Entera Bio

Global Leader in Oral Peptide Therapeutics

Corporate Presentation

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Entera Highlights

- **First-in-Class Oral Peptide and Protein Replacement Therapies**
- **Proprietary N-Tab™ Platform Stabilizes Peptide in GI Tract and Facilitates Systemic Absorption**
- **Tablet Format Designed to Unlock Patient Acceptance and Drive Superior Health Outcomes**
- **Programs across GYN/Endocrinology, GI and Metabolic Diseases (Validated Peptide Targets)**
- **EB613 is the first daily PTH (1-34) osteoanabolic tablet treatment in development to address treatment chasm in ~40% of 200 million osteoporosis patients globally (Phase 3, planned H2 2025)**
- Additional Programs:
  - **EB612: first oral PTH (1-34) peptide replacement therapy for hypoparathyroidism (Phase 1)**
  - **GLP-2 and GLP-1/Glucagon oral tablet programs with OPKO Health for SBS and Obesity (pre-clinical)**
- **Cash runway through H2 2026 – Nasdaq: ENTX**

Entera Oral Peptide Pipeline

Program	Indication	Target	Preclinical	Phase 1	Phase 2	Phase 3	Partner
EB613	Osteoporosis	PTH 1-34					
EB612	Hypoparathyroidism	PTH 1-34					
EB613	Stress Fractures	PTH 1-34					Investigator Sponsored Trial
GLP-2	Short Bowel Syndrome	Long Acting GLP-2					OPKO
OXM	Obesity / Metabolic	GLP-1 & Glucagon Agonist					OPKO

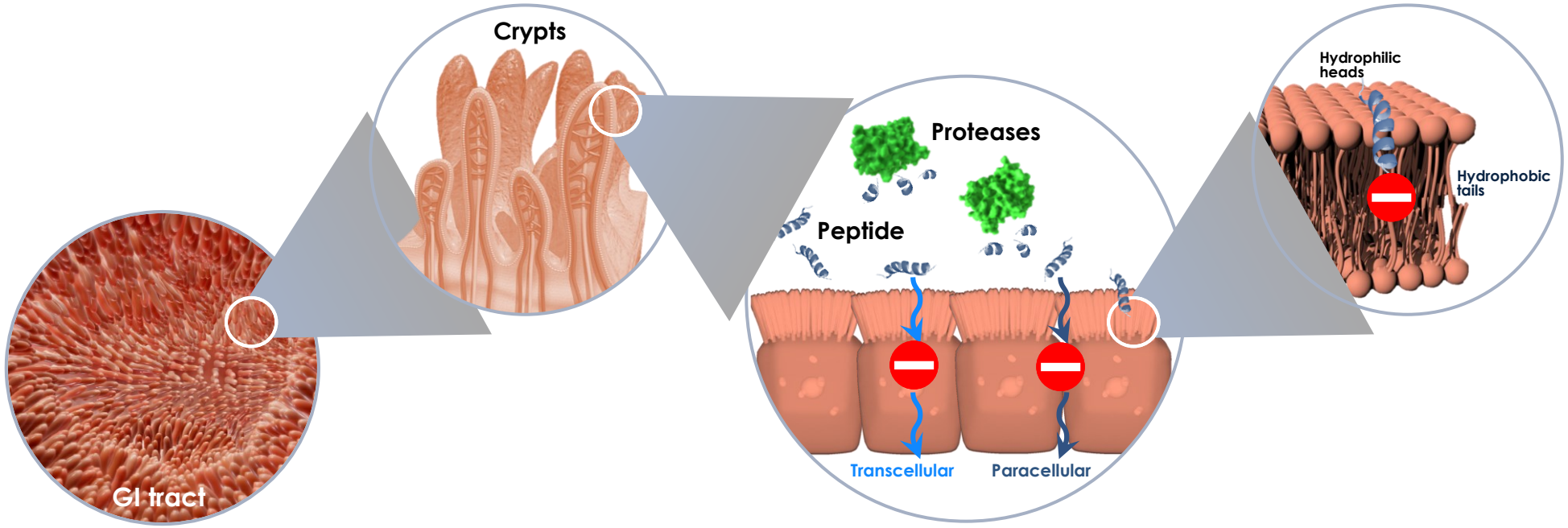
N-Tab™ Proprietary Platform

Oral Bioavailability of Therapeutic Peptides is Negligible

GI system is designed to breakdown proteins and peptides into amino acids

- Pepsin and acid environment (H+ ions) act in stomach
- Trypsin and α-chymotrypsin further degrade protein in intestinal lumen

Peptide drug absorption is limited by polarity (transcellular) and size (paracellular)



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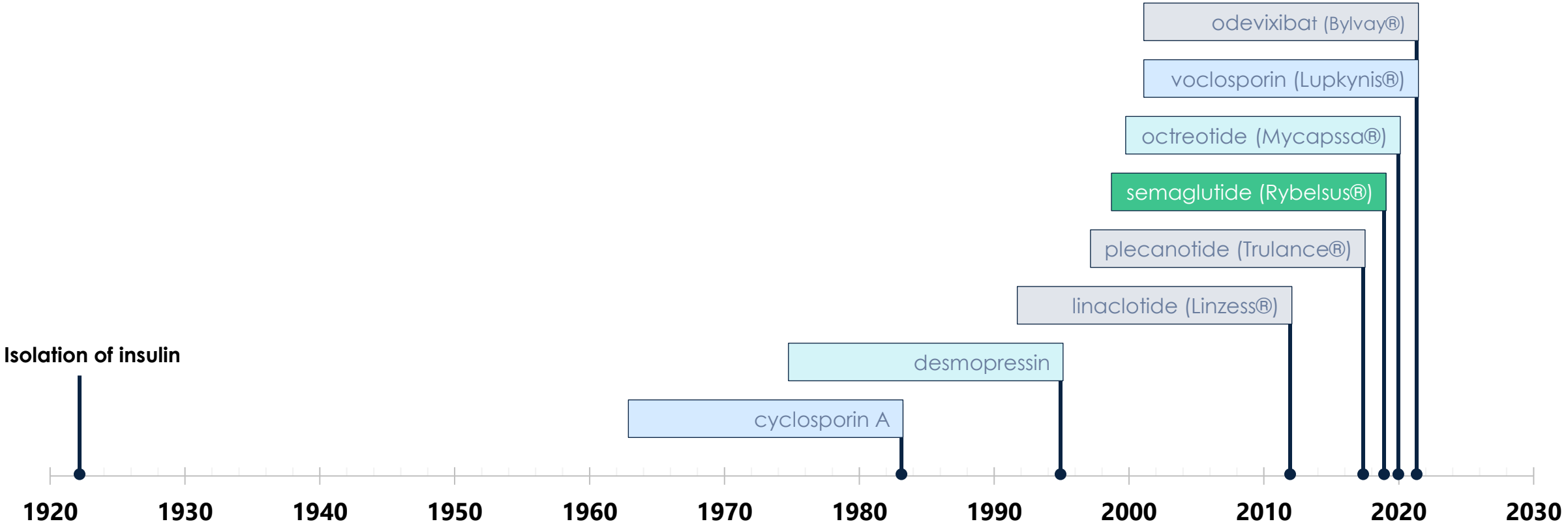
Oral Delivery of Peptide Drugs Has Lagged

Out of >80 approved injectable peptide therapies, there is only one approved oral peptide >4kDa (GLP-1, Rybelsus®)



Large linear hydrophilic peptides >4 kDa | Small lypophilic peptides | Peptides with local effect in GI tract | Small cyclic peptides ~1kDa

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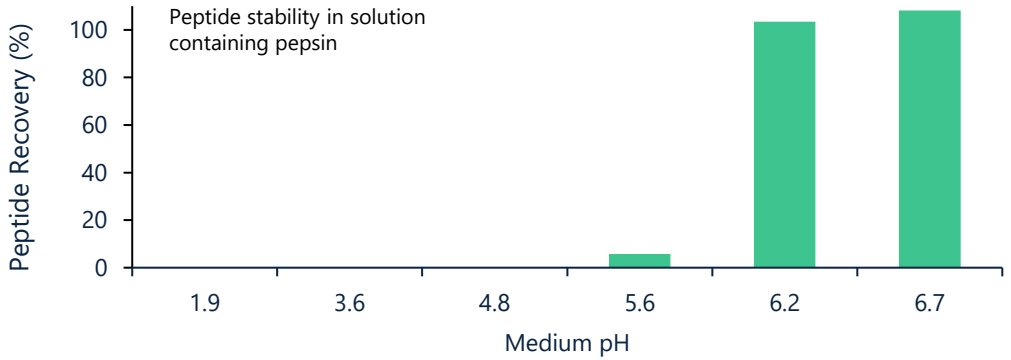
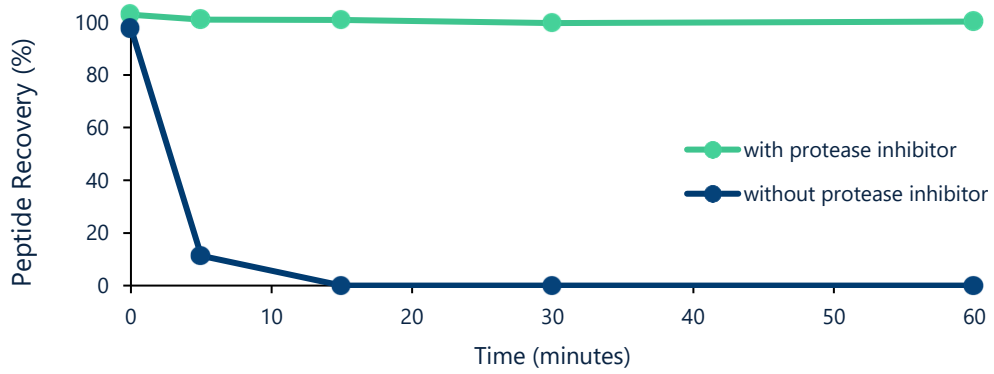
N-Tab™ Platform Inhibits Proteolysis in GI Tract and Enables Bioavailability

Proteolysis Inhibition

Locally Elevated Gastric pH Inactivates Pepsin

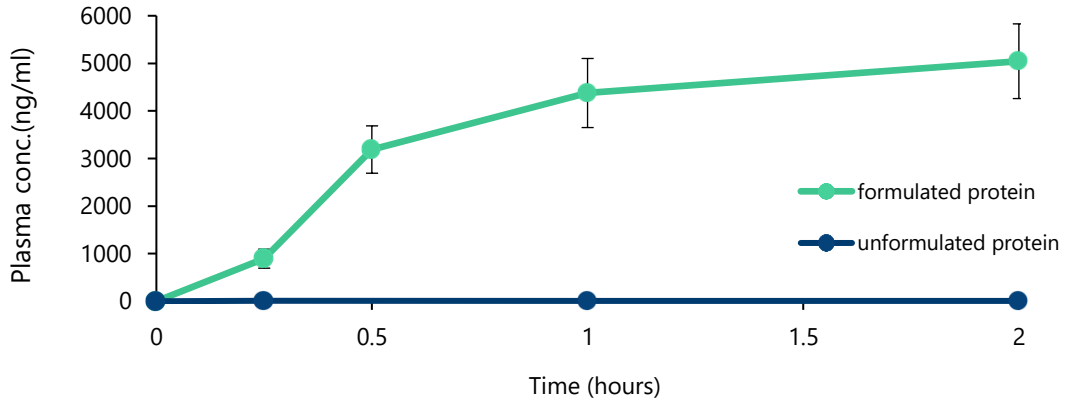


Protease Activity Inhibited

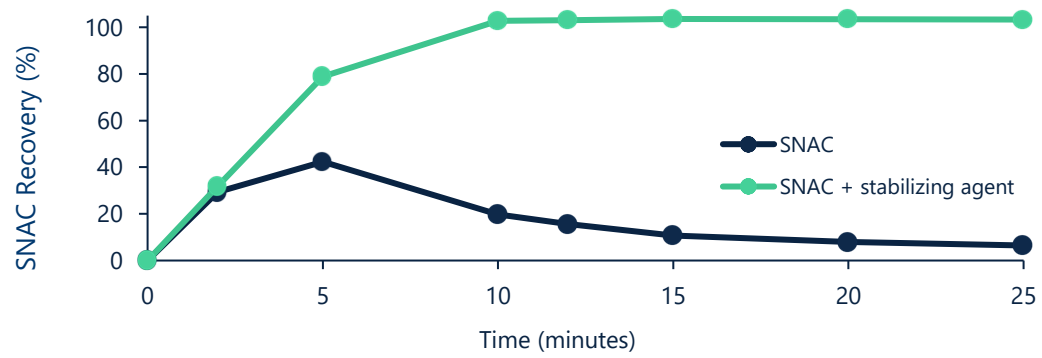


Absorption Enhancement

SNAC Increases Transcellular Absorption via Enterocyte Membrane



SNAC Further Stabilized to Enhance Activity



Note: SNAC (Salcaprozate sodium) increases gastric epithelial membrane fluidity without affecting tight junctions, thereby allowing transcellular passage into systemic circulation of the protein API. SNAC is a component of Novo Nordisk's Rybelsus® which has been approved by the FDA and EMA.

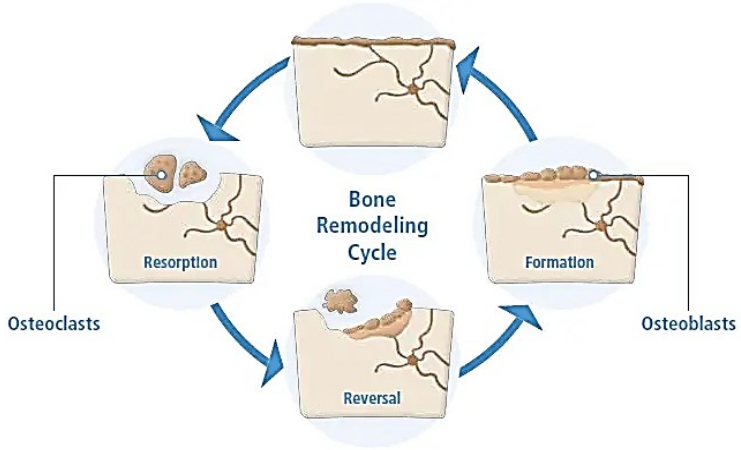
EB613 Oral PTH (1-34)

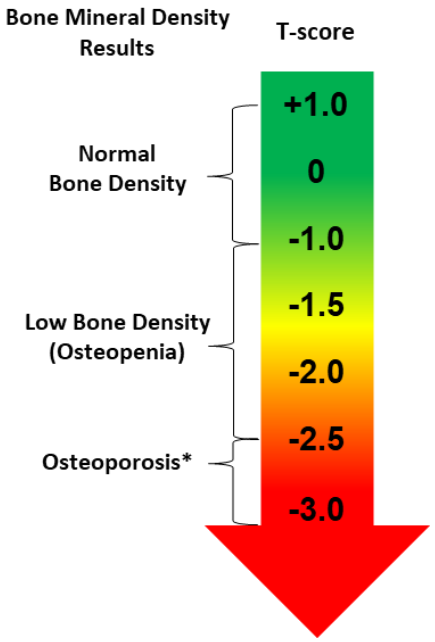
First Once Daily Osteoanabolic Tablet Treatment in development for Post-Menopausal Women at High Risk of Osteoporotic Fracture

Osteoporosis

- **Dysregulated Bone Remodeling and Increased Osteoclast Activity**
  - ↑ resorption (CTX biomarker), ↓ formation (P1NP biomarker)
- Osteoporosis is a chronic, debilitating and often lethal disease

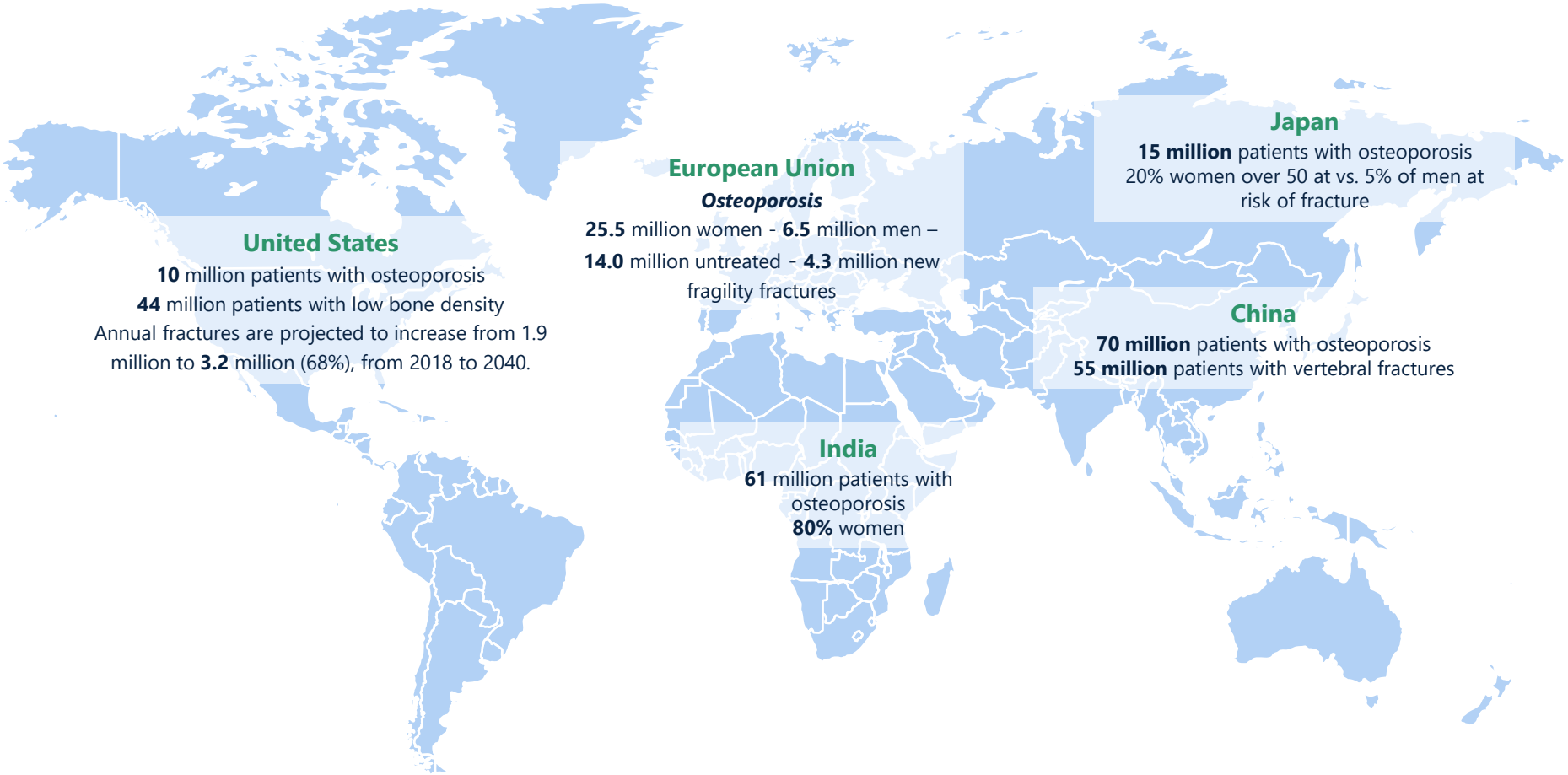
- **Diagnosed and Managed via Bone Mineral Density (BMD) T- Score**
  - Standard bone density test is used to measure bone mineral content and density
  - Non-invasive X-rays, dual-energy X-ray absorptiometry (DXA) scan to determine bone density of the hip, femur or spine
  - T-Score stages severity of low bone mass and osteoporosis





Globally, Osteoporosis Afflicts ~200 million Women

More than Heart Attack, Stroke, and Breast Cancer Combined



~50% of women over the age of 50 will experience an osteoporosis-related fracture

~1 billion women globally will enter menopause in the coming years

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Osteoporosis Treatment Chasm

Anabolic Agents are More Effective in High Risk Patients; Injectable Format Limits Patient Acceptance

Anti-Resorptive

1st Line

Bisphosphonates	SERMs	RANK-Ligand Inhibitor (SC)
Fosamax® *Alendronate*	**Evista®** *Raloxifene*	**Prolia®** *Denosumab*
Boniva® *Ibandronate Acid*		
Atelvia® & Actonel® *Risedronic Acid*		
Reclast® (IV) *Zoledronic Acid*		

EB613 Positioning

Low BMD at High Risk of Fracture
(*Phase 3 protocol design*)

EB613
Oral *PTH (1-34)*
Daily Tablets

Injectable Anabolic

1st Line Very High Risk
2nd Line, Intolerant to Other Tx

Monoclonal Antibodies	PTH receptor agonist
Evenity® *Romosozumab-apqg*	**Forteo®** *Teriparatide*
	Tymlos® *Abaloparatide*

- ~3 million patients are estimated to be treated in the U.S. with osteoporosis therapy
  - ~40% of patients are recommended to take anabolic treatment
  - ~10% of patients are estimated to be on an injectable anabolic agent
- **EB613 is positioned as the first oral anabolic treatment to support earlier intervention in post-menopausal women with high risk osteoporosis**

EB613 Phase 2 Results

A Six-Month Study of Oral PTH in Post-Menopausal Women with Low Bone Mass or Osteoporosis

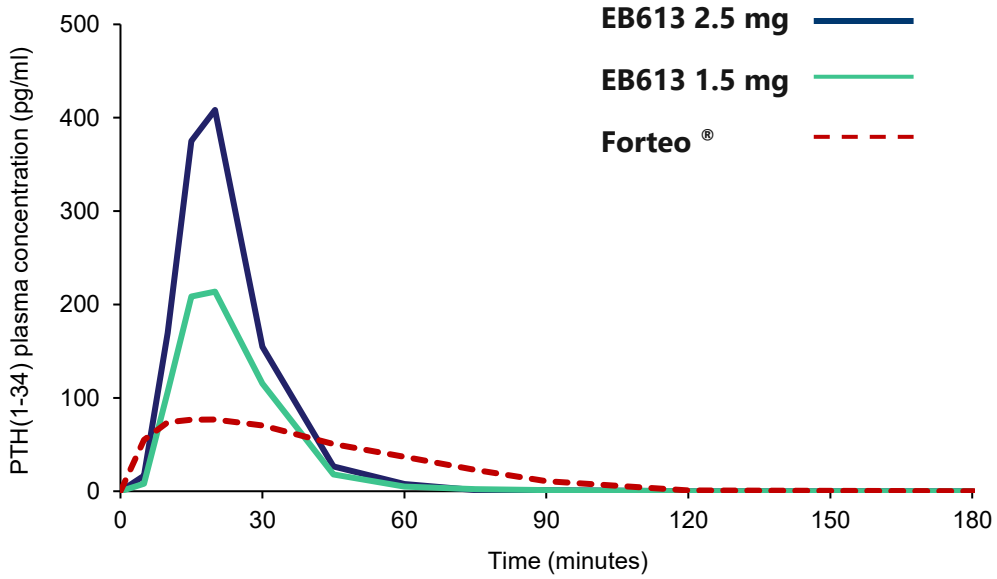
EB613 Oral PTH(1-34) Pharmacokinetics (PK)

EB613 consistently demonstrates rapid increases in PTH(1-34) plasma levels and robust bioavailability in Phase 1 and 2 studies

- Short absorption phase with Tmax similar to that observed with SC injection, Forteo®(≤20 minutes)
- Rapid elimination ($T_{1/2}$ of ~10 minutes) results in shorter duration of systemic exposure as compared to SC injection, Forteo® which has potential safety benefit
- Dose proportional increase in Cmax and AUC with EBP05 1.5mg and 2.5mg doses

PK parameters Measured Following Administration of 2.5 mg and 1.5 mg EB613 tablets, and Forteo® SC injection (0.02 mg)

Treatment	C_{max} (pg/ml; mean, SE)	AUC_{last} (pg/ml*min; mean, SE)	T_{max} (min, median, range)	T_{last} (min, median, range)
EBP05 1.5 mg	270 (109)	4590 (2200)	15 (10-20)	20 (10-90)
EBP05 2.5 mg	488 (122)	7590 (2000)	15 (10-20)	30 (20-90)
Forsteo® 0.02 mg	89.3 (10.5)	4080 (466)	20 (5-45)	75 (30-120)



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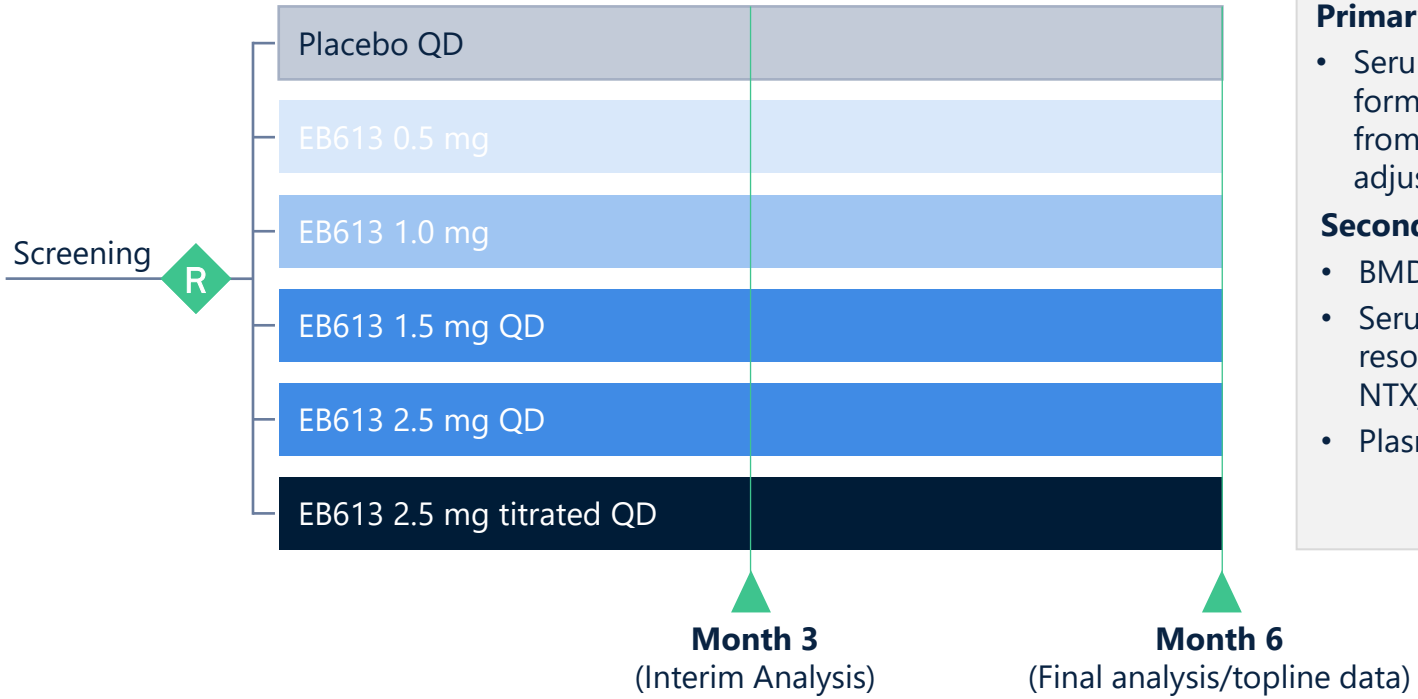
EB613 Phase 2 Clinical Study Design

Key Inclusion Criteria
- 50+ years old
- 3+ years post-menopause
- Low bone mass
- High risk; no prior fracture

Key Exclusion Criteria
- Osteoporosis treatment within last 2 years
- Severe osteoporosis that precludes placebo

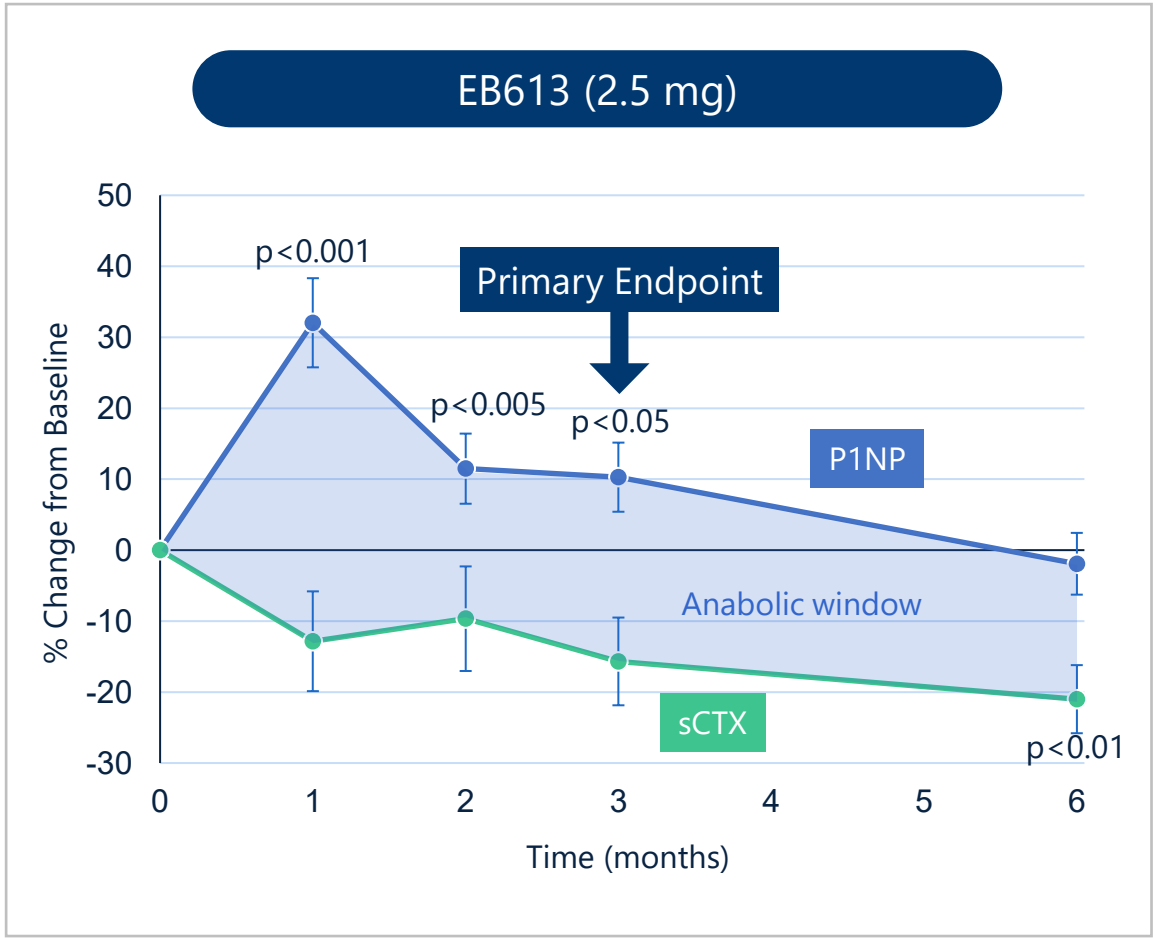


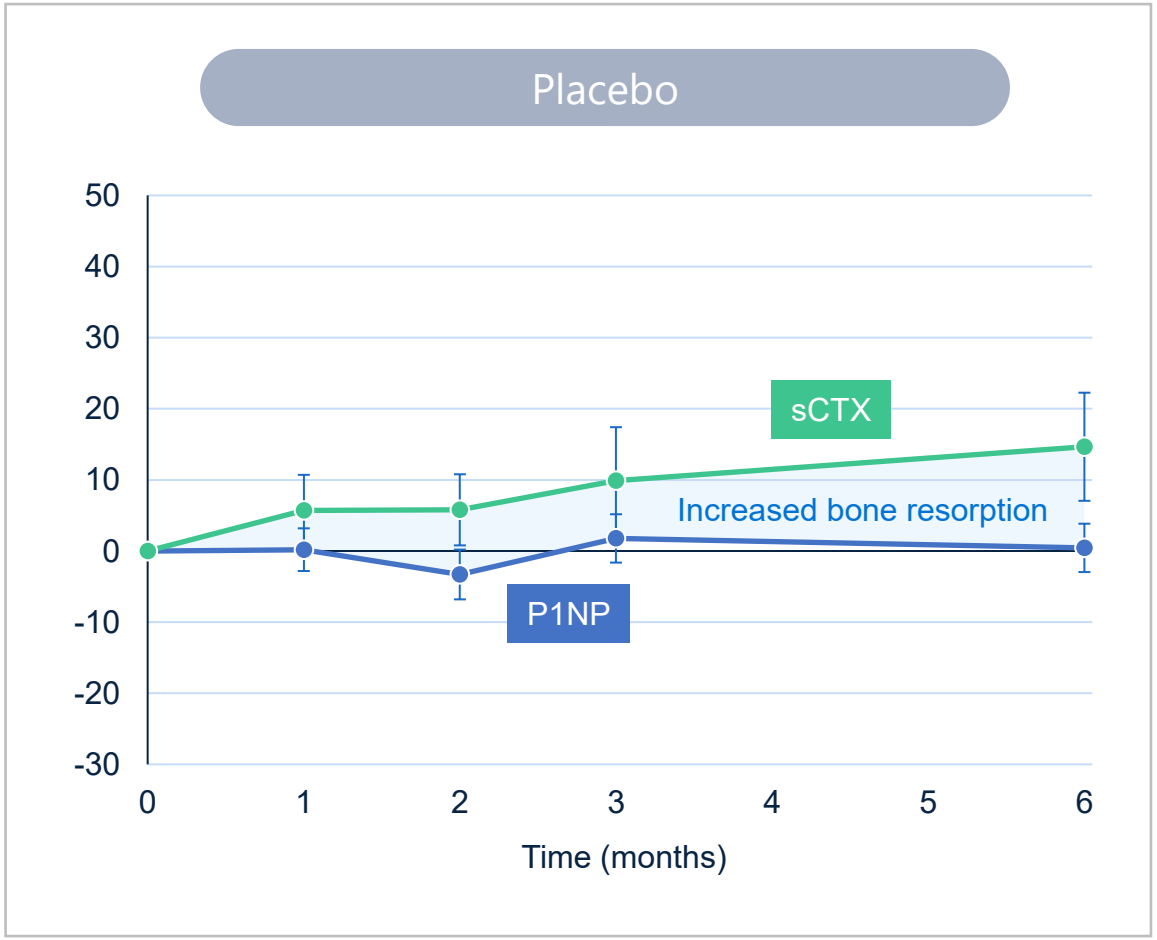
Primary Endpoint
- Serum P1NP (key bone formation marker) change from baseline (placebo-adjusted) at Month 3

Secondary Endpoints
- BMD change from baseline
- Serum CTX (key bone resorption marker), urine NTX/creatinine
- Plasma hPTH (1-34) at T15 min

- 6-month, randomized, dose-ranging, placebo-controlled study in post-menopausal women with osteoporosis
- Conducted at 4 sites; Enrollment: 161 patients (118 active, 43 placebo)

Phase 2: Biochemical Markers of Bone Turnover Showed EB613 Distinct Profile of Increased Bone Formation (P1NP) and Reduced Bone Resorption(CTX)





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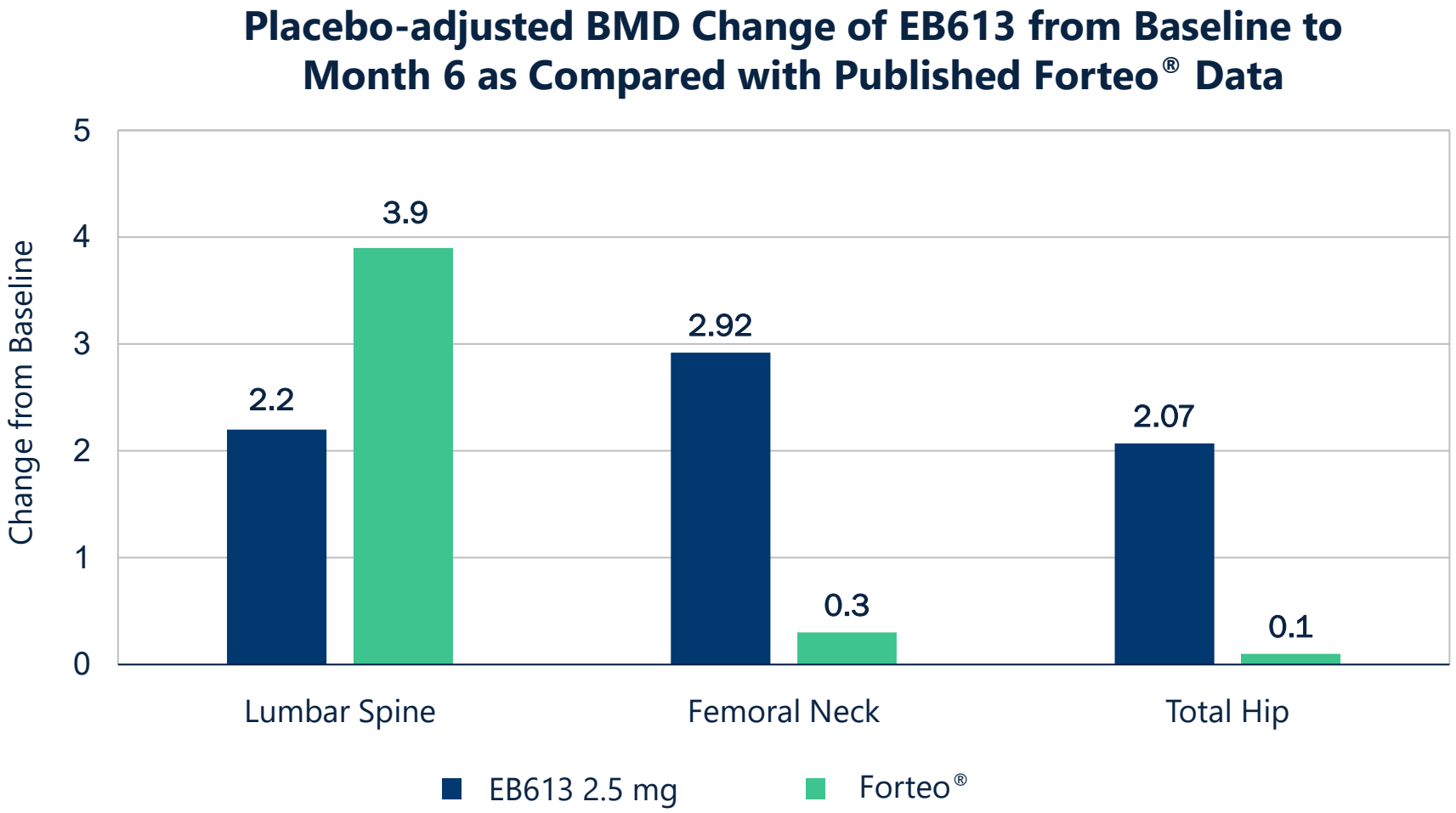
Phase 2: EB613 Increased BMD at All Major Skeletal Sites



Faster onset and greater increases of hip and femoral neck BMD vs. Forteo® in similar patient population open label study at month 6

- Forteo® data based on 20µg injection in open label ph2 study in a similar patient population at 6 months, cross trial comparison- Leder BZ et.al. JCEM (2015)
- EB613 data based on titrated 2.5mg tablets– Tripto-Shkolnik L et.al. JBMR (2024)

EB613 Safety Profile Consistent with PTH Targeted Injectables

Most Common Treatment Emergent AE (≥5% of participants)	EB613 Treated (N=118) n (%)
Headache	21 (17.8)
Nausea	18 (15.3)
Dizziness	13 (11.0)
Nasopharyngitis	7 (5.9)
Back pain	7 (5.9)
Palpitation	6 (5.1)
Dyspepsia	6 (5.1)
Presyncope	6 (5.1)

- Adverse event profile - similar to AE profile reported with Forteo® and typical of orthostatic hypotension
- EB613 was not associated with serum calcium increases or hypercalcemia adverse events
- 2.5 mg dose with titration (1.5mg for 1 month, 2.0mg for the next month and 2.5mg during months 3 to 6) well tolerated
- AEs commonly attributed to vasodilatation with subcutaneous injectable PTH were observed (headache, nausea, presyncope and dizziness)
- No serious AEs related to EB613

EB613 Phase 3 Study Design

Global Phase 3 24-Month Double-Blind Placebo-Controlled Registrational Study

ASBMR-Foundation for the National Institutes of Health (FNIH) Strategy to Advance BMD as a Regulatory Endpoint (SABRE)

Challenges Related to Osteoporosis Drug Development

- Fractures are the regulatory endpoint for all osteoporosis trials
- Ethical concern for high fracture risk patients to be potentially randomized to placebo (ECs/IRBs)
- Evaluation of moderate risk patients would require large studies to evaluate treatment effectiveness

Dearth in Osteoporosis Drug Development

- No new osteoporosis therapy has been approved since 2019

The use of treatment related change in bone mineral density (BMD) as a surrogate endpoint for fractures in future trials of new anti-osteoporosis drugs is now undergoing review at the FDA

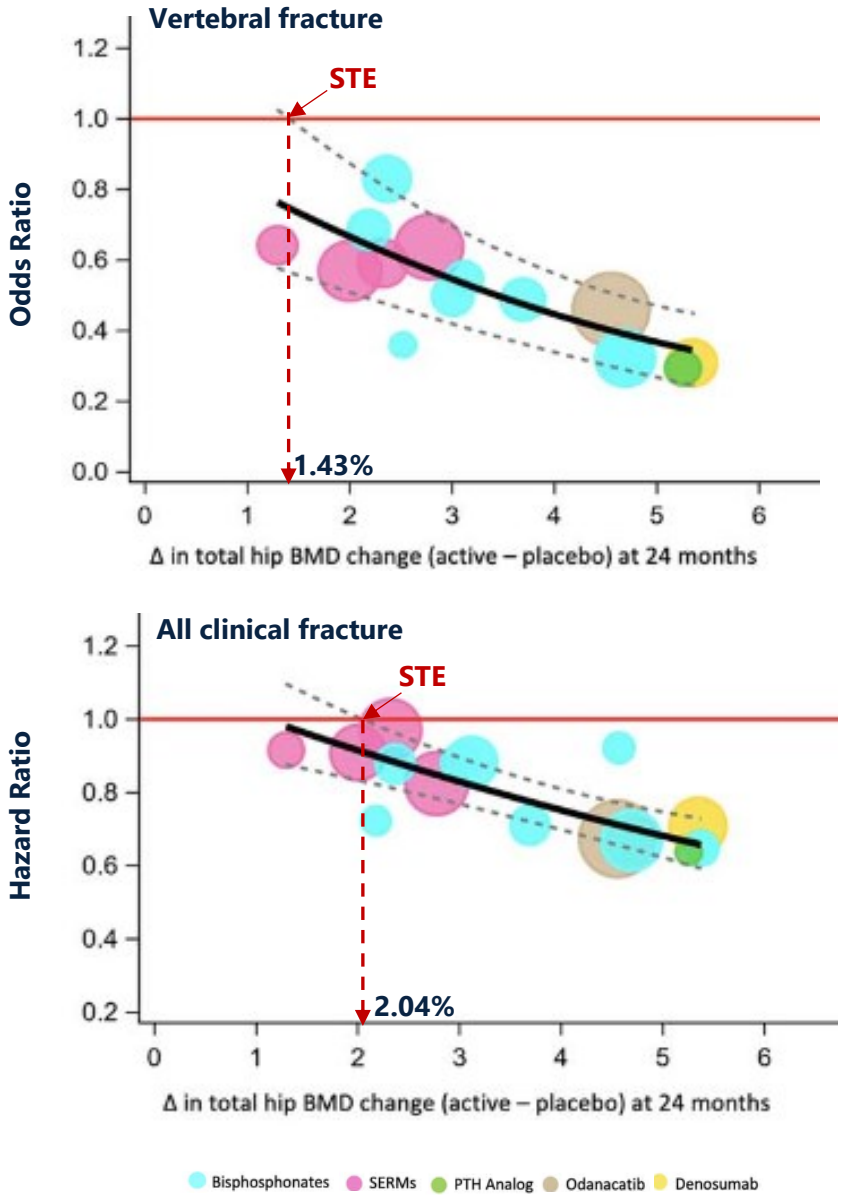
- **FDA qualification of the proposed BMD endpoint is expected by January 2025 – critical path for EB613 Phase 3 initiation**

Published Surrogate Threshold Effects (STE) Across Fracture Categories

- **The FNIH collected data from over 50 randomized trials and individual data from over 170,000 patients**
- **STEs depict the treatment difference in total hip BMD (active – placebo) at 24 months that are significantly associated with fracture risk reduction**

Fracture Category	Surrogate Threshold Effect (STE)*
Vertebral	**1.43%**
All clinical (non-vertebral + clinical vertebral)	**2.04%**
Non-vertebral	2.13%
Hip	3.07%

*24-month Interval for BMD changes (active – placebo)



Vilaca T Bone Miner Res. 2024; Black DM Lancet Diab & Endo 2020; Eastell R JBMR 2022

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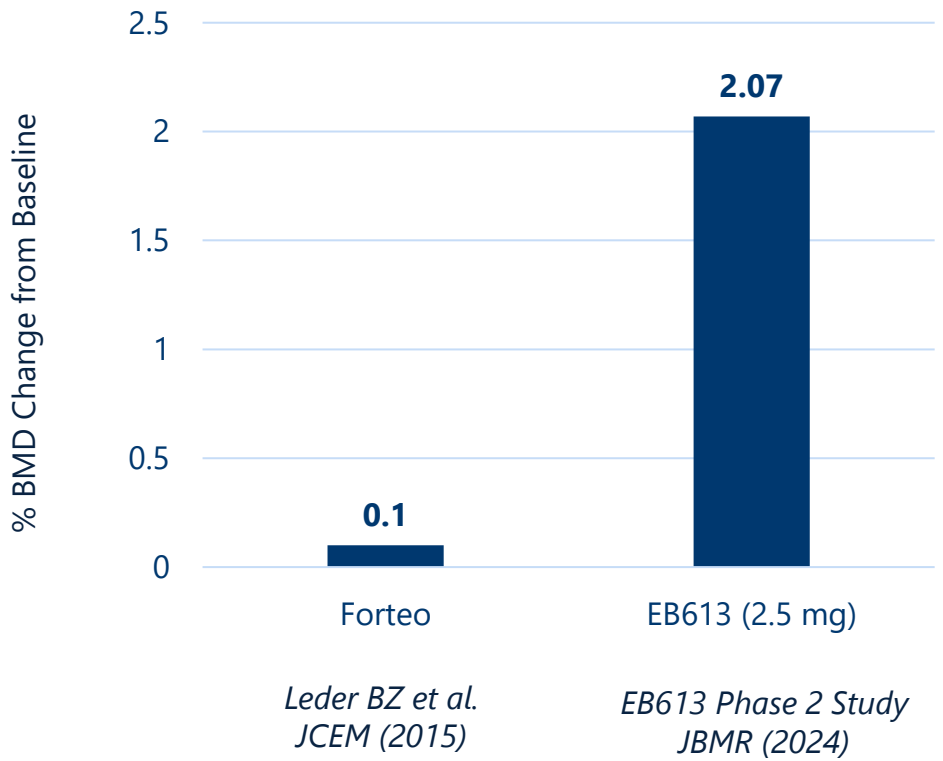
Proposed Primary Analysis for EB613 Phase 3 Study: Placebo Adjusted % Change in Total Hip BMD Employing SABRE STEs

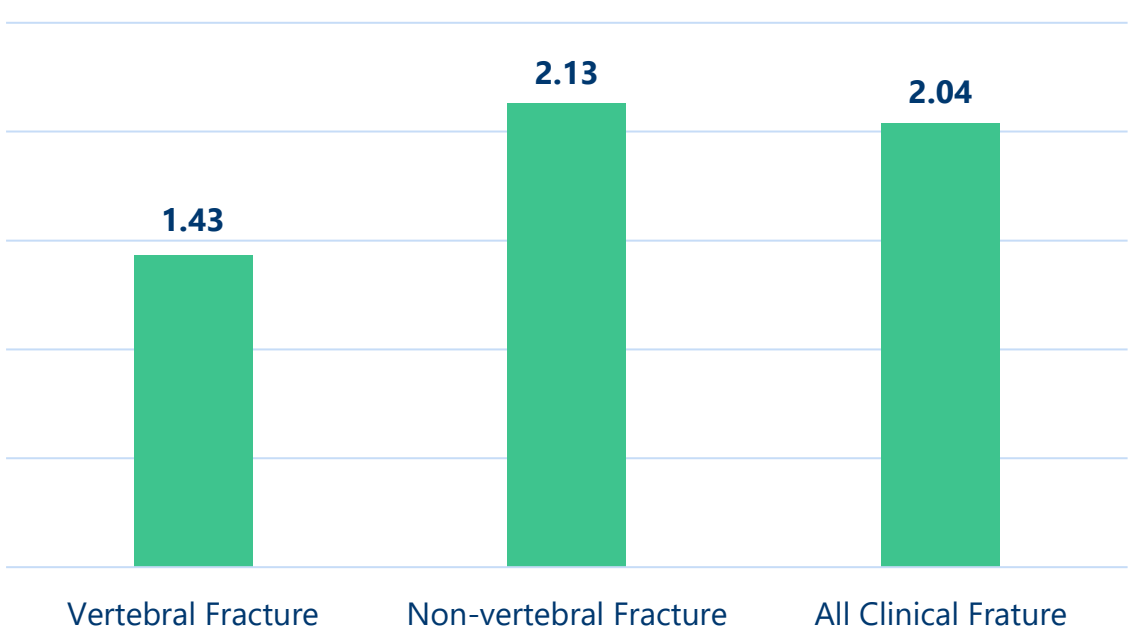
Total Hip BMD Change from Baseline at Month 6



Leder BZ et al. JCEM (2015)

EB613 Phase 2 Study JBMR (2024)

FNIH STE* Targets at Month 24 to be Used in EB613 Phase 3 Study



*ASBMR-Foundation for the National Institutes of Health (FNIH) Surrogate Threshold Effects (STE)

Proposed Multinational Randomized, Double-Blinded Placebo-Controlled Ph 3

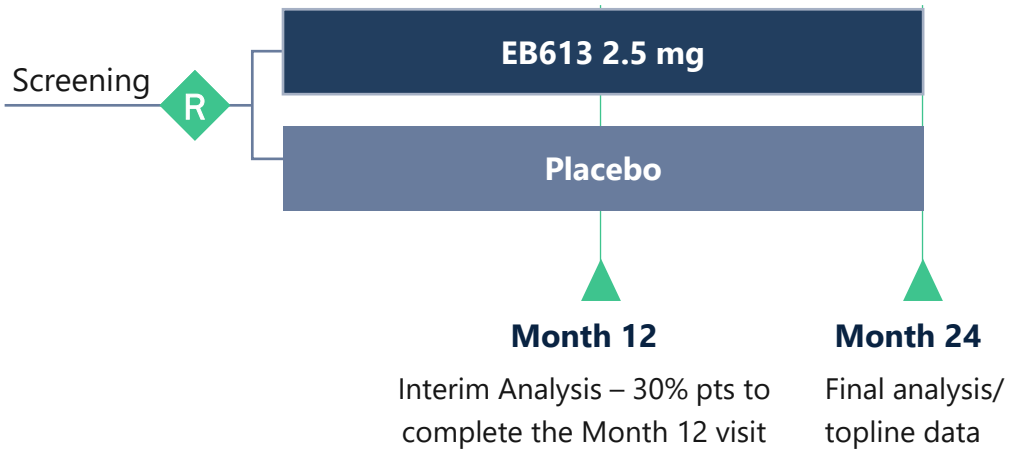
Study Design Overview for EB613 Schema*

Key Inclusion Criteria

- 50-80 years old
- 5+ years postmenopausal
- BMD T-score ≤ -2.5

Key Exclusion Criteria

- Very High risk for fracture
- Specified criteria for past use of agents affecting bone metabolism



Primary Efficacy Endpoint

- Treatment change in total hip BMD at Month 24 significantly associated with fracture risk reduction

Secondary Efficacy Endpoints

- Treatment change in LS, FN, TH BMD at Month 6,12,18, 24
- Substudies planned to evaluate bone quality and histomorphometry (bone biopsy) and changes in bone turnover markers

Safety Endpoints include

- Treatment-emergent AEs, changes in vital signs, and clinical labs
- Fracture outcomes at Months 12 & 24

- **24-month, double-blind, placebo-controlled registrational study in postmenopausal women with osteoporosis at high risk of fracture**

*Schema provided for study design. STE = Surrogate Treatment Effects; 24-month STEs are those reported by FNIH-ASBMR-SABRE (Vilaca T 2024).

EB612 Program

First Daily Oral PTH Replacement Therapy for the Treatment of Hypoparathyroidism

Hypoparathyroidism: PTH Dependent Orphan Indication

Background

- A rare condition in which the parathyroid glands fail to produce sufficient levels of PTH
- Approximately 200K -300K in the US, EU, and Japan
- PTH replacement therapy aimed to displace standard of care (calcium and vitamin D supplements) which results in severe long term co-morbidities (cardiovascular, renal, neurologic, and skeletal)

Competitive Landscape

- Natpara® (PTH(1-84)) injection will be permanently phased out globally by end of 2024 (Takeda)
- TransCon PTH, once-daily injectable, long-acting prodrug of parathyroid hormone (PTH(1-34)) developed by Ascendis Pharma FDA Approved (August 13 2024); EU Approved (November 20, 2023)
- Eneboparatide, once-daily injectable long-acting parathyroid hormone 1 (PTH1) receptor agonist, developed by Amolyt Pharma (acquired by AstraZeneca for $1BN 2024) Phase 3 (Topline data H1 2025E)
- Long acting once weekly injectable PTH peptide prodrug (MBX2109, Ph2 Avail™ topline data Q3 2025E), oral small molecule PTHR1 (SEP786, Septerna)

EB612: Oral PTH (1-34) Daily Tablets for Hypoparathyroidism

Study Design

Phase 2a, open-label, 16 week, multicenter pilot study to evaluate the safety, tolerability and PK (NCT02152228)

Population: N=19 with hypoPT ≥ 1 year, taking ≥1 g/day calcium and 25(OH)D 20 ng/ml

Treatment: first 3 doses of EB612 0.75 mg QID administered at research center; then self administered

Results

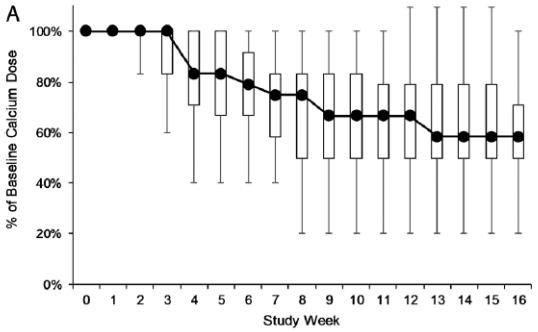
Efficacy:

- **42% reduction (p=0.001) from baseline in median calcium supplement use**
- **Maintenance of median Ca levels above the lower target level for hypoparathyroidism patients (>7.5 mg/dL) throughout the study**
- **Rapid decline of 23% (p=0.0003) in median serum phosphate levels 2 hours post first dose maintained for the duration of the study**

Safety:

- One subject experienced 4 AEs and left the study after the first day
- One subject experienced an unrelated SAE prior to the administration of the first dose

Oral Calcium Intake
Per Protocol Analysis (N=15)



Phase 1 Study Results Of EB612, A First-in-Class Oral PTH(1-34) Analog For The Treatment Of Hypoparathyroidism (June 2024, ENDO2024 Poster)

- Study tested a new generation of N-Tab™ with PTH(1-34) dosed twice a day (BID) in healthy volunteers (n=15)
- Significant systemic exposure was reported following both administrations of EB612 tablets with PD effects (serum levels of calcium (albumin corrected), phosphate, and 1,25(OH)2-Vitamin D, endogenous PTH)

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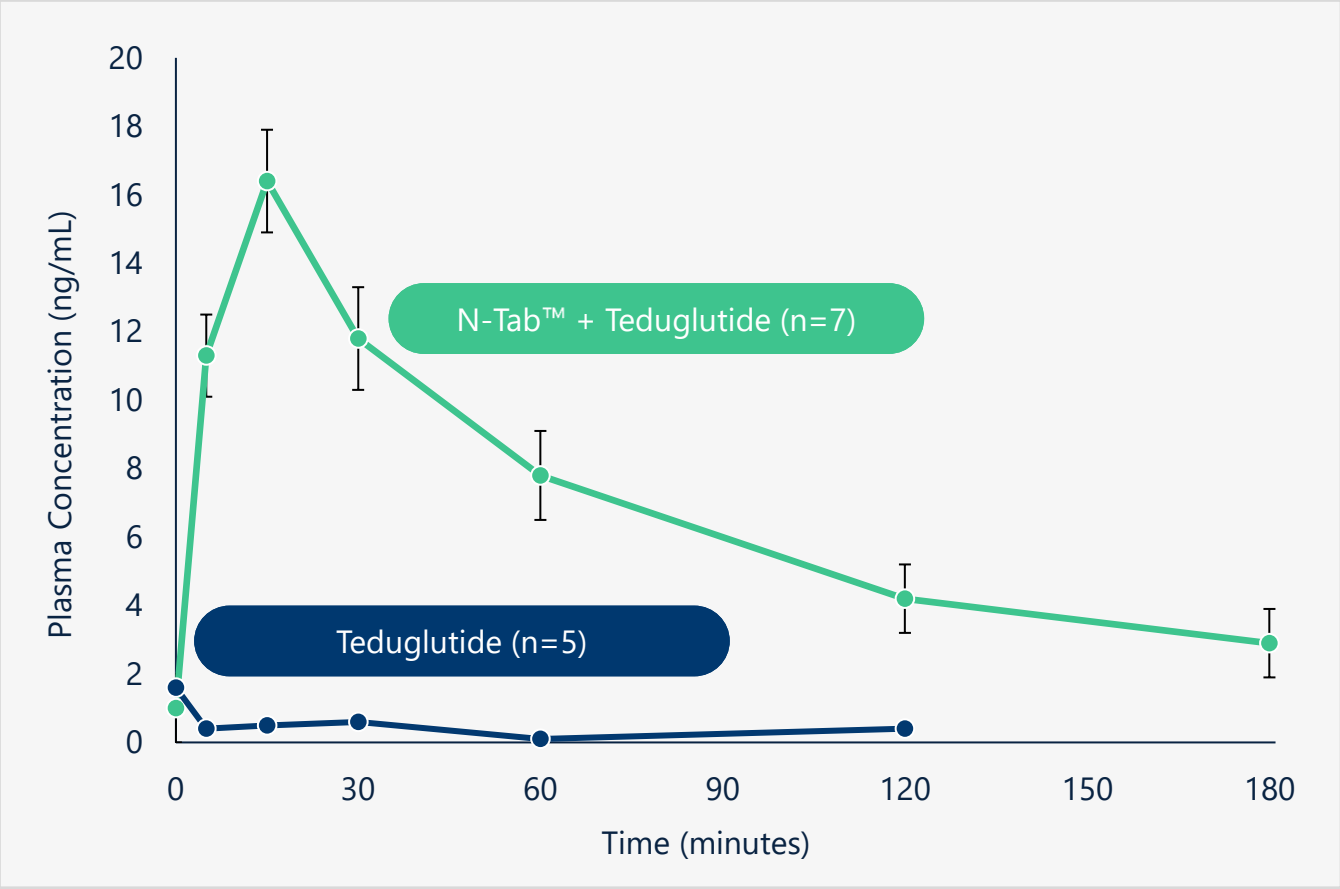
GLP2
GLP1/Glucagon

Oral GLP-2 Analog Tablets for Short Bowel Syndrome (SBS)

Entera published pre-clinical data on gastromucosal absorption of oral GLP-2 tablets using the standard of care GLP-2 peptide (Gattex®)



Devastating and potentially life-threatening organ failure condition

Rare disease: 30K patients across the US and EU

50% require lifelong parenteral nutrition (PN)

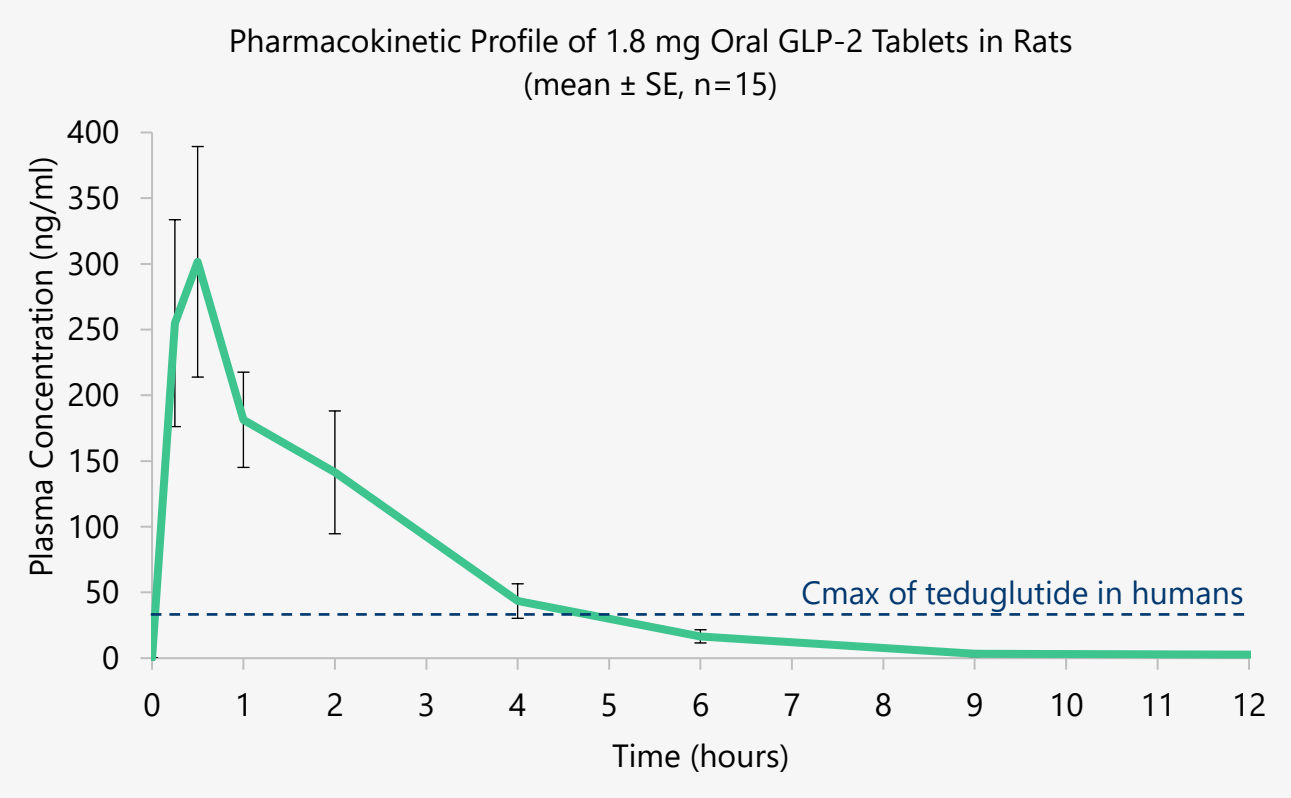
Treatment with glucagon-like peptide-2 (GLP-2) improves absorption of nutrients and reduce PN

Gattex® (teduglutide), the only approved GLP-2, requires daily SC injections (~$600M sales in 2023)

Once-weekly SC injectables - Zealand (glepaglutide, PDUFA 12/22/24) Vectiv/ Ironwood (apraglutide, Phase 3, acquired $1.1B)

Entera/Opko: Oral Long Acting GLP-2 Tablet In Vivo PK Data

Proof-of-concept single dose pharmacokinetic study in rodents showed robust systemic absorption of N-Tab™ Oral GLP-2 analog



- **The plasma half-life of the GLP-2 peptide following IV injection was found to be about 6 times longer than the half-life reported for teduglutide in the same animal model**

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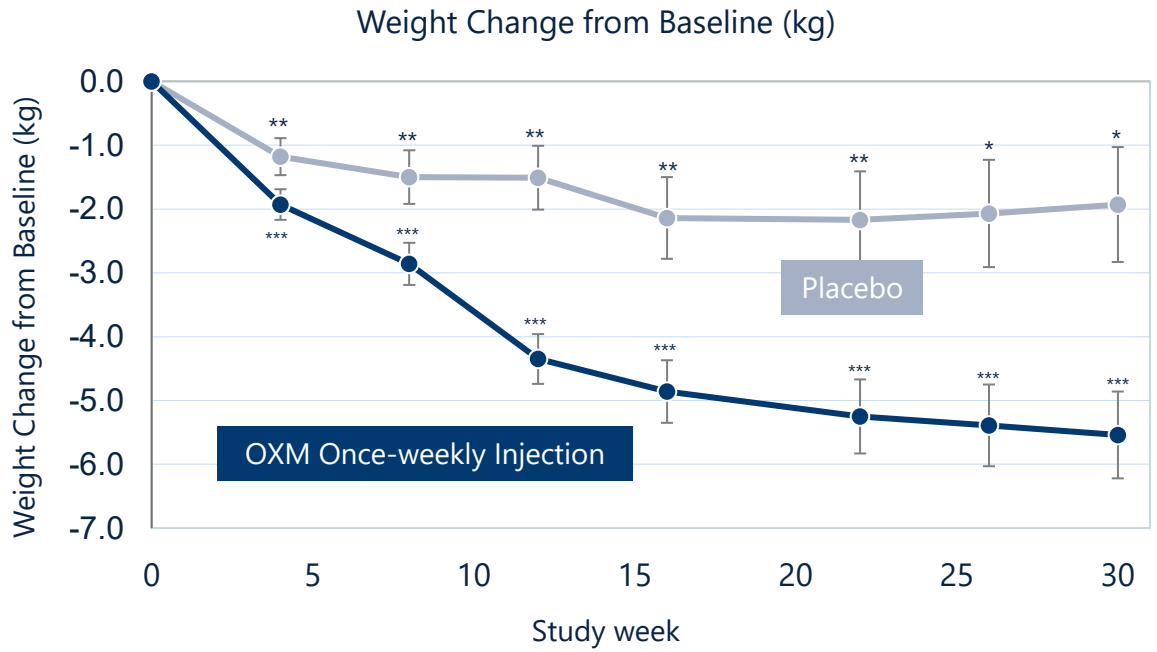
Entera/Opko: Oral GLP-1/Glucagon Agonist for Obesity / Metabolic Disorders

Injectable OXM Phase 2B Results



Parameter	OXM (N=45)	Placebo (N=28)
Triglycerides (mg/dL)	-40.5 (12.52) (p=00019)	-9.7 (16.34)m(p=0.5554)
Total Cholesterol (mg/dL)	-13.9 (4.79) (p=0.0080)	-2.4 (6.23) (p=0.7066)

- Oxyntomodulin (OXM) is a next generation GLP-1/glucagon dual agonist; No approved OXM agonists; those in development require subcutaneous injections
- >1 billion people suffer from obesity globally; market is estimated to grow to $100B by 2030
- Phase 2B study with Opko *once-weekly injectable* OXM demonstrated significant weight loss and reduction in HbA1, triglyceride and cholesterol levels in 113 obese and diabetic patients
- N-Tab™ Oral OXM tablets exhibited significant systemic exposure, a favorable PK and robust bioavailability following a single dose in 2 *in vivo* models
- Oral OXM tablets rapidly reduced plasma glucose levels compared with placebo *in vivo*

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Key Recent and Near-Term Milestones

EB613

FDA type C & D mtg. (Concurrence on Placebo, unique patient population, BMD Endpoint)

Expect BMD Endpoint Qualification **(Expected by January 2025)**

EB612

Selection of optimal candidate for oral PTH peptide replacement tablet therapy for HypoPT **(H1 2025E)**

EB613

Phase 2 study in young athletes with stress fractured due to intense training **(Update on IST Study Design 2025E)**

GLP-2

Data from oral GLP-2 tablets (in vivo PK Data March 2024; PD Data H2 2024E)

-Move to pre-IND enabling steps (H1 2025)

OXM

Data from oral OXM tablets (in vivo PK/Preliminary PD Data PR September 2024)

Move to pre-IND enabling steps (H1 2025)

Thank you

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