HLB PEP

No.1 Peptide Company in Korea

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01) **Understanding Peptide Pharmaceuticals**

02) The Nation’s Leading Peptide Expert

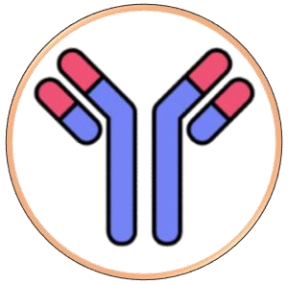
03) Peptide Value Chain & HLB PEP

04) Key Business Areas and Pipeline

Diversifying Pharmaceutical Market

Small Molecule Compounds

- Over USD 90 billion
- Easy Mass Production, High Dosing Convenience
- Issues with Selectivity and Resistance



Monoclonal Antibodies

- Over USD 200 billion
- High Target Specificity, Immune Activation
- High Production Costs, Concerns About Immunogenicity

Peptide

- Over USD 50 billion
- High Affinity and Safety
- Rapid Onset of Action, Advantageous Drug Design
- Short Half-life, High Synthesis Complexity

Cell Therapy Drug

Gene Therapy Drug

Micro biome

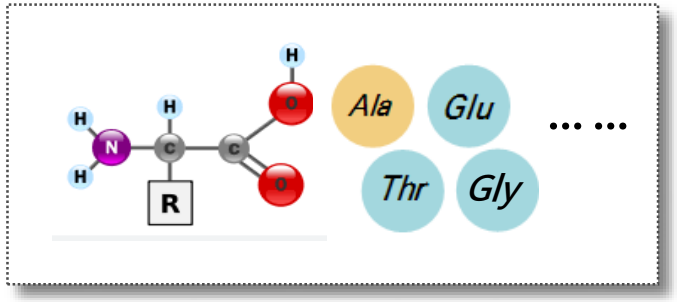
PRO TAC

…

Peptide Pharmaceuticals?

Amino acid

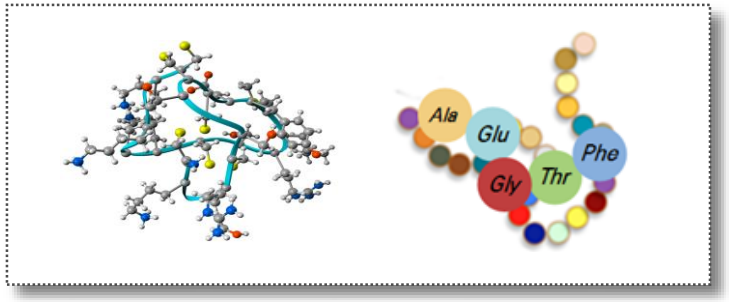
Fundamental units of proteins that make up living organisms
Molecules composed of C, H, O, and N / 20 different types



Amino Acid Infusion Solution

Peptide

A chain of 2 to 50 amino acids linked by peptide bonds.
When more than 10 amino acids are linked, it is called a polypeptide.

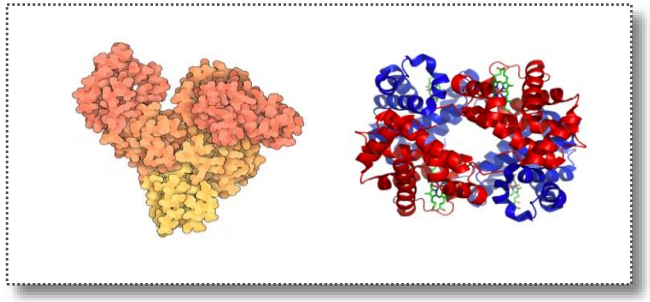


Obesity / Diabetes Medications

Infertility / Prostate Cancer Medications

Protein

A polymer composed of multiple polypeptides linked together.



Rheumatoid Arthritis / Joint Disease Treatments

Breast Cancer Treatments

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The Rapidly Advancing Peptide Market

Why Peptide Biopharmaceuticals?

- Peptide drugs are hormone-based biopharmaceuticals that are involved in signal transmission and functional regulation within the human body, making them biocompatible and human-friendly therapeutic agents.
- Driven by advancements in biotechnology, the peptide sector is entering a phase of rapid expansion and is quickly emerging as a game-changer in the pharmaceutical industry.
- Promising Areas
  - ❶ Chronic Metabolic Disease Treatments (e.g., Diabetes, Obesity)
  - ❷ Cardiovascular Disease and Anti-Cancer Treatments
  - ✓ ❸ Peptide Material (API) Development and Production

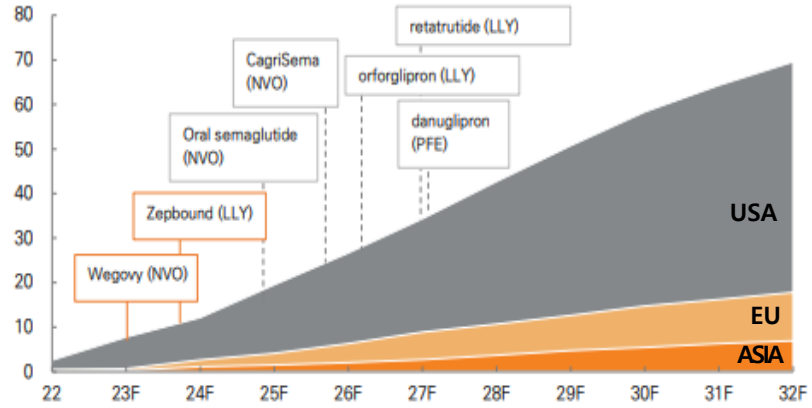
Peptide GLP-1, Chronic Disease Treatments (Obesity/Diabetes)
Projected to Reach a 100 Trillion KRW Market by 2030

Lilly novo nordisk

Global Peptide Pharmaceuticals Market Size and Growth Rate

IN 2025 USD 52.5 billion
CAGR 7.5% (2023~2032)
IN 2034 USD 83.7 billon

Market Outlook for Peptide Pharmaceuticals and Obesity Treatments



Sources and Terminology

① Precedence Research (2025)
② GLP-1 (Glucagon -like Peptide) : A glucagon-like peptide that stimulates insulin secretion and inhibits glucagon, targeting diabetes and obesity.

HLB PEP

Korea's 'Best' Peptide Expert

Dr. Jae Il, Kim

- Tokyo University, Ph.D. (Biophysics and Biochemistry)
- Assistant Prof. of Tokyo Univ.
  (Pharmaceutical Sciences School)
- Mitsubishi R&D center (Researcher)
- Prof. of GIST(Gwangju Institute of Science & Technology)
- Published over 150 research papers, including in Nature, and holds 37 patents.


nature International weekly journal of science

Article

Portability of paddle motif function and pharmacology in voltage sensors

Voltage sensing domains enable membrane proteins to sense and react to changes in membrane voltage. Although identifiable S1–S4 voltage sensing domains are found in an array of conventional ion channels and in other membrane proteins that lack pore domains, the extent to which their voltage sensing mechanisms are conserved is unknown. Here we show that the voltage sensor paddle, a motif composed of S3b and S4 helices, can drive channel opening with membrane depolarization when transplanted from an archaebacterial voltage activated potassium channel (KvAP) or voltage sensing domain proteins (Hv1 and Ci-VSP) into eukaryotic voltage activated potassium channels. Tarantula toxins that partition into membranes can interact with these paddle motifs at the protein–lipid interface and similarly perturb voltage sensor activation in both ion channels and proteins with a voltage sensing domain. Our results show that paddle motifs are modular, that their functions are conserved in voltage sensors, and that they move in the relatively unconstrained environment of the lipid

2000 ~2010

00 **Founded Anygen Co., Ltd.**

Venture Business Certification / Small and Medium Business Administration

05 Technology Innovation (INNO-BIZ) Selection of SMEs

06 Obtained ISO 9001 and ISO 14001 Certifications

10 **Peptide GMP Plant 1 (Jangseong, Jeollanam-do)**

2011 ~2015

✓ 11 **Korea's First GMP Certification for Peptide Active Pharmaceutical Ingredients**
Leuprorelin Approval

12 Approval for Desmopressin

Leuprorelin DMF Submission / U.S. Food and Drug Administration (FDA)

13 Approval for Exenatide
Approval for Ziconotide

2016 ~2025

✓ 16 **Listed on the KOSDAQ Market**

India DCGI Approval for Leuprorelin

✓ 18 **Completed Construction of Osong Plant No. 2 (Peptide Pharm Osong)**

20 **GMP Certification for Peptide Active Pharmaceutical Ingredients at Osong Plant No. 2**

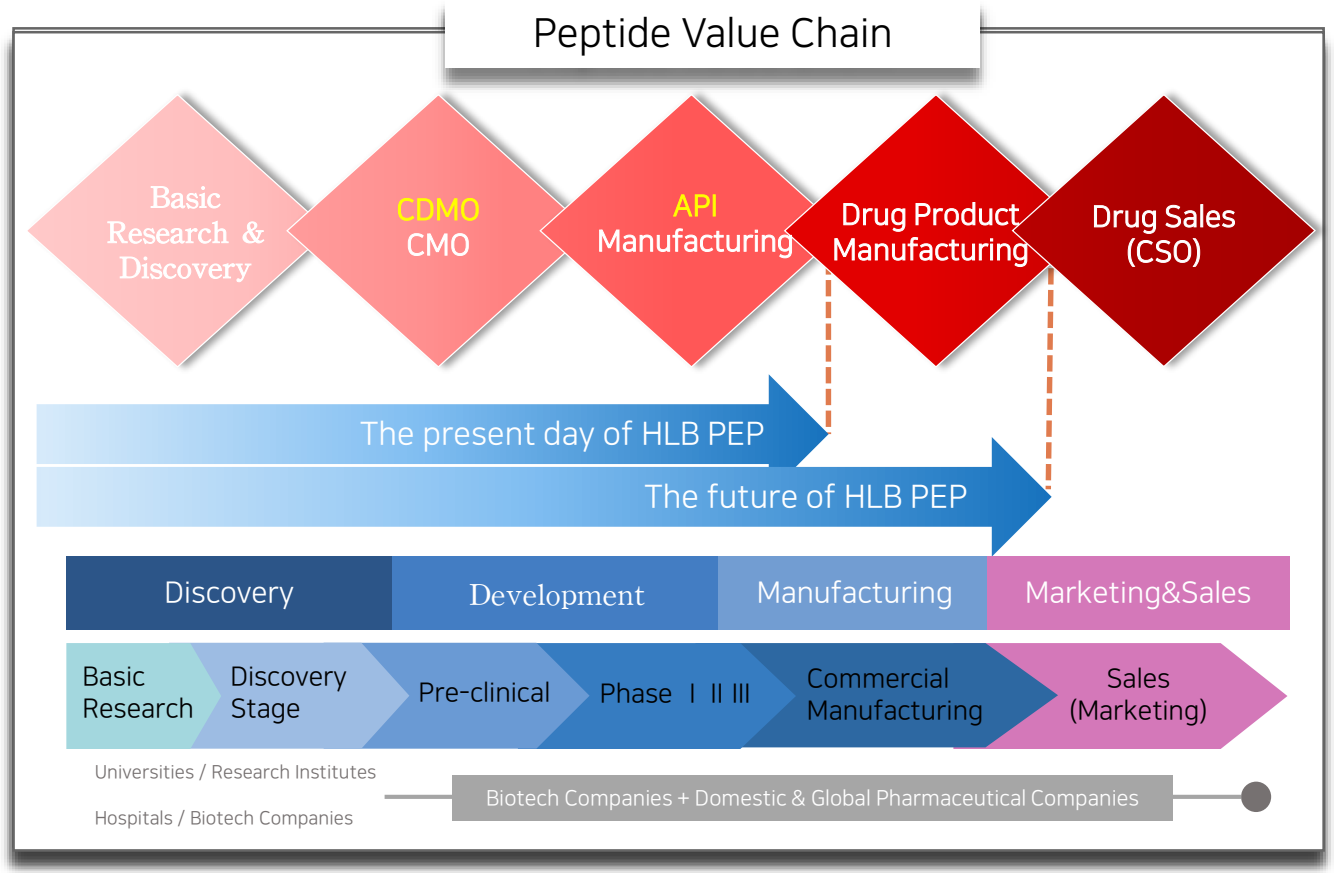
24 **Ganirelix DMF Submission / U.S. Food and Drug Administration (FDA)**

25 **Acquisition by HLB Group (Company Name Changed to HLB PEP)**

Peptide Value Chain & HLB PEP

Role & Position of HLB PEP

- Peptide pharmaceuticals are developed into new drugs through the process of <Discovery → Research → Clinical Trials → Review → Approval>
- Activating Collaboration Systems Due to High Technical Complexity
  - ❶ Discovery and Production of Basic Research Materials (Non-GMP)
  - ❷ Large-Scale GMP Production of Clinical-Grade Active Pharmaceutical Ingredients (API)
  - ❸ Manufacturing and Sales of Finished Dosage Pharmaceutical Products (DP) (CSO)
- HLB PEP provides comprehensive services ranging from basic research to pharmaceutical material development, production, and clinical protocol preparation.



Term

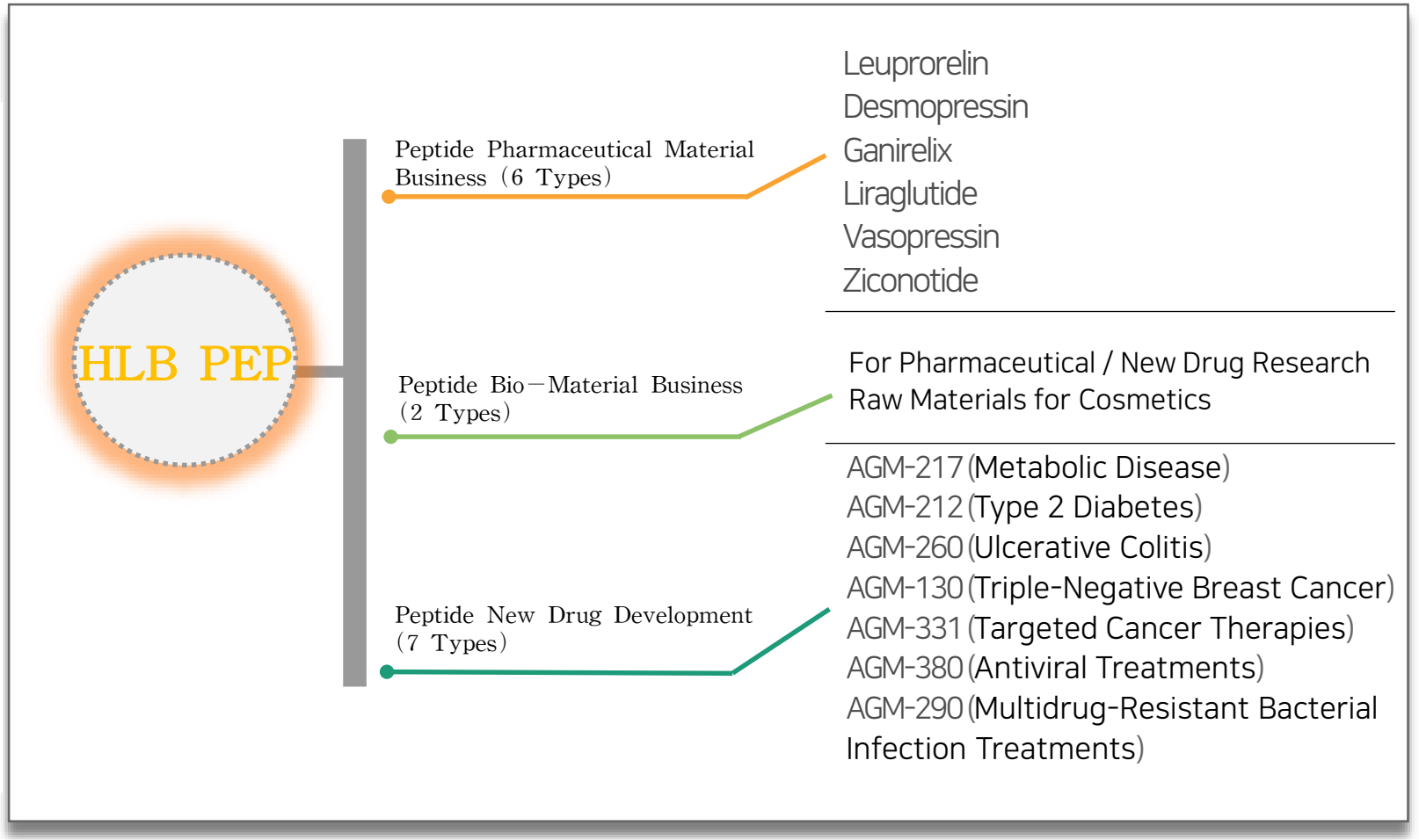
① CRO (Contract Research Organization) ② CMO (Contract Manufacturing Organization)
③ CDMO (Contract Development Manufacturing Organization)
④ API (Active Pharmaceutical Ingredient) ⑤ DP (Drug Product)
⑥ CSO (Contract Sales Organization)

Key Business Areas and Pipeline

Distinctive Development Capabilities

- In the global peptide pharmaceutical materials market, which is dominated by a limited number of companies, HLB PEP became the first in Korea to obtain GMP certification and has produced over 5,000 types of peptide materials per year.

- By supplying customized peptide products—distinct from those of existing global competitors—to domestic and international pharmaceutical companies, HLB PEP promotes the development of improved new drugs.



2. Core Competitiveness

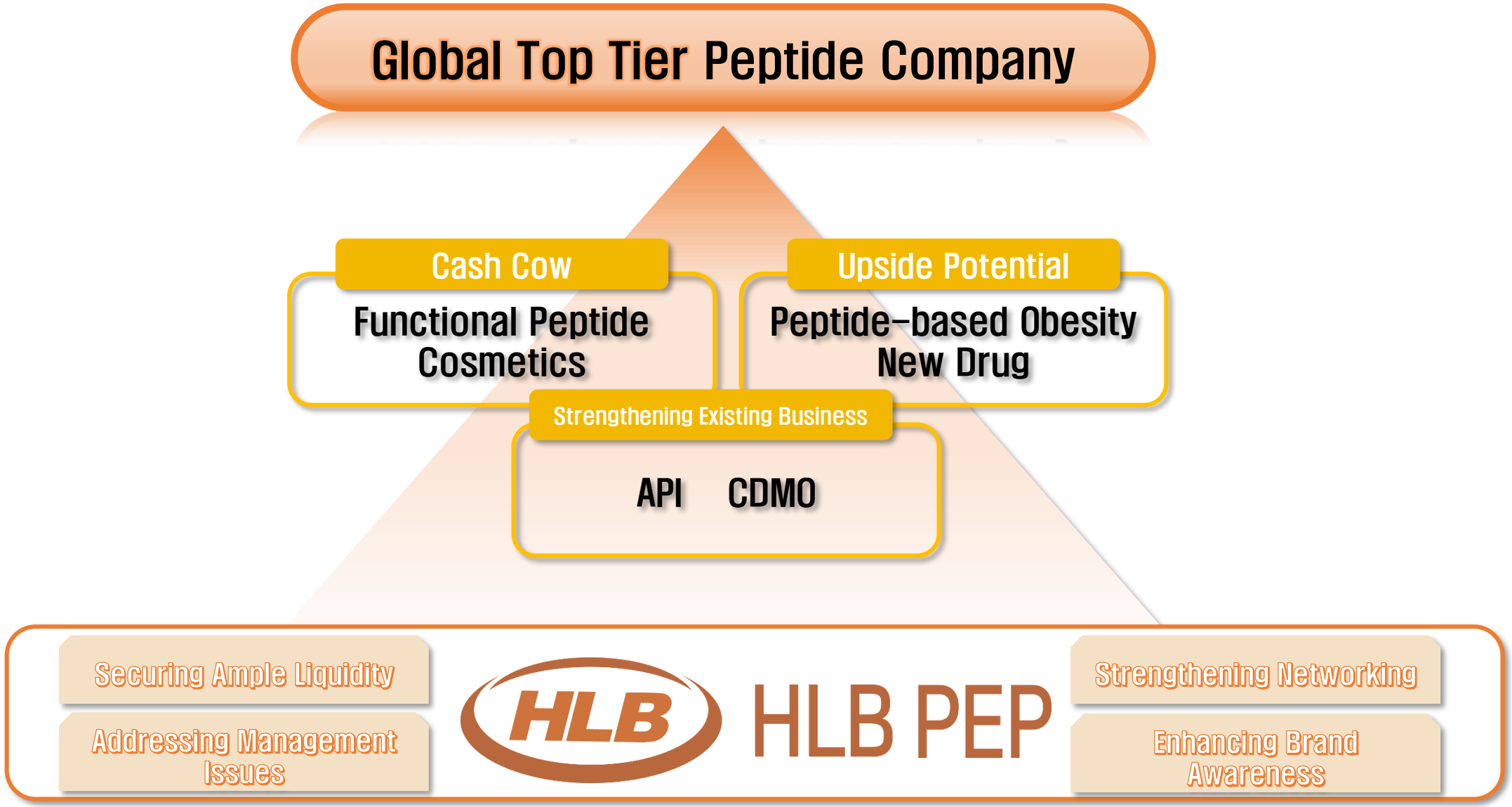
01) Overview

02) Strengthening Core Business(API, CDMO)

03) Securing Cash Cow (Cosmetics)

04) Upside Potential (New Drug Development)

Overview


Global Top Tier Peptide Company
Cash Cow
Functional Peptide Cosmetics
Upside Potential
Peptide-based Obesity New Drug
Strengthening Existing Business
API CDMO
Securing Ample Liquidity
Addressing Management Issues
HLB PEP
Strengthening Networking
Enhancing Brand Awareness

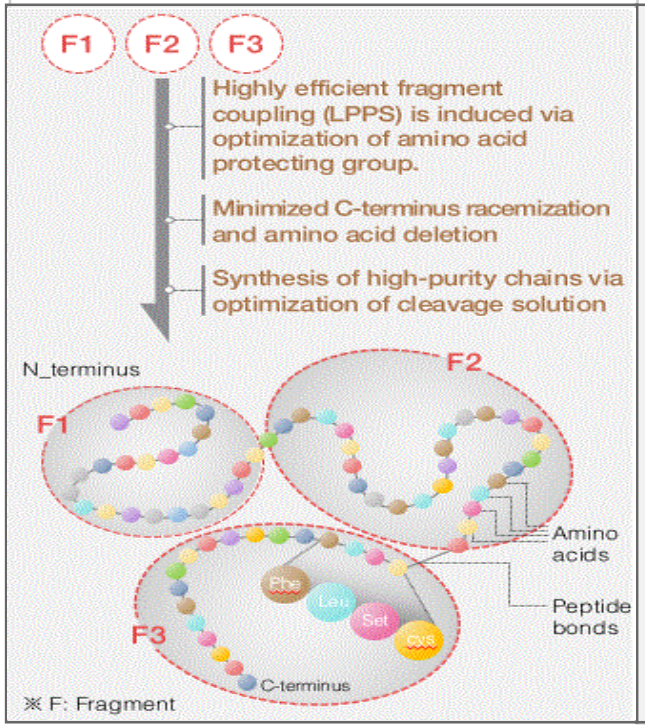
Strengthening Core Business – Advancing API Development Technology

HLB PEP
3 Core Technologies

1. Long Chain Technology

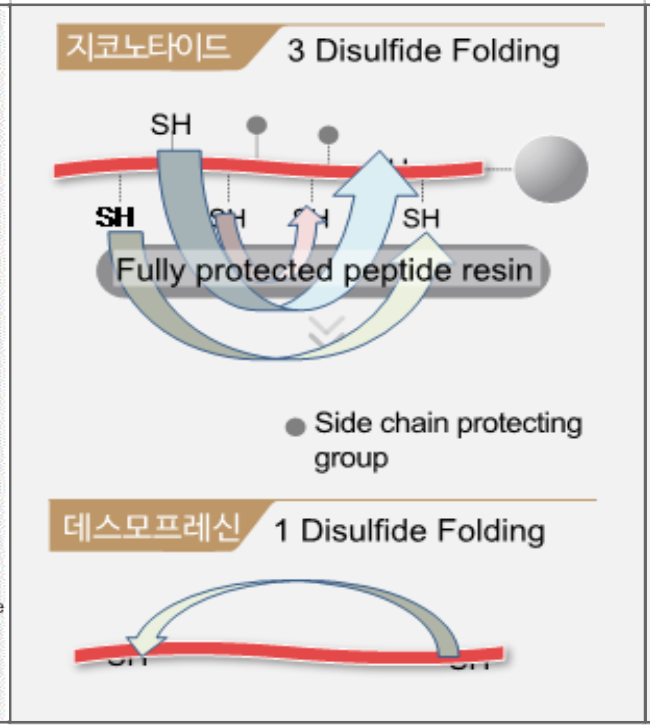
Securing Unique Convergent Manufacturing Technology

Overcoming increased synthetic complexity associated with longer peptide chains



2. Cys rich disulfide folding Technology

Cysteine disulfide bond technology with impurity minimization.



3. Modified Peptide Synthesis Technology

All modifications possible (e.g., FITC, Cyclic, pNA, etc.)

N-terminal	Side Chain	C-terminal
Acetylation / Biotinylation		Amidation
Fluorescence Dye (FITC/Cy3/Cy5 and its derivative)		Esterification
DNP (2,3-D-Niroanilide)		pNA (p-Niroanilide)
Dabcyl/Dabsyl/ Dancyl	Phosphorylation (Ser,Thr, Tyr)	AMC (Aminomethylcoumarin)
Fatty acid	Disulfide Bonds	MAP (Multiple Antigen peptide)
PEG	Cyclization	EDANS
KLH/BSA Conjugation to Antibody Production		

GMP service package for CDMO

GMP Service Package

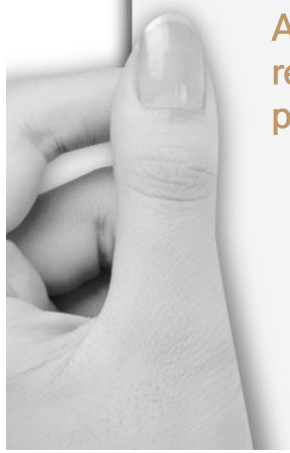
Analytical Development and Characterization

Method Validation

Full stability testing according to KFDA/ICH guidelines over 48 months

Process Validation

All batch documentation and any support documentation required, including a CTD
package and a US or European DMF when needed.



GMP Standard Specifications

- Appearance
- Solubility
- Identity by Mass Spectral Analysis (LC–MS)
- Amino acid Analysis
- Peptide Purity by HPLC
- Related Substances by HPLC
- Assay by Peptide Content
- Bacterial Endotoxins
- Counter–ion Content
- Water Content
- Mass Balance
- Specific Rotation
- Residual Organic Solvents by GC
- Trifluoroacetic acid Content
- Inorganic Fluoride
- Bioburden
- UV
- FT–IR

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Global business market

- Accreditation **Certificate of Foreign Drug Manufacturer** / Ministry of Health, Labor and Welfare of **Japan**
- Acquiring orders on CDMO business for clinical drugs in progress
- **Management of offices in Japan (7 branches)**
- CDMO Service from Japanese customers

- DMF Registration of Lleuprorelin, Ganirelix to FDA
- Consultation for cGMP and FDA approval (Interchem, U.S.)

- **Exporting Leuprorelin to Taiwan**
- **Exporting Desmopressin to Taiwan**
- CDMO Service from Taiwan customers

- EU-GMP approval in progress after Gap Analysis
- QP Qualified from Italy company
- CDMO Service form EU Customers

- **Exporting Leuprorelin to Mexico**
- New market entry with BIRMEX (Govern. Company)

HLB PEP

Has many track records in global clinical trials (CDMO)

Applicant	Stage	Contents
Company "N"	Phase 1	Process development, API manufacturing, CMC, 36 months stability 300 g (100 g * three batches)
Company "C"	Phase 1	Process development, API manufacturing, CMC, 36 months stability 300 g (100 g * three batches)
Company "O	Phase 1	CMC, 36 months stability 2 g
Company "C"	Phase 1, 2	API manufacturing, stability 30 g (10 g * three batches)
Company "Y"	Phase 1, 2	Product manufacturing, CMC 70 g, 5 g
Company "E"	Phase 1	Process development, API manufacturing, CMC, 36 months stability 680 g (340 g * two batches)

Applicant	Stage	Contents
Company "H"	Phase 1	Process development, API manufacturing, CMC, 36 months stability 450 g (150 g * three batches)
Company "N"	Phase 1	Process development, API manufacturing, CMC, 36 months stability 300 g (100 g * three batches)
Company "A"	Phase 1	Process development, API manufacturing, CMC, 36 months stability 300 g (100 g * three batches)
Company "A"	Phase 1	Process development, API manufacturing, CMC, 36 months stability 300 g (100 g * three batches)
Company "G"	Phase 1	Process development, API manufacturing, CMC, 36 months stability 270 g (90 g * three batches)
Company "D"	Phase 1	API production 100 g
Company "H"	Phase 1	Product manufacturing, CMC

HLB PEP

Development of product (API) with high market value

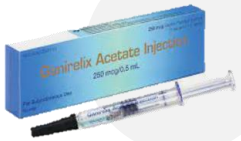
Takeda
Approximately
KRW 3,000 billion

Precocious puberty

Nocturnal enuresis

Sanofi-Aventis
Approximately
KRW 1,840 billion

New Era Pharmacy
Approximately
KRW 550 billion

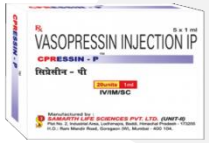


Infertility

Obesity

novo nordisk
Approximately
KRW 3,300 billion

Samarath Pharma
Approximately
KRW 1,100 billion



Anti-uretic, vasoconstriction (First aid kit)

Neuropathic Pain

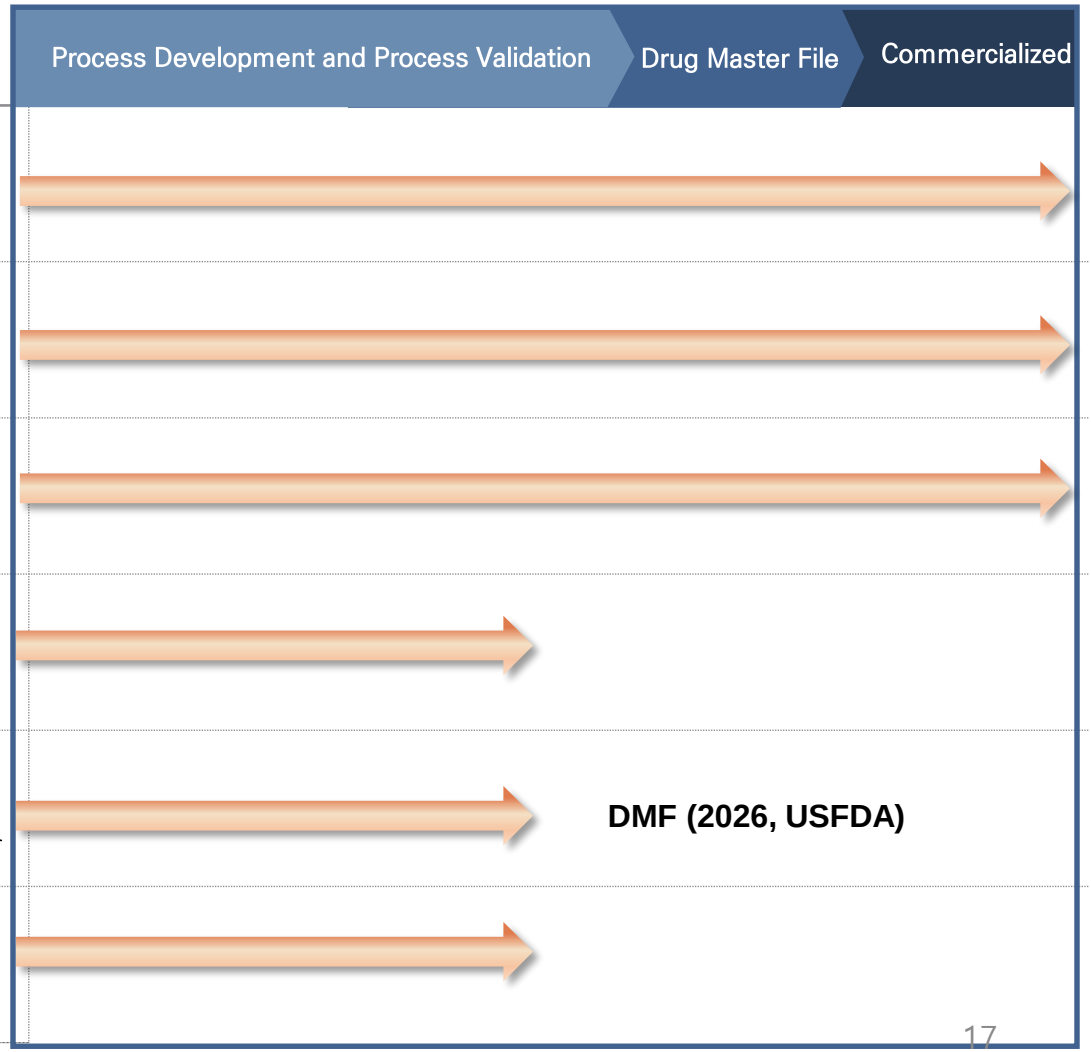
Elan Corp.
Approximately
KRW 80 billion

December 2020, based on New port global, medicinal product market size

Strengthening Core Business – Expanding API Indications & Markets

Beyond Korea to the World!

	APIs	Indications
Products Aligned with Low Birthrate Policies	Leuprorelin DMF, Ph Eur, USP, USFDA #25878, ANDA	Prostate cancer,Precocious precocious puberty for IVF
	Desmopressin DMF, Ph Eur, USP	Nocturnal enuresis
Products Aligned with Low Birthrate Policies	Ganirelix DMF, USFDA #040573, ANDA	Fertility treatment
	Liraglutide	Diabetes, Obesity
	Vasopressin Scheduled for US FDA Submission in 2026	Antidiuretic hormone anti−diuretic, vasoconstriction
	Ziconotide	Pain Killer



Strengthening Core Business – Expanding Production Capacity

Expansion of production lines and advancement of synthesis/purification processes, securing cGMP certification.

Plant 1) Jangseong GMP

○ Korea's First Dedicated Peptide GMP Facility

○ European Medicines Agency QP Certification

Korea's First GMP-Certified Smart Factory

Currently pursuing cGMP certifications from Japan's PMDA, the U.S. FDA, and EU-GMP certification from Europe.

✓ Entering the Global CDMO Market

✓ Export of Active Pharmaceutical Ingredients(API)

Currently implementing and advancing smart factory systems

Implemented system

MES (Manufacturing Execution System)	Bar-Code System

Plant 2) Osong GMP

○ KGMP Certification

○ EU-GMP, cGMP, PMDA Approval in Progress

○ European Medicines Agency QP Certification

○ USFDA Preliminary Inspection Completed

○ LIMS Implementation in Progress

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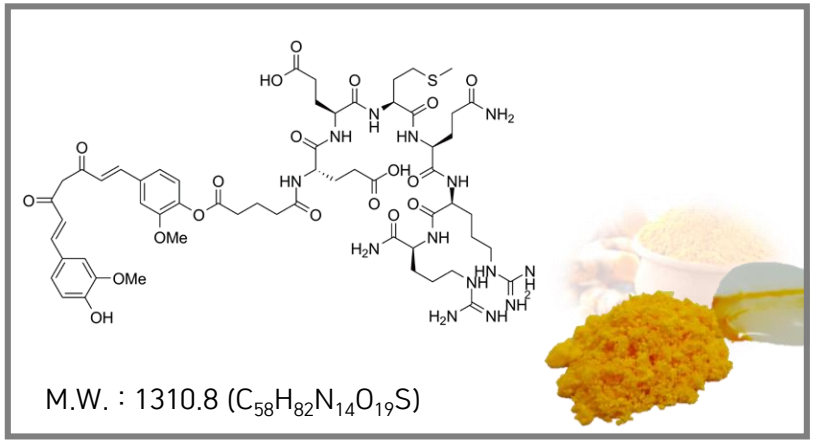
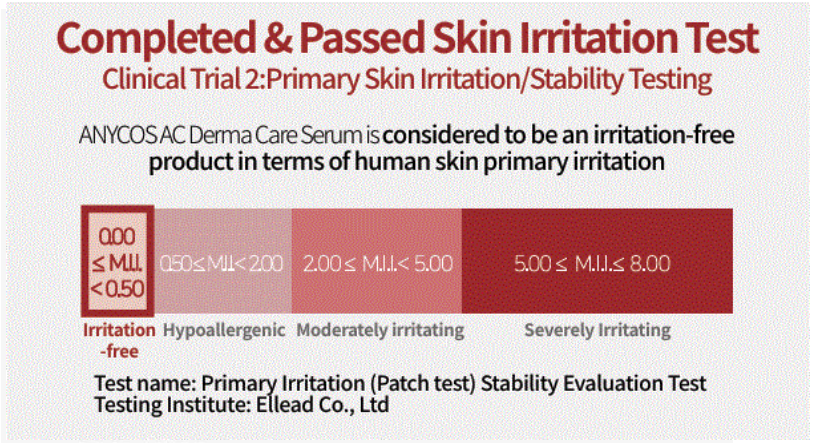
Securing Cash Cow – Development of Functional Cosmetics

➢ Patented Curcumin Technology: Solving the Absorption Challenge

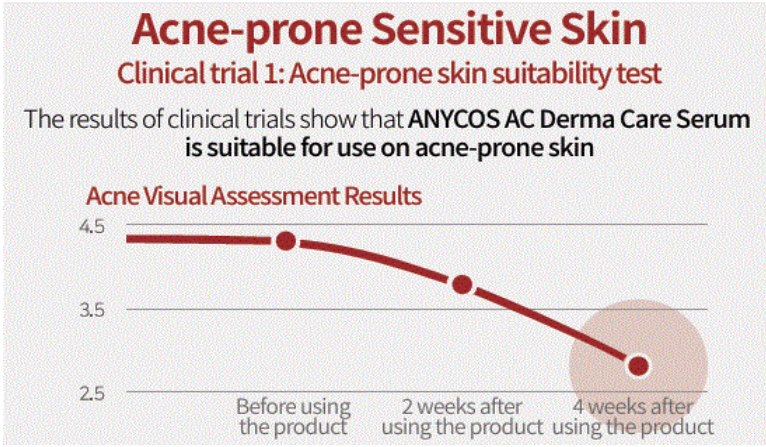
INCI Name: Curcuminyl Glutaroyl Hexapeptide-24 Amide

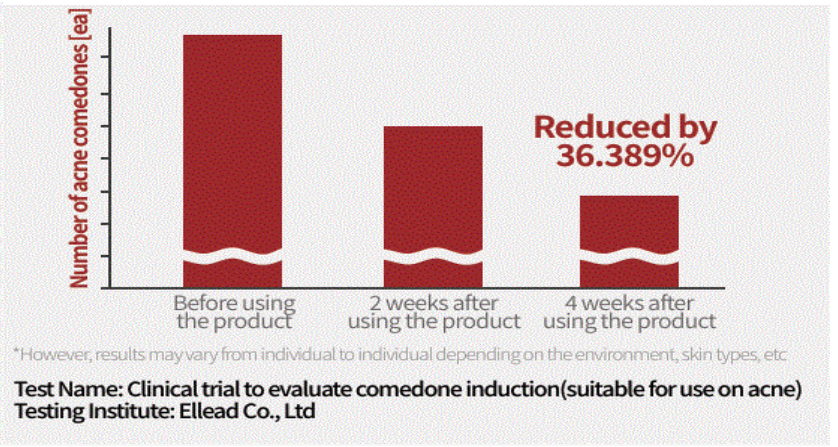


➢ Skin Irritation Evaluation Results



➢ Suitability Assessment for Use on Acne-Prone Skin (Clinical Human Trial)

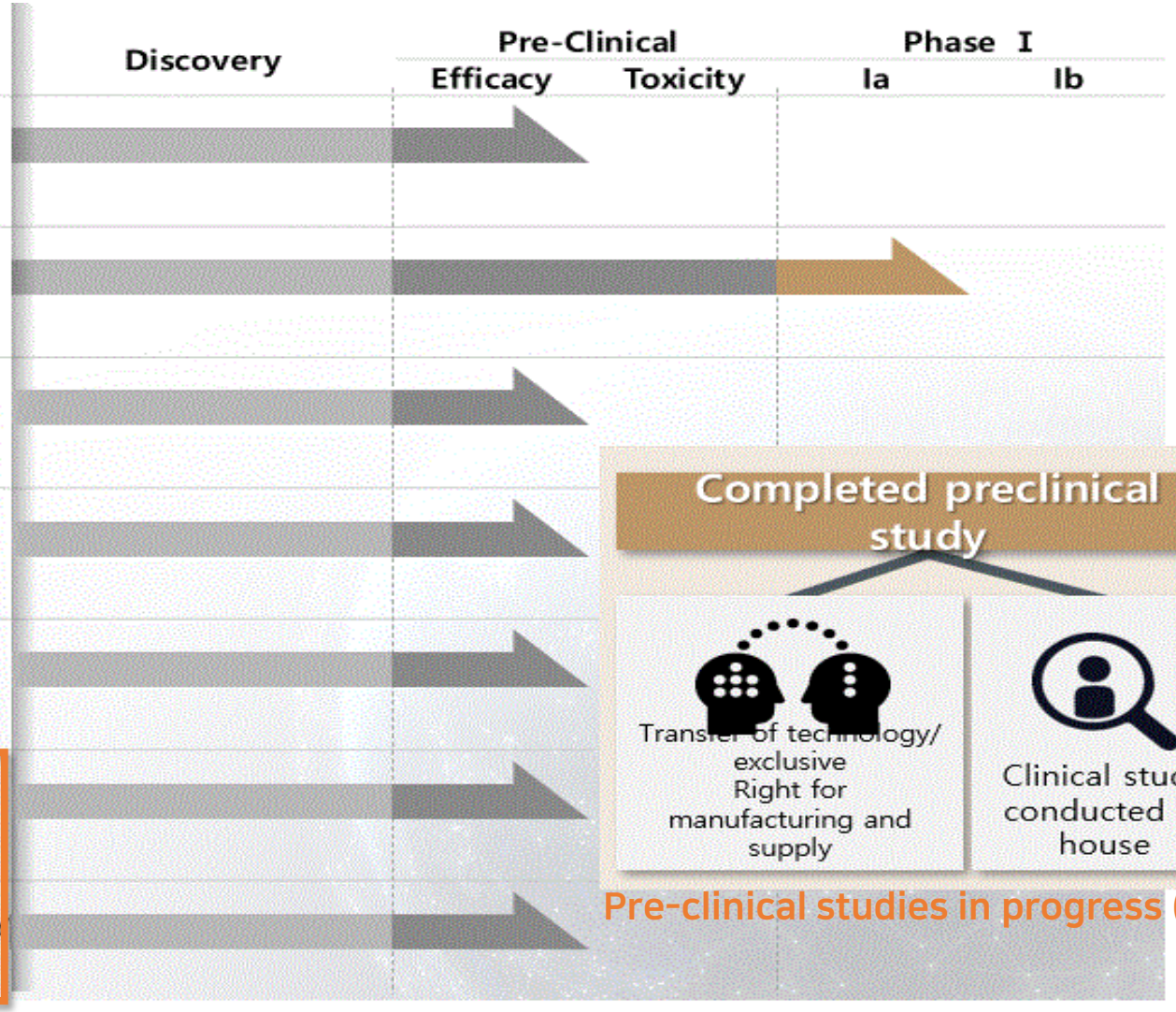




Securing Cash Cow – Development of Functional Cosmetics

Advancing as a Global New Drug Development Company Utilizing Peptide Technology

Category	Project	Indication
Cancer	AGM-331	Selectively binds to cancer cell in vivo Targeted anti-cancer therapy
	AGM-130	specific for without targeted therapy Treatment for Triple Negative Breast Cancer
Virus Infection	AGM-380	General anti-viral agent Treatment for viral infection
Super Bacteria	AGM-290	General anti-bacterial agent Treatment for infection caused by multidrug resistant bacteria
Metabolic Disease	AGM-212	With low level of side effects such as antibody generation Treatment for Type 2 Diabetes
	AGM-217	To treat diabetes and obesity Treatment for metabolic diseases
	AGM-260	Without specific targeted therapy Treatment for Ulcerative colitis



Completed preclinical study

- Transfer of technology/ exclusive Right for manufacturing and supply
- Clinical study conducted in house

Pre-clinical studies in progress (Japan)

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Upside Potential – Development of Obesity New Drugs

USA
Gila monster

Obesity Treatments

New Drug

Market

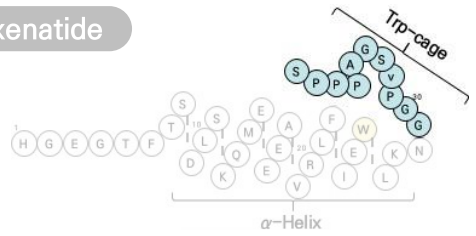
$19.5 billion
CAGR : 6.1 %

AGM-212 Treatment for type 2 diabetes

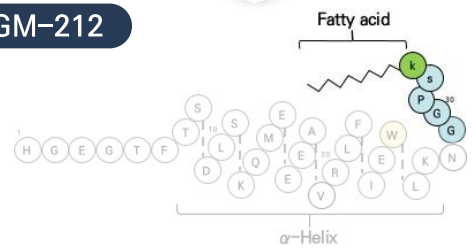
- Exenatide (exenatide) based type 2 diabetes
- Based on superior in vivo safety improved sustained blood glucose level lowering effect compared to liraglutide
- Prominent reduction of side effects such as antibody formation
- Completed registration of invention of matter and use

Authority	Application number	Filing date	Name of invention
Domestic	10-1768446	8/9/2017	Newly developed derivative of exenatide and its use
Japan	6438563	11/22/2018	
Europe	3121195	1/2/2019	
China	ZL 201580015260.9	3/16/2021	
USA	11,103,557	8/31/2021	

Exenatide



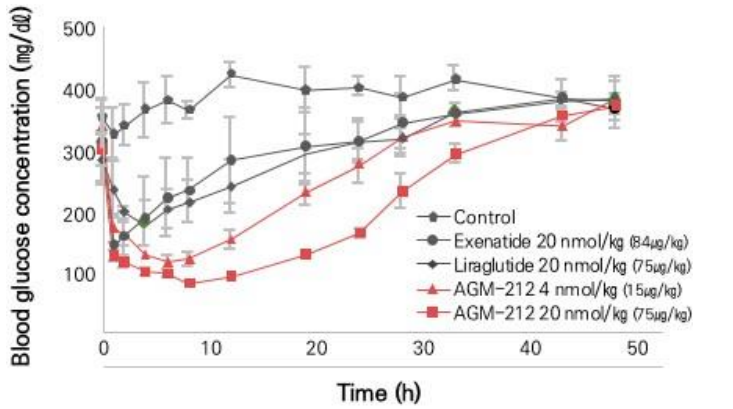
AGM-212



Using rat model **in vivo safety study**

Parameter	Exendin-4	AGM-212
$t_{1/2\ (h)}$	0.47	2.25
$T_{max\ (h)}$	0.88	2.5
$C_{max\ (ng/mL)}$	69.2	354
AUC $_{(ng\ h/mL)}$	92.2	1817.8
Vd $_{(mL/kg)}$	3759.8	833.2
Cl $_{(mL/h/kg)}$	5483.5	256.9

In diabetes mouse model **study on anti-diabetic efficacy**



Biochemical Pharmacology 151 (2018) 59-68

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Upside Potential – Development of Obesity New Drugs

U.S. Lizard

Obesity Treatments

New Drug

Over 20 trillion KRW
CAGR 21.1%

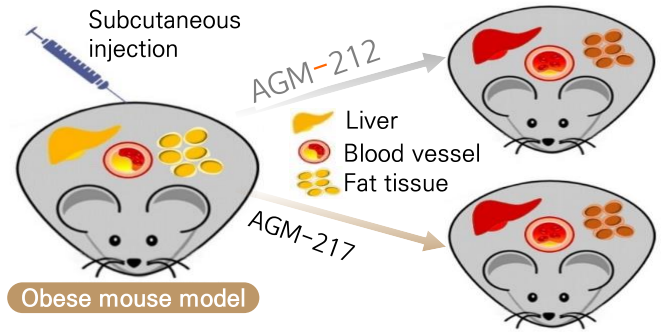
135 trillion KRW by 2030

AGM-217 Metabolic Obesity Treatment Peptides

- ✓ 'Fat-burning' effect surpassing existing treatments
- ✓ Long-acting (SR) and patch formulations under consideration for development

Country of application	Application Number (Registration Number)	Application Date (Registration Date)	Title of the Invention
Korea	(10-2496719)	(2023-02-01)	Exenatide Heterodimer Analog and Its Uses
Canada	3147770	2022-02-11	Exenatide Analog and Its Uses
United States (U.S.)	17/635,039	2022-02-14	
China	202080057405.2	2022-02-11	
Europe	20852849.7	2022-02-16	
Japan	7425855	2024-01-23	

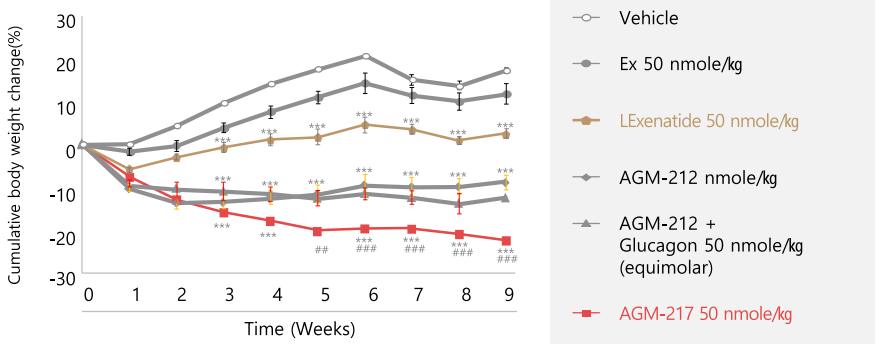
Regulation of metabolic functions in the body by AGM-217



↓	Body weight	↑	Energy expenditure
↓	Cholesterol	↑	Browning/UCP-1 level
↓↓↓	Triglyceride	↑↑↑	Glycemic control
↓↓↓	Steatohepatitis		

↓↓↓	Body weight	↑↑↑	Energy expenditure
↓↓↓	Cholesterol	↑↑↑	Browning/UCP-1 level
↓↓↓	Triglyceride	↑↑↑	Lipolysis
↓↓↓	Steatohepatitis	↑↑↑	Glycemic control

Weight loss efficacy in obese mouse models



Diabetes Obes Metab. 2021;1–11

Upside Potential – Development of Ulcerative Colitis New Drugs

New Target

Ulcerative Colitis Treatment

New Drug

Over 14 trillion KRW
CAGR 5%
20 trillion KRW by 2030

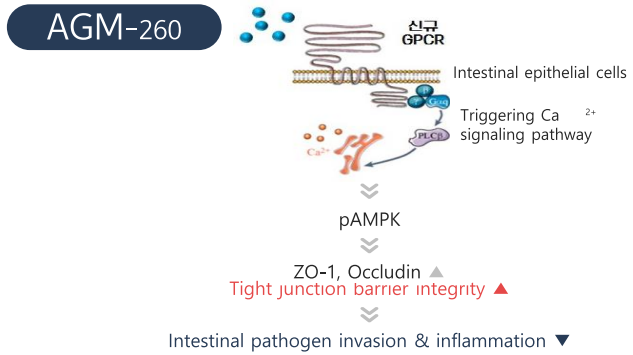
AGM-260 Ulcerative Colitis Treatment

- ✓ Discovery of highly specific optimal GPCR (Novel Therapeutic Agent)
- ✓ Local anti-inflammatory effect and promotion of intestinal mucosal healing
- ✓ Oral formulation under consideration

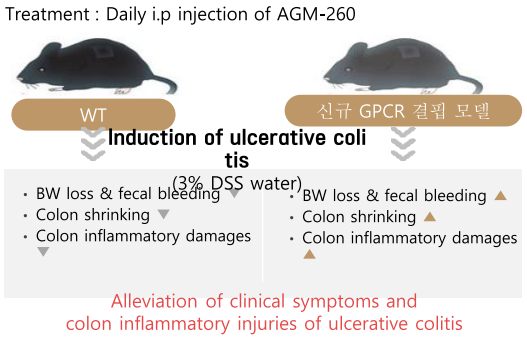
Korea	10-2021-0120647	2021-09-09
United States (U.S.)	18/557,576	2023-10-26
Europe	22867732.4	2023-10-26
China	202280032063.8	2023-10-30
Japan	2023-560932	2023-10-02
Canada	-	2023-10-25
Australia	2022342994	2023-09-27

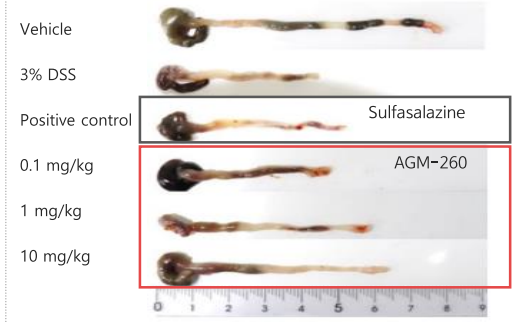
Composition containing a novel compound for the prevention or treatment of inflammatory bowel disease

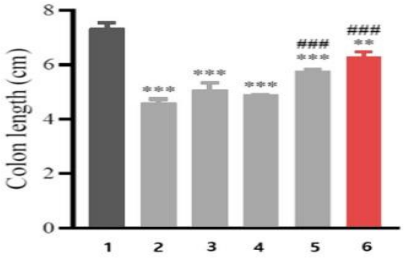
Mechanism of action of AGM-260 in intestinal cells



Confirmed anti-inflammatory effects in ulcerative colitis animal model mice







Thank you !

HLB PEP

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