Promising effects of IMU-856, an orally available epigenetic modulator of barrier regeneration - biomarker findings from a Phase 1 clinical study

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Disclosures

Dr. Amelie Schreieck is an employee of Immunic AG and owns shares and stock options of the parent company of Immunic AG.

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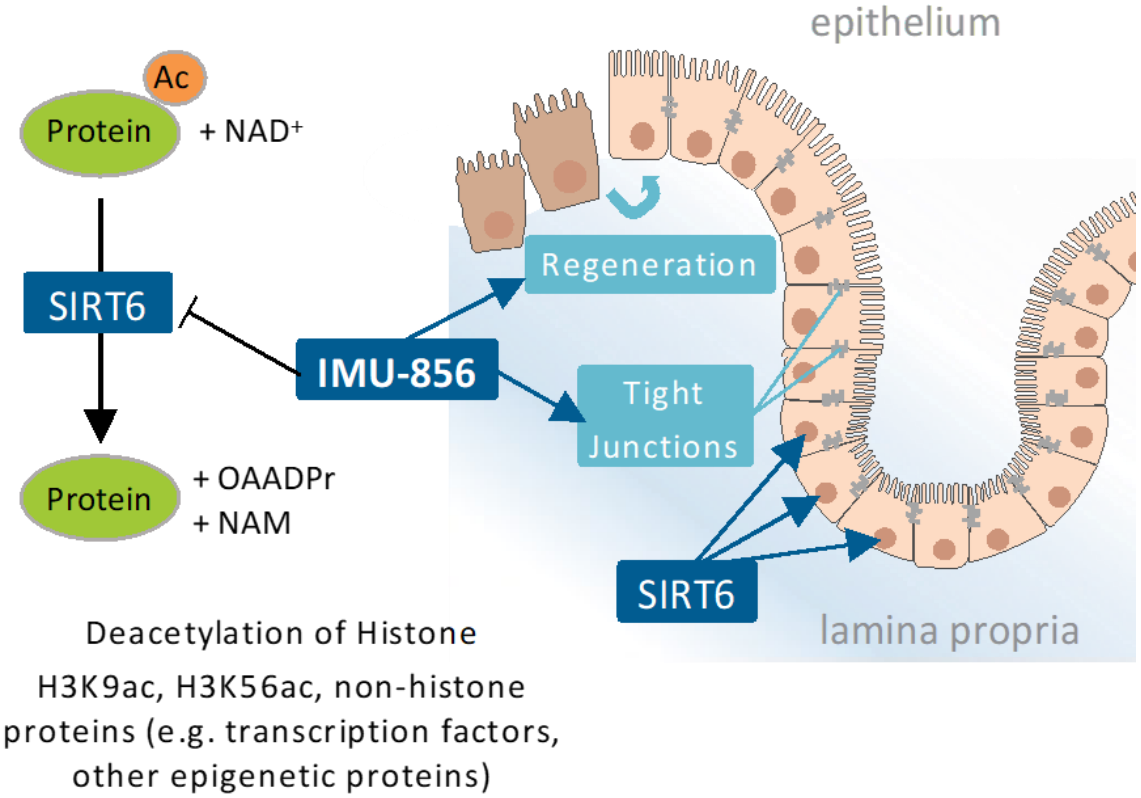
Immunic THERAPEUTICS

IMU-856 Mode of Action



- IMU-856 is a highly selective and potent modulator of the enzymatic activity and stability of SIRT6 (sirtuin 6)
- IMU-856 promotes intestinal regeneration and improves barrier function in human cell and animal models
- No known effect on immune cells

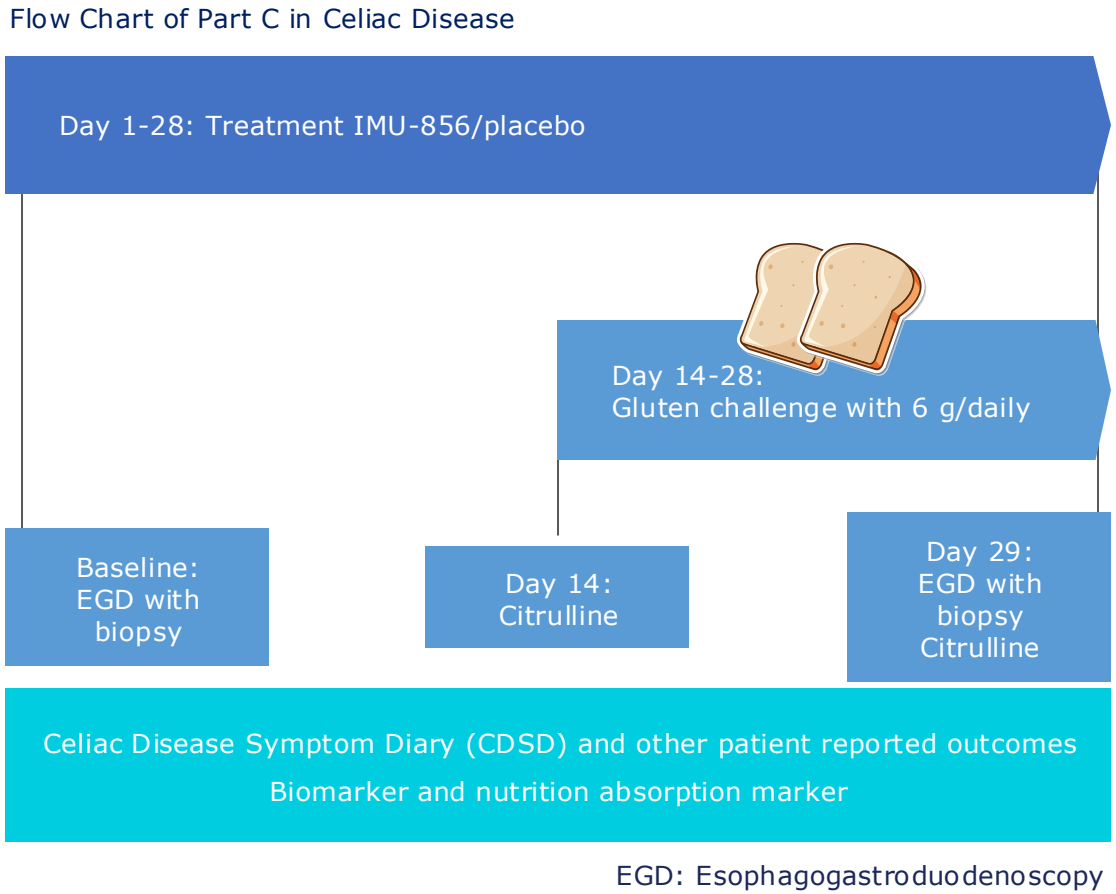
Preclinical Data
Dr. Martina Wirth
Abstract: EC25-1096
DOP116, 21st Feb, 6:27-6:33 pm

Phase 1b Clinical Gluten Challenge Trial of IMU-856 in CeD

- Population of well-controlled CeD patients with gluten challenge of 6g/day for 15 days
- Dosing: 80 and 160 mg PO once daily
- N=43 (80 mg: N=14, 160 mg: N=15)

- **Proof of concept study:**
  - histological changes
  - blood biomarkers
  - nutrient uptake
  - disease-related symptoms

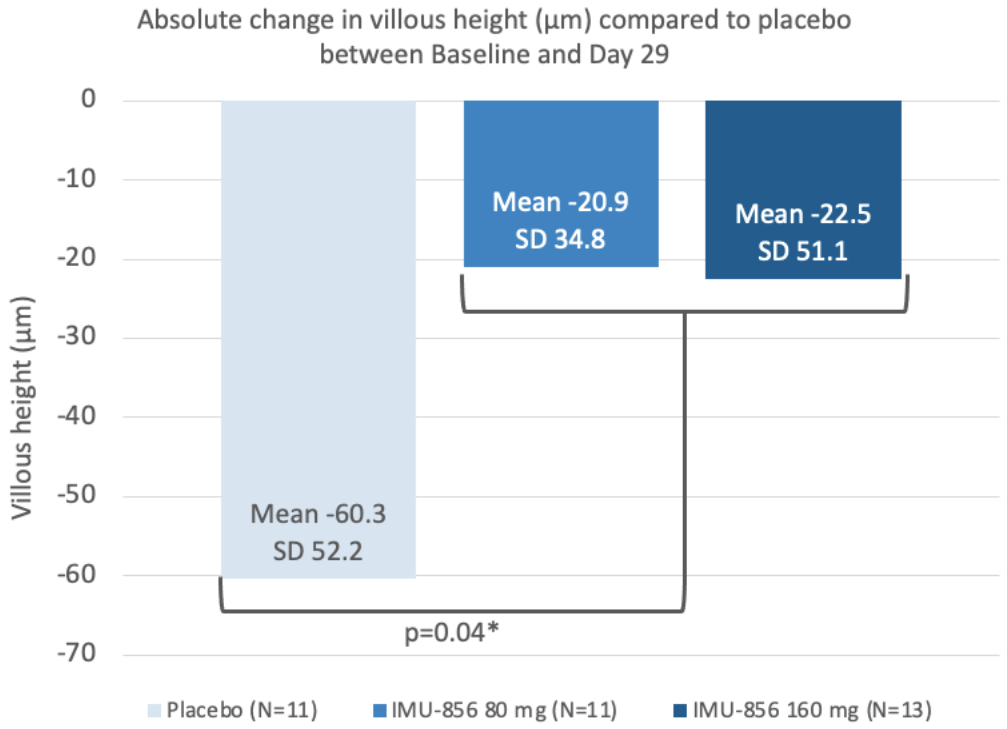
- IMU-856 observed to be **safe and well-tolerated**



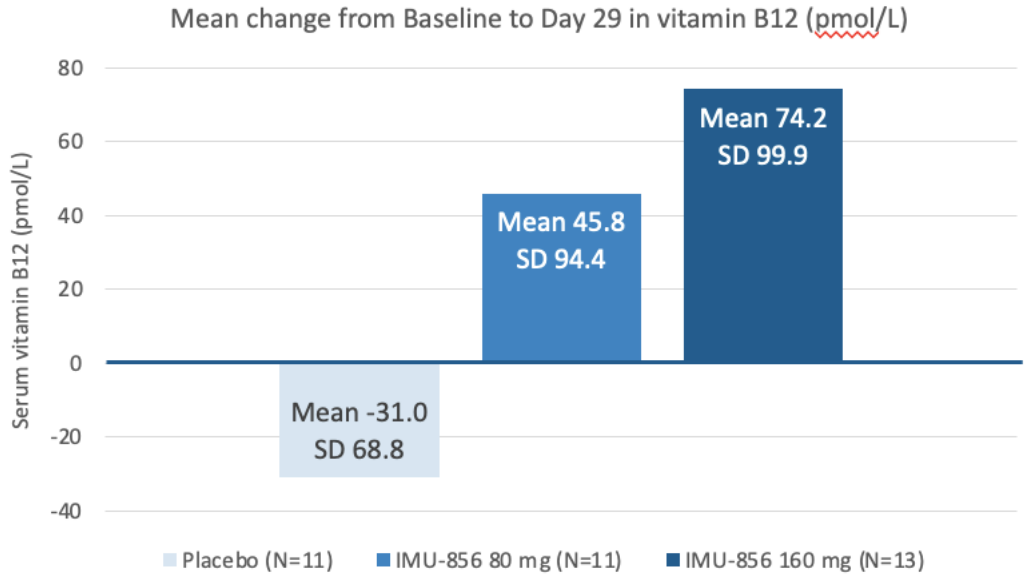
EGD: Esophagogastroduodenoscopy

IMU-856 - Positive Effects in Four Dimensions of Clinical Outcome in CeD

1) IMU-856 effectively protected against gluten-induced intestinal damage (villous height)



2) IMU-856 improved nutrient uptake (vitamin B12)

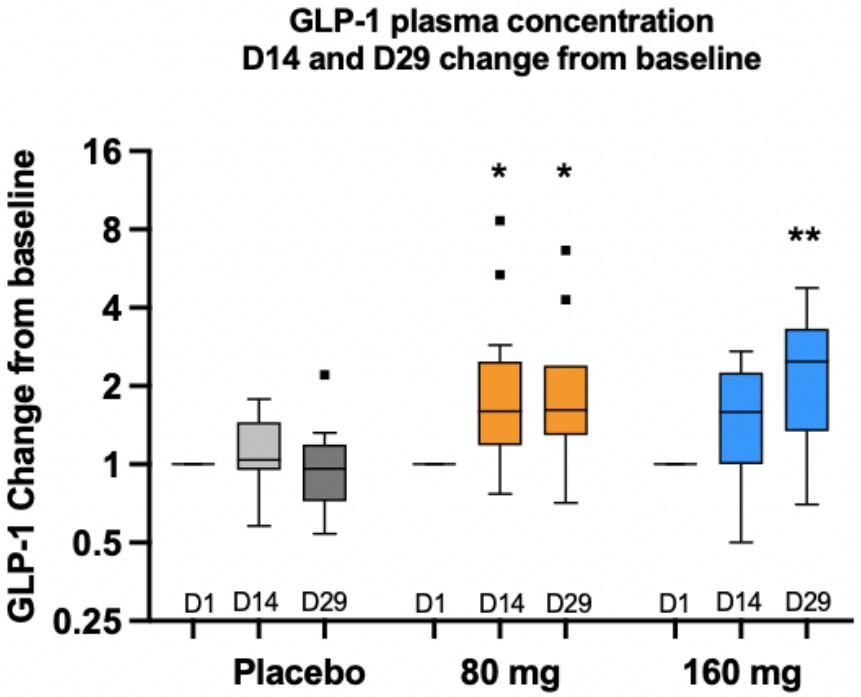


3) IMU-856 reduced/reversed reported gluten-induced symptoms

4) IMU-856 improved blood citrulline levels

Daveson, A James M et al., The Lancet Gastroenterology & Hepatology, Volume 10, Issue 1, 44 - 54

IMU-856 Substantially Increases GLP-1 in CeD Patients



y-axis log2 scale, statistics: two-sided Mann-Whitney U - treatment vs placebo at Day 14 and Day 29

GLP-1

- Peptide hormone secreted in response to **nutrient ingestion** and neuroendocrine stimulation
- GLP-1 increase leads to slow gut motility, lower food intake, increase satiety and induce insulin secretion

- Patients measured for plasma GLP-1 concentrations:
  - N=11 (placebo)
  - N=13 (80 mg)
  - N=13 (160 mg)
- 3 timepoints per treatment arm:
  - Left: Day 1 (baseline)
  - Middle: Day 14 (before start of gluten challenge)
  - Right: Day 29 (after last treatment on Day 28)

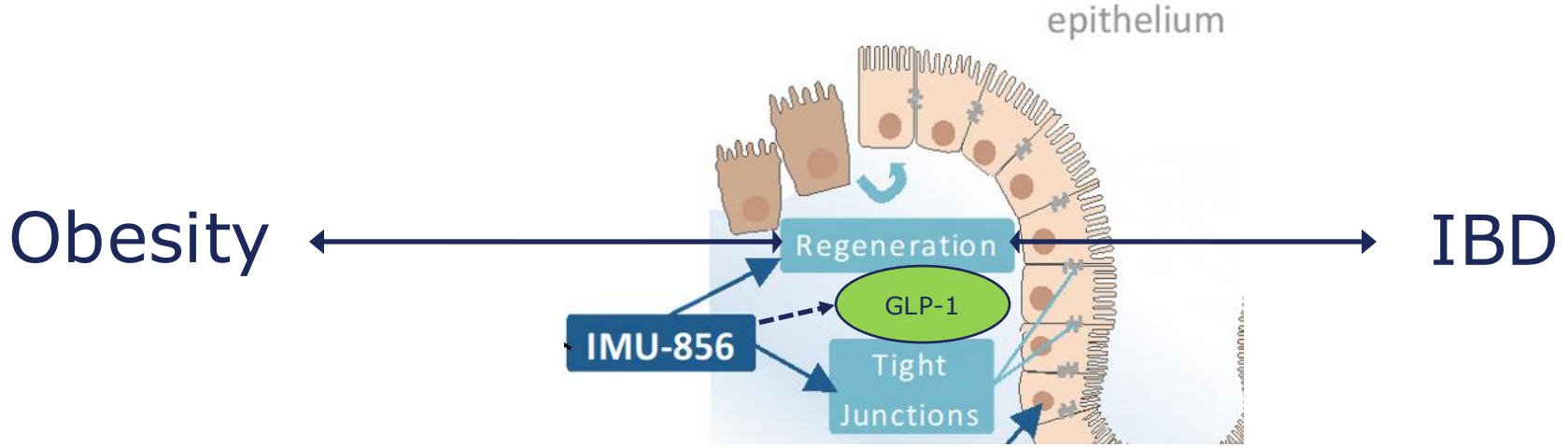
IMU-856 – from CeD to IBD and beyond

GLP-1

- influence on gastric emptying
- anti-inflammatory properties
- intestinotrophic effects → intestinal health and repair

IMU-856 → SIRT6

- regenerates gut barrier (cell renewal / differentiation)
- drives gut barrier tightness (via tight junction proteins)



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Thank you very much for your attention.