



Immunic
THERAPEUTICS

First-in-Human Trial of IMU-856, an Orally Available Epigenetic Modulator of Barrier Function and Regeneration for the Treatment of Celiac Disease

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Symposium 234: Mucosal Immunology – A Translational View into the Clinic
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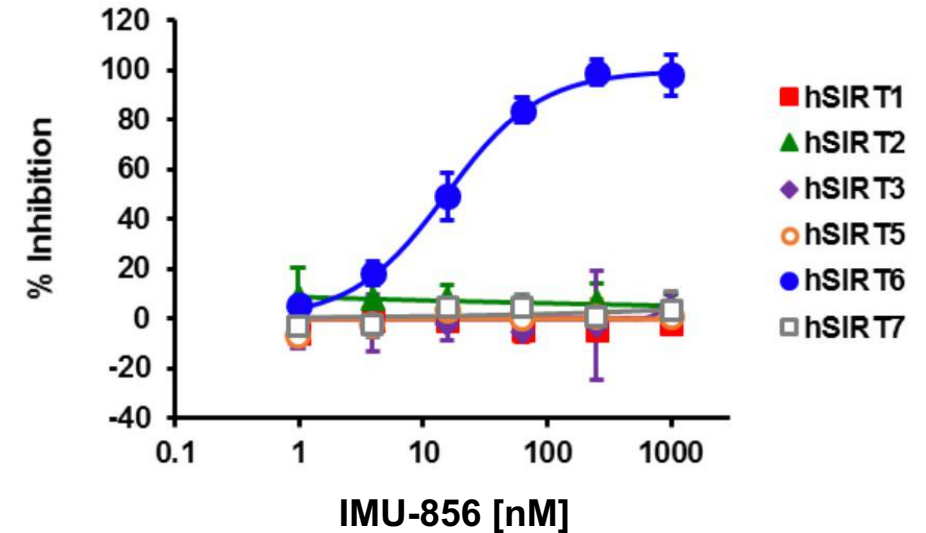
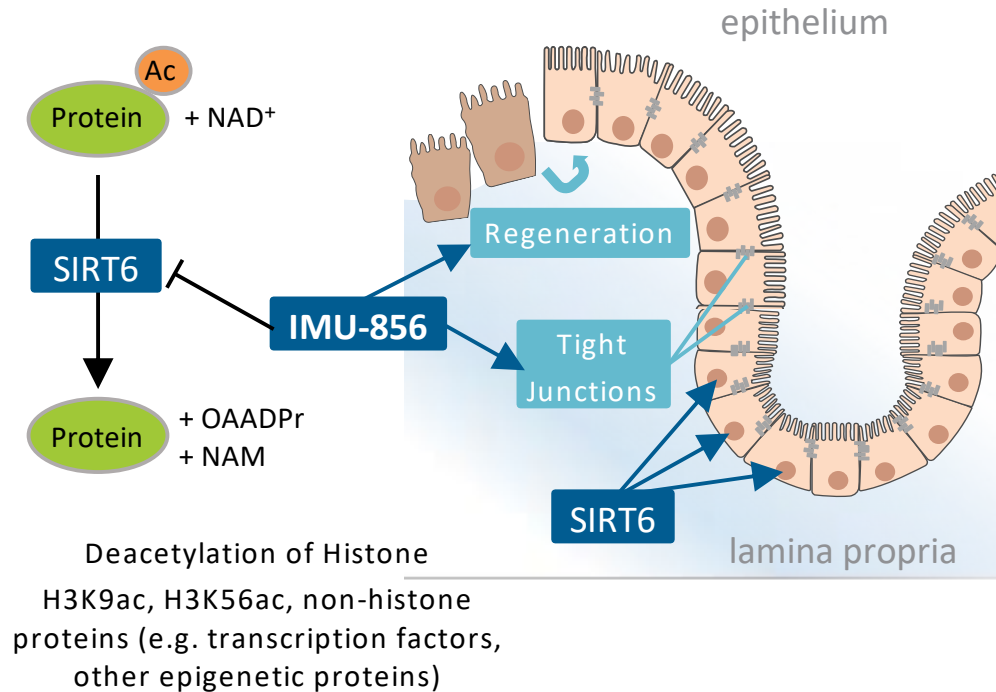
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IMU-856's Mode of Action: Targeted to Restore Intestinal Barrier Function and Regeneration



Highly selective and potent inhibition of the histone/protein deacetylase activity of SIRT6 over other sirtuin family members

- IMU-856 is a highly selective and potent modulator of the enzymatic activity and stability of SIRT6 (sirtuin 6)
- IMU-856 improves intestinal regeneration and barrier function in human cell and animal models

Phase 1b Clinical Trial of IMU-856 in Celiac Disease

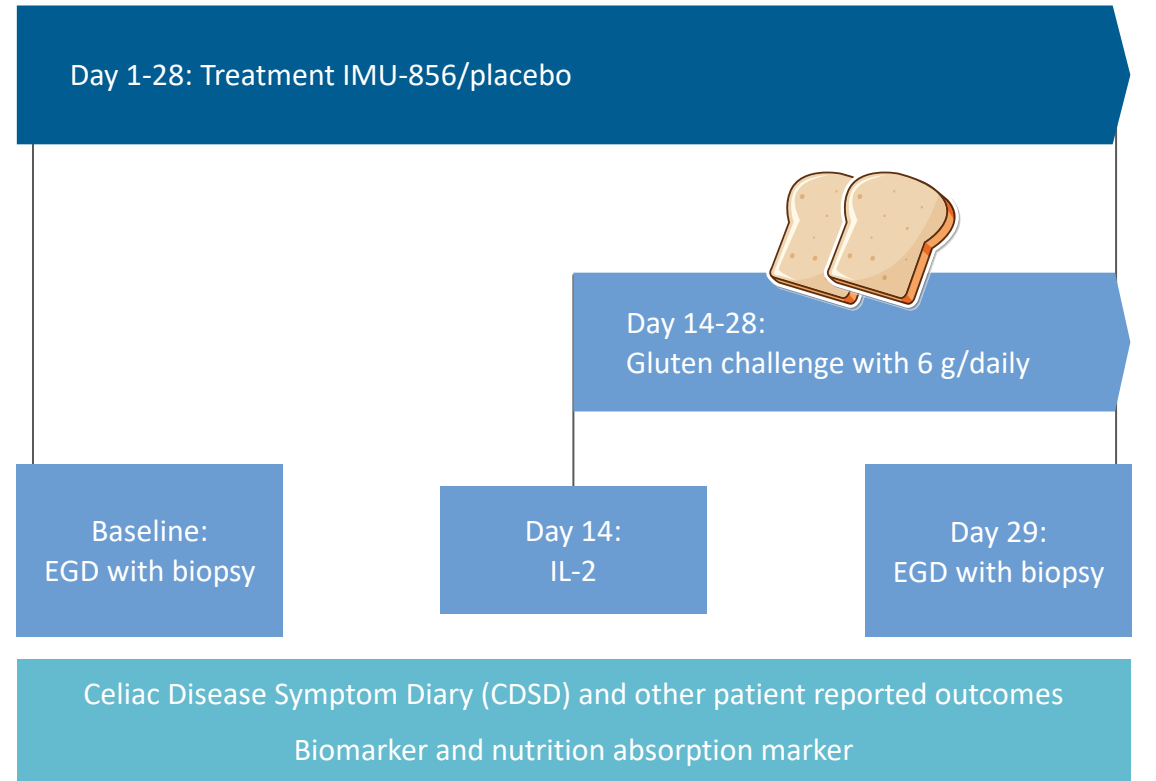
Designed as a Gluten Challenge Trial



Proof-of-Concept Study

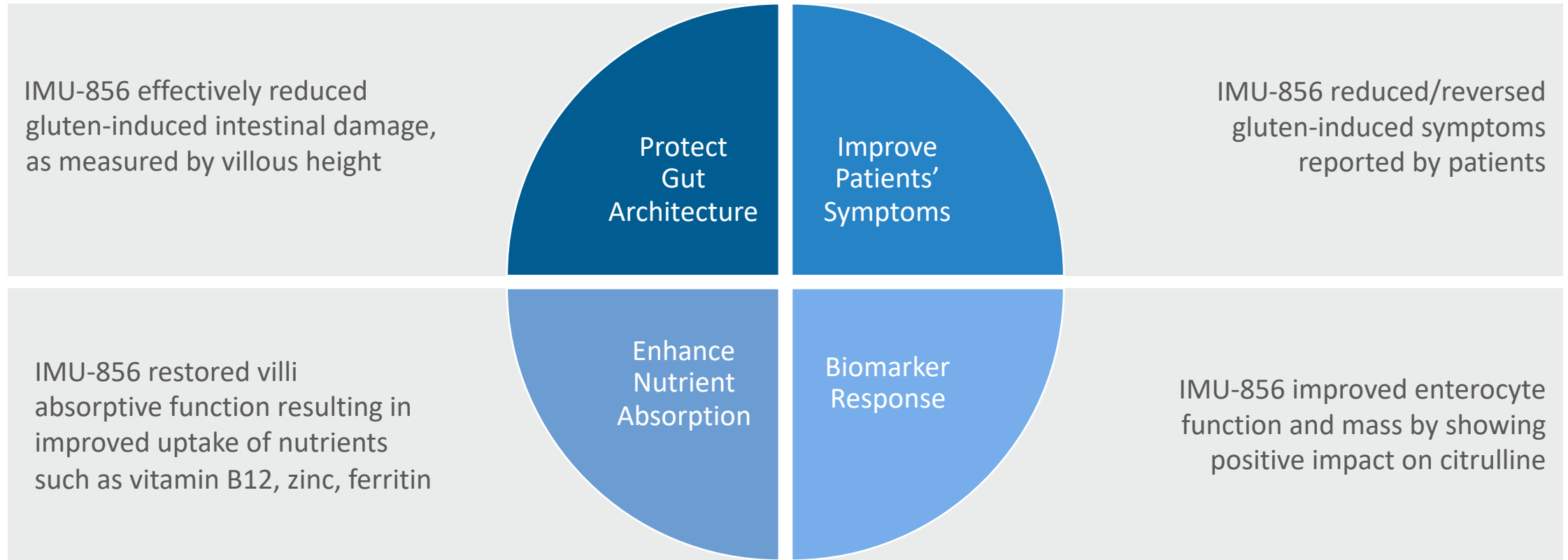
- Part C planned to include a well-controlled celiac disease patient population
- Dosing: 80 and 160 mg QD of IMU-856
- 43 patients enrolled
- Performed at sites in Australia and New Zealand
- Designed to assess safety, tolerability and pharmacokinetics of IMU-856
- Measured histologic changes, blood biomarkers, nutrient uptake and disease-related symptoms

Flow Chart of Part C in Celiac Disease



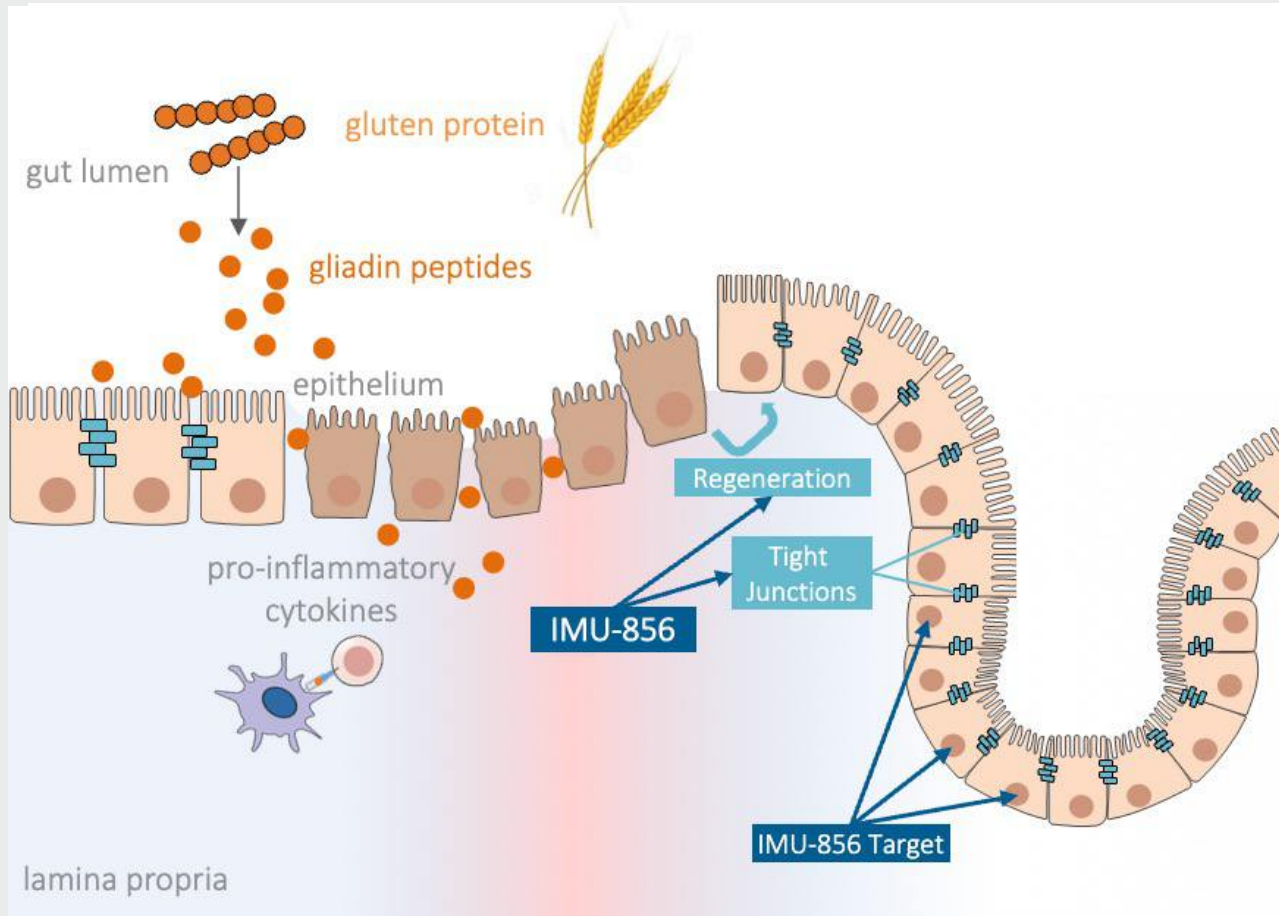
QD: quaque die = once-daily; EGD: esophagogastroduodenoscopy; IL: interleukin

Phase 1b Clinical Trial: IMU-856 Showed Positive Effects in Main Four Dimensions of Clinical Outcome in Celiac Disease Patients



All these effects achieved without any known suppression of the immune system

Conclusion: Extensive Potential for IMU-856 in Celiac Disease and Beyond



- IMU-856 is a highly selective and potent modulator of SIRT6 (sirtuin 6), an epigenetic regulator of gene expression
- IMU-856 was shown to **be safe and well tolerated** in healthy volunteers and celiac disease patients in a phase 1 clinical trial
- In the phase 1b proof-of-concept study in celiac disease patients, IMU-856 demonstrated its potential to protect mucosal architecture and promote gut regeneration and repair
- IMU-856 may offer extensive potential beyond celiac disease in other gastrointestinal diseases
- Immunic is preparing phase 2 testing in ongoing active celiac disease

Thank You!

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Presenter Disclosure

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I have the following Relationships with commercial interests:

- Research/Clinical Trials: Manager Translational Pharmacology at Immunic AG
- Other:
 - Past Employee: UCL (industry collaboration with Eisai Ltd, Hatfield, UK)
 - Investments: Immunic, Inc. stock

Speaking Fees for current program:

- Falk Foundation covers my costs for travel, accommodation and the conference fee for attending this meeting