
FORTE BIOSCIENCES

FBI02

CELIAC DISEASE PHASE 1B RESULTS

JUNE 2025

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- 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 Act of 1995, known as the PSLRA. These include statements regarding management's intention, 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. Forte Biosciences, Inc. ("we", the "Company" or "Forte") 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," "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.
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- We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy and financial needs, and these statements represent our views as of the date of this presentation. We may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. Information regarding certain risks, uncertainties and assumptions may be found in our filings with the Securities and Exchange Commission, including under the caption "Risk Factors" and elsewhere in our Quarterly Report on Form 10-Q for the period ending March 31, 2025, and other filings with the Securities and Exchange Commission. New risk factors emerge from time to time and it is not possible for our management team to predict all risk factors or assess the impact of all factors on the business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements. While we may elect to update these forward-looking statements at some point in the future, we specifically disclaim any obligation to do so. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this presentation.

CLINICAL STAGE FB-102

- CD122 is a subunit of the intermediate affinity IL-2/IL-15 receptor expressed on NK and T cells and is a subunit of the high affinity IL-2 receptor expressed on Tregs
- FB102 (Forte's anti-CD122 antibody) is designed to mediate both the IL-2 and the IL-15 induced proliferation and activation of pathogenic NK and T cells
- Celiac disease (CeD) phase 1b trial completed and demonstrated positive histological and symptom data for FB102 treated subjects compared to placebo
- FB102 Phase 2 celiac disease initiating with data expected in 2026
- FB102 Phase 1b vitiligo trial enrolling with topline results expected in 1H26

ALIGNMENT OF DISEASE BIOLOGY AND MECHANISM FOR FBI02 HIGHLIGHTS “PIPELINE-IN-A-PRODUCT” POTENTIAL FOR FBI02 IN AUTOIMMUNE DISEASES WITH HIGH UNMET NEED

Disease	Species	Outcome	Reference
Celiac disease	Mouse	Improved IL-15-induced mucosal damage	PNAS, 2009
Vitiligo	Mouse	Enhanced repigmentation	Sci Transl Med, 2018
Alopecia areata	Mouse	Prevented fur loss	Nature Med, 2014
Type 1 diabetes	Mouse	Delayed disease onset	JCI Insight, 2018

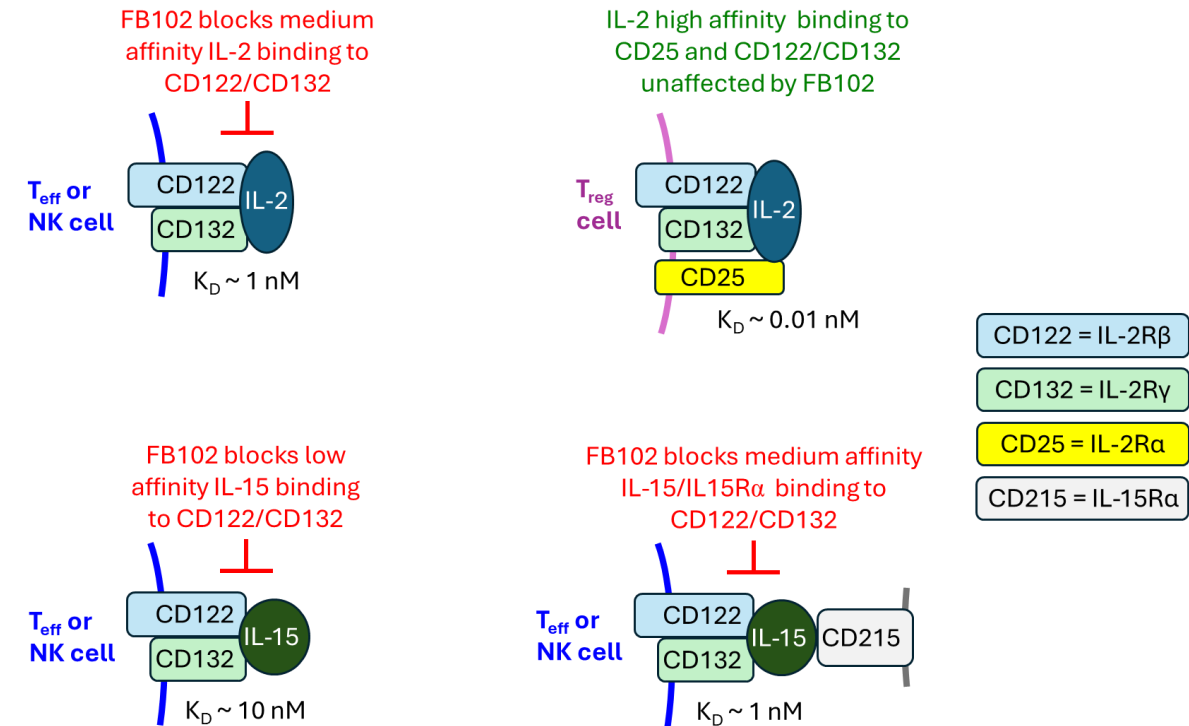


FBI02 CDI22 ANTAGONIST MECHANISM

CLINICAL STAGE FB102 OVERVIEW

CD122 is a subunit of the intermediate affinity IL-2/IL-15 receptor expressed on NK cells, certain T cell subtypes and is a subunit of the high affinity IL-2 receptor expressed on Tregs

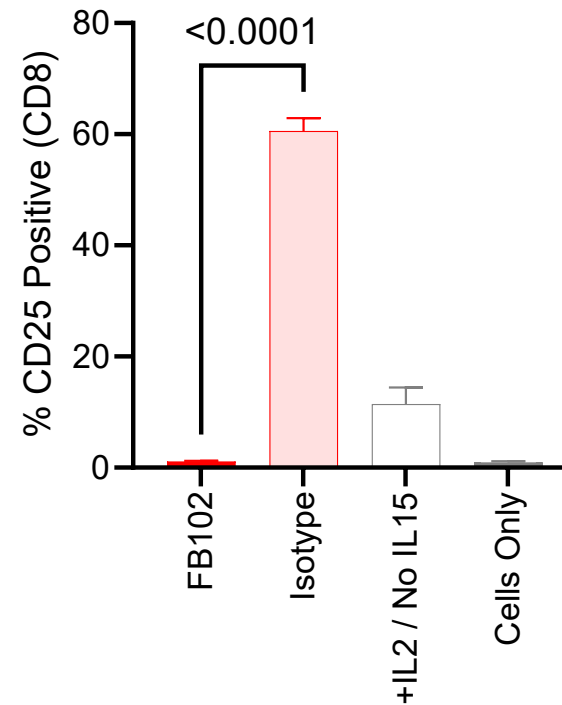
FB102 (Forte's anti-CD122 antibody) is designed to mediate both the IL-2 and the IL-15 induced proliferation and activation of pathogenic NK cells, certain T cell subtypes without effecting the IL-2 biology of beneficial Tregs



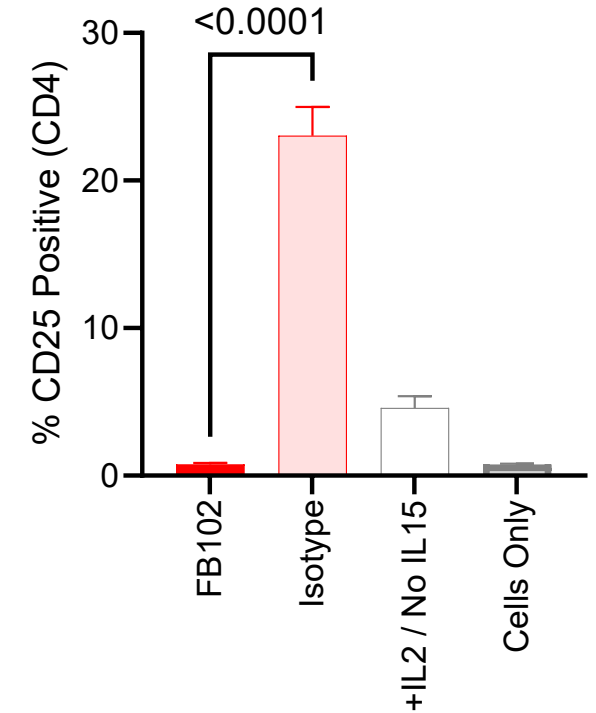
FBI02 INHIBITS IL-2/IL-15 CD4+ AND CD8+ T CELL ACTIVATION IN IN VITRO DISEASE MODEL

CD4+ and CD8+ T cells were treated with IL2 for 24 hours then with IL15 for 24 hours, simulating disease activity in the presence or absence of FBI02

FBI02 provides nearly complete inhibition of T cell activation



CD8+ T Cells



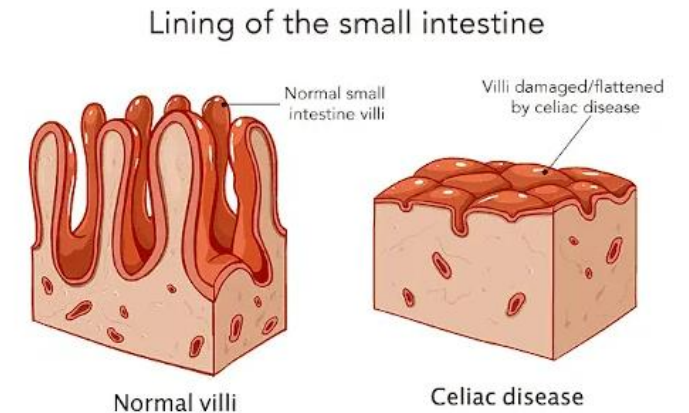
CD4+ T Cells



CELIAC DISEASE

NO APPROVED THERAPIES FOR CELIAC DISEASE; POTENTIAL FOR A SIGNIFICANT MARKET OPPORTUNITY

- Celiac disease is an autoimmune disease that's triggered by consuming gluten and results in damage to the small intestine
- Symptoms include diarrhea, fatigue, headaches, anemia, nausea, dermatitis herpetiformis (an itchy skin rash)
- Significant patient population does not respond to gluten free diet
- Health consequences for not treating include malnourishment, cancer, other autoimmune conditions
- Market Opportunity
 - Estimated 1:133 in US (2.5 million people) with celiac disease (Fasano, Arch Intern Med. 2003 PMID: 12578508)
 - 0.3% to 0.5% of celiac disease patients are non-responsive (Malamut Gastroenterology. 2024 38556189)
 - No approved treatment options for celiac disease



IL-2 AND IL-15 IN CELIAC DISEASE (CED)

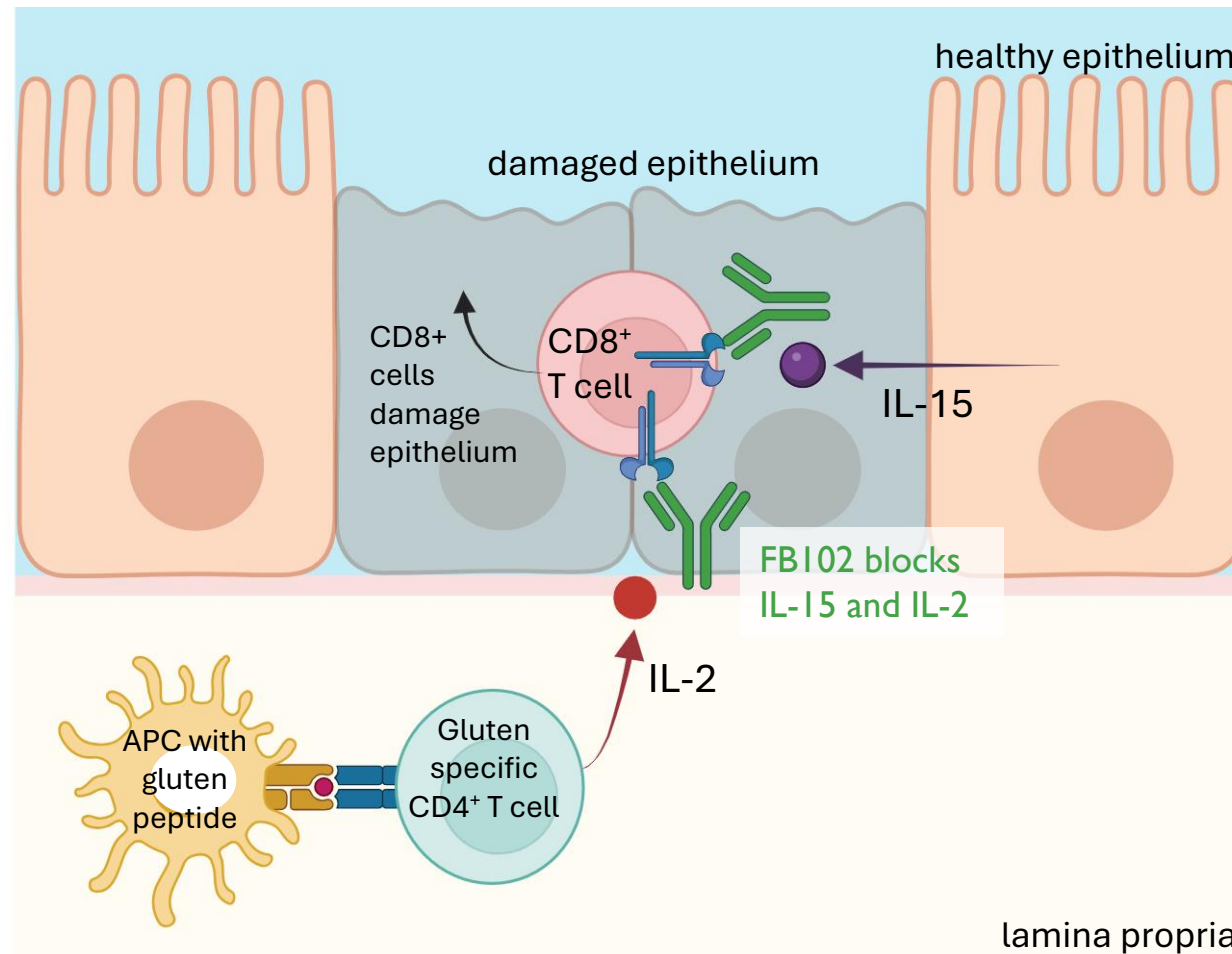
IL-2

- Clear genetic basis for involvement of IL-2 in CeD
- Gluten-induced IL-2 production differentiates true CeD from non-gluten induced GI symptoms
- IL-2 strongly correlates with symptom severity and Serum IL-2 peaks within 4 hours after gluten exposure
- IL-2 production is followed by increases in Intraepithelial lymphocyte (IELs) and inflammatory Th-1 type cytokine IFN- γ

IL-15

- Clear genetic basis for involvement of IL-15 in CeD
- IL-15 levels in intestinal tissue correlate with intestinal damage
- IL-15 is overexpressed in gut epithelium and immune cells upon gluten exposure
- IL-15Ra is overexpressed in Intraepithelial lymphocyte (IELs) in patients with CeD
- IL-15 induces proliferation and activation of Intraepithelial lymphocyte (IELs) and inflammatory cytokines IFN- γ and TNF- α
- IL-15 activates intestinal cytotoxic CD8+ T cells that kill gut epithelium
- IL-15 impairs immunosuppressive and gut-protective activity of CD4+ Tregs and TGF- β

FBI02 BLOCKS GLUTEN-INDUCED INTESTINAL DAMAGE IN CELIAC SUBJECT BY BLOCKING IL-2 AND IL-15 ACTIVATION OF CD8+ T CELLS



FB102 BLOCKS BOTH IL-2 AND IL-15, PROVIDING POTENTIAL ADVANTAGES OVER OTHER DRUGS BEING CLINICALLY INVESTIGATED FOR CELIAC DISEASE

Immunomodulators

Gluten Modification

IMGX-003



TAK-062



E40



Immunotolerance

CNP-101/TAK-101



TMP502



KAN-101



TAK227/ZED1227



DONQ52



Gut Healing

IMU-856



Single targeting

IL-15 → CALY-002



IL 15 → Ordesekimab



IL 15 → TEV-53408



OX40L amltelimab



Multi targeting

CD122 (IL-2/IL-15) → FB102

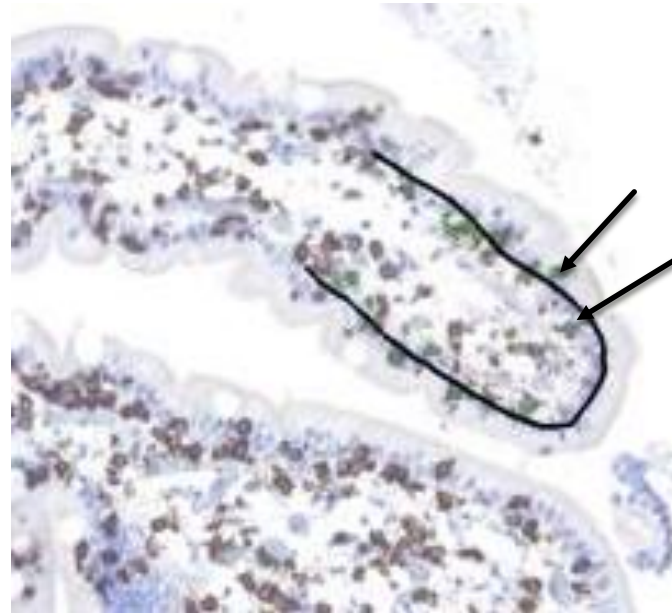
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IL15/IL-21 → EQ-102



CELIAC DISEASE MORPHOLOGIC AND HISTOLOGICAL MEASUREMENTS IN CELIAC DISEASE

INTRAEPIHELIAL LYMPHOCYTES ARE MEDIATORS OF DAMAGE TO VILLI IN CELIAC DISEASE

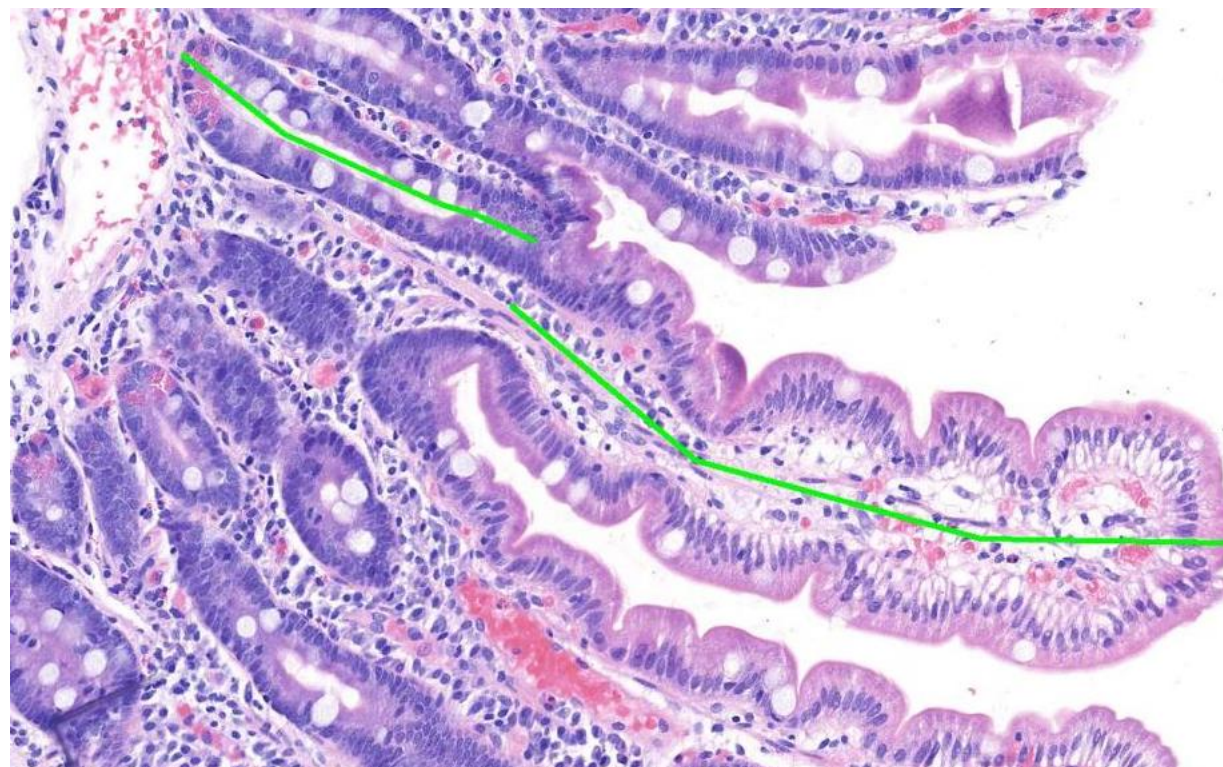


- Intraepithelial lymphocyte (IELs) are CD3⁺T cells that infiltrate the villus upon gluten challenge in celiac disease leading to villus atrophy
- IEL count is measured as a density of CD3⁺ T cells per 100 enterocytes
- Subjects with celiac disease typically have IEL count density of 20-30 and can increase 30%+ on exposure to gluten

Taavela J, PLoS One. PMID: 24146832; PMCID: PMC3795762.

Rostami K Gut. 2017 Dec; PMID: 28893865; PMCID: PMC5749338.

VILLUS HEIGHT TO CRYPT DEPTH RATIO (VH:CD)



- Villus height to crypt depth (Vh:Cd) ratio measures morphological damage due to IEL infiltration after gluten exposure in celiac disease
- Vh:Cd ratio in patients with CeD is ~2.0-3.0 when the patients are on Gluten Free Diet

COMPOSITE HISTOLOGICAL SCALE FOR CELIAC DISEASE

Clinical Gastroenterology and Hepatology 2024;22:1238–1244

A Composite Morphometric Duodenal Biopsy Mucosal Scale for Celiac Disease Encompassing Both Morphology and Inflammation



Jack A. Syage,¹ Markku Mäki,² Daniel A. Leffler,³ Jocelyn A. Silvester,³ Jennifer A. Sealey-Voyksner,¹ Tsung-Teh Wu,⁴ and Joseph A. Murray⁴

¹ImmunogenX, Inc, Newport Beach, California; ²Faculty of Medicine and Health Technology, Tampere University, Tampere, Finland; ³Celiac Disease Research Program, Harvard Medical School, Boston, Massachusetts; and ⁴Mayo Clinic, Rochester, Minnesota

Findings:

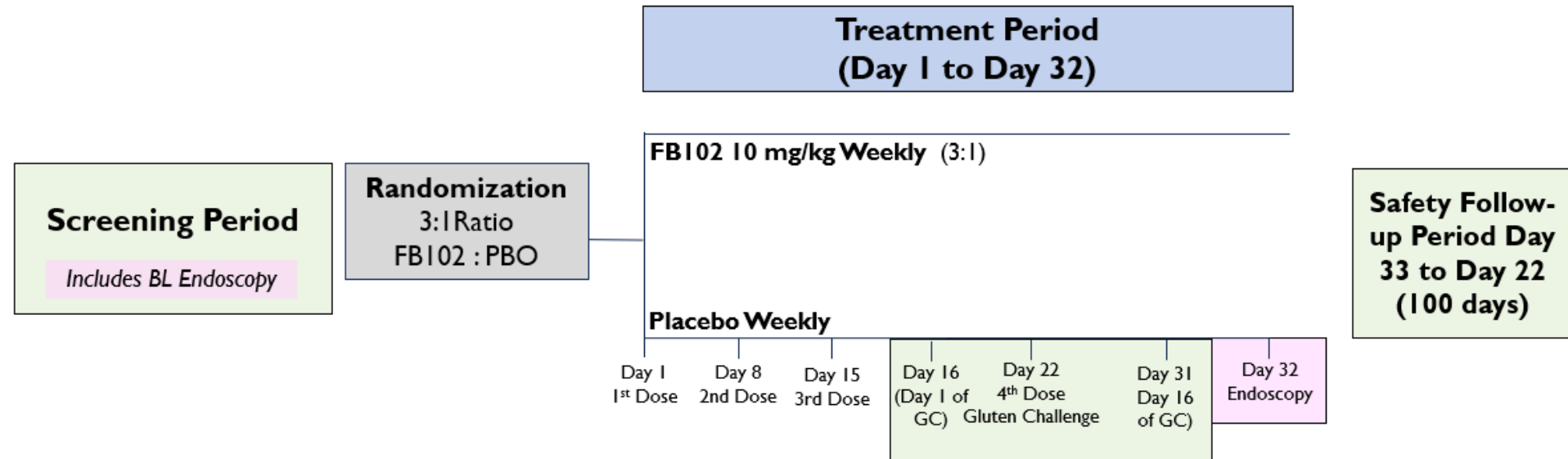
A composite scale VCIEL comprising individual subject values for Vh:Cd and IEL with equal weighting appears to offer better accuracy and statistical precision, particularly for population analysis in clinical trials, as well as potentially offering a broader measure of mucosal health.

$$VCIEL = \left[\frac{Vh:Cd - \langle Vh:Cd \rangle}{\sigma_{Vh:Cd}} - \frac{IEL - \langle IEL \rangle}{\sigma_{IEL}} \right]$$



FBI02 PHASE 1B CELIAC DISEASE STUDY

CELIAC DISEASE PHASE I B DESIGN



- 32 subjects were enrolled at 9 sites (AUS/NZ)
- Randomized 3:1 to FBI02 vs PBO (24:8)
- Subjects received 3 of 4 doses of either FBI02 (10mg/kg) or placebo then began 16 day gluten challenge (2g,4g, 8g for 14 days)
 - 4th dose of either FBI02 or placebo on day 22
- Endoscopy/biopsy at baseline and at end of gluten challenge (central review of histology endpoints)
- Gluten challenge symptoms collected in patient diaries/AE reporting
- All subjects completed day 32 biopsy

BASELINE DEMOGRAPHICS

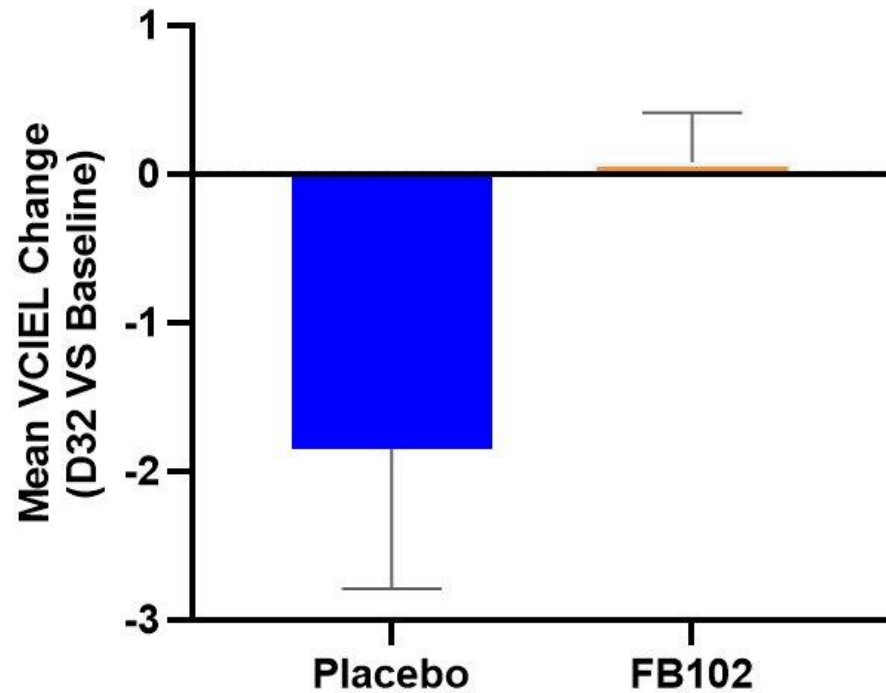
Parameter		Placebo N=8	FB102 N=24	Overall N=32
Age (Years)	Mean	38.3	40.8	40.1
Sex [n (%)]	Female	5 (62.5%)	19 (79.2%)	24 (75.0%)
	Male	3 (37.5%)	5 (20.8%)	8 (25.0%)
Ethnicity [n (%)]	Hispanic or Latino	0	0	0
	Not Hispanic or Latino	7 (87.5%)	23 (95.8%)	30 (93.8%)
	Not Reported	1 (12.5%)	1 (4.2%)	2 (6.3%)
	Unknown	0	0	0
Body Mass Index (kg/m ²) at Screening	Mean	25.61	24.8	25
Baseline Villus height to Crypt depth ratio	Mean	2.756	2.818	
	Standard error of mean	0.1398	0.1099	
Baseline CD3 positive IELs per 100 enterocyte	Mean	25.6	23.5	
	Standard error of mean	3.83	1.68	



**FBI02 DEMONSTRATES SIGNIFICANT BENEFIT IN PHASE 1B
CELIAC DISEASE STUDY**

FBI02 DEMONSTRATES STATISTICALLY SIGNIFICANT COMPOSITE HISTOLOGY (VCIEL) BENEFIT COMPARED TO PLACEBO

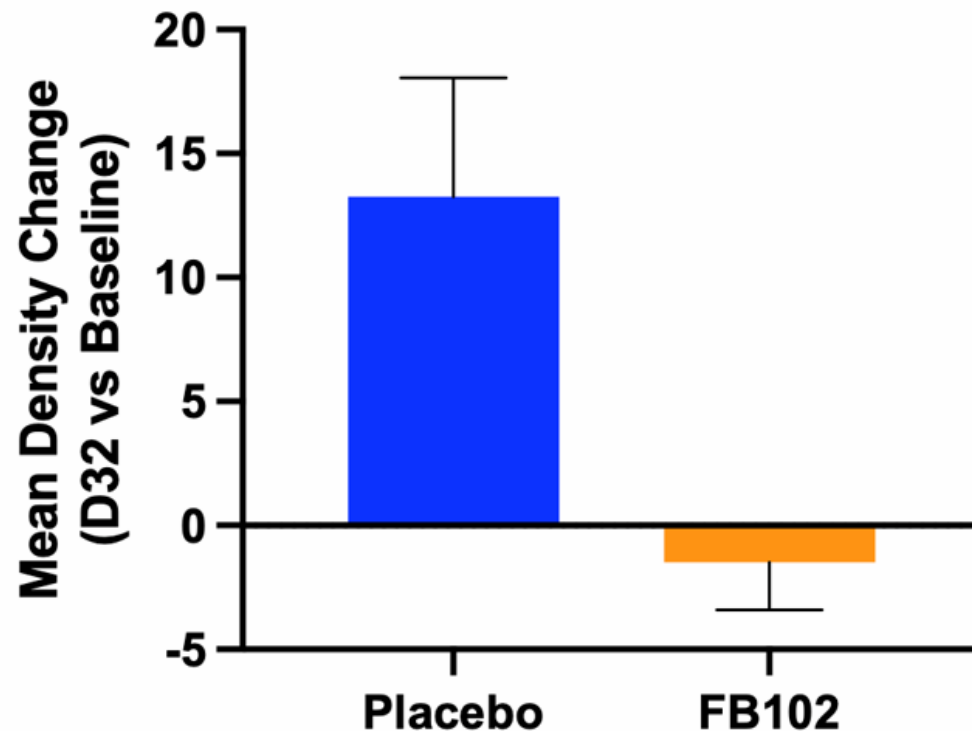
Change in VCIEL Composite Histology Score



Day 32 vs baseline VCIEL composite score -1.849 for PBO compared to 0.079 for FBI02 treated subjects ($p=0.0099$)

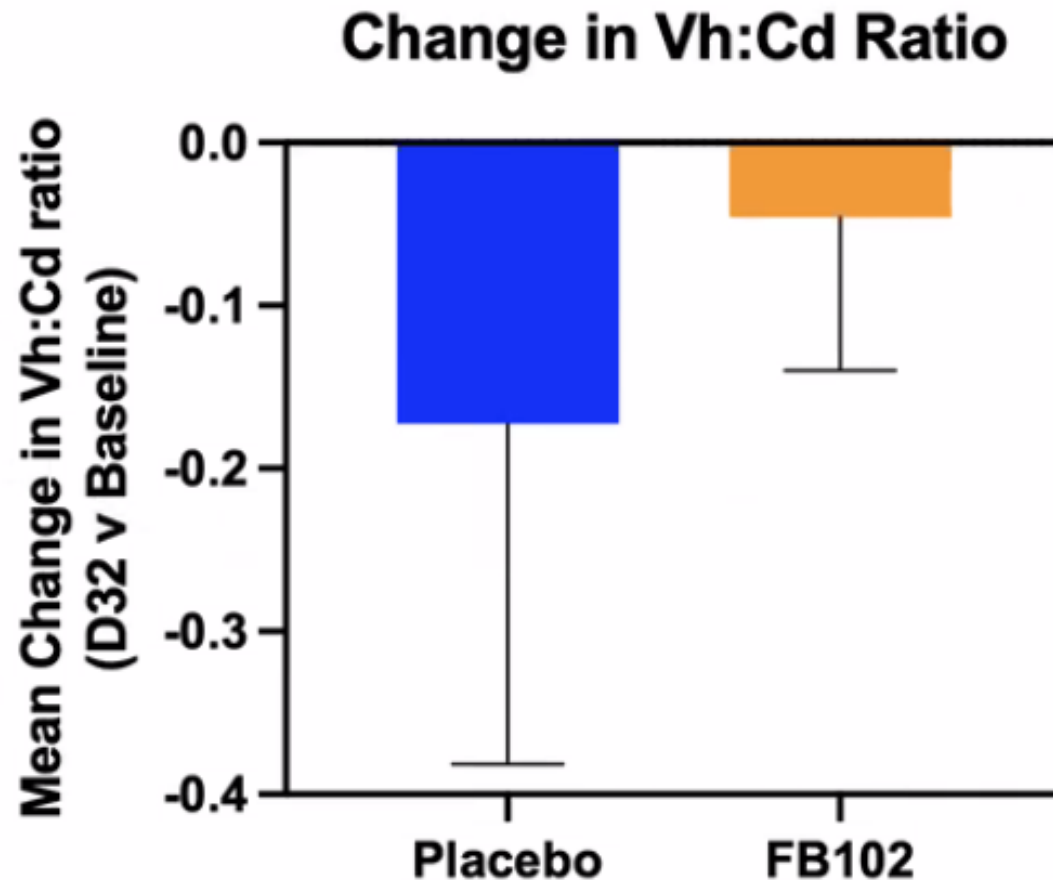
FBI02 DEMONSTRATES STATISTICALLY SIGNIFICANT DIFFERENCE IN CHANGE IN IEL DENSITY COMPARED TO PLACEBO

Change in IEL Density (Per 100 Enterocytes)



Day 32 vs baseline mean IEL density increase of 13.3 for PBO compared to a decrease of 1.5 for FBI02 treated subjects (p=0.0035)

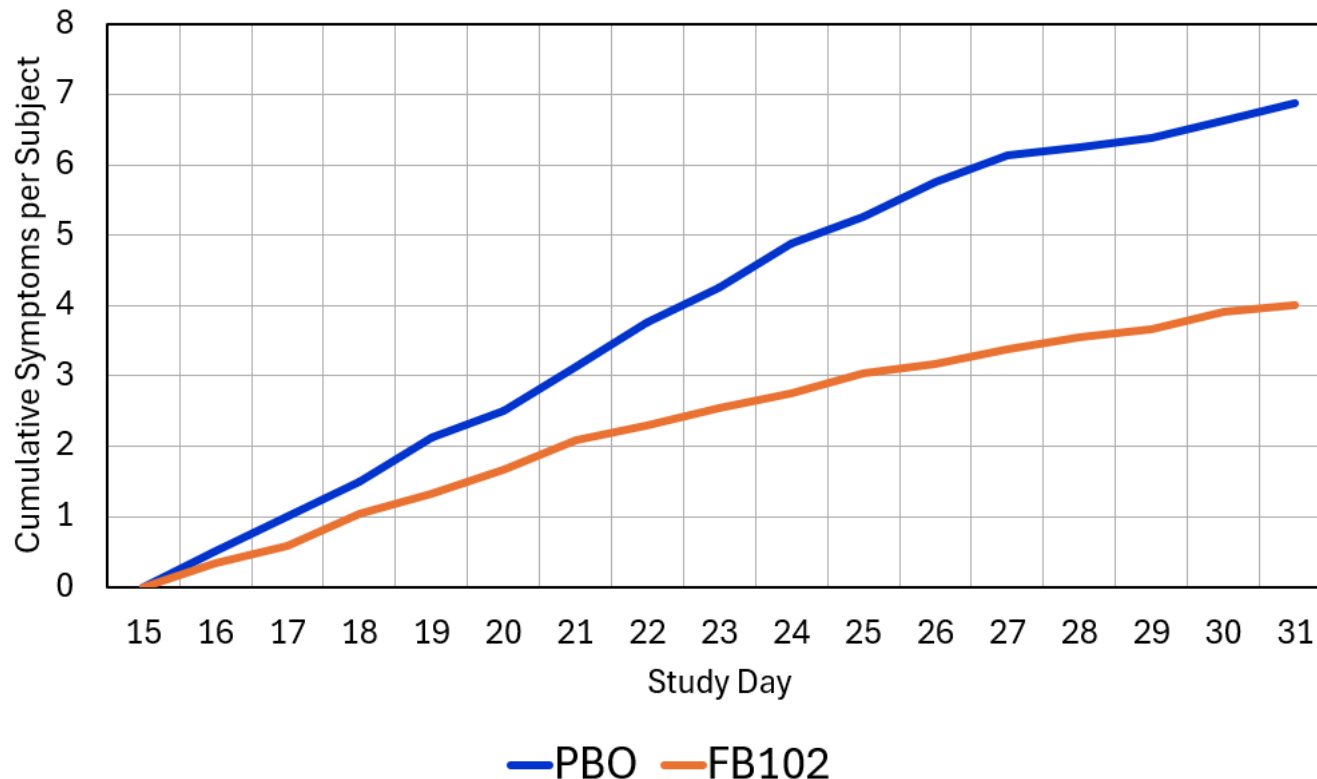
VH:CD RATIO IMPROVEMENT OBSERVED FOR FB102 VS PLACEBO



Day 32 vs baseline Vh:Cd ratio improvement of 73% for FB102 (-0.046) compared to PBO (-0.173)

FBI02 DEMONSTRATED GLUTEN CHALLENGE SYMPTOM EVENT BENEFIT VS PLACEBO

Cumulative Symptom per Subject during the Gluten Challenge
by study day for Placebo and FB102
Placebo N = 8, FB102 N=24



Gluten challenge (GC) symptoms reported in patient diaries/AE collection

GC induced GI symptoms tracked: nausea, diarrhea, vomiting, abdominal pain, abdominal bloating

Through the 16 day gluten challenge FBI02 demonstrated a 42% symptom benefit vs placebo (average of 6.9 events per subject on placebo compared to 4.0 events per subject on FBI02)



FB I 02 PHASE IB CELIAC DISEASE STUDY
SAFETY SUMMARY

FBI 02 GENERALLY SAFE AND WELL TOLERATED

Treatment Emergent Adverse Events By Grade

	Placebo (N=8)		FBI02 (N=24)		Overall (N=32)	
	n (Participant Count)	%	n (Participant Count)	%	n (Participant Count)	%
All Any Grade	8	100.0%	23	95.8%	31	96.9%
Grade 1 (Mild)	8	100.0%	22	91.7%	30	93.8%
Grade 2 (Moderate)	6	75.0%	9	37.5%	15	46.9%
Grade 3 (Severe)	1	12.5%	0	0.0%	1	3.1%

FBI 02 GENERALLY SAFE AND WELL TOLERATED

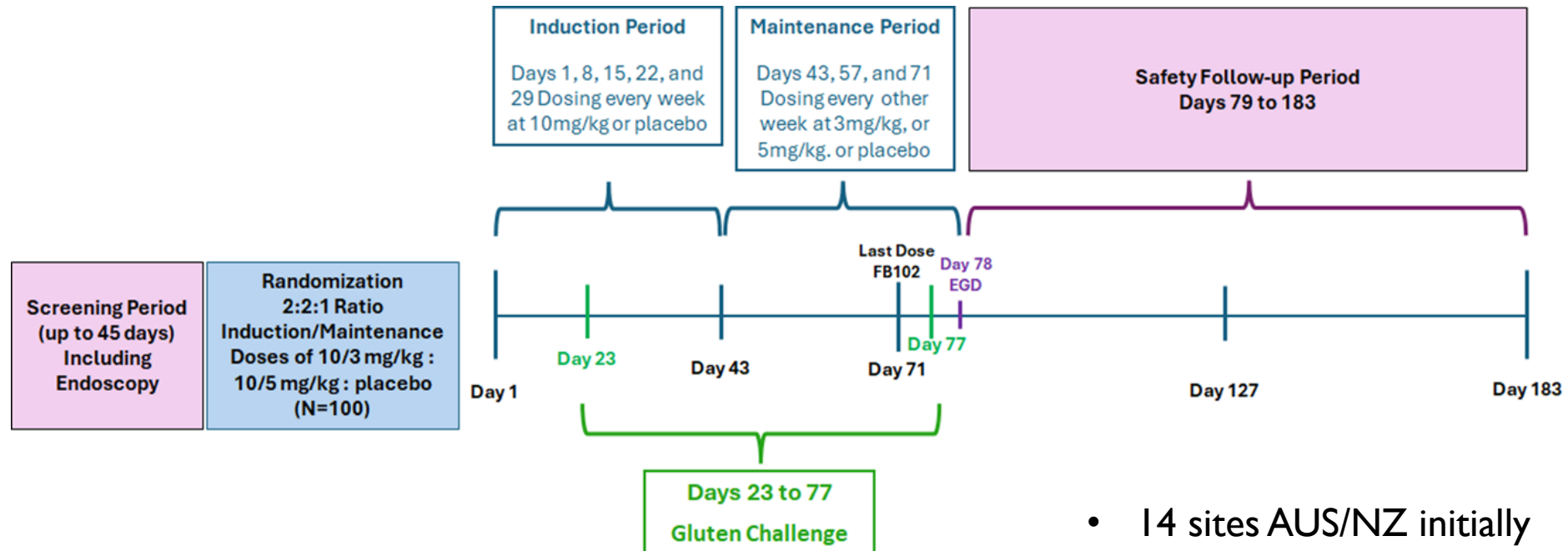
Treatment Emergent Adverse Events By Organ Class

System Organ Class Summary	Placebo (N=8)		FBI02 (N=24)		Overall (N=32)	
	n (Participant Count)	%	n (Participant Count)	%	n (Participant Count)	%
Participants with at least one TEAE	8	100.0%	23	95.8%	31	96.9%
Gastrointestinal disorders	7	87.5%	21	87.5%	28	87.5%
Nervous system disorders	5	62.5%	10	41.7%	15	46.9%
General disorders and administration site conditions	2	25.0%	5	20.8%	7	21.9%
Infections and infestations	3	37.5%	4	16.7%	7	21.9%
Metabolism and nutrition disorders	2	25.0%	2	8.3%	4	12.5%
Musculoskeletal and connective tissue disorders	1	12.5%	2	8.3%	3	9.4%
Blood and lymphatic system disorders	2	25.0%	0	0.0%	2	6.3%
Psychiatric disorders	1	12.5%	1	4.2%	2	6.3%
Respiratory, thoracic and mediastinal disorders	2	25.0%	0	0.0%	2	6.3%
Ear and labyrinth disorders	0	0.0%	1	4.2%	1	3.1%
Vascular disorders	0	0.0%	1	4.2%	1	3.1%



**CELIAC DISEASE FB102
PHASE 2 TRIAL OVERVIEW**

CELIAC DISEASE PHASE 2 DESIGN



Study Day	Amount of Gluten (grams)
Day 1 to 22	0 grams of gluten per day
Days 23 to 36	8 grams of gluten per day
Days 37 to 77	3 grams of gluten per day
Day 78	EGD

- 14 sites AUS/NZ initially
- Initiation in 2H25
- US IND expected late 2025/early 2026
- Topline data readout expected in 2026



DEVELOPMENT TIMELINES

FBI02 PROPOSED 12 MONTH CLINICAL DEVELOPMENT

Celiac Disease

Phase 1b

Initiation 3Q24

Positive Topline readout in June 2025

Phase 2

Initiation 2H25

Topline data expected in 2026

Vitiligo

Phase 1b Study

Initiated 1H25

Topline data expected 1H26

Phase 2

Initiation 2026

Alopecia Areata

Phase 2

Initiation 2026

Type 1 Diabetes

Evaluating study design and initiation



SUMMARY

CLINICAL STAGE FB-102

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