
# Making Our World Healthier Together

## DAEWOONG PHARMACEUTICAL CO.,LTD.

Pharmaceutical

Chemical

Biologics

Finished Dosages

Active Pharmaceutical Ingredient

Out Licensing

Open Collaboration

DAEWOONG PHARMACEUTICAL CO.,LTD.

# Business Overview

## General Overview

Daewoong Pharmaceutical has established the most extensive infrastructure in various countries among Republic of Korean pharmaceutical companies, conducting research, development, and production of globally competitive pharmaceuticals. Having achieved the success of new drug development for two consecutive years, we lead the domestic and international pharmaceutical industries, fulfilling our management philosophy of patriotism through medicine.
We have tablet pharmaceutical manufacturing facilities meeting KGMP standards in the Hyangnam Industrial Complex in Hwaseong, Gyeonggi-do, and the Osong Plant in Chungcheongbuk-do. Additionally, we possess state-of-the-art facilities, including the latest specialized cell therapy cGMP facilities, advanced biopharmaceutical manufacturing licenses, human cell management licenses, and cell processing facility licenses, enabling the production of products incorporating advanced medical technologies.

| Company Name | Daewoong Co.,Ltd | Daewoong Pharmaceutical Co., Ltd |
|---|---|---|
| CEO | Jae-chun Yoon | Chang-jae Lee, Sung-soo Park |
| Establishment Date | August 15, 1945 | October 02, 2002 |
| Headquarters | 244, Galmachi-ro, Jungwon-gu, Seongnam, Gyeonggi-do, Republic of Korea | **Headquarters** 12, Bongeunsa-ro 114-gil, Gangnam-gu, Seoul, Republic of Korea<br>**Factories** 35-14, Jeyakgongdan 4-gil, Hyangnam-eup, Hwaseong-si, Gyeonggi-do, Republic of Korea<br>1, Osongsaengmyeong 2-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea<br>**Research Center** 72, Dugye-ro, Pogok-eup, Cheoin-gu, Yongin-si, Gyeonggi-do, Republic of Korea |
| Business Portfolio | Investment Business and Management Services as a Holding Company | Production and Sales of Pharmaceuticals |

# Global Healthcare Group Daewoong

## Daewoong Pharmaceutical takes the lead in advancing human health beyond Republic of Korea.

### Patriotism through Medicine

Daewoong Pharmaceutical was founded in 1945 with the belief of “patriotism through medicine,” which means “making good medicine to protect the health of the people and create a healthy society.”

### Success in New Drug Development for Two Consecutive Years

With the success of new drug development for two consecutive years, we have proven our R&D capabilities and lead the development of the pharmaceutical industry domestically and internationally as a leader in the healthcare industry.

### 2030 KRW 1 Trillion Sales in New Drugs (KRW 1 Trillion per Product)

By achieving KRW 1 trillion in global sales of self-developed new drugs, we strengthen our global status and aim to become a global big pharma that contributes to a healthy and happy life for humanity through the development of future innovative new drugs and the provision of total healthcare solutions.

# Company History

## The Footprint of Daewoong Pharmaceutical

### Establishment

**1945** Founded Joseon Ganyu Pharmaceutical Company
**1961** Changed company name to Daehan Vitamin Industries and launched Ursa
**1978** Changed company name to Daewoong Pharmaceutical Co., Ltd.

### 1980 ~

**1980** Exceeded KRW 10 billion in sales
**1982** Established Daewoong Lilly Pharmaceutical Co., Ltd.
**1986** Ursa designated as an official supplier for the Asian Games and 1988 Seoul Olympics
**1987** Received 2 Million Dollar Export Tower Presidential Award
**1992** Completed the 2nd KGMP plant in Hyangnam
**1994** Exceeded KRW 100 billion in sales

### 2000 ~

**2001** Launched Easyef (EGF), South Korea's first biotechnology new drug
**2002** Division of Daewoong Co., Ltd. and Daewoong Pharmaceutical
**2003** Daewoong Pharmaceutical's Hyangnam Plant obtains ISO 14001 certification
**2009** Opens Pharmaceutical R&D Center in India



### 2010 ~

**2010** Ursa selected as a world-class product
**2012** Established a joint venture "Daewoong Infion (PT. DAEWOONG INFION)" in Indonesia
**2014** Domestic release of botulinum toxin preparation "NABOTA" selected as a world-class product
**2018** · Acquisition of ISO 37001 Anti-bribery Management System
· Obtained US cGMP approval for the NABOTA plant
**2019** · Botulinum toxin developed by the company obtained Asia's first USFDA approval
· Bersiporocin (DWN12088) has been granted Orphan Drug Designation in the US by FDA for the treatment of idiopathic pulmonary fibrosis (IPF), a new drug candidate for idiopathic pulmonary fibrosis, designated as an orphan drug by USFDA
· Daewoong Pharmaceutical's separate sales exceeded KRW 1 trillion for the first time in its history

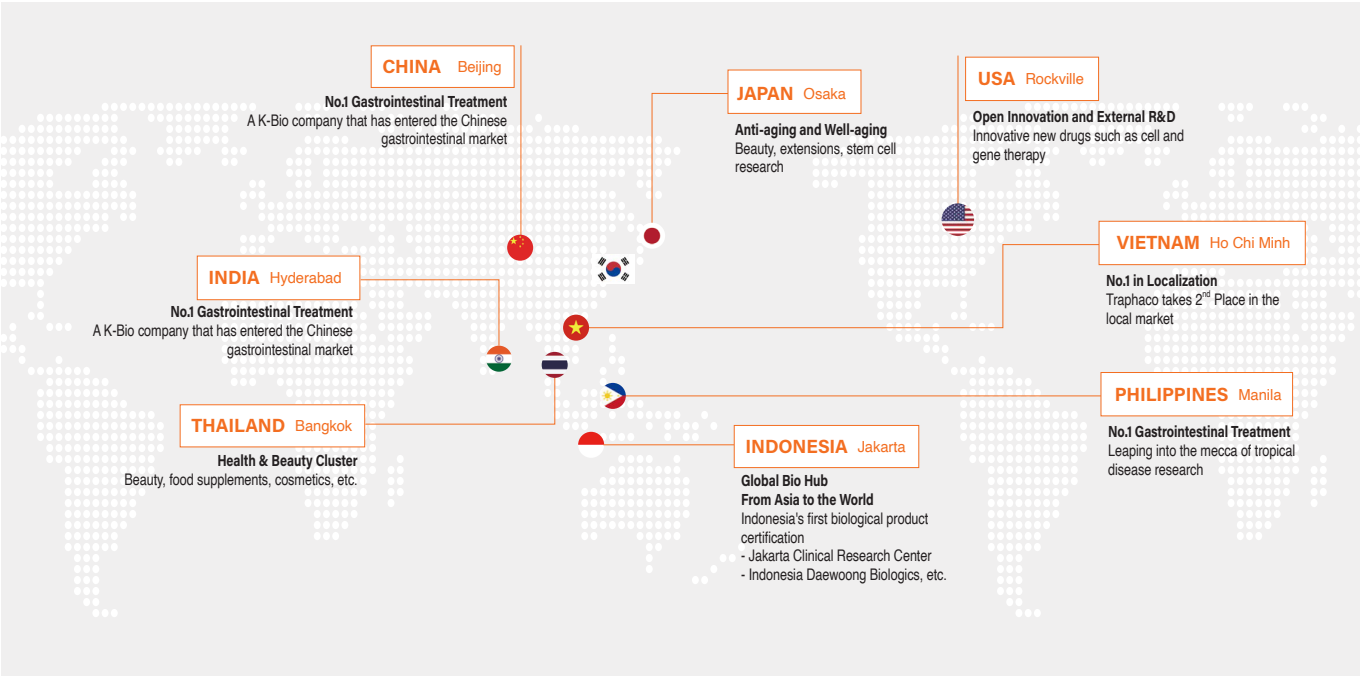
### 2020 to Present

**2020** Enavoglifozin has been granted Fast Track Designation in Korea by MFDS for the treatment of Diabetes was designated for expedited review for the first time in Korea and conducted a Phase 3 clinical trial
**2021** · Acquired domestic sales approval of Fexuclue for gastroesophageal reflux disease, as the 34th developed new drug in Korea
· Ranked 10th Asia's Best Workplaces by GPTW
**2022** · Launched "Fexuclue," a drug for gastroesophageal reflux disease
· The New drug "Fexuclue" won the Grand Prize at the Korea New Drug Development Awards
· "Envlo" the 36th new diabetes treatment drug, approved for sale in Korea
**2023** · Launched a new drug 'Envlo Tab' the first made-in-Korea SGLT-2 inhibitor for diabetes treatment in Korea
· Acquired product approval in Chile, Ecuador for gastroesophageal reflux disease drug Fexuclue
**2024** · Acquired product approval in Mexico for gastroesophageal reflux disease drug Fexuclue

# Global Network

In order to leap forward as an Asian bio hub strategically based in the 8 countries where its overseas branches are located, Daewoong Pharmaceutical is bolstering local viability by laying the groundwork for operating overseas subsidiaries, R&D centers, and branches, and is developing various collaboration infrastructures such as research, development, manufacturing, and sales. By localizing the value chain through overseas M&A, expanding global marketing, and expanding major markets in the U.S. and EU, the company is striving to achieve strategic growth and the expansion of its global base.

| Sales | Branch Operations in Asia & US | R&D Centers | Partners |
|---|---|---|---|
| USD 1,067 Mil | 8 Branches | 4 Centers | 100+ Companies |



# Pan-Global Specialized Manufacturing Capabilities

## Korea

Daewoong Pharmaceutical has a number of strategically located manufacturing sites, each of which specializes in various production lines such as depot, liquid suspension, biologics, and etc.

### Osong Plant Chungcheongbuk-do, South Korea

01. Highly automated mass production facility
02. Qualified injection manufacturing facility
    - Depot injection & ampoule, vial, drip infusion kit
    - First in Korea to be equipped with Dual Chamber Syringe (DCS) charging line)
03. Capacity: Dual Chamber Syringe (0.35M), Prefilled Syringe (0.25M), Tablet (2B)

Area: 40,892 $m^2$ (440,158 $ft^2$)
Manufacturing Products: Oral Solid, Depot Injection, Vial, Ampoule

### Hyangnam Plant Hyangnam, South Korea

01. Main manufacturing site for oral solids, suspensions, injectables and biologics
02. Produces Korea's first new biomedicine 'EGF'(Epidermal Growth Factor)
03. Supports clinical trial(phase 1-3) batch sizes and clinical scale-up manufacturing
04. Capacity: Tablet (1B), Prefilled Syringe (1M)

Area: 31,735 $m^2$ (341,598 $ft^2$)
Manufacturing Products: Oral Solid, Microbial Product, Cell cultured Product

### Seongnam Plant Seongnam, South Korea

01. Top cephalosporin CMO facility
02. RABS (Restricted-access barrier system) ensures sterility and validated aseptic-quality products
03. Capacity: Powder Injection Filling Line (24M Vial), Tablet (100M), Capsule (100M)

Area: 7,535 $m^2$ (81,106 $ft^2$)
Manufacturing Products: Cephalosporin Injection, Tablet, Capsule


### Anseong Daewoong-Bio Plant
Anseong, South Korea

Area
8,180 $m^2$ (88,048 $ft^2$)

Manufacturing Products
Oral Solid

### Daejeon Plant (HANALL BIOPHARMA)
Daejeon, South Korea

Area
9,011 $m^2$ (96,993 $ft^2$)

Manufacturing Products
A/A infusion, Oral Solid

## Global

Maximizing our accumulated know-how, we have acquired or built plants in strategic geographical locations to better address the needs of local markets.

### Surabaya Plant Surabaya, Indonesia

01. Dedicated to Biological products (EPO, EGF, Somatropin)
02. Independent production lines preventing cross-contamination
03. HALAL certified process management from drug substance to finished products
04. Capacity: Prefilled Syringe (4M)

Area: 2,484 $m^2$ (26,737 $ft^2$)
Manufacturing Products: Biopharmaceutical Products (EPO, EGF, hGH, BMP)

### Liaoning Plant Liaoning, China

01. Closed system throughout the production process
02. BIN System based transfer and handling
03. Unmanned ingredient transfer using line and pump
04. Capacity: Oral Liquid (200M pouch, 30M bottle)

Area: 9,586 $m^2$ (103,182 $ft^2$)
Manufacturing Products: Liquid for oral administration

### Sichuan Plant Sichuan, China

01. Top gall bladder-related production technology
02. UDCA intermediate production
03. API & CDCA (Chenodeoxycholic acid)

Area: 10,000 $m^2$ (107,639 $ft^2$)
Manufacturing Products: Chenodeoxycholic acid, crude Cholic acid

### Total Capacity per Year

| Type | Quantity | Type | Quantity | Type | Quantity |
|---|---|---|---|---|---|
| Tablet | 6.7 Billion | Bottle | 102 Million | Bag | 0.5 Million |
| Capsule | 205 Million | Pouch | 130 Million | Ampoule | 0.1 Billion |
| Vial | 70 Million | Syringe | 5.6 Million | Kit | 7 Million |

# Global R&D Centers

Daewoong's R&D Centers strive to develop innovative drugs through the utilization of internal resources and open collaboration on ideas and technologies from external resources

## Daewoong Bio Center Yongin, South Korea, Oct. 2016

01. Recombinant products including therapeutic antibodies
    - Bio-betters using long-acting technology, Growth factors
02. Stem cell research for enhancement of efficacy
    - Innovative stem cell line establishment
    - Discovery of new indications


## Jakarta Research Center Indonesia, Dec 2016

01. Development of biotechnology-driven products
    - EPO, EGF, hGH
    - Extensions of indication through clinical studies
02. Focus on reverse innovation and open collaboration
    (ex. Univ. of Indonesia)

## Life Science Research Institute Yongin, South Korea

01. New Chemical Entity (NCE)
    - Therapeutic areas: Autoimmune diseases, Metabolic diseases
    - In-vitro/in-vivo evaluation for autoimmune drugs
02. Incrementally Modified Drugs
    - Sustained-release technologies including Depot
    - Differentiated fixed-dose combination technology


## Liaoning Research Center China, Oct 2014

01. Development of generics for China market entry
02. Formulation R&D
    - New oral solutions, Suspension products, Sustained-release drugs
03. Academic collaboration (ex. Shenyang Pharmaceutical Univ.)

## Hyderabad Research Center India, Jan 2009

01. Development of first generics
02. Development of global generics for EU/US market entry
    - Sustained-release drugs, Formulation change

# Research & Development

## Strategic Approach to R&D

Daewoong's R&D Strategy is to focus and invest resources to develop First-in-Class or Best-in-Class therapies to better serve unmet medical needs.

First-in-Class


Best-in-Class

## Areas of Focus

### Core Competencies

**Gastric/Metabolic Diseases**

- GERD
- Diabetes, Obesity
- Osteoporosis
- Ulcerative colitis

### Diseases of Target High Unmet Needs

**Inflammatory/ Immune Diseases / Pain**

- Fibrosis (Lung, Liver, Kidney, Skin)
- Dry Eye Syndrome
- Autoimmune Diseases

Anti-cancer

- Targeted & IO therapy
- Ab-based Immunotherapy
- Supportive Care of Cancer

### Forefront of Innovation

**Stem Cell Therapy**

- Degenerative
- Orphan/Rare Disease

## New Chemical Entity

| Project | MoA | Best in Class First in Class | Indication | Status |
|---|---|---|---|---|
| Fexuclue | P-CAB | BIC | Treatment of EE*, Gastritis,Risk reduction of NSAIDs associated ulcer | P3 |
| | | BIC | H. Pylori, NERD | P3 |
| Envlo | SGLT2 inhibitor | BIC | Type 2 diabetes | NDA |
| Bersiporocin (DWN12088) | PRS Inhibitor | FIC | Idiopathic Pulmonary Fibrosis (IPF) | P2 |
| Aneratrigine (DWP17061) | Nav1.7 blocker | FIC | Post Herpetic Pain(PHN), Trigeminal Neuralgia(TN), Osteoarthritis pain(OA) | P2 |
| DWP213388 | BTK/ITK inhibitor | FIC | Autoimmune disease (SLE, RA) | P1 |
| DWP212525 | JAK3/TFK inhibitor | BIC | Autoimmune diseases (RA) | P1 |
| DWJ1520 | sodium channel blocker | FIC | long acting ropivacaine | Pre |
| DWJ807S057 | serotonin-dopamine activity modulator | FIC | long-acting brexpiprazole | Pre |
| DWJ807S059 | partial Dopamine agonist | FIC | long acting cariprazine | Pre |

*EE: Erosive Esophagitis

## Biologics

| | | | |
|---|---|---|---|
| DWP457 | Long acting insulin | Diabetes | R |
| DWP458 | Undisclosed Protein | Osteoporosis | R |
| DWP817S004 | Undisclosed Protein | Sarcopenia | R |
| DWP820 | Stem Cell | Severe Acute Pancreatitis (SAP), Idiopathic Pulmonary Fibrosis (IPF) | Pre |
| DWP820S | Stem Cell | Retinitis Pigmentosa (RP) | R |

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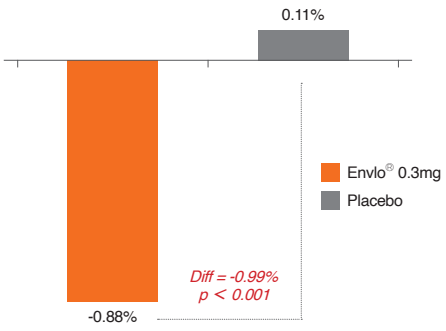
# Envlo®

**MOA: Sodium Glucose Co-Transporter 2 (SGLT2) Inhibitor**

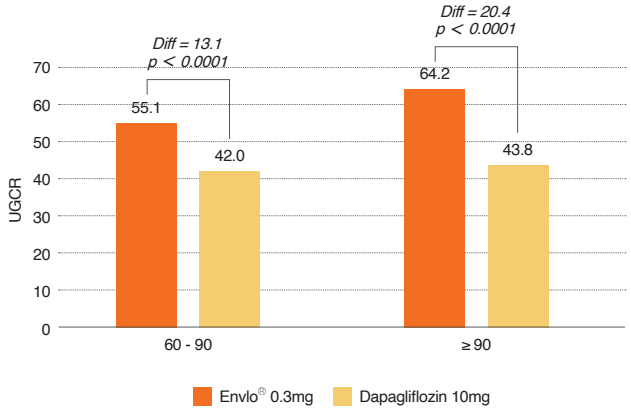
**Indication: Type 2 diabetes (T2DM), Obesity, Albuminuria and other conditions**

- From the phase 3 study in T2DM patients, Envlo showed clinically significant hemoglobin A1c reduction at week 24
- In T2DM patients with mild reduced kidney function, Envlo demonstrated significantly greater hemoglobin A1c reduction at week 6, 12, 18, and 24 compared to Dapagliflozin
- DPP-4 inhibitor combination drug is under development

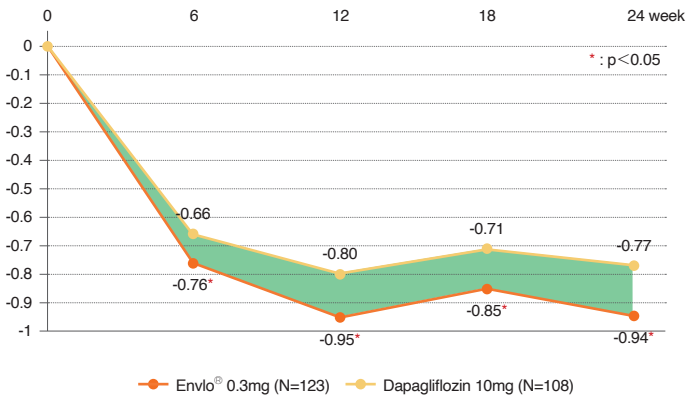
## Phase III Results in Korea (T2DM)




LS mean change from baseline in HbA1c (%)
at week 24 for Envlo monotherapy




Changes in UGCR by eGFR level at baseline




LS mean change from baseline in HbA1c in patients with mild reduced kidney function

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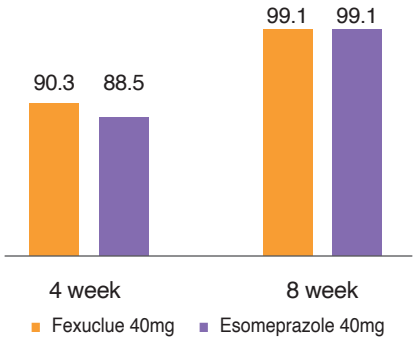
# Fexuclue®

**MOA: Potassium-Competitive Acid Blocker (P-CAB)**

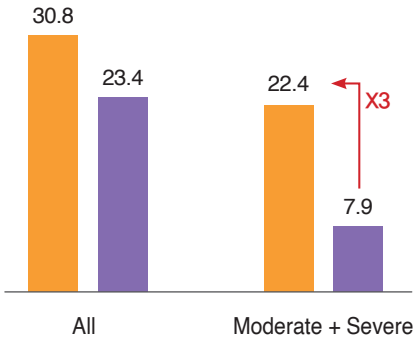
**Indication: Erosive Esophagitis (EE), risk reduction of NSAIDs associated ulcer, H.pylori eradication, Non-Erosive Reflux Disease(NERD), etc.**

- Approved in Korea for the treatment of erosive gastroesophageal reflux disease (40 mg), and the improvement of gastric mucosal lesions in acute gastritis and chronic gastritis (10 mg)
- From the phase 3 study in Erosive Esophagitis patients, Fexuclue was efficacious and safe up to 8 weeks.
- At week 4 and 8, Fexuclue 40mg was proven to be non-inferior to Esomeprazole 40 mg as the healing rate was 99% at week 8
- Compared to Esomeprazole, Fexuclue showed greater symptom relief in heartburn during 3 days of treatment (Fast onset)
  Enhanced atypical symptom relief (cough) during 3 and 7 days of treatment
- From the IIT(investigator initiated trial), Fexuclue demonstrated equal effectiveness regardless of food intake
- Indications for H.pylori eradication and NERD are in the development plan
- Risk reduction of NSAIDs associated ulcer

## Phase III Results in Korea (EE)




Healing rate(%)
at Week 4 and Week 8 (Based on endoscopy)




Proportion of subject without symptom (HB)

Symptom relief for heartburn
(Fast onset)

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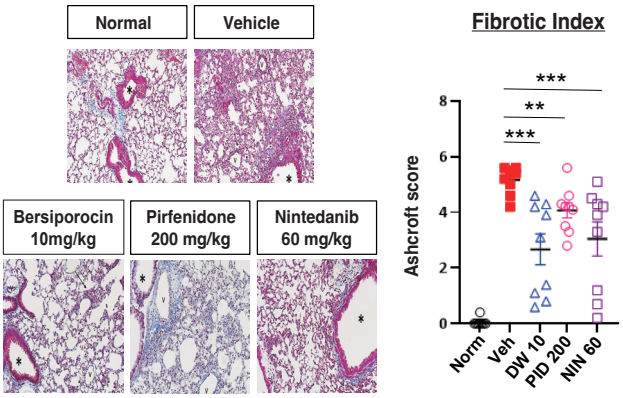
# Bersiporocin (DWN12088)

**PRS**

**Indication: First-in-Class Oral Anti-Fibrotic Agent**

- Selective PRS (prolyl-tRNA synthetase) Small Molecule Inhibitor
- Phase II for Idiopathic Pulmonary Fibrosis
- FDA Fast Track Designation Granted
- FDA Orphan Drug Designation Granted
- EMA Orphan Drug Designation Granted

## Bersiporocin (DWN12088) in IPF Animal Model




Bersiporocin (DWN12088) reduces fibrosis in the IPF lung

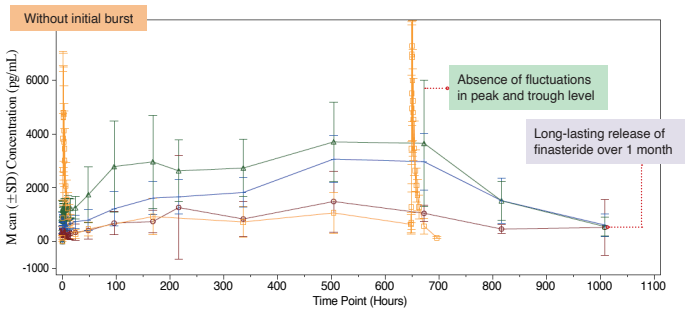
# DWJ1528 (IVL3001)

**MOA: Finasteride Depot Injection (FNS LAI), 5α-reductase inhibitor**

**Indication : Androgenic alopecia**

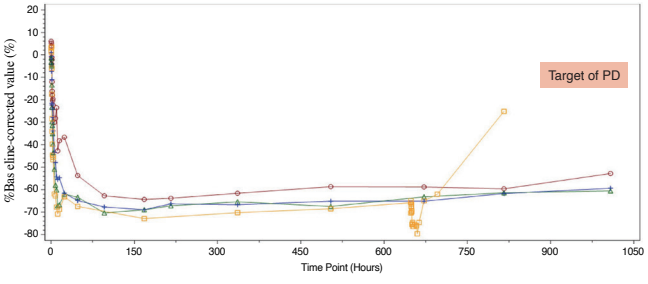
- DWJ1528 is developed by IVL and Daewoong is aiming to ease the inconvenience by 1M / 3M depot injection while minimizing side effects of API exposure.
- DWJ1528 was shown to be safe and well tolerated in Australia Phase I trial.
- DWJ1528 demonstrated consistent FNS plasma concentration, without initial burst, compared to Propecia and reduced DHT level without interfering Testosterone level.
- Phase III IND submission in Korea (2Q, 2024), MA approval in Korea (2027)

## Phase Ⅰ Clinical Study : Results (1) Pharmacokinetics




Mean (±SD) Plasma Concentration vs. Time
- PK Concentration population (Linear Scale)

## Phase Ⅰ Clinical Study : Results (2) Pharmacodynamics




Baseline Corrected Dihydrotestosterone Median
Pharmacodynamic Measurements by Treatment (Linear Scale)

DWJ1528 low dose (n=10) | DWJ1528 medium dose (n=9) | DWJ1528 high dose (n=10) | Propecia 1mg (n=9)

# iN1011-N17(DWP17061, Aneratrigine)

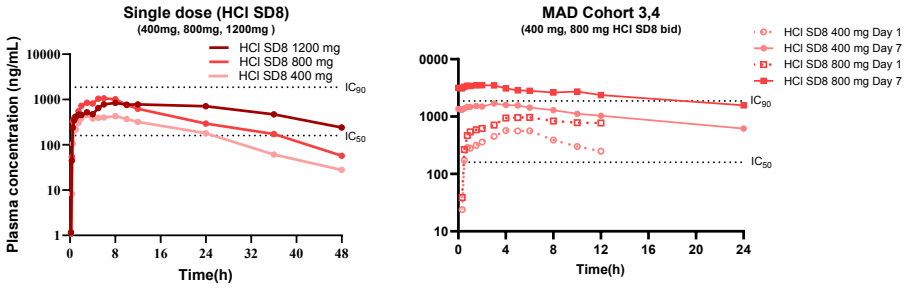
**MoA: Voltage-gated Sodium Channel 1.7 (Nav1.7) Inhibitor**

**Expected Indication: a. Post-Herpetic Neuralgia(PHN) b. Trigeminal Neuralgia c. Osteoarthritis Pain, etc.**

**Stage: Clinical Phase II (24.3Q~)**

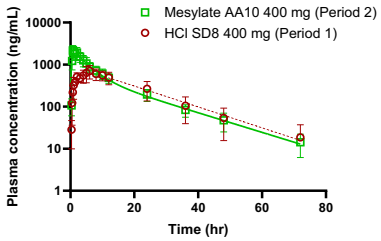
- Our leading pipeline iN1011-N17 (Aneratrigine) achieved an enhanced profile in five key aspects compared to pre-developed drugs, including 1) higher free drug levels and 2) excellent distribution to the dorsal root ganglion in rodent species & human, a crucial tissue for pain transmission. It also 3) demonstrated a strong in vitro-in vivo correlation using the VITVO, iN Therapeutics innovative proprietary electrophysiological evaluation platform. Clinical trials (ph1) 4) indicated Nav1.7 engaged sensory AE without any SAE, 5) suggesting a broad therapeutic index.
- We successfully developed a new salt-capsule formulation that enhanced clinical exposure, sufficiently covering the predicted clinically effective exposure. A simulation based on phase 2 clinical data of a pre-development drug predicted excellent analgesic efficacy for iN1011-N17. This program will be enter clinical phase II in 24.3Q

## [PK profile in Phase 1 trial]




## Relative Bioavailability PK profile (400 mg)

## HCl SD8 Nano capsule / New salt capsule




| Parameters (unit) | HCl (SD8 Nano capsule) | New salt (capsule formulation) |
|---|---|---|
| $C_{max}$ (ng/mL) | 748 ± 209 | 2,530 ± 459 |
| $AUC_{inf}$ (ng·hr/mL) | 14,900 ± 5,580 | 19,300 ± 3,820 |
| $AUC_{0\text{-}12}$ (ng·hr/mL) | 6,290 ± 1,640 | 12,200 ± 1,860 |
| $T_{1/2}$ (hr) | 12.9 ± 2.43 | 13.4 ± 2.35 |
| $T_{max}$ (hr) | 6.10 ± 3.78 | 1.06 ± 0.625 |

## Estimated Target Plasma Exposure from PK/PD simulation(in human)

| | | IC50 or ED50 | IC90 or ED90 |
|---|---|---|---|
| 1 | In vitro (mouse/human) value | 18 nM/46 nM | |
| 2 | Ex vivo (mouse/human DRG) value | 54 nM/71 nM | 1,110 nM/829 nM |
| 3 | In vivo pain DRG AP recording | 14.0 nM (6 ~ 8 mg/kg) | 55.3 nM (16 ~ 24 mg/kg) |
| 4 | In vivo Pain behavior test | 12 mg/kg | 27 mg/kg |
| 5 | PK/PD calculations | $IC50_p = \frac{IC50_u}{f_{up} \cdot k_{p,uu}}$ | $IC90_p = \frac{IC90_u}{f_{up} \cdot k_{p,uu}}$ |
| 6 | Target total plasma concentrations estimated for human | 74.2 ~ 31.6 ng/mL (in vivo mouse DRG AP recording)<br>160 ~ 376 ng/mL (ex vivo human DRG) | 125 ~ 293 ng/mL (in vivo mouse DRG AP recording)<br>1,870 ~ 4,400 ng/mL (ex vivo human DRG) |
| 7 | Corresponding dose that can achieve #6 in human exposure (iN1011-N17, New salt) | <100 mg QD (SAD)<br><50 mg BID (MAD) | 400 mg QD (SAD)<br>≒ 200 mg BID (MAD) |

## PK/PD Modeling for iN1011-N17 in the Neuropathic pain, Diabetic peripheral neuropathy

| Compound | Subtype | In vitro $IC_{50}$ (ng/mL) | In vivo $IC_{50}$ (ng/mL) | IVIVC scaling factor | | Avg Pain score | Avg DSIS |
|---|---|---|---|---|---|---|---|
| PF-05089771 | hNav1.7 | 5.5 | 27.5~38.3 | 5.00~6.96 | → | Baseline: 6.38Placebo: | Baseline: 5.09Placebo: |
| iN1011-N17 | hNav1.7 | 22.4 | 112~156 | 5.00~6.96 | | 5.66PF-771: 5.23 iN1011-N17: 4.20 | 4.43PF-771: 3.94iN1011-N17: 3.05 |

The iN1011-N17 (400 mg bid) is expected to be more effective than PF-05089771 (150 mg bid) for treatment of diabetic peripheral neuropathy in man, with a clinically significant level of pain score reduction (i.e., < 2.0)

Sources: [Clin Pharmacokinet. 2016; doi: 10.1007/s40262-015-0365-0][Pain. 2018; doi: 10.1097/j.pain.0000000000001227]

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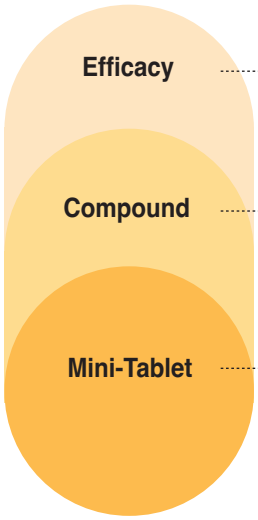
# Indication: Colonoscopy Bowel Preparation

- A new formulation for higher patient compliance
- Comparable cleansing ability with a less dosage compared to the reference product
- Non-clinical trial completed and patent application filed (KR/US/CA/AU)
- Top-line results from Phase 3 clinical trial (Korea)
  ➞ Demonstrated non-inferiority compared to the active control group and confirmed reduction in side effects
- Expected to be able to enter directly into P3CT based on competitor drug precedents



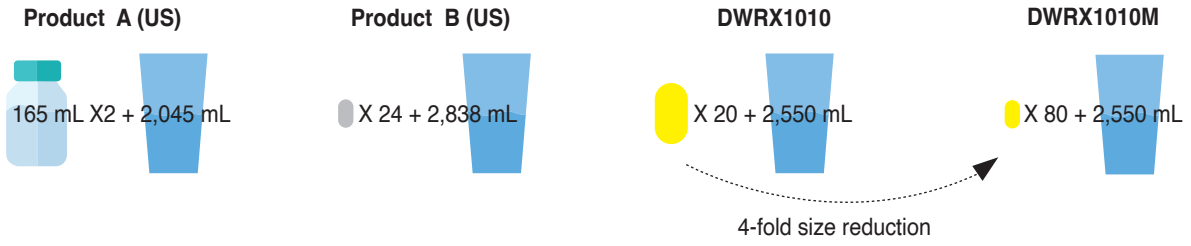

**Efficacy** ..... Sulfate-based laxative as the basic base for **excellent safety and efficacy**

**Compound** ..... To reduce the dosage compared to existing sulfate formulations, DWRXs are combined with the stimulant laxative, **sodium picosulfate**.
**Simethicone**, which removes colonic bubbles during pre-treatment, is combined in the formulation

**Mini-Tablet** ..... **Specialized coating** minimizes GI adhesion and formulated as **mini-tablets**
With current tablet formulation, adhesion to the gastrointestinal mucosa frequently occurs, leading to delayed dissolution and mottling at the site

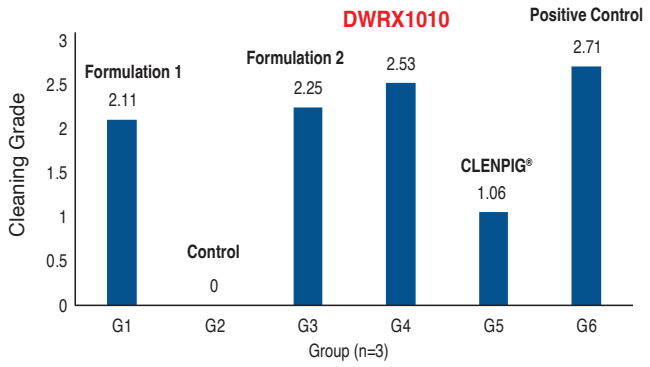
➞ **Maximize patient compliance**

## Comparison with Marketed Product




### Efficacy study in rats

Non-clinical data demonstrates that DWRXs have sufficient cleansing ability with a solid dosage of 66.7% compared to SUTAB tablet.

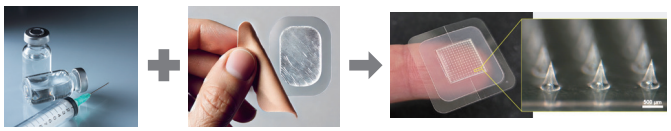



**Bowel Cleaning Quality in rats**

DAEWOONG PHARMACEUTICAL CO.,LTD.

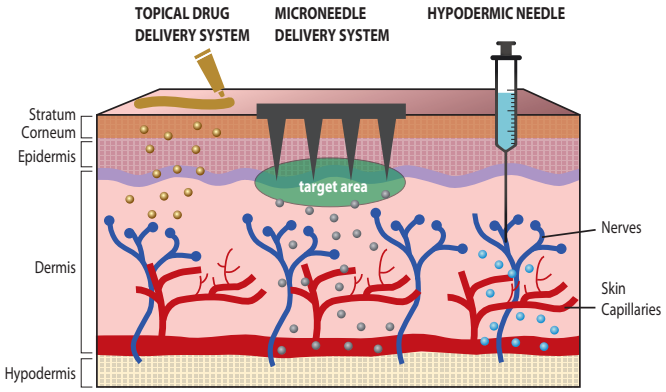
# Dissolving Microneedle Array Patch Platform Technology

**Microneedle, the most evolved form of transdermal drug delivery, utilizes micro-sized (usually under 1 mm) needles to deliver drugs.**



Injection Patch Microneedle Patch

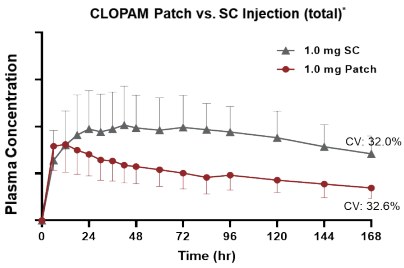
- Microneedles bypass the stratum corneum and target the epidermis and upper dermis.
- It enables efficient delivery of payloads, especially hydrophilic and high molecular weight substances, which were not possible with conventional transdermal patch formulations.
- It also minimizes pain by reducing direct contacts with nerve cells in the dermis.



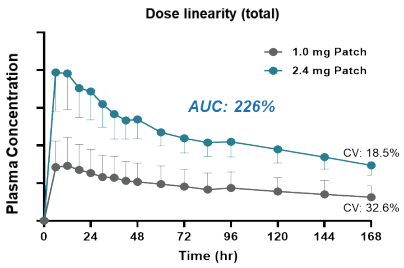

**CLOPAM** is Daewoong Therapeutics' patented technology that ensures efficient drug delivery and the highest manufacturing standards

## High Bioavailability and Bioequivalence

58.0% AUC with CLOPAM®




Dose Linearity Observed




**First-in-human** study (Investigator-Initiated Trial) with GLP-1RA showed

- **Once-Weekly** dosage as the reference product
- **PK consistency (59% and 58%)**
- **Dose linear PK profile** between 1.0 mg & 2.4 mg CLOPAM® patches

→ Confirming its feasibility as an alternative to injectables

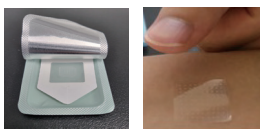
## Broad Applicability

- CLOPAM® enables transdermal administration for both COSMETICS and THERAPEUTICS
- Key development milestones:
  - First Korean IND submitted for biopharmaceutical for systemic delivery
  - First-in-human data of microneedle secured


## Safe & Simple Alternative to Injectables

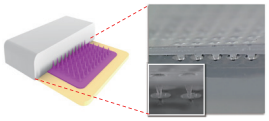
**Simper Administration**

- User-friendly Design



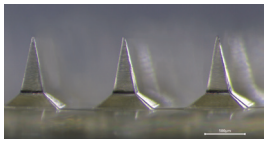
**Absolute Protection**

- Stability at long-term & accelerated conditions up to 6 months



**Product Consistency**

- Consistency between needles, patches, and batches



DAEWOONG PHARMACEUTICAL CO.,LTD.

## NABOTA® 50, 100, 200Units / Vial-Inj.


**•Botulinum toxin type A**

**•Indication: Glabella Lines (Approved in KR, US, Canada, EU), Post Stroke Upper Limb Spasticity (Approved in KR), Crow's feet (Approved in KR), Blepharospasm (Approved in KR)**

- Nabota™ is the only 900kDa neurotoxin approved in US, EU/England since Botox™
- It has proven efficacy & safety with the large-scale global clinical studies for more than 2,000 subjects in the US and Europe for the first time by Korean botulinum toxin.
- It is produced with a patented technology for purity, minimizing the presence of impurities

## Eposis 2000, 3000, 4000, 5000, 8000IU / Pre-filled syringe Inj.

**•rhEPO (recombinant human erythropoietin)**

**•Indication: Anemia in chronic renal failure**

- Eposis™ increased hemoglobin level significantly for the patients with Chronic Renal Failure (CRF).
- Eposis™ demonstrated significant improvement and safety for patients with anemia in Chronic Renal Failure (CRF).

## V-OLET 20mg/2mL / Vial-Inj.


**•Ingredient: Deoxycholic acid (DCA)**

**•Indication: Improvement in the appearance of moderate to severe convexity or fullness associated with submental fat (SMF) in adults.**

- An only injectable drug for reduction of SMF approved by the Ministry of Food and Drug Safety in Korea.
- Mechanism of action of irreversible destruction of fat cells (adipocytolysis) and neocollagenesis.
- Significant effect in improvements in SMF and safety confirmed through clinical trials targeting Koreans.

## URSA 100, 200, 300mg - Tab.


**•DCA (Ursodeoxycholic Acid)**

**•Indication: Cholestasis(include PBC, PSC), Viral hepatitis C, Gallstone**

- URSA improves liver function in chronic hepatitis patients, improves symptom and histo-pathology in Cholestatis patients, and UDCA is the only drug approved for PBC by the US FDA.

DAEWOONG PHARMACEUTICAL CO.,LTD.

## Fexuclue® 40mg. 10mg - Tab.


**•Fexuprazan (Potassium-Competitive Acid Blocker (P-CAB))**
**•Indication: Erosive Esophagitis(EE) (Approved in KR, Philippine, Ecuador, Chile, Mexico)**

- Fexuclue is the Best-in-Class novel anti acid secretion agent with rapid onset time and potent acid suppressive effect, addressing the growing unmet needs of PPIs.
- Various dosages and indications are under development, including 10mg, 20mg and more

## Envlo® 0.3mg - Tab.


**•Enavoglilflozin (Sodium Glucose Co-Transporter 2 Inhibitor)**
**•Indication: Type 2 diabetes (Approved in KR)**

- Envlo was approved in Korea for treatment of type 2 diabetes mellitus, and metformin combination drug, Envlomet was also approved in Korea
- Envlo is the smallest but most potent novel SGLT2i with excellent efficacy and safety

## CREZET 10/20mg, 10/10mg,10/5mg -Tab.


**•Ezetimibe, Rosuvastatin calcium**
**•Indication : Treatment of primary hypercholesterolemia or to decrease elevated fat level in blood (mixed hyperlipidemia) in adult patients**

- Signed a license-out and cooperation contract with AstraZeneca Korea for Crezet, its hyperlipidemia treatment, in four Asian countries - Indonesia, Thailand, Malaysia, and the Philippines.
- CREZET improve not only a greater LDL-C / HDL-C ratio improvement effect but also significantly TG lowering effects compared to high-dose statin monotherapy in T2DM patients.

## Luphere Depot 3.75mg-Inj.


**•Leuprorelin Acetate**
**•Indication: Prostate cancer, Endometriosis, Pre-menopausal breast cancer, Uterine leiomyomata (Fibroids), Central Precocious Puberty**

- Luphere has two formulations; Daewoongs' proprietary patented spray-drying formulation and the emulsion formulation which will make it one of few bioequivalent generics in the market.
- Emulsion of 3.75mg, 7.5mg, 11.25mg, 22.5mg, 30mg are under development.
- Advancing development through a global partnership with Zydus Lifesciences.

# Products Available for Discussion

| Classification | | Brand Name | Active Ingredient | Strength | Dosage Form |
|---|---|---|---|---|---|
| Biologics | Central Nervous System | NABOTA<br>US: Jeuveau<br>EU: Nuceiva | Botulinum Toxin Type A | 50, 100, 200Units | Inj. |
| | Endocrinology | CareTropin | Somatropin | 22.5IU | Cartridge Inj. |
| | Nephrology | Eposis | rhEPO | 2000IU, 3000IU , 4000IU, 5000IU, 6000IU, 8000IU, 10000IU | Prefilled Syringe Inj. |
| | Wound | Easyef Solution | rhEGF | 5mg/10ml | Topical Solution |
| | Wound | Easyef Ointment | rhEGF | 1ug/g | Ointment |
| Chemical | Gastrointestinal | Fexuclue | Fexuprazan HCL | 40mg | Tab. |
| | Diabetes | Envlo | Enavogliflozin | 0.3mg | Tab. |
| | Antineoplastics | Luphere Depot | Leuprorelin acetate | 3.75mg, 7.5mg, 30mg | Vial |
| | Cardiovascular | Crezet | Ezetimibe / Rosuvastatin | 10mg/5mg, 10mg/10mg, 10mg/20mg | Tab. |
| | Gastrointestinal | URSA | Ursodeoxycholic acid | 100mg, 200mg, 300mg | Tab. |
| | Gastrointestinal | URSA | Ursodeoxycholic acid | 250mg | Cap. |
| | Gastrointestinal | URSA | Ursodeoxycholic acid | 50mg, 100mg | Soft Cap. |
| | Urologic | Nurigra | Sildenafil citrate | 100mg | Tab. |
| | Lipolytic | V-OLET | Deoxycholic Acid | 20mg/2mL | Vial/Inj. |
| OTC | Antacid | Newlanta | $Al_2O_3$ / $Mg(OH)_2$ | 200mg/400mg | Suspension |
| | Digestive | Bearse | Multi-enzymes (incl.Biodiastase 2000 III, Lipase I, Ursodeoxycholic Acid) | - | Tab. |
| | Iron Supplement | Hemo Q Plus | Polysaccharide iron complex/ Cyanocobalamin 0.1%/Folic acid | 326mg/25mg/1mg | Cap. |

| Classification | | Status | Active Ingredient | Strength | Dosage Form |
|---|---|---|---|---|---|
| Under development | Gastrointestinal | Phase III | Fexuprazan HCl | 20mg | Tab. |
| | Endocrine | Phase III | Enavogliflozin | 0.3mg | Tab. |
| | Endocrine | Phase I | Enavogliflozin / Metformin | 0.15mg/1000mg, 0.15mg / 750mg. 0.15mg / 500mg | Tab. |
| | Antineoplastics | Clinical (11.25mg, 30mg) Marketed (3.75mg) | Leuprorelin acetate | 3.75mg(Vial, 1month), 11.25mg (Vial, DCS, 3month), 30mg(DCS, 3/4month-US) | Vial, DCS |
| | Central Nervous System | Pre-clinical | Aripiprazole Monohydrate | 300mg, 400mg | Vial / Inj. |
| | Pulmonary Disease | Phase II | DWN12088 | 150mg | Tab. |
| | Epidermal Growth Factor Receptor Inhibitor Related Skin Toxicities | Phase II | EGF(Epidermal Growth Factor) | 10 ug/g, 20 ug/g, 40 ug/g | Cream |
| | Benign Masseteric Hypertrophy | Phase III | Botulinum Toxin | 48U | Vial |
| | Ulcerative Colitis | Phase II | Pellino-1 inhibitor(DWP305401) | TBD | Oral Capsule |
| | Neurological | Phase I | iN1011-N17(DWP17061) | TBD | TBD |
| | Topical | Phase III | Finasteride(DWJ1528) | - | Inj. |
| | Endocrine | Phase I | Somatropin | - | Microneedle Array Patch(MAP) |
| | Gastrointestinal | Pre-clinical | Semaglutide | - | Microneedle Array Patch(MAP) |
| | Aesthetic | Pre-clinical | Botulinum Toxin | - | Microneedle Array Patch(MAP) |
| | Colonoscopy Prep. | Phase III | Magnesium sulfate, Potassium sulfate, Sodium sulfate, Picosulfate sodium, Simethicone | 108mg, 211.1mg, 1177.5mg, 1mg, 16mg | Tablet |

# For Further Information, Please get in touch with us


## Daewoong Pharmaceutical Co., Ltd.

Address 12, Bongeunsa-ro 114-gil, Gangnam-gu, Seoul, Korea, #06170
Phone 82 2 550 8112
E-mail arkim135@daewoong.co.kr
grace.jeong@daewoong.co.kr
leokim@daewoong.co.kr
panyunpei95@daewoong.co.kr
Homepage www.daewoong.com

## Daewoong Bio Inc.

Address 12, Bongeunsa-ro 114-gil, Gangnam-gu, Seoul, Korea, #06170
Import lpgchoco@daewoong-bio.co.kr
Export urahwan01@daewoong-bio.co.kr
Homepage www.daewoongchemical.com