

# Peptelligence®

## An Innovative Oral Drug Delivery Technology for Peptides and Small Molecules

### About Enteris

Enteris BioPharma is a privately held, New Jersey based company with an innovative formulation solution derived from our proprietary oral drug delivery technology. Our strategic and clinically proven platform technology, combined with our expert staff, has positioned Enteris BioPharma as an industry leader in innovative oral dosage formulation.

Our innovative formulation solution enables the oral delivery of peptides, including BCS class II, III, and IV compounds, in an enteric-coated tablet.

### Overcoming the Challenge

**Advanced oral delivery of peptides and challenging small molecules has two key challenges: *solubility* and *permeability*.**

Enteris's formulations utilize a unique combination of functional excipients. One class of excipient solves solubility issues, while together these combined excipients address permeability challenges to increase the systemic absorption of the active pharmaceutical ingredient.

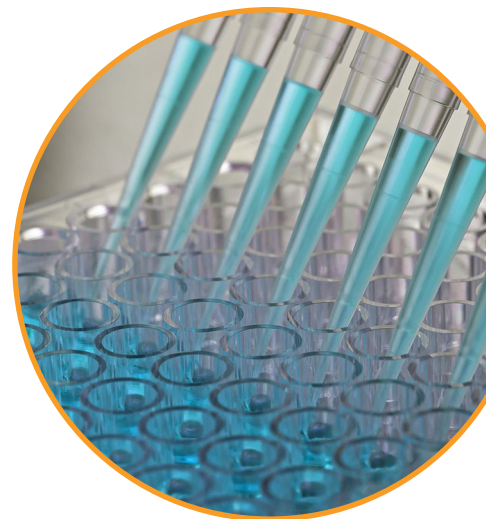
**Enteris's unique oral drug delivery technology enables the development of formulations that are:**

Evaluated in a rapid proof-of-concept model

Cost effective

Easily manufactured

Clinically proven





## Achieving Oral Drug Delivery

As your partner for oral formulation, our team is experienced in applying our clinically validated oral delivery technology to our clients' peptides and challenging small molecules. Our technology solutions for oral drug delivery are **easily scalable** and are **compatible with multiple formulation and manufacturing processes**.

Within our cGMP facility, we can support your formulation—from pre-clinical through Phase 2 clinical development programs—in the US, EU, and around the world. From process development through GMP manufacture, Enteris offers full Quality and Regulatory support for your products in our dedicated manufacturing suites. This includes raw material testing, final product release, optimization and validation, and stability studies.

**By partnering with Enteris, you leverage robust IP protection, regulatory CMC support, and finished solid dosage formulations for preclinical and clinical studies.**

## Mechanism of Delivery

Enteris BioPharma offers the ability to effectively deliver a variety of molecules across multiple therapeutic indications. Our clinically proven, cutting-edge formulation technology enables the oral delivery of peptides, including BCS class II, III, and IV compounds, in an enteric-coated tablet.

**Enteris's formulation technology is made up of two key components:**

**Permeation enhancers** which transiently loosen tight junctions in the intestinal enterocytes and allow paracellular transport. The permeation enhancers, which are surfactants, act as excellent solubilizing agents.

**A main excipient acts in a multifunctional role as a pH lowering agent** that increases absorptive flux, an enzyme inhibitor, a calcium chelator and membrane permeation enhancer, and a membrane wetting/charge dispersal agent.



### *Enteris' Mechanism of Delivery is Summarized in Four Key Steps:*

1

Enteric Coating protects the tablet from low pH and proteases of the stomach

2

The Enteric Coat dissolves at a neutral pH targeting the small intestine

3

pH Lowering Agent, Permeability Enhancers, and API are released

4

API is absorbed across the intestinal wall via paracellular transport

## Peptelligence<sup>®a</sup> Pipeline

Candidate	Preclinical	Phase 1	Phase 2	Phase 3	NDA	Sponsor
Ovarest <sup>®</sup> (oral leuprolide tablet)	Endometriosis					enteris BIOPHARMA
Tobrate <sup>™</sup> (oral tobramycin tablet)	uUTI					enteris BIOPHARMA
Oral Octreotide Tablet	NET Assoc. Disorders					enteris BIOPHARMA
TBRIA <sup>™</sup> (oral calcitonin)	Osteoporosis					R-PHARM <sup>b,c</sup>
KORSUVA <sup>™</sup> (oral CR845)	Chronic Pain – Osteoarthritis					CARA THERAPEUTICS
KORSUVA <sup>™</sup> (oral CR845)	Pruritus CKD – HD					CARA THERAPEUTICS
KORSUVA <sup>™</sup> (oral CR845)	Pruritus CKD (III–IV)					CARA THERAPEUTICS
KORSUVA <sup>™</sup> (oral CR845)	Pruritus CLD					CARA THERAPEUTICS
Oral Peptide Therapeutic	Undisclosed					FERRING <sup>c</sup> PHARMACEUTICALS
Oral Peptide Therapeutic	Undisclosed					FERRING <sup>c</sup> PHARMACEUTICALS
DACRA Peptides <sup>d</sup>	Metabolic Disorder					NORDIC BIOSCIENCE
GLP-1 Analogs	Type 2 Diabetes					Undisclosed
Peptides & Small Molecules	Various					Undisclosed

<sup>a</sup>Peptelligence<sup>®</sup> technology has been used in more than 25 pre-clinical feasibility programs. <sup>b</sup>R-Pharm required to run another phase 3 because active comparator (Miacalcin<sup>®</sup> nasal spray) did not separate from placebo in BMD marker. <sup>c</sup>Peptelligence<sup>®</sup> licensee. <sup>d</sup>DACRA Peptides have been licensed to Eli Lilly; Source – Eli Lilly Press Release, June 8, 2017.

### Clinically Validated

Enteris has demonstrated a simple proof-of-concept model with a track record of clinical success across a range of compounds and therapeutic indications. Multiple clinical chronic dosing studies have been carried out with peptides utilizing our proprietary technology including:

Positive Phase 3  
oral Calcitonin

Positive Phase 2a  
oral leuprolide

Phase 2b oral CR845,  
kappa opioid agonist

## Make Enteris BioPharma your partner of choice for oral delivery

For more information about working with Enteris, please contact:

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