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Oral Peptide Delivery: Successful Technologies Progressing in the Clinic and Future Challenges

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2016

IPSEN
Innovation for patient care

PEPTIDE DELIVERY LANDSCAPE

Peptide Delivery: Routes of Administration

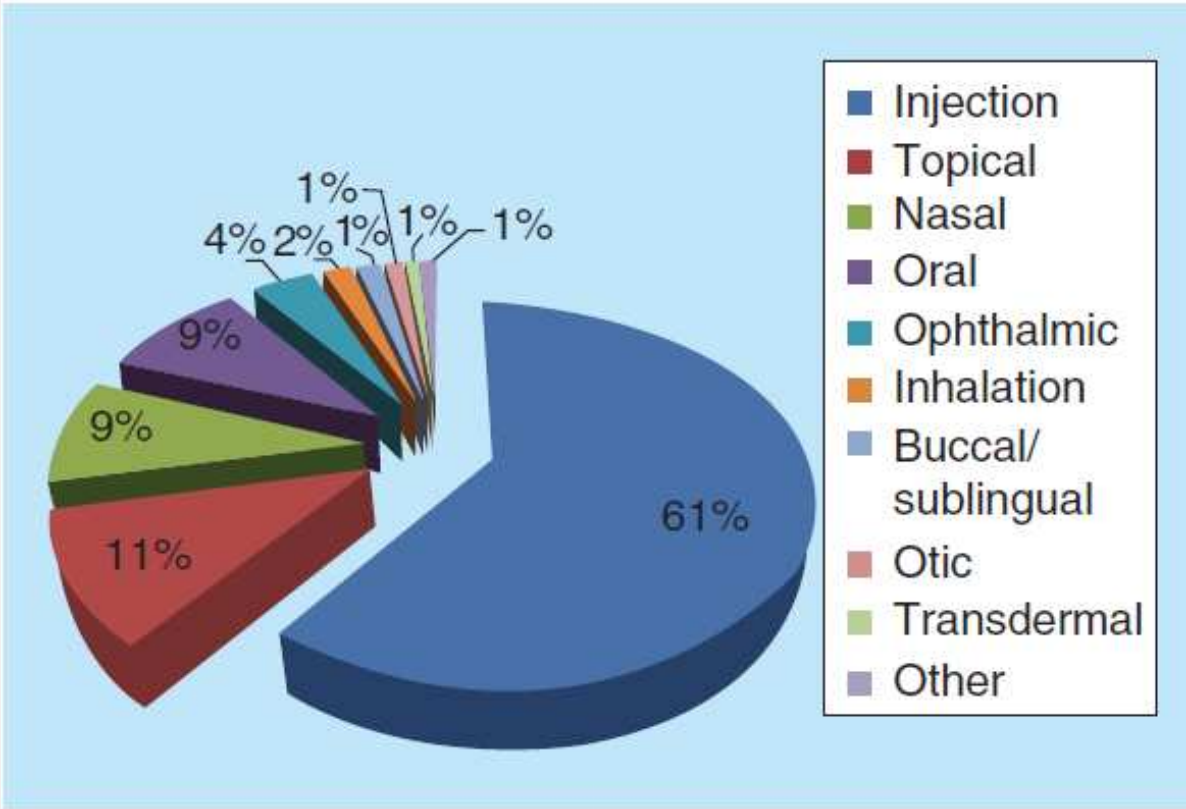


Figure 1. Routes of delivery of marketed peptide products (Pharmacircle™).

Most of the marketed peptides are injectable

Peptide Delivery: Technology Landscape

Table 1. Leading peptide products (excluding insulin) and their delivery systems.

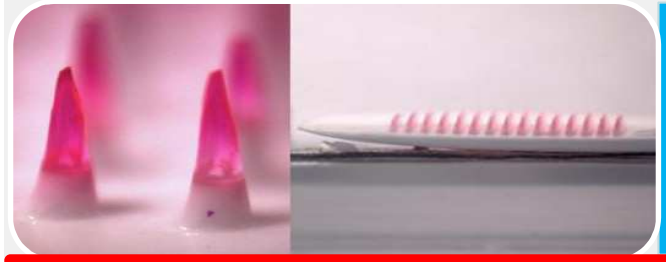
Product	Peptide	Indication(s)	First approval	Sales (2013, US $Billion)	Route	Needle gauge	Dose volume (ml)	Dosing schedule	Drug delivery technology	Manufacturing
Copaxone®	Glatiramer acetate	Multiple sclerosis	1996	4.3	s.c.	29G	1	Immediate release	–	Solution
Lupron® Depot	Leuprolide	Prostate cancer	1989	2.0	i.m.	22G	1	1, 3, 4, 6 month SR	PLGA microparticles	Emulsion/solvent extraction
Velcade®	Bortezomib	Myeloma	2003	1.7	s.c/i.v	n.s	1 – 3.5	Immediate release	–	Lyophilization
Sandostatin® LAR	Octreotide	Acromegaly cancer	1998	1.6	i.m.	19G	2	month SR	PLGA glucose star polymer	Coacervation
Zoladex®	Goserelin	Prostate cancer	1996	1.0	s.c.	14G	N/A	1 and 3 month SR	PLGA implant	Melt extrusion
Byetta® / Bydureon®	Exenatide	Diabetes	2005† 2011†	0.5	s.c.	31G† 23G‡	0.04† 0.65‡	Twice daily† Once weekly†	– PLGA microparticles‡	Solution† Coacervation‡
Decapeptyl®	Triptorelin	Prostate cancer	1986	0.3	s.c./ i.m	21G	1.5	Immediate release and 1, 3, 4, 6 month SR	Lyophilizate PLGA microparticles	Coacervation, lyophilization, melt extrusion and insoluble salts
Somatuline® Autogel®	Lanreotide	Acromegaly cancer	2001	0.25	s.c.	18G		1 month SR	Nanotubes	Peptide self-assembly
Eligard®	Leuprolide	Prostate cancer	2002	0.25§	s.c.	19–20G	0.25–0.5	1, 3, 4, 6 month SR	*In situ* solidifying PLGA depot	*N*-methylpyrolidone/ PLGA injection vehicle mixed immediately prior to administration
Supprelin® LA	Histrelin	Precocious puberty	2007	0.06	s.c.		N/A	2 month SR	Nonbiodegradable implant	3.5cm × 3 mm cylindrical polymeric reservoir
Suprefact®	Buserelin	Endometriosis, IVF	1990	N/A	Nasal	N/A	N/A	tds	Nasal spray	Solution
Synarel®	Nafarelin	Endometriosis, IVF	1990	N/A	Nasal	N/A	N/A	bd	Nasal spray	Solution

From A. Lewis, J. Richard; Therapeutic Delivery 6(2), 149-163, (2015)

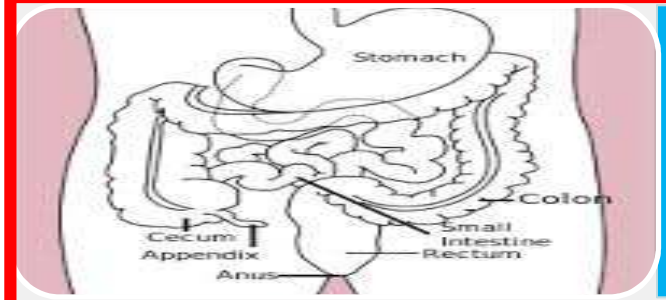
Peptide Delivery: Technology Trends



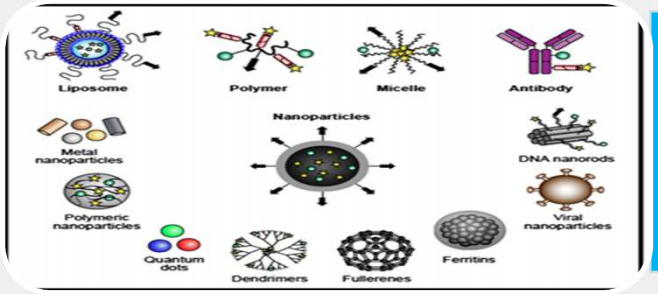
- **Injectable Sustained Release**
  - Current standard for peptide formulations: 1M to 6M
  - Various technologies available (microspheres, implants, self-assembly technologies, . . .)
  - Ready-to-use formulations in pre-filled syringes
  - Narrow gauge needles



- **Transdermal Peptide Delivery**
  - Proof of technology on-going for many technologies
  - Positive clinical Phase II results reported for micro-needle technologies (3M, Zosano, Nanopass . . .)



- **Oral Peptide Delivery**
  - A broad range of technologies
  - Numerous technologies now validated clinically in late stage trials (Phase II and III)
  - Octreolin filing of 505(b)(2) dossier by Chiasma in the US (Mycapssa™)
  - Strong competitive pressure

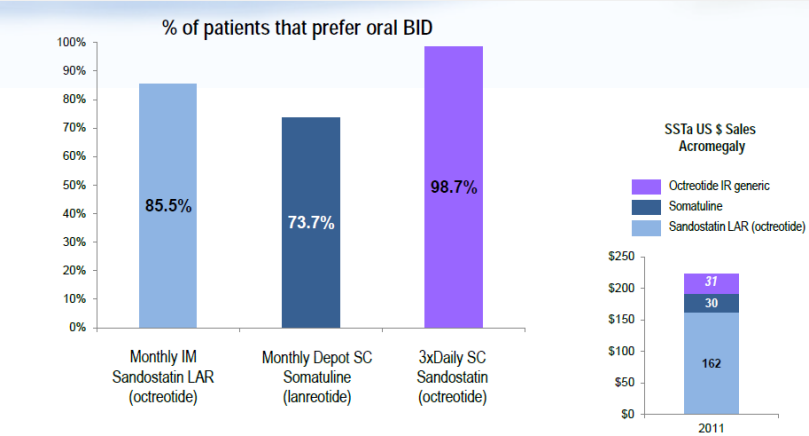


- **Intracellular Peptide Delivery**
  - Targeting of cancer cells for new oncology drugs
  - Brain targeting

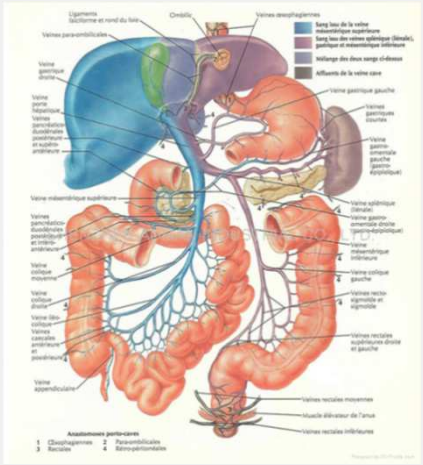
FOCUS ON ORAL PEPTIDE DELIVERY

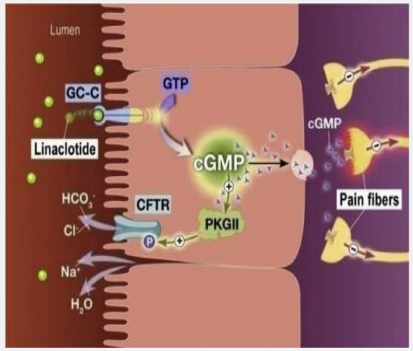
Oral Peptide Delivery: Strong Expectations from the Market

Unmet medical need



Delivery to site of action





Oral Linaclotide – Targeting Receptors in the GI Tract

J. Castro et al, Gastroenterology, 145(6), 2013, 1334-1346

Competitive environment

FierceBiotech
THE BIOTECH INDUSTRY'S DAILY MONITOR

CHIASMA

Chiasma hauls in $70M to w… …oche future

February 27, 2015 | By Damian…

With the money, C… treatment f… q… its … …reotide, a …it the drug next …n it soon thereafter, using …am.

Chiasma Announces FDA Acceptance For Filing of New Drug Application for Octreotide Capsules in Acromegaly

- Brand name of Mycapssa™ also conditionally accepted by agency -

NEWTON, Mass. and JERUSALEM, Israel, Aug. 17, 2015 /PRNewswire/

…ide capsules would be the first … somatostatin analog, providing … option to patients currently receiving …ful injections"

Late stage of development

in-Pharma Technologist.com

23-Feb-2015

Drug delivery te… it helps N… hur…

Emisphere Signs License Agreement With Novo Nordisk to Develop Oral Formulations of Four Molecules Targeting Metabolic Indications and Amends GLP-1 Agreement

Emisphere to Receive $14 Million Upfront for New License and Amendment, Eligible for More Than $207 Million in Milestone Payments, Plus Royalties on Product Sales

…Nordisk has met the … shares of Emisphere … formulate the oral version of … as much as 70% on Friday.

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Marketed Oral Peptides

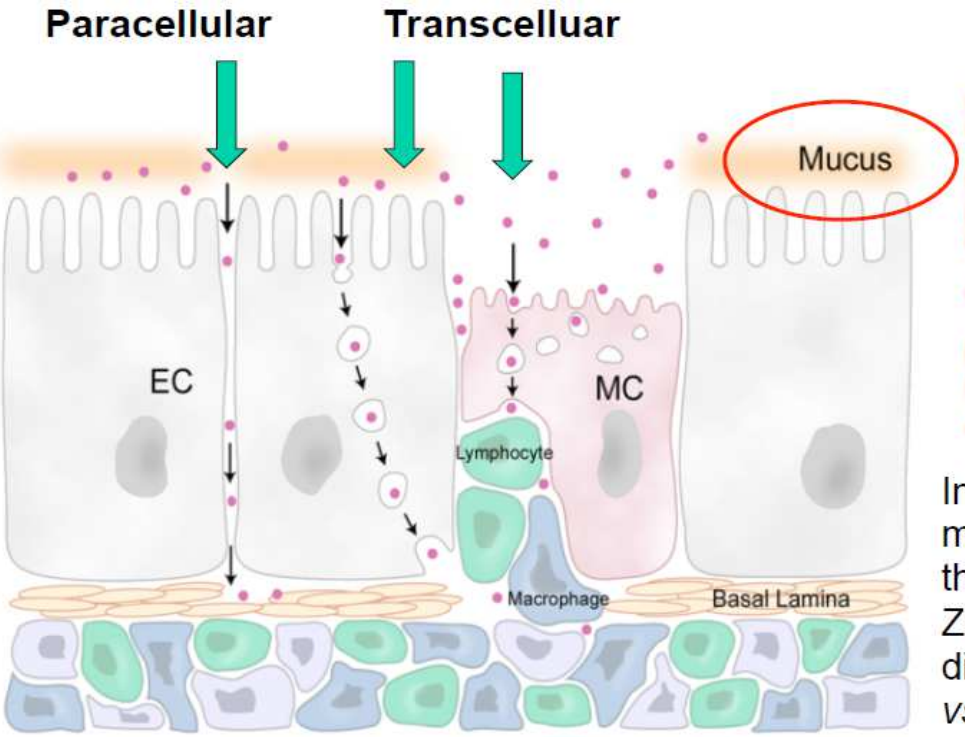
- Most are used **for local action** in the gastrointestinal tract (not absorbed systemically)
- Striking number of **cyclic** peptides – resistance to exopeptidases
- Those that are systemically absorbed are important as they **demonstrate financial viability and efficacy are possible even with low and variable bioavailability**

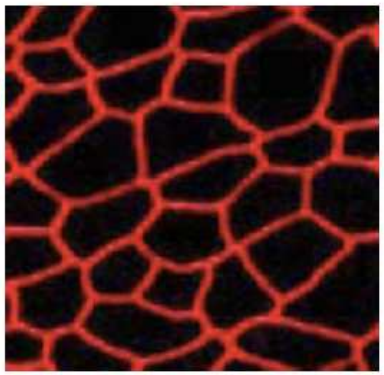
Product	Indication	Peptide	Mw (g/mole)	Comment
Colomycin®	Infection	colistin sulfate	1268	**Cyclic peptide**
Neoral® Sandimmune	Immunosuppression	cyclosporine	1202	**Cyclic peptide**, practically insoluble in water
Minrin® Minrin® Melt	Nocturia Diabetes insipidus	desmopressin acetate hydrate	1183	Soluble salt of **cyclic peptide**. F = 5% compared to intranasal DDAVP, and about 0.16% absolute bioavailability. Sublingual (melt) formulation achieves 0.25%
Cachexon®	AIDS-related cachexia	glutathione	307	Tripeptide also found in a number of health supplements
Linzess®	Irritable bowel syndrome, constipation	linaclotide	1527	**Cyclic peptide** agonist of guanylate cyclase 2C derived from E.Coli enterotoxin
Ceredist® Ceredist OD	Spinocerebellar ataxia	taltirelin hydrate	477	Practically insoluble Thyrotropin Releasing Hormone (TRH) analogue. **Centrally acting**.
Angiovag®	Pharyngitis	tyrothricin	1228	**Cyclic polypeptide**, practically insoluble
Vancocin®	Infection	vancomycin hydrochloride	1485	**Tricyclic glycopeptide** antibiotic, freely soluble

Source: Pharmacircle Database

IPSEN Innovation for patient care

Main Challenge: Peptides Are Poorly Absorbable Through the GI Tract, Whatever the Transport Mechanism



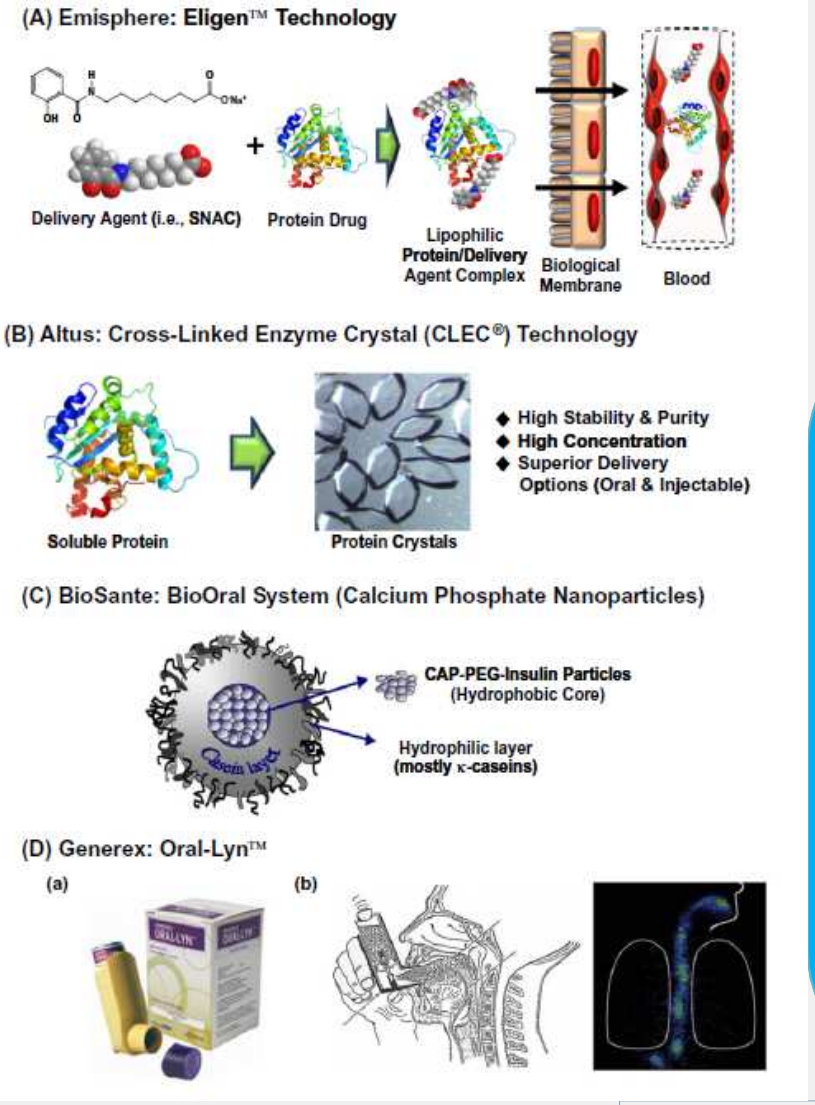


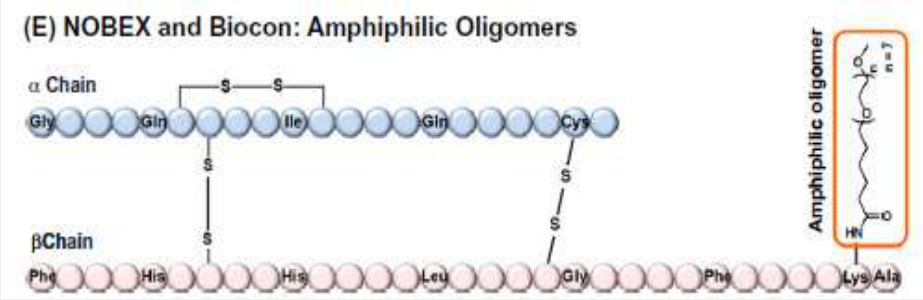
Intestinal epithelial monolayer stained for the tight junction protein ZO-1. Note surface area differences: transcellular *vs* paracelluar routes

Jung, et al., 2000 *Eur. J. Pharm. Biopharm.*, 50:147-160

- Opportunity to target receptors in the GI tract:
  - Local treatment of GI disorders (e.g. IBS)
  - Triggering a signal transduction cascade
- To increase absorption, need for permeation enhancers:
  - Novel excipients
  - Nanoparticle approaches

Oral Peptide Delivery: A Wide Set of Technologies Investigated in Clinical Development





- Examples of oral technologies progressed into the clinics
- Formation of lipophilic transportable complex by weak non-covalent interactions with a carrier
- Formation of crystals (specific of particular APIs)
- Formation of calcium phosphate (CAP) nanoparticles (e.g. CAP-PEG-insulin-casein nanoparticles)
- Formation of micellar solutions for buccal delivery (e.g. Oral-LynTM, comercialized in India)
- Formation of amphiphilic oligomers by modification with lipophilic moieties to enhance transcellular absorption and peptide stability (e.g. hexyl-insulin monoconjugate 2, HIM2 commercialized as Insugen™ in India)

From K. Park et al.; Reactive & Functional Polymers 71, 280-287 (2011)

Technological Approaches

Absorption enhancers

- Acylcarnitine
- Bile salts
- Fatty acids and th
- Acylated am SNAC, 5-CNAC
- Salts
- omatic alcohols
- charides

Most commonly investigated and successful approach

Enzymes inhibitors

- Inorganic acids e.g. citric acid
- Soy bean trypsin inhibitor
- SEDDS systems
- Aprotinin

Mucoadhesive systems

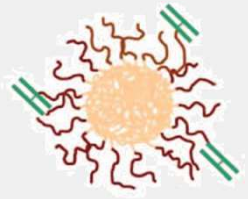
- Chitosan and derivatives
- Polymeric

Conjugates

- Bacterial toxin conjugates
- Cell penetrating peptides
- PEG and glycolipid conjugates

Functionalized Nanoparticles

Pridgen *et al.*, 2013



Merrion Technology - GIPET (I, II, III)
Gastro-Intestinal Permeation Enhancement Technology

- Medium chain fatty acids and their salts – sodium caprylate, sodium caprate and sodium laurate
- Absorption enhancer is blended with API and formulated into enteric coated tablet

➢ Clinical Stage
- ❑ Phase II for oral zolendronic acid
- ❑ Phase I for oral insulin (with NovoNordisk)
- ❑ Phase I for oral GLP-1



GIPET I: powder … coated tablet
GIPET II: … surfactant and drug in enteri…
… enteric coated gel

BUSINESS & LEADER…

Merrion Pharma… progresses… devel… …un

29.05.2014

Novo Nord… …t expects to progress an insulin tablet formulated … …armaceuticals' GIPET proprietary drug delivery technology in… …ase 2a proof-of-principle trial.

Merrion Pharma to sell assets to Novo Nordisk

Merrion will use the proceeds to pay off $5m loan from Irelandia Investments

Tue, Dec 15, 2015, 21:29

…nologist.com

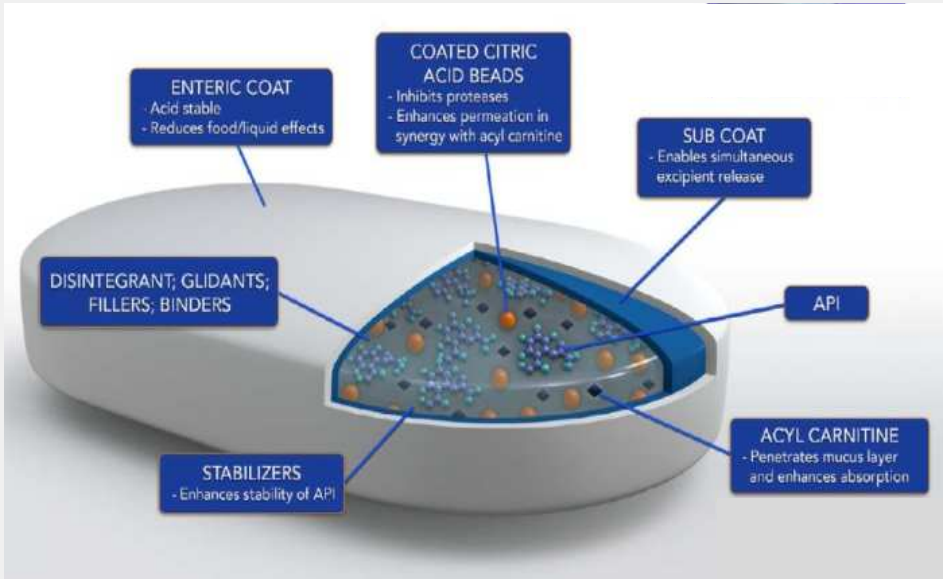
…-Jan-2009

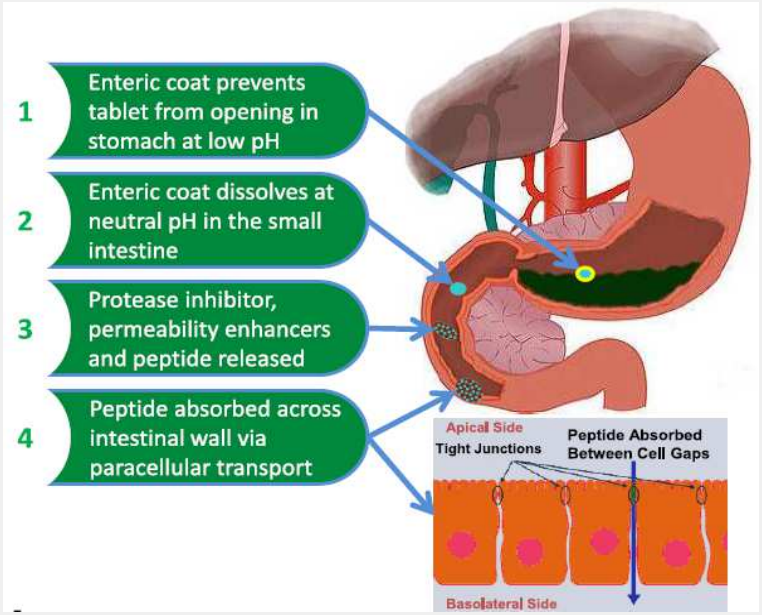
Merrion to develop oral GLP-1 drug for Novo

Ireland's Merrion Pharmaceuticals' GIPET oral delivery technology platform has won the firm its second licensing agreement with Danish insulin giant Novo Nordisk.

The deal, which could earn Merrion up to $58m, will see the firm develop an oral formulation of Novo's GLP-1 receptor antagonist candidate, extending the initial agreement the two companies signed in November.

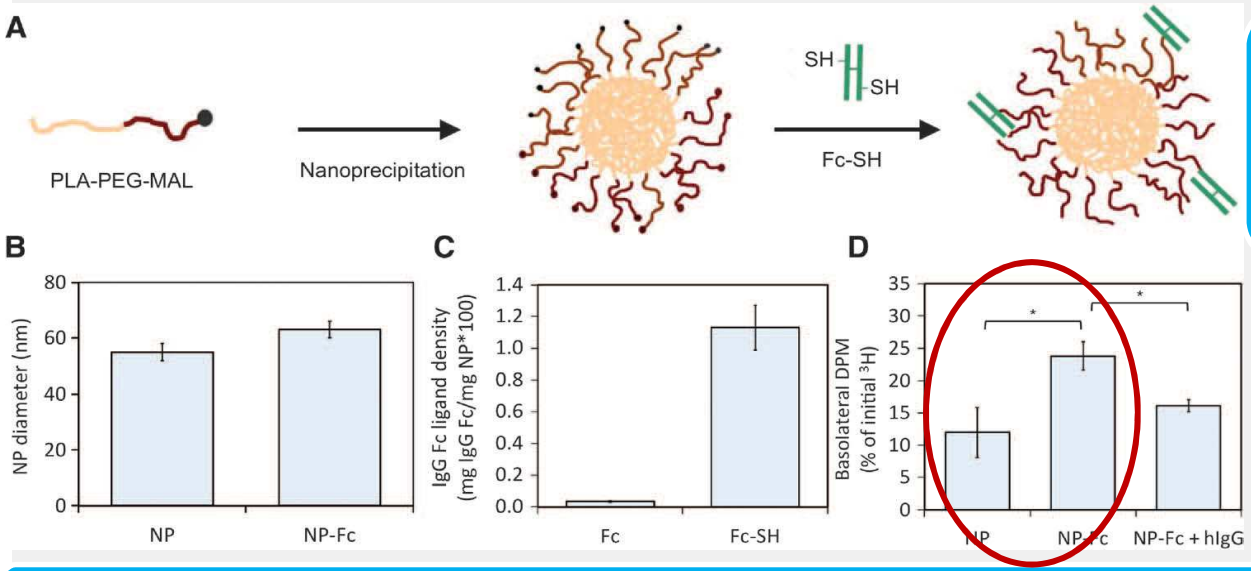
Enteris Biopharma – Technology Peptelligence





- Completed numerous clinical studies
  - Phase III for oral Calcitonin: Osteoporosis – demonstrated increased efficacy vs nasal spray
  - Phase II for oral PTH: Osteoporosis – increased bone density but not as much as injection
  - Phase II for oral Calcitonin: Osteopenia
  - Phase I for oral CR845: Neuropathic Pain
- Paternerships with Tarsa, Cara Therapeutics and Nordic Bioscience
- Enteris has full development and clinical manufacturing and testing capabilities for the technology

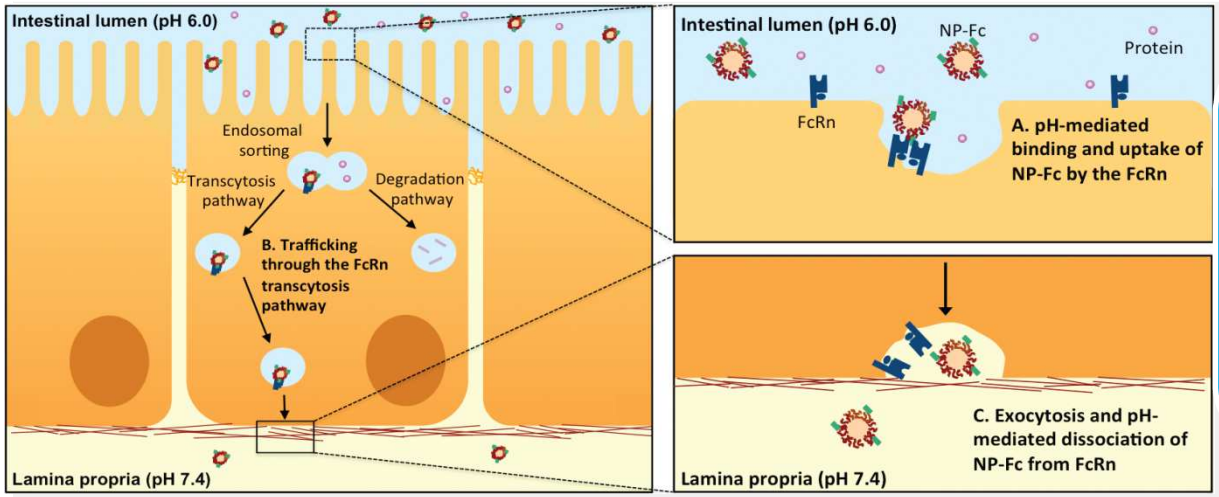
Fc-Targeted Nanoparticles (NPs) For Oral Peptide Delivery



- NP assembly, functionalization, and *in vitro* transepithelial transport

DPM = basolateral ^{3}H disintegrations per minute, as a percentage of the initial amount of ^{3}H. An excess of human IgG Fc is used as a blocking agent for FcRn.

Transepithelial Transport by the Neonatal Fc Receptor (FcRn)



Schematic of Fc-targeted NP active transportation mechanism across the intestinal epithelium by the FcRn through a transcytosis pathway

From E.M. Pridgen et al.; www.ScienceTranslationalMedicine.org 27 November 2013 Vol 5 Issue 213 213ra167

Fc-Targeted Nanoparticles: Absorption and Biodistribution in Mice

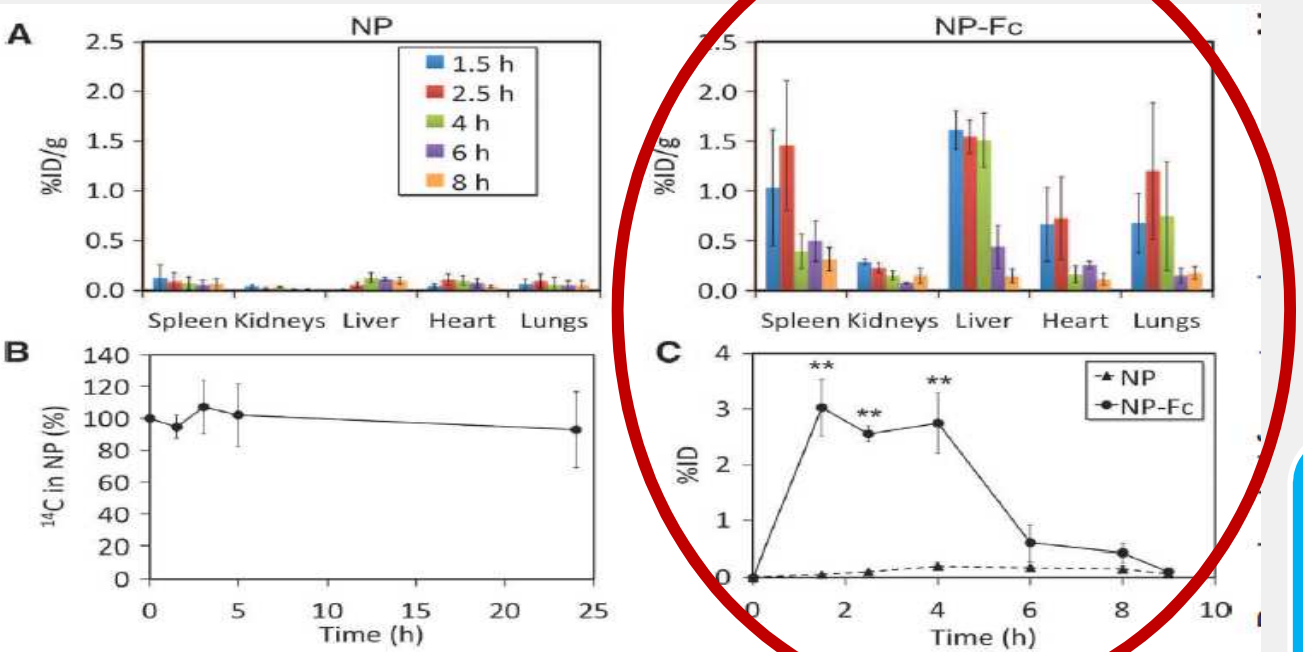


Fig. 4. NP absorption and biodistribution in mice. (**A**) Biodistribution of ^{14}C-labeled nontargeted NPs and NP-Fc after oral administration to fasted WT mice. Data are mean percent initial dose (%ID) per gram of tissue ± SEM (n = 5 mice per time point). (**B**) Release of ^{14}C from ^{14}C-labeled NPs in PBS at 37°C. Data are means ± SD for n = 4 release experiments. (**C**) Total absorbed ^{14}C over time for nontargeted NPs and NP-Fc after administration by oral gavage. Data are mean %ID measured in all of the organs added together ± SEM (n = 5 mice per time point). $^{**}P < 0.01$ for comparison of nontargeted NPs and NP-Fc at respective time point, two-tailed Student's t test.

- Oral absorption of NP-Fc is strongly enhanced in mice vs non targeted NPs

From E.M. Pridgen et al.; www.ScienceTranslationalMedicine.org 27 November 2013 Vol 5 Issue 213 213ra167

Technologies Progressed in the Clinic

Company	API	Technology name	Technology	Stage of Development
Chiasma	Octreotide	TPE	Enteric coated liquid filled capsules containing a **suspension of drug particles in oils**	Filing
Enteris Biopharma	Calcitonin	Peptelligence	Enteric coated capsule containing peptide with **absorption enhancer (acyl carnitine)** and **enzyme inhibitor** (organic acid)	Phase III
Nobex/ Biocon	Insulin conjugate	HIM2	Peptide amphiphilic **conjugate pro-drug** technology in which the peptide is covalently linked to **PEG, glycolipids or fatty acids** and formulated with **absorption enhancers**	Phase III
Oramed	Insulin and exenatide	POD	Peptide with **absorption enhancer and enzyme inhibitors** in enteric coated tablet/capsule	Phase II
Emisphere	GLP-1 analogue	eligen	Tablet formulation based on **absorption enhancers SNAC, SNAD, 5-CNAC**	Phase II
Merrion	Insulin and GLP-1	GIPET	Enteric coated tablets containing **medium chain fatty acids** (sodium caprate) as **absorption enhancer**	Phase I
MidaTech	Insulin and GLP-1	GNP / Nanocells	Surface modified **gold nanoparticles** complexed with peptides and formulated into **adhesive buccal** patch	Phase I
Nod Pharma	Insulin and GLP-1	NOD	**Calcium nanoparticles** in **mucoadhesive** tablet formulation	Phase I

Intra-Enteral Injection Using “Robotic Pills”: A Paradigm Shift

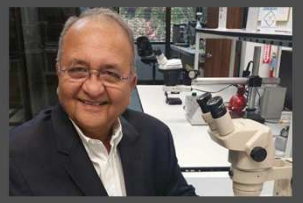
THE WALL STREET JOURNAL.

Feb. 17, 2014

NEXT IN TECH

Can 'Robotic' Pills Replace Injections?

Entrepreneur Mir Imran Hopes to Change Diabetes Treatment



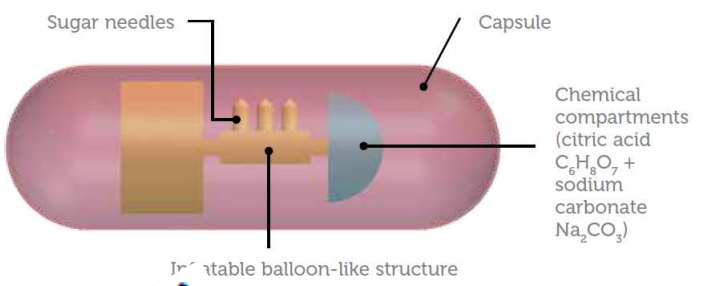
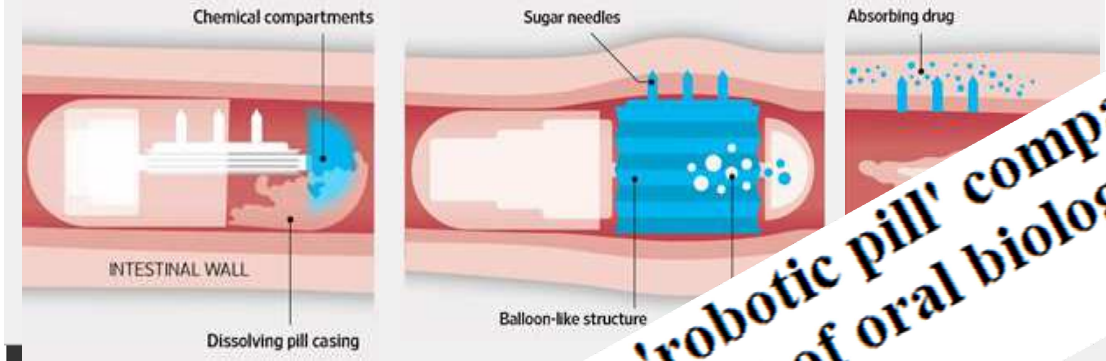


Figure 2: Sch… of “robotic pill” concept comprising a capsule contain… ments composed of citric acid and sodium carbonate in … a valve, and an inflatable balloon-like structure with …ugar and preloaded with the therapeutic peptide.



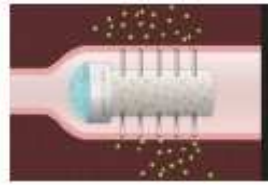
PR Newswire
A UBM plc company

AstraZeneca funds 'robotic pill' company Rani Therapeutics in pursuit of oral biologics

…E DESK

…ıe Pill with Needles: New form of Injection

…ording to the study revealed by Massachusetts Institute of Technology (MIT) and Massachusetts General Hospital (MGH) researchers, in which they tested the micro-needle pill in the gastrointestinal (GI) tracts of pigs. The study is published in the Journal of Pharmaceutical Sciences.



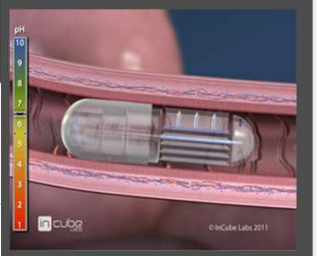
Rani Therape… …oration with Major Pharmaceutical Company

THE … U.S. EDITION

Novarti… Startup R… …erapeutics

February 29, 2016 | By Varun Saxena

Novartis AG has an extensive line of biologic drugs that can only be taken by injection, but now the pharmaceutical giant is making a bet on a “robotic pill,” a preclinical product that could make drugs like insulin available for the first time without the use of a needle.



in-Pharma Technologist.com 08-Sep-2015

Novo Nordisk and MIT on the hunt for oral peptide route



If the project is successful, peptide drugs could switch from injections to pill form

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LESSONS LEARNT FROM CLINICAL STUDIES: ADDRESSING THE CHALLENGES OF PEPTIDE STABILITY IN THE GI TRACT AND ORAL BIOAVAILABILITY

Achieving Similar Pharmacokinetics to S.C. Injection

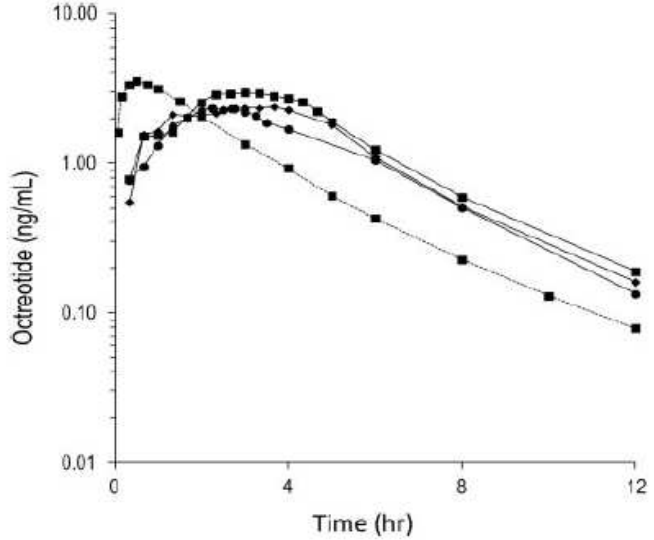


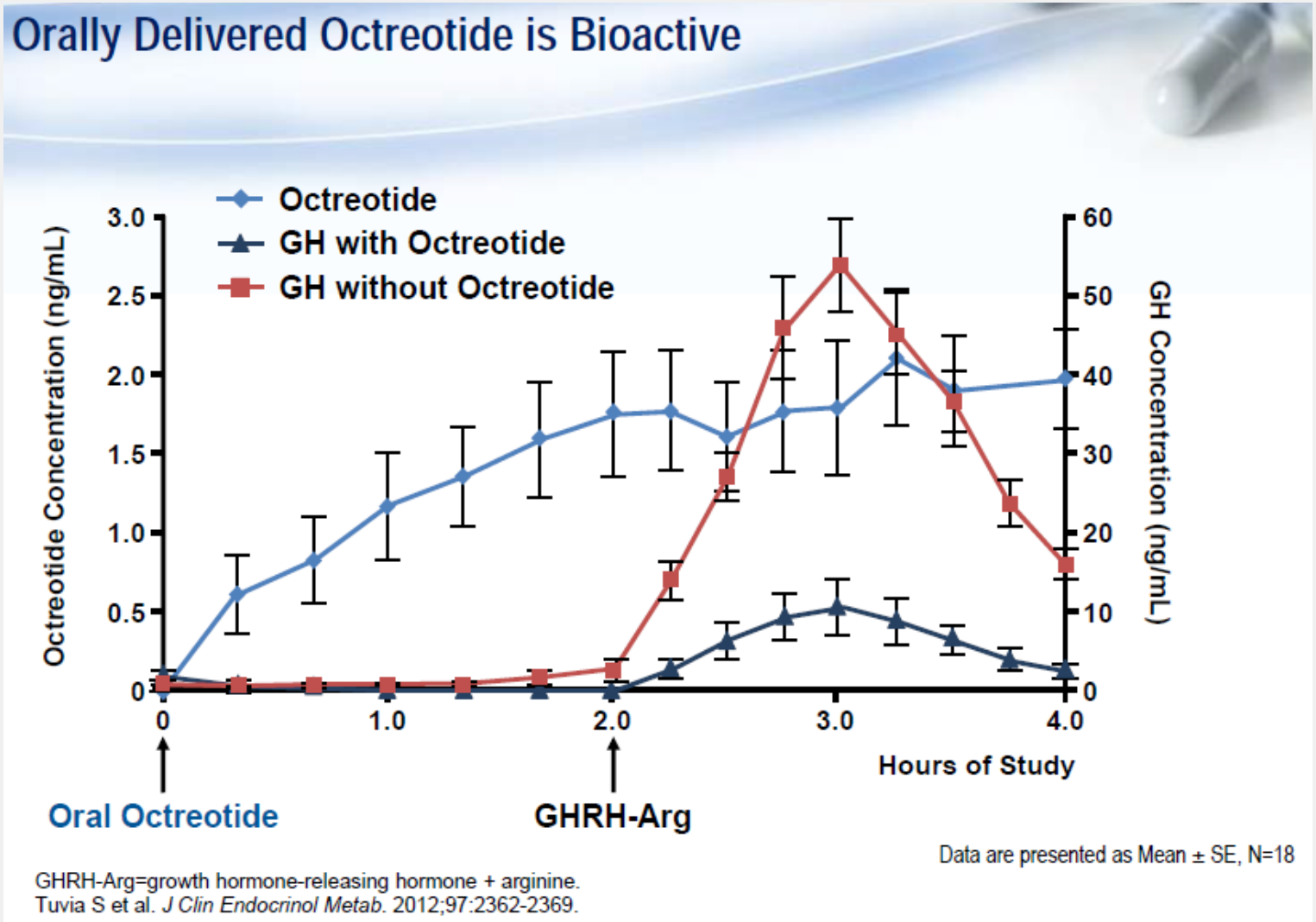
FIG. 3. Comparable plasma octreotide concentrations after oral or sc injection of octreotide acetate. Mean plasma concentrations of octreotide after a single oral administration of 20 mg octreotide acetate (*closed diamonds*, n = 24; *closed squares*, n = 12; *closed circles*, n = 17) and single sc injection of 0.1 mg octreotide acetate (*closed squares, dotted line*; n = 14) to healthy volunteers.

Tuvia et al, JCEM, 97(7) 2362-2369, 2012

- Chiasma Octreolin Phase I data (4 studies & 75 patients)
  - PK (12 males), dose escalation vs s.c
  - Food effects (11 females / 13 males)
  - PK/PD (13 females / 11 males)
  - Duration of intestinal permeability
  - Effect of proton pump inhibitor

- **20 mg oral Octreotide achieved similar PK parameters to 0.1 mg subcutaneous injection**
- **Food and PPIs decreased bioavailability (90% and 40% respectively)**

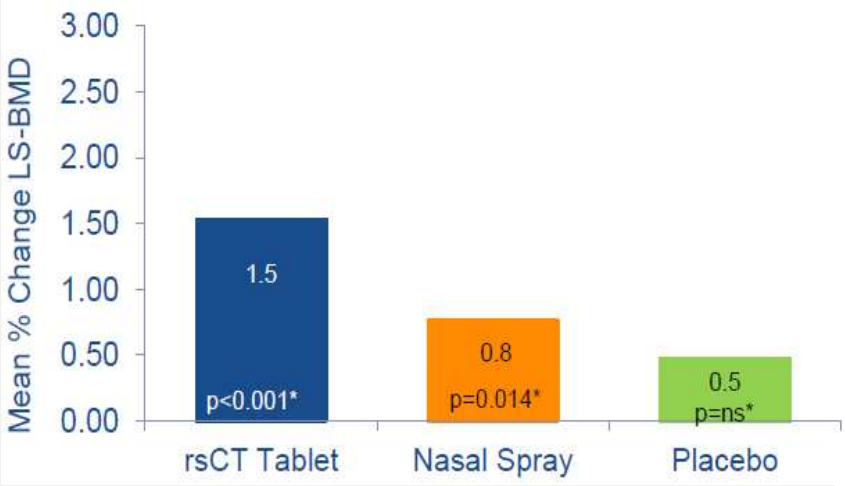
Orally-Delivered Peptide Remains Bioactive

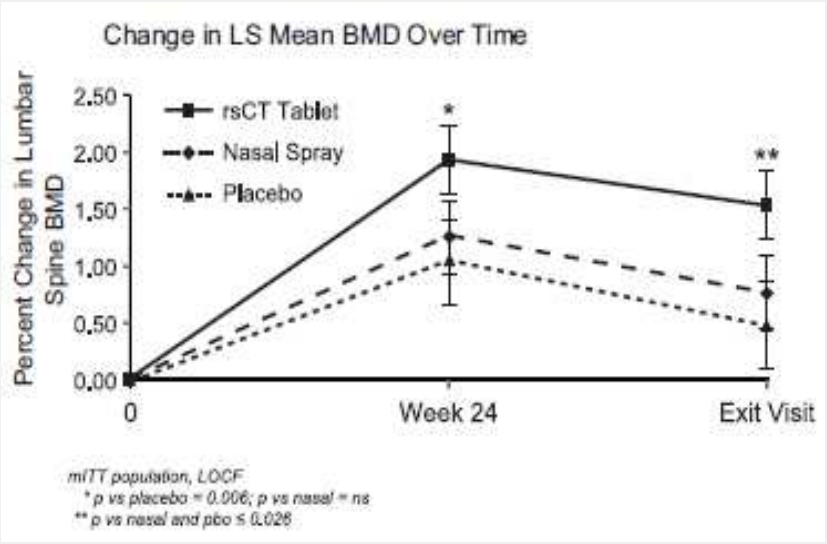


Tuvia et al, J Clin Endocrinol Metab, 97(7), 2362-2369, 2012)

Increased Efficacy from Oral Peptide Delivery

- Tarsa Therapeutics / Unigene labs technology Phase III on oral calcitonin
  - 565 post-menopausal women with documented osteoporosis
  - 0.2mg sCT orally vs placebo and marketed nasal spray (33µg sCT)
  - Note: formulation did not contain acyl carnitine





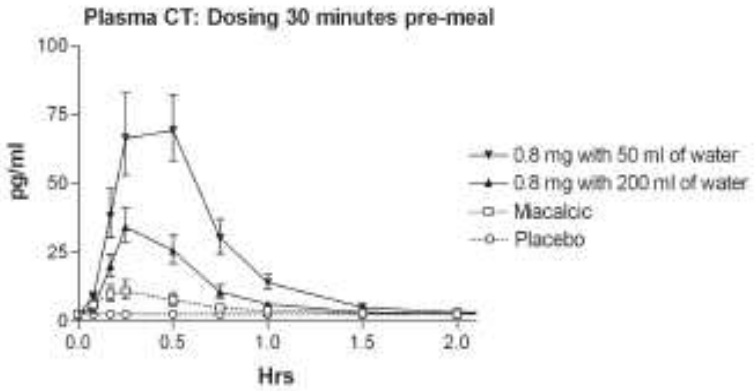
Binkley et al, JMBR 27 (8), 1821-1829, 2012

- Safe and well tolerated
- Greater increase in lumbar spine bone mineral density (LS-BMD)
- FDA and EMA subsequently advised against use of calcitonin in osteoporosis

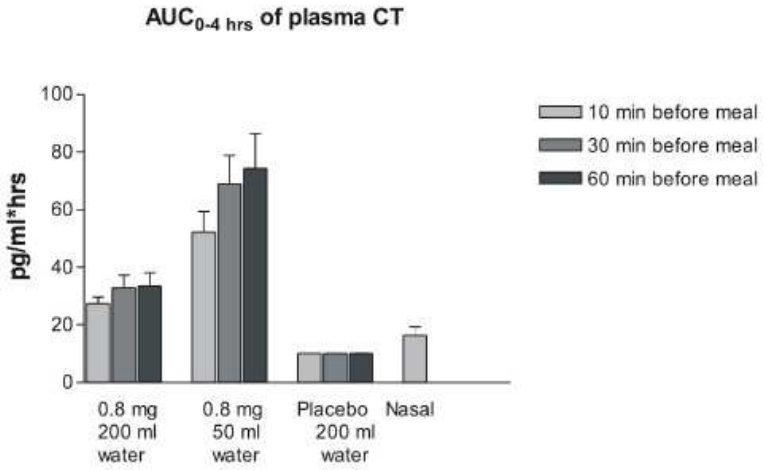
Potential Unexpected Food Effects

- Nordic Biosciences / Emisphere oral calcitonin
  - 40 post-menopausal healthy volunteers
  - 0.8mg calcitonin orally
  - Effect of 50mL vs 200mL water
  - Effect of dosing time before meal
- Bioavailability 4x greater than nasal calcitonin

C_{max} increased 2 – 3x when taken with 50mL water vs 200mL



Bioavailability increased with increasing time before the meal



Karsdal et al, BMC Clinical Pharmacology, 2008

FUTURE CHALLENGES

Anticipating the Switch From Injection to the Oral Route

- Relative bioavailabilities are expected to remain quite low (< 5%), even for smallest peptide in state of the art technologies
- Dosing frequency may need to increase (i.e. once daily s.c. to twice daily oral) – Impact on attractiveness of oral treatment vs injections every 3M or 6M
- The anticipated CoGs (at least for the API) are therefore likely to be high, however:
  - No need for aseptic manufacturing (cheaper to manufacture the drug product)
  - Cost of API decreases as production scale increases
  - Would the switch bring an upside in sales?
- The impact on API demands needs to be considered:
  - May require significant investment in new facility and high yield synthesis processes
- Will a (more expensive?) oral treatment be reimbursed?
  - **Demonstrate superiority vs reference treatment?**
  - **Increased safety or efficacy?**

Bioavailability and Competing Technologies

Route of Delivery	Technology	Companies	Most Advanced Stage of Development	Highest Relative Bioavailability (v.s. s.c.) Reported
Transdermal	Microneedles	Nanopass	Phase III(vaccines)	Dose sparing effect
		Zosano	Phase II (PTH)	40% PTH in man, increased efficacy[1], RT stable 2 years
Nasal	Absorption Enhancers	Serenity Pharma	Phase III (vasopressin analogue)	Same technology achieved 20% for insulin in man[2]
		Azelon	Phase II (PTH)	39% PTH in non-human primates[3]
		Critical Pharma	Phase I(hGH)	20% hGH in non-human primates[4]
Inhaled	Novel excipient	Mannkind Corporation	Received marketing authorisation (Insulin - Afrezza)	30% insulin in man[5]

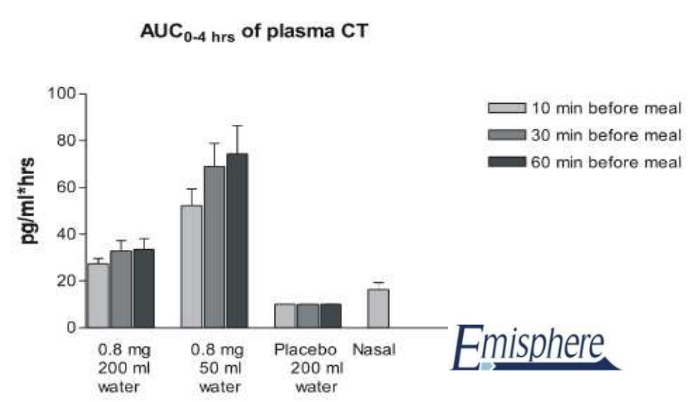
- The oral route offers the lowest biovailability for peptide delivery compared to other alternative routes (transdermal, nasal, . . .)

1. http://www.zosanopharma.com/index.php/Press-Release-12-9-2008.html
2. Leary et al Diabetes Technology and Therapeutics 8, 1, (2006)
3. Eddy, P., Krause, D., Merutka, G. & Macdonald, B. ASBMR 30th Annu. Meet. 031, (2008)
4. Lewis, A. L., Jordan, F. & Illum, L. Drug Deliv. Transl. Res. 3, 26–32 (2012)
5. FDA Briefing Document, Endocrinologic and Metabolic Drugs Advisory Committee Meeting, April 1, (2014)

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Key Challenges: A Summary

Food effects & DDI



Bioavailability decreased

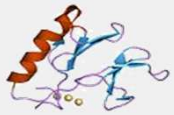
- ❑ **90% - Food**
- ❑ **40%- PPIs**

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Bioavailability and variability vs other routes

Route of Delivery	Technology	Companies	Most Advanced Stage of Development	Highest Relative Bioavailability (v.s. s.c.) Reported
Transdermal	Microneedles	Nanopass	Phase 3 (vaccines)	Dose sparing effect
		Zosano	Phase 2 (PTH)	40% PTH in man, increased efficacy[1], RT stable 2 years
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		Azelon	Phase 2 (PTH)	39% PTH in non-human primates[3]
		Critical Pharma	Phase 1 (hGH)	20% hGH in non-human primates[4]
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Peptide stabilization



Absorption enhancers safety

PR Newswire
A UBM plc company

Feb. 9, 2015

Newly Published Phase III Study Results Show Positive Outcomes for Octreotide Capsules in People with Acromegaly, a Serious Hormonal Disorder

Data showed maintenance of disease control with an investigational oral form of octreotide

The investigational drug, octreotide capsules, is an oral form of the peptide octreotide, a somatostatin analog, for potential use in the treatment of adults with acromegaly, a rare endocrine disease. Patients were evaluated for biochemical and symptomatic disease control over a 13-month period following treatment with octreotide capsules. Sixty-five percent of patients who received octreotide capsules twice-a-day achieved disease control, as measured by circulating concentrations of insulin-like growth factor-1 (IGF-1) and growth hormone (GH) concentrations, at 7 months (core treatment period), meeting the primary endpoint and 62% achieved disease control at 13 months (end of treatment). The severity and incidence of acromegaly symptoms improved, while on octreotide capsules, compared to baseline.

MPR

March 19, 2015

New Prescription Vitamin B12 Tabs May Eliminate Need for Injection

Emisphere Technologies announced the launch of Eligen B12 (cyanocobalamin 100mcg, salcaprozate sodium [SNAC] 100mg) for the dietary management of patients who have a vitamin B12 deficiency associated with a disease or condition that cannot be managed by a modification of the normal diet alone.



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CONCLUSIONS

Future Prospects for Oral Peptide Delivery

- Oral formulations of peptides are highly desirable:
  - Increase therapeutic options, with unmet needs more particularly in Oncology
  - Help patient adherence and convenience
- Technologies to enhance systemic bioavailability of orally administered peptides are now clinically proven:
  - Successfully completing Phase III and progressing to fast track filing
  - Enhanced efficacy
  - Demonstrated safety
- An oral peptide formulation soon on the market:
  - Chiasma's oral formulation of octreotide, brand name MyCapssa™, with orphan drug status in the US and EU
  - Treatment of acromegaly in the US with a PDUFA expected in April 2016 (Chiasma Press release January 8, 2016)
  - EMA approval to initiate a Phase III trial in acromegaly for market authorization submission in Europe with EMA approval expected in 2019/2020

Future Prospects for Oral Peptide Delivery

- Numerous factors must be considered to identify good candidates for oral peptide delivery:
  - Bioavailability, food effects, CoGs, manufacturing strategy, market access, upside in sales
  - For this reason it is likely that peptides will continue to be mostly administered via the injectable route in the next years

- However, over the next 5 – 10 years, increasing number of peptides will likely be delivered via the oral route.

- What impact the success or failure of next oral peptides on the market (e.g. Mycapssa™) will have on development of oral peptide delivery technologies?

ACKNOWLEDGEMENTS

L. Hassani , PhD Senior Scientist, Novel Delivery Technologies, Ipsen

A. Lewis, PhD Director, Novel Delivery Technologies, Ipsen

J. Richard, Ph.D.
Senior Vice President, Peptides
2016

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THANK YOU

Questions?

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2 – Oral peptide delivery: technology status landscape and current status ONdrugDELIVERY (2015) 59, 12-17 – L.N. Hassani, A.L. Lewis, J. Richard

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