<sup>[5] [6]</sup>
  - Safety profile<sup>[7] [8] [9] [10]</sup>
  - Drug-drug interaction potential<sup>[6]</sup>
- Start phase 2 trial in patients with multiple sclerosis planned for H1 2019

[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®

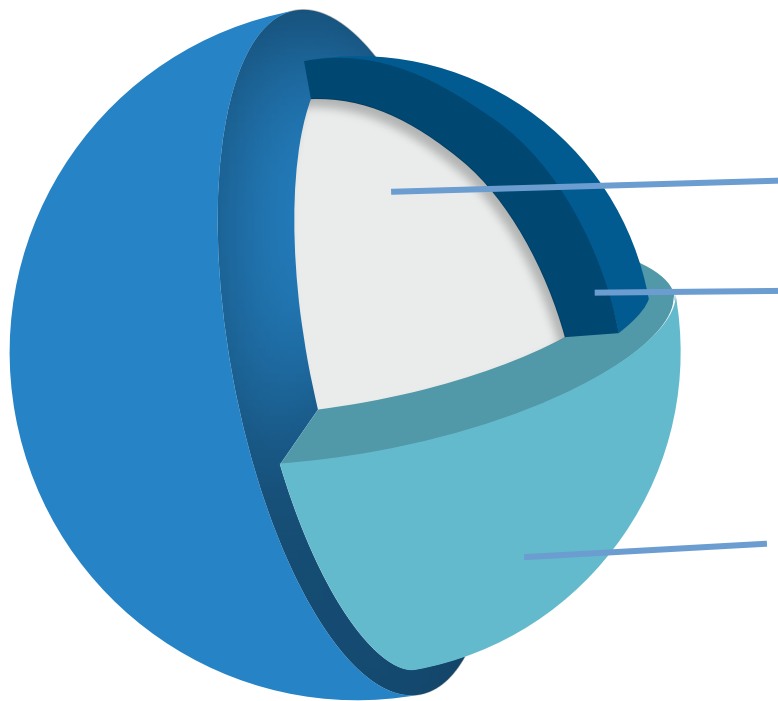
[8] FDA CDER Medical Review Teriflunomide, 2012

[9] O'Connor et al, NEJM 365: 1293-1303, 2011

[10] O'Connor et al, NEJM 365: supplementary appendix, 2011

# IP Position of IMU-838: Several Layers of IP

- IMU-838 is protected by several layers of patents



Patent on the specific **salt form and pharmaceutical composition of IMU-838**, granted in the US, EU and other key markets – expires in 2031

New patent filed in 2018 on the specific **polymorph** of IMU-838 used in current studies

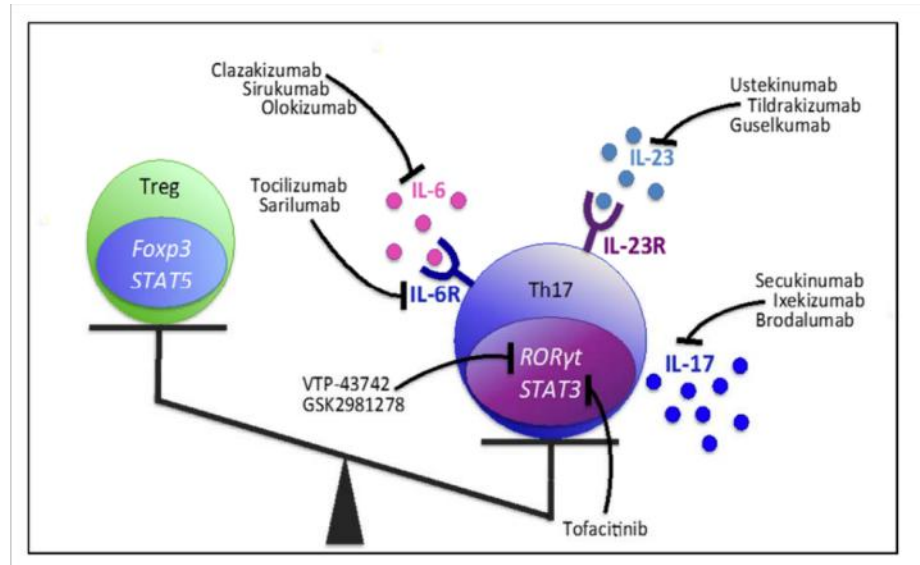
New **dosing regimen**, which was developed during phase 1 testing – protecting the applied dosing scheme of all ongoing and planned phase 2 studies – new patent application **filed in 2017**

# Further Information IMU-935



# Autoimmune Diseases: Broad Disease Spectrum

- Autoimmune diseases are frequent diseases, affecting millions of patients worldwide<sup>[1]</sup>
- Disruption of the human immune system is a root cause of autoimmune diseases<sup>[2]</sup>
- ROR $\gamma$ t is an important regulator of auto immunity related diseases<sup>[2]</sup>



Source: Fasching, Patrizia, et al. *Molecules* 2017; 22.1: 134.

Psoriasis

IL-23 axis in psoriasis

MS

Th1/Th17 – key role in MS

Uveitis

Key role for Th17 in Uveitis

Lupus

IFN $\gamma$  driven autoimmune disease



## IMU-935: Project Status

- Preclinical IND enabling studies currently ongoing
- Start of clinical phase 1 test of IMU-935 in healthy volunteers planned for mid-2019
- Further options for clinical development
  - Test of IMU-935 in phase 1b/2a trial in patients with mild to moderate psoriasis – 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

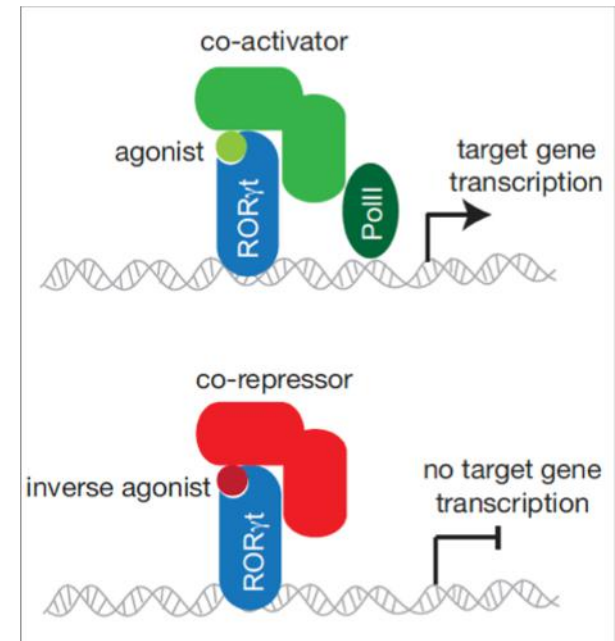
# IMU-935: Unique ROR $\gamma$ t-Inverse Agonist

IMU-935 (IM105935) is a small molecule immune modulator

- Inverse agonist of ROR $\gamma$ t
- Potent inhibitor of
  - IL17A, IL17F and IFN $\gamma$  production
  - TH17 differentiation

## Target indication

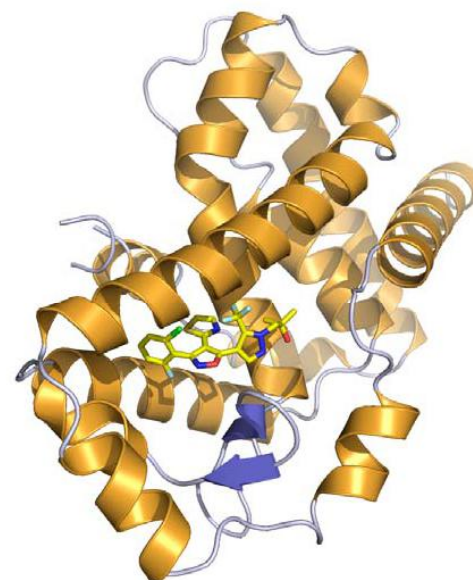
- Psoriasis or psoriatic arthritis (first)
- Various autoimmune and chronic inflammatory diseases with dysregulated Th17 and Th1 response



# IMU-935: Cytokine Inhibition in Low Nanomolar Range

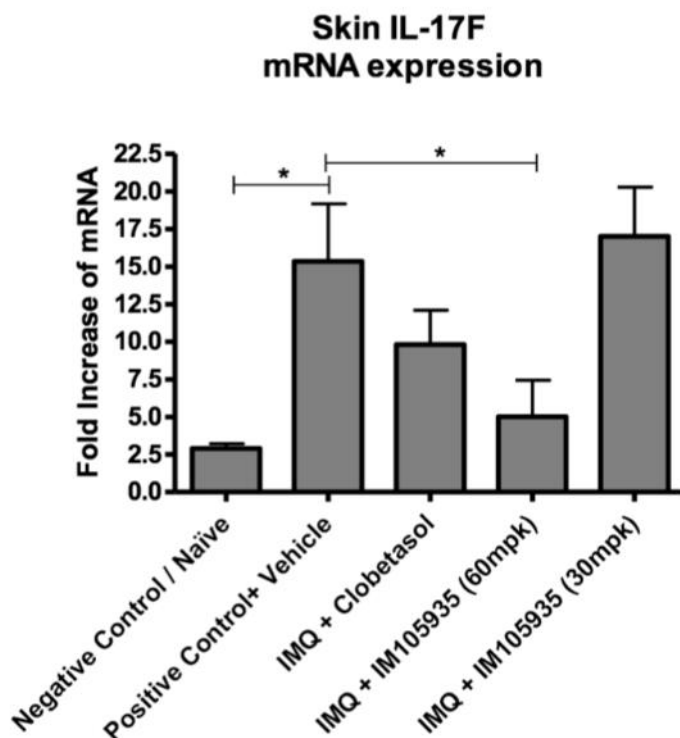
- Effect of the development compound IM105935 (IMU-935) in stimulated human PBMCs
  - Read-out: effect on cytokine production after 48 h

	IC <sub>50</sub> [μM]
IL-17A	0.005
IL-17F	0.004
IFN <sub>γ</sub>	0.003
IL-1a and b	no inhibition
IL-4,5,6,8	no inhibition
ROR <sub>γ</sub>	24 nM (MST)
ROR <sub>γ</sub> (cellular, rep.)	20 nM
Th17 differentiation	100 nM



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

# IMU-935: Strong Efficacy Signal in Imiquimod-induced IL-17F Model



- Activity of IMU-935 on IL-17F expression in skin was tested in an imiquimod (IMQ) induced mouse model
  - Topical induction of inflammation with imiquimod
  - Oral application of IM105935
- **Results**
  - Dose dependent inhibition of IL-17F mRNA expression in-vivo
  - IM105935 was more potent in IL-17F suppression than the corticosteroid control Clobetasol

# Further Information

## IMU-856





## 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 Concept

- Main indication: Crohn's disease (CD)
- Clinical development concept
  - Phase 1 single and multiple ascending dose studies are expected to start in H1 2020
- IMU-856 has substantial further potential for orphan diseases outside IBD
- Product is covered by a global PCT patent application