

# Making Our World Healthier Together

# Daewoong

Pharmaceutical Co., Ltd.

Pharmaceutical  
Chemical  
Biologics  
Finished Dosages  
Active Pharmaceutical Ingredient  
Out Licensing  
Open Collaboration

# Group Overview

## VISION

A global healthcare group dedicated to improving the quality of life

## MISSION

To provide the most beneficial total solutions in pharmaceuticals and services that contribute to improving quality of life of valued consumers



1.2B

Sales USD

Leading Korean  
Pharmaceuticals

Only 1

Korean Neurotoxin

Approved by FDA

100+

Partners

in Worldwide

2,400+

Employees

in 8 Countries

5

R&D centers

Korea (2), China, India,  
and Indonesia

8

Manufacturing sites

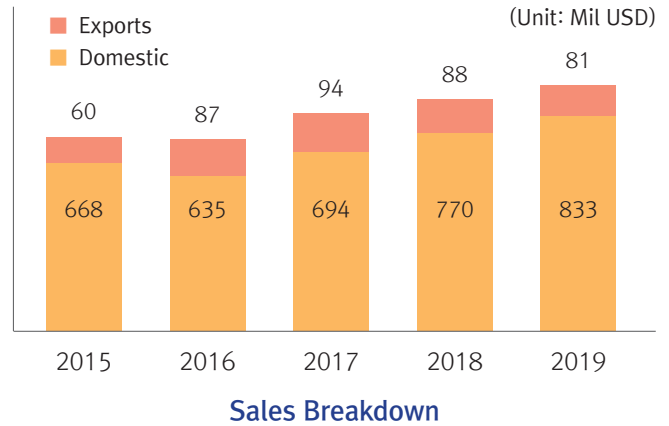
in 8 Countries

- 2020**
  - NABOTA approved by Brazil and Taiwan
  - Fexuprazan : Ground in Latin America through an Export Agreement with Brazil and Mexico
  - Enavogliflozin: Best-in-class SGLT-2 Inhibitor, completed Phase II clinical trial in Korea.
  - Camostat: COVID-19 Inhibitor, Ongoing Phase II
  - Niclosamide: COVID-19 Inhibitor, Ongoing Phase1 study in Korea, India and Philippines
  - Stem Cell: COVID-19 Inhibitor, Ongoing Phase1 study in Indonesia
  
- 2019**
  - NABOTA approved by USFDA and EU EMA 
  - Fexuprazan : Best-in-class antiulcerant, completed Phase III clinical trial in Korea.
  - DWN 12088 : First-in-Class PRS Inhibitor for IPF Ongoing Phase1 study in Aus.
  
- 2018**
  - NABOTA approved by Health Canada
  - BBT-401: The First-in-class Pellino-1 inhibitor for UC Treatment, completed Phase I in the USA
  - By acquiring shares in Traphaco, obtained local manufacturing site in Vietnam
  
- 2017**
  - Established Japan Branch
  - Launched Indonesia's first biologic product Epodion, gained #1 MS
  
- 2016**
  - Completion of Daewoong Lifescience Lab 'Bio-innovation Center'
  - Completion of Osong cGMP Manufacturing Plant
  - Received National Award for Quality Management Honor
  
- 2015**
  - Established #1st Biopharmaceutical Manufacturing plant in Indonesia
  - Acquired HANALL BIOPHARMA Co. Ltd
  
- 2014**
  - Established Daewoong Liaoning R&D Institute in China
  - Launched NABOTA
  
- 2013**
  - Acquired Liaoning Baifeng, Chinese drug manufacturer
  - Hyangnam Plant Expansion
  
- 2011**
  - Completion of Daewoong Bio
  - API Manufacturing plant
  
- 2009**
  - Established India Research Center
  - Established US Branch
  - Established Beijing Research Center
  
- 2008**
  - Established China Branch Office
  
- 1992**
  - Established Hyangnam Manufacturing Plant
  
- 1983**
  - Changed Corporate Name to Daewoong Pharmaceutical Co.Ltd
  
- 1978**
  - Established Daewoong Chemical Co.Ltd(Now Daewoong Bio. Inc)
  
- 1945**
  - Established as Daehan Chemical Industry Co. Ltd

## 2019 Summary of Financials

Sales increased by 6.5%

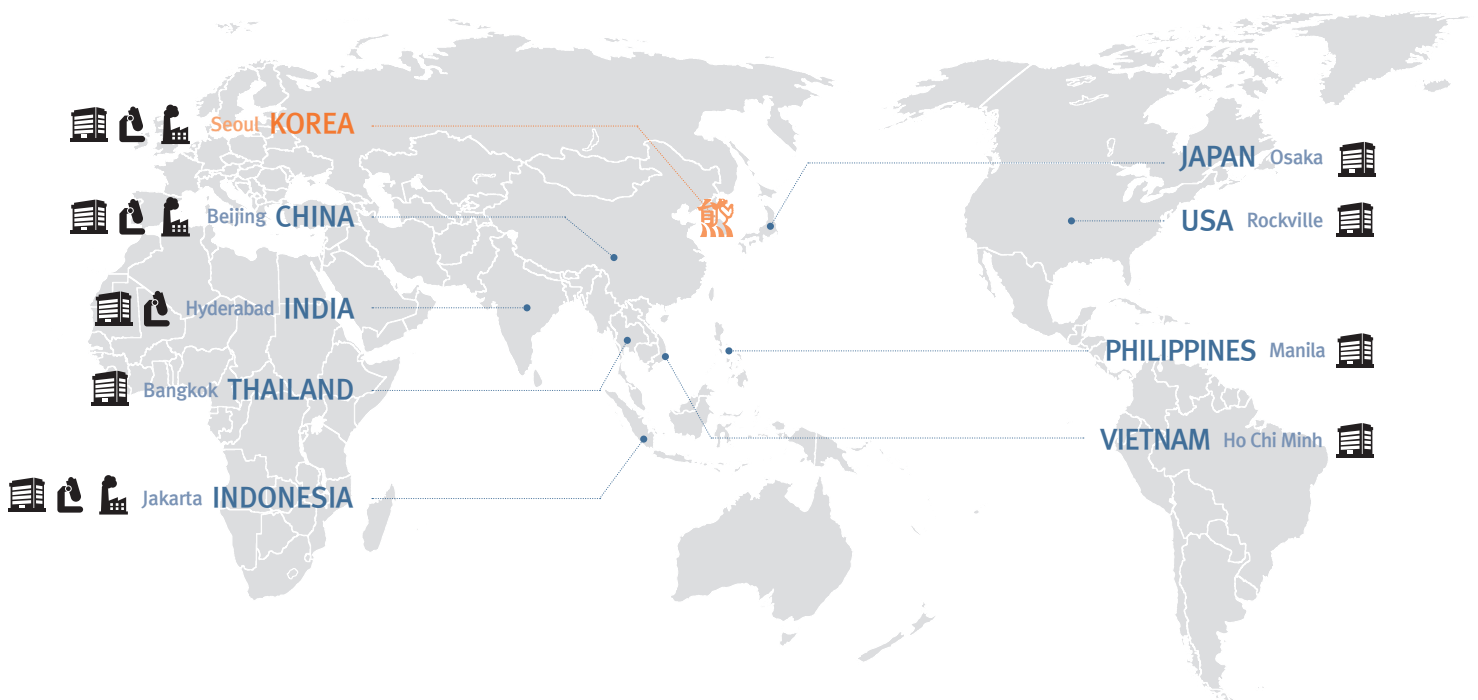
Invested 12.6% of Sales in R&D



## Global Presence

○ 100+ Partners worldwide

- Office
- R&D Center
- Manufacturing Site



## 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<sup>2</sup> (440,158 ft<sup>2</sup>)

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<sup>2</sup> (341,598 ft<sup>2</sup>)

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<sup>2</sup> (81,106 ft<sup>2</sup>)

Manufacturing Products: Cephalosporin Injection, Tablet, Capsule



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

Area  
8,180 m<sup>2</sup> (88,048 ft<sup>2</sup>)

Manufacturing Products  
Oral Solid



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

Area  
9,011 m<sup>2</sup> (96,993 ft<sup>2</sup>)

Manufacturing Products  
A/A infusion, Oral Solid

## Global

Maximizing our accumulated knowhow, we have acquired or built plants in strategic geographical locations that better enable us to address the local markets' needs.

### | Surabaya Plant Surabaya, Indonesia



- 01. Dedicated for 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<sup>2</sup> (26,737 ft<sup>2</sup>)

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<sup>2</sup> (103,182 ft<sup>2</sup>)

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<sup>2</sup> (107,639 ft<sup>2</sup>)

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

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





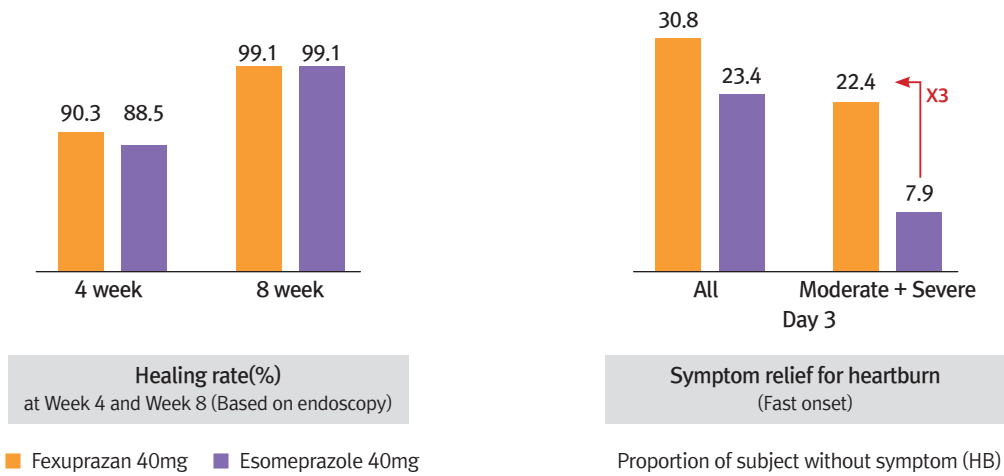
## Fexuprazan

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

Indication: Erosive Esophagitis(EE), maintenance of EE, risk reduction of NSAIDs associated ulcer etc.

- Fexuprazan 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.
- From the phase 3 study in Erosive Esophagitis patients, Fexuprazan was efficacious and safe up to 8weeks.

### [Phase III Results in Korea (EE)]



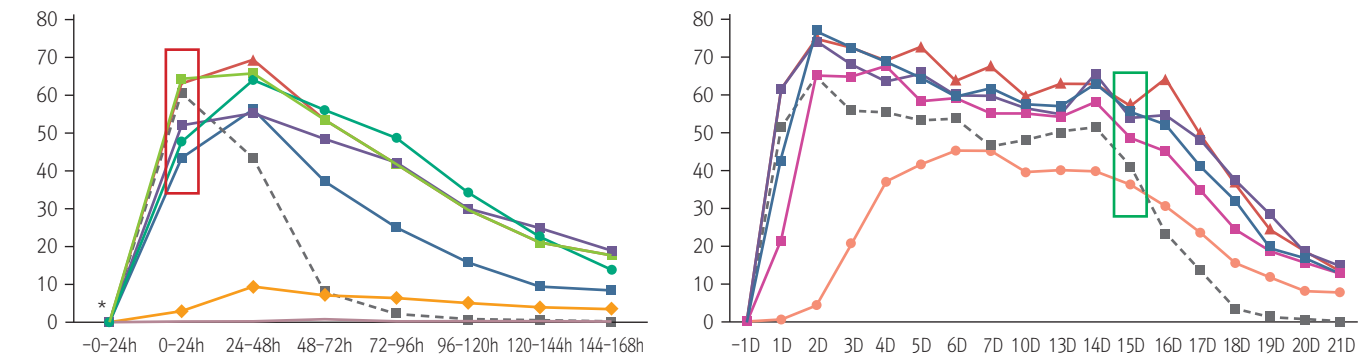
## Enavogliflozin

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

Indication: Type 2 diabetes

- DWP16001 demonstrated long lasting (over 3 days) and high potent urinary glucose excretion effect in human, excellent safety and tolerability and favorable pharmacokinetic profiles.

### [Urine Glucose Excretion, g/day]



SAD (Single Ascending Dose) : Pharmacodynamics

- ◆ DWP 16001 0.2mg
- DWP 16001 0.5mg
- ▲ DWP 16001 1mg
- DWP 16001 2mg (Fed)
- DWP 16001 5mg
- Dapagliflozin 10mg
- Placebo

MAD (Multiple Ascending Dose) : Pharmacodynamics

- DWP 16001 0.1mg
- DWP 16001 0.3mg
- DWP 16001 0.5mg
- ▲ DWP 16001 1mg (Fasting)
- DWP 16001 2mg (Fed)
- Dapagliflozin 10mg

## DWN12088

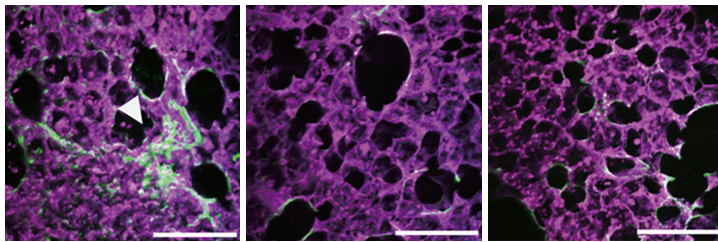
MOA: Prolyl-tRNA Synthetase Inhibitor

Indication: Idiopathic Pulmonary Fibrosis, Systemic Sclerosis, Cardiac Fibrosis, NASH, etc.

- Novel Target: First-in-Class PRS Inhibitor
- Efficacy: Superior anti-fibrotic effects in mouse pulmonary fibrosis model
- Safety: Confirmed wider safety margin compared to current Standard of Care (Esbriet®, Ofev®)

### [Mouse Pulmonary Fibrosis Model]

● Lung Tissue (Autofluorescence) ● Collagen (SHG)

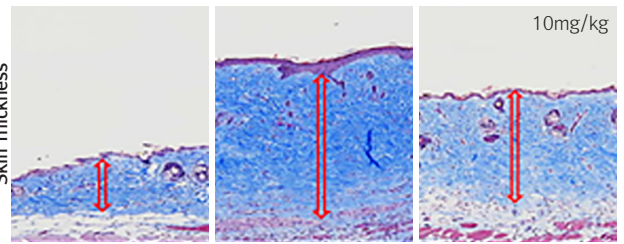


Vehicle

10mg/kg DWN 12088

200mg/kg Prifenidone

### [Mouse Skin Fibrosis model]



Normal

Vehicle

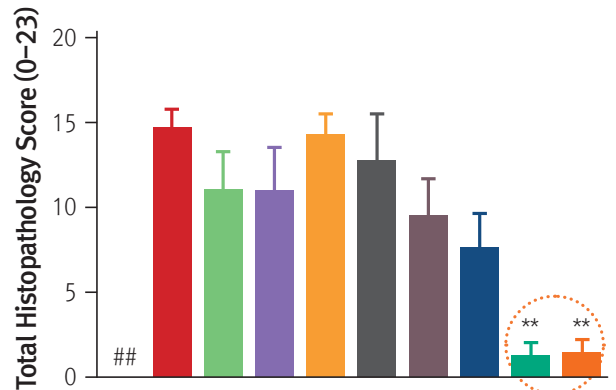
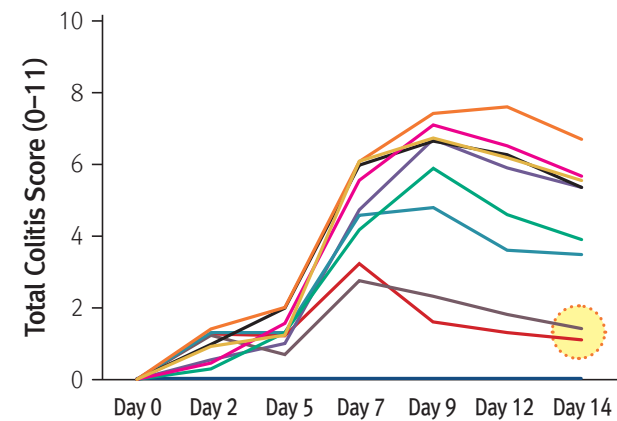
DWN12088

## DWP305401

MOA: DWP305401 is a novel inhibitor of Pellino-1. DWP305401 can inhibit NF-κB-mediated inflammatory signals stimulated by MyD88 and RIP1 complexes.

Indication: Ulcerative Colitis (UC)

- DWP305401 is a First in Class oral Pellino-1 inhibitor to treat Ulcerative Colitis
- DWP305401 was shown to be safe and well tolerated, with no systemic exposure in healthy subjects in US Phase I trial.
- Obtained development and commercial right for Asian market from Bridge Biotherapeutics
- 1st interim efficacy readout from Phase II (first in patient) trials is available in March 2020.
- Phase I in China IND was cleared in Dec. 2019. Expect to activate site in 2Q 2020 but subject to COVID-19.



Disease-causing	-	+	+	+	+	+	+	+	+	+
Antibody treatment	-	-	+	-	-	-	-	-	-	-
DWP305401	-	-	-	-	25	50	100	200	300	400

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



- Botulinum toxin type A
- Indication: Glabellar Lines (Approved in KR, US, EU, Canada), Post Stroke Upper Limb Spasticity (Approved in KR), Crow’s feet (Approved in KR), Blepharospasm (Approved in KR)

- The only 900kDa neurotoxin approved in US and EU after Botox™
- It has proven efficacy & safety from the large-scale global clinical studies with more than 2,000 subjects in the US and Europe for the first time by Asian botulinum toxin.
- It is produced with a patented technology for purity, minimizing the presence of impurities (HI-pure™ Technology)

\* Prabotulinumtoxin A : Registered as NABOTA™ in Korea and Asia, JEUVEAU™ in the US, and NUCEIVA™ in Canada and EU

## Epodion™ 2000, 3000, 4000, 10000IU / Pre-filled syringe Inj.



- rhEPO (recombinant human erythropoietin)
- Indication: Anemia in chronic renal failure

Epodion™ is PFS type of Erythropoietin – alpha (rhEPO) for improving the hemoglobin and hematocrit level in chronic kidney disease patients.

## DWP 710 Injection of cryopreserved cell

- Mesenchymal stem cell
- Indication:
  - Coronavirus Disease (COVID-19)
  - Suppression of cytokine storm caused by overactive immune response
  - Acute respiratory distress Syndrome due to lung damages
- MoA: MSC releases anti-inflammatory factors to control inflammatory response

Immuno-modulation	Efficacy study on ARDS animal model	Cryo-perservative
<b>Superior Factors</b> <ul style="list-style-type: none"> <li>• IGF-2: Stem cell functional improvement</li> <li>• IL-6: Angiogenesis and Immune response</li> </ul>	Improved Survival ratio at LPS-induced animal model <ul style="list-style-type: none"> <li>• Control Survival ratio: 28.6%</li> <li>• DW-MSc survival ratio: 75%</li> </ul>	<ul style="list-style-type: none"> <li>• Freeze-storage products can be stored in hospitals</li> <li>• Can be used directly in the hospital in the event of a patient's illness</li> </ul>
Cell banking system	No Donor variation	MoA
<b>Cell banking system:</b> mass-produced and supplied with consistent products	Advantages compare with other adult-derived MSC 1 Donor; Product consistency	Confirms immunomodulatory ability to directly inhibit Cytokine storms

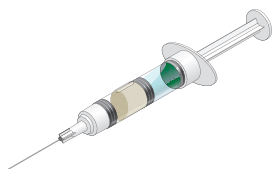
## Luphere™ Depot 3.75mg-Inj.



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

Luphere has two formulations: Daewoong’s proprietary patented spray-drying formulation and the emulsion formulation which will make it one of few bio-equivalent generics in the market.

## Aripiprazole™



- Aripiprazole Monohydrate
- Indication: Treatment of Schizophrenia and Bipolar I Disorder

Daewoong has been developing AB rated generic product for US market and has its own patented DCS device which is one of two dosage forms of Aripiprazole LAI and only few companies have the capability.

## Niclosamide IM Depot Injection

- Formulation: IM, Single Injectable
- Indication:
  - Coronavirus Disease (COVID-19)
  - Pulmonary arterial hypertension (PAH)
  - Idiopathic Pulmonary Fibrosis (IPF)
- MoA: SKP2 Inhibitor, STAT3 & TMEM16A Inhibitor

Highest Antiviral Potency	Extensive Activity Regardless of Tolerance	Optimal PK Profiles for Infection
<ul style="list-style-type: none"> <li>• 40 times vs. Remdesivir</li> <li>• 26 times vs. Chloroquine</li> <li>• 15 times vs. Ciclesonide</li> </ul>	Dual MoA effective in suppressing lung damage	<b>New Drug Reformulation:</b> effective delivery with single dosage lasting for 2-weeks
Improve Various Complications	No safety concerns expected	Benefits of New Formulation
Inflammatory cell infiltration in lung tissue ↓ CV risk in severe patients ↓	No systemic AE predicted 50 years ↑ use experience No increase in systemic exposure compared to PO	Overcomes the draw backs of Oral formulation i.e., Gastrointestinal disorder and Low absorption

## Olostar™ 20/10mg and 40/20mg – Tab.



- Olmesartan medoxomil, Rosuvastatin
- Indication: Concomitant Hypertension and Dyslipidemia

World's 1st fixed dose combination of olmesartan and rosuvastatin

1. Developed with Daewoong's patented formulation technology
2. Indicated for the treatment of both hypertension and dyslipidemia
3. Combination of the most potent ARB and statin in their respective classes
4. Minimized drug to drug interaction in metabolism and absorption

## URSA™ 25, 50, 100, 200, 250, 300mg – Tab., Soft Cap., Hard Cap.



- UDCA (Ursodeoxycholic Acid)
- Indication: Cholestasis(include PBC, PSC), Viral hepatitis C, Gallstone

URSA improves liver function in chronic hepatitis patients, improves symptom and histopathology in Cholestasis patients, and UDCA is the only drug approved for PBC by the US FDA.

## Foistar™



- Camostat Mesilate
- Indication:
  - SARS-CoV-2 infection (COVID19)
  - Acute symptoms of chronic pancreatitis
  - Postoperative reflux esophagitis
- MoA: TMPRSS-2 inhibitor

<b>Antiviral Effect</b>	<b>Fast-Development (Drug repositioning)</b>
<ul style="list-style-type: none"> <li>• TMPRSS2 inhibitor</li> <li>• Suppressing viral infection</li> <li>• A broad-spectrum anti-viral agent</li> </ul>	<ul style="list-style-type: none"> <li>• A commercially available drug with proven safety (marketed since 2012)</li> <li>• Emergency use after CT Phase 2</li> <li>• Numerous clinical &amp; development experience</li> </ul>
<b>Oral Drug</b>	<b>Stable Supply</b>
<ul style="list-style-type: none"> <li>• Easy to Take Unlike Nafamostat (intravenously)</li> <li>• Patient compliance ↑</li> <li>• Low DDI</li> <li>• Low manufacturing cost</li> </ul>	<ul style="list-style-type: none"> <li>• Mass production of high-quality product</li> <li>• Reliable distribution &amp; supply</li> </ul>

	Classification	Brand Name	Active Ingredient	Strength	Dosage Form
Biologics	Central Nervous System	NABOTA	Botulinum Toxin Type A	50, 100, 200Units	Inj.
	Endocrinology	CareTropin	Somatropin	22.5IU	Cartridge Inj.
	Musculoskeletal	Novosis	rhBMP-2	0.25mg, 1mg, 3mg	Lyophilized Powder
	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	Antineoplastics	Luphere Depot	Leuprorelin acetate	3.75mg	Vial
	Cardiovascular	Olostar	Olmesartan medoxomil/ Rosuvastatin	20mg/10mg, 40mg/20mg	Tab.
	Cardiovascular	Olomax	Olmesartan medoxomil/ Amlodipine/Rosuvastatin	40/10/20mg, 40/10/10mg, 40/5/10mg, 20/5/10mg	Tab.
	Cardiovascular	DW Pitavastatin	Pitavastatin calcium	2mg	Tab.
	Cardiovascular	Crezet	Ezetimibe / Rosuvastatin	10mg/5mg, 10mg/10mg, 10mg/20mg	Tab.
	Gastrointestinal	URSA	Ursodeoxycholic acid	100mg, 200mg, 250mg, 300mg	Tab.
	Gastrointestinal	URSA	Ursodeoxycholic acid	250mg	Cap.
	Gastrointestinal	URSA	Ursodeoxycholic acid	100mg	Soft Cap.
	Metabolic	Risenplus	Risedronate Sodium	35 mg	Tab.
	Antiviral	Tamivict	Oseltamivir Phosphate	30mg, 45mg, 75mg	Cap.
OTC	Analgesic	EZN 6 Pro	Dexibuprofen	300mg	Soft Cap.
	Antacid	Newlanta	Al <sub>2</sub> O <sub>3</sub> / Mg(OH) <sub>2</sub>	200mg/400mg	Suspension
	Digestive	Bearse	Multi-enzymes (incl. Bodiastase 2000 III, Lipase I, Ursodeoxycholic Acid)	-	Tab.
	Iron Supplement	Hemo Q Plus	Polysaccharide iron complex/ Cyanocobalamin 0.1%/Folic acid	326mg/25mg/1mg	Cap.
	Muti-Vitamin	Impactamin Power	Vitamin B Complex (incl. Benfotiamin)	-	Tab.

	Classification	Status	Active Ingredient	Strength	Dosage Form
Under development	Gastrointestinal	Phase III	Fexuprazan HCl	40mg	Tab.
	Endocrine	Phase III	Enavogliflozin	0.3mg	Tab.
	Gastrointestinal	Phase II	DWP305401	-	Cap.
	Obesity	Phase III	Deoxycholic Acid	10mg/mL	Vial
	Antiviral	Formulation	Tenofovir Alafenamide Fumarate	25mg	Tab.
	Antineoplastics	Formulation	Leuprorelin acetate	-	DCS
	Central Nervous System	Pre-clinical	Aripiprazole Monohydrate	300mg, 400mg	Vial / Inj.
	COVID-19	Phase II Phase III	Camostat	100mg	Tab.
	COVID-19	Phase I	Niclosamide	-	Vial (Long acting Inj)
	COVID-19 (Human Stem cell)	Phase I	DWP710	-	Vial
	Antiparkinsonian	Formulation	Zonisamide	25mg, 50mg	ODT
	NOAC (Anticoagulant)	Formulation	Rivaroxaban	10mg, 15mg	ODT

	Classification	Status	Product Line	Components	Package
Devices	IVD	Marketed	COVID-19 PCR Kit	buffer, Enzyme, Control etc.	100 tests/box
	IVD	Marketed	COVID-19 IgG/IgM RDT	Kit, buffer, pipette	20EA/box
	IVD	Marketed	COVID-19 Rapid PCR Kit	buffer, Enzyme, Control, 8 cap strip & 96 well plates	100 tests/box
	IVD	Marketed	COVID-19 Antigen RDT	Test device, buffer, filter cap, nasal swab	25 tests/box
	Medical Device	Marketed	UTM/VTM : Viral transport medium	Transport medium+2 swabs (Nasopharyngeal, Oropharyngeal)	50EA/box

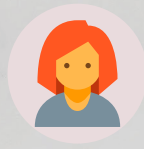
# Meet Our Team Members



**Hakkyu Lee** BD

Territory: US, LATAM, MENA

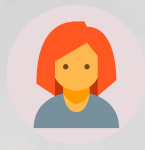
E-mail: hklee028@daewoong.co.kr



**Young Han** M.D., Ph.D. / BD

Territory: Asia, Europe, Russia, CIS

E-mail: yhan248@daewoong.co.kr



**Sophia Park** BD

Territory: Latin America

E-mail: ypark039@daewoong.co.kr



**Haeyeon Heo** BD

Territory: Asia, Europe

E-mail: hyheo@daewoong.co.kr



**Annes Tomas** BD

Territory: MENA

E-mail: tomas405@daewoong.co.kr



**Gabriel Park** BD

Territory: Russia, CIS

E-mail: ytpark179@daewoong.co.kr



**Billy Priyanto** BD

Territory: US

E-mail: globalstrategy1@daewoong.co.kr



**Young ah Kim** BD

Territory: Japan

E-mail: yakim404@daewoong.co.kr

