inno.N (KS.195940)

# Investor Presentation





## **Disclaimer**



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# innovate New & Next

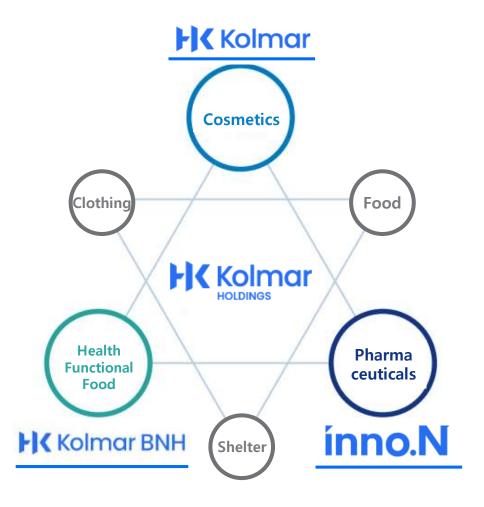
Contents inno.N

**Company Overview** 

Core Business - ETC / H&B / R&D

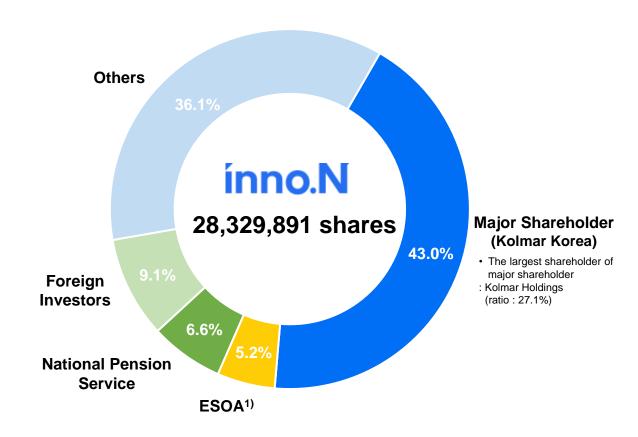
## **Company Overview**

## **Kolmar Korea Group**



## **Shareholders**

As of Mar 31, 2024



1) Employee Stock Ownership Association

## **ESG**

## **Initiatives**

## **ESG** Ratings

## **UNGC (UN Global Compact)**



HK inno.N joined UNGC in October of 2021 and ever since has been submitting an annual report (COP) on how it has implemented the 10 principles of UNGC in its business operations.



RE 100 is a global renewable energy initiative aiming to have power generated using environment-friendly and renewable energy sources, such as through photovoltaic power or wind power, make up 100% of the electric power demanded.

Since joining the Korean version of RE 100, often referred to as K-RE 100, in 2023, HK inno.N has been implementing detailed programs to have 100% of its energy needs met through renewable energy sources by year 2050.



Year	Total
2023	ВВВ

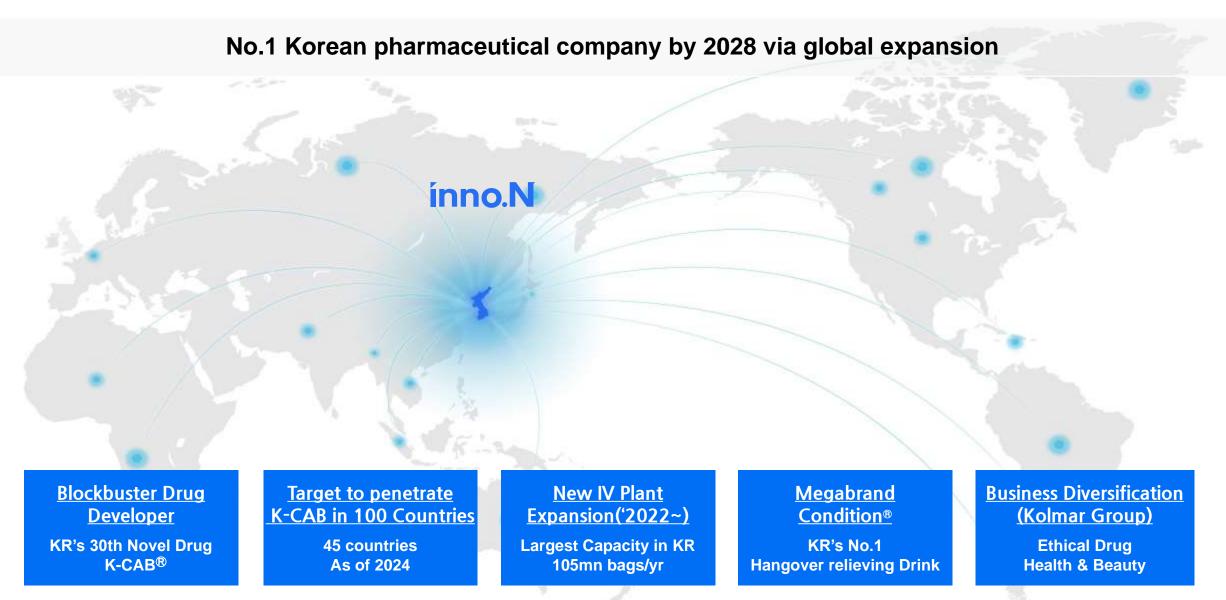


Year	Total	E	S	G
2023	Α	Α	<b>A</b> +	Α



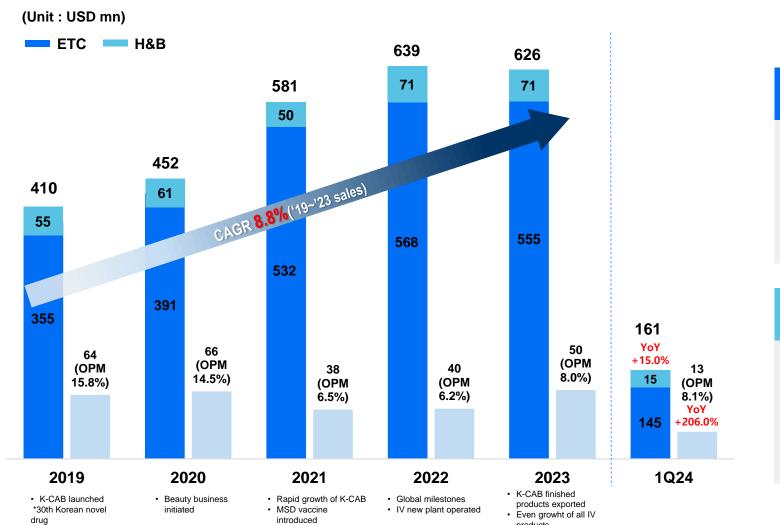
Year	Asset Size	Total
1H2024	AA	AA
2H2023	AA	AA
1H2023	AA	AA

## **Corporate Identity**



## **Business Performance**

## Rapid sales growth since launch of K-CAB['19~'23 sales CAGR: 8.8%]



#### **ETC** (90%)

- Ethical drug lineup in more than 7 treatment areas (cardiovascular, gastrointestinal, diabetes/kidney, anticancer, etc.)
- Essential medicines for national bas ic medical care and disaster prepar edness, such as IV and vaccines









SAN STREET,

Diabetes/Kidney

### H&B (10%)

- · Health: hangover relieving drink, healthcare beverage
- Beauty: hair loss care, cosmetics



Hangover



Healthcare beverage



Hair care

Cosmetics

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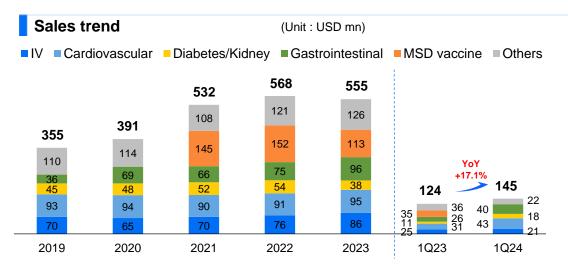
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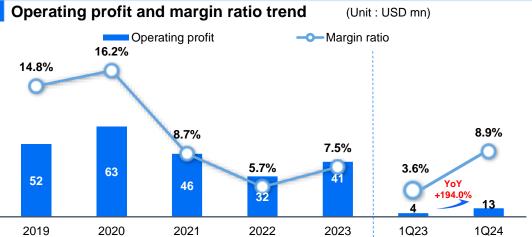
**Company Overview** 

Core Business - ETC/H&B/R&D

## **ETC – Business Status**

# Continuous Rapid Growth via K-CAB / IV Significant Profitability Improvement from 2024





Major achievements

Continuous K-CAB Growth(5<sup>th</sup> year since launch)
USD 26 mn in sales('19) → USD 90 mn in sales('23)

2 Additional growth momentum via new Osong IV plant
Production capacity Expansion
: 50 mn bags per a year → 105 mn bags per a year

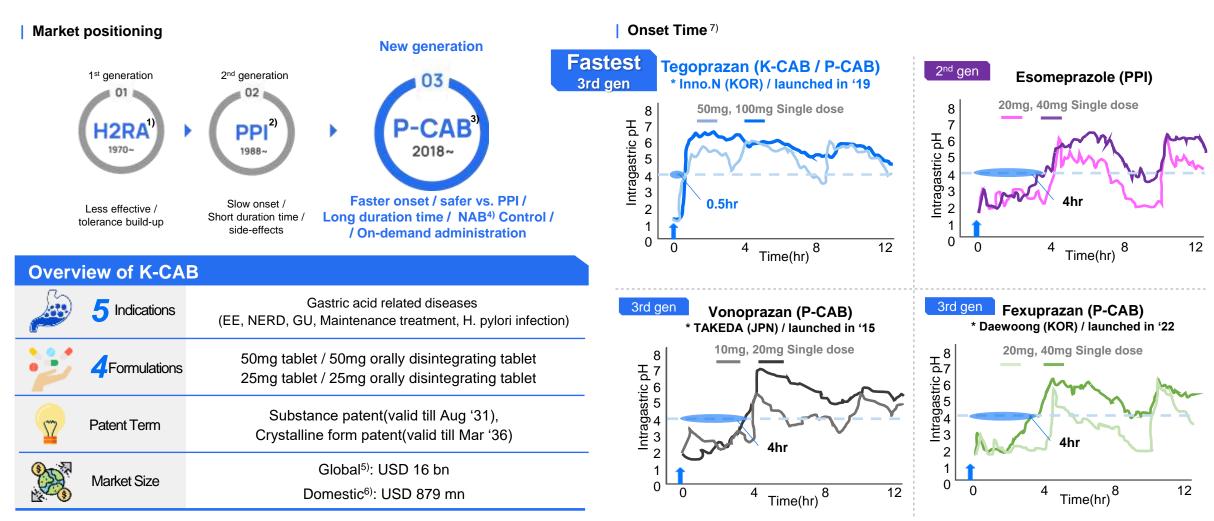
Strengthening cardiovascular and diabetes portfolios
And improving profitability
Salas of 4 types of Kenerh family, Vigdue, etc. from 2024

Sales of 4 types of Kanarb family, Xigduo, etc. from 2024

Source: Company data, DART

## K-CAB®: Next Generation A2B Drug

## Unparalleled advantages over PPI / H2RA and other competing P-CAB drugs



Source: Company data, UBIST data, BCC Research

## K-CAB®: Shortest time to reach 100mn in sales, unrivaled No.1 A2B Drug

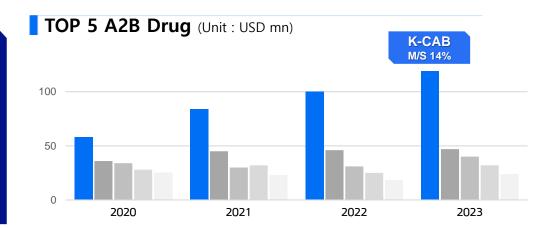
Launched in Mar, 2019

**Co-Promotion with** Boryung (Jan 2024~)

Accumulated prescription sales (63 months) USD 442mn

Prescription performance exceeded **USD 11mn** on average per a month

#1 A2B drug since 3Q19 (market size **USD 956mn**)







Source: UBIST, Company data

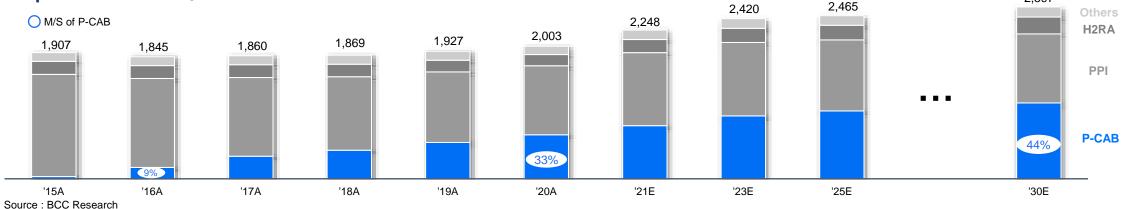
## **Domestic/Japanese A2B Market status**

# Rapid switching phenomenon from PPIs to P-CABs in the A2B market

## **Domestic Market M/S** (Unit: %)



## Japanese Market M/S (Unit: USD mn)



2,597

## K-CAB®: Global Strategy

## Licensed Out to 45 countries including US and China

License out to 100 countries by 2028



5 countries in Eastern Europe

: L/O signed in May 2022 / TBD

- Monos: No.1 Mongolian pharma in GERD treatment
- L/O signed in 2020 / Launched (Oct 2022)





Southeast

Asia (6)

**USD 378** 

- Luoxin: Specializes in gastroenterology products
- **Tablet Formulation** : L/O signed in 2015
- Launched (May 2022) NRDL Registration(Mar 2023 ~)



Tegoprazan 50mg

Canada

**USD 378** 

- 5 companies including Kalbe (#1 pharma in Southeast Asia)
- L/O signed in 2018~2020 / Targeted launch in 2022~2023

× KALBE

- -Philippines: Launched (Nov 2022) -Indonesia: Launched (July 2023) -Singapore: Launched (Aug 2023)
- -Malaysia: L/O signed in 2021 / TBD







- L/O singed in US & Canada, Dec 2021
  - : Braintree Laboratories (subsidary of Sebela US Inc.) (Specialized in A2B Drugs)

Phase 3 clinical trials in progress(as of Sep 2022)

**USA USD 2.8** bn

> Brazil **USD 604**



: L/O signed in Jan 2023

South Ameria (17)USD 453



- Carnot: No.1 player in Mexican gastrointestinal market
- Contracted in 2019
- Mexico: Launched (May 2023)
- Peru: Launched (Oct 2023)
- · Chile, Dominican Republic, Nicaragua, Honduras, Guatemala, and El Salvador
- : Marketing authorization approved
- 11 countries : Review in progress 12



Source: Company data Note: 1) National Reimbursement Drug List

## K-CAB®: Tech Transfer(China, USA)

# China Launch, US Phase III Clinical Trials





## 泰欣赞 (Taixinzan) launched, registered on NRDL<sup>1)</sup>

- L/O contract in 2015(Amount : USD 95mn)
- MA approval in Apr 2022 / Launched in May 2022
  - -Listed as innovative new drug in China (1st class)
  - -Indications : GERD, Duodenal ulcer, H. pylori infection(apply for permission)
- Registered on NRDL, Mar 2023
- Global No.1 A2B market, 2nd largest pharmaceutical market
   -Chinese A2B market expected to reach USD 3.1 bn in 2021

## NRDL registration to boost rapid growth in China

- Term : Mar 2023 ~ Dec 2024(Gradual registration by province)
- Registered in 31 provinces, sale activity and marketing commencement
- Market penetration via strong sales force and product competence
- · Sales growth via high price and high volume
- Royalty payment receipt in 3Q23 First payment after NRDL registration



USA



### L/O Contract

• Braintree Laboratories, a subsidiary of Sebela US Inc. (Amount: USD 54mn)

#### USA GERD Market

- 65m+ GERD patients in the US
- 40m PPI patients
  ~20% are refractory patients, 30~40% are irresponsive
- Min. potential → 20%~30% of PPI users, Potential sales of \$1 billion USD

## R&D Pipeline Progress

1. 11. 22	Stage				
Indication	Phase 1	Phase 2	Phase 3	NDA Submission	FDA Approval
Erosive esophagitis (n=1,250)		SKIP -			
Non erosive reflux disease (n=800)		SKIP —			

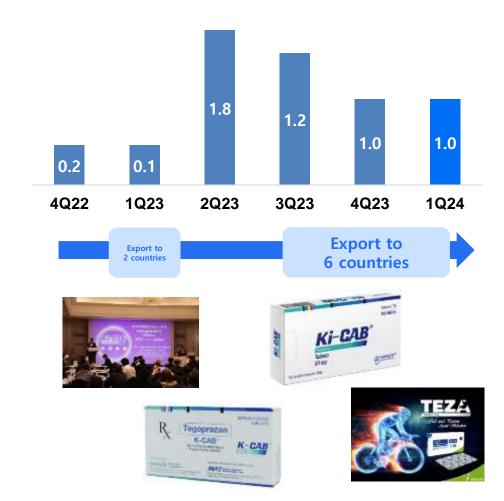
## **K-CAB®: Finished Product Exports**

# Global Launch and Sales Initiation via Marketing Authorization Approval

## K-CAB finished product export countries

No.	Region	Country	Launch
1	-	Mongolia	Oct 2022
2	C H-	Philippines	Nov 2022
3	South- East Asia	Indonesia	Jul 2023
4	Asia	Singapore	Aug 2023
5		<ul><li>Mexico</li></ul>	May 2023
6		<b>↔</b> Peru	Oct 2023
7		<b>⊌</b> Chile	
8	South	<b>♣</b> Dominican Republic	<u>Marketing</u>
9	America	<b>©</b> Nicaragua	authorization approved
10		C Honduras	•
11		<b>(→)</b> Guatemala	Launch (TBD)
12		😅 El Salvador	

K-CAB finished product export sales trend (unit : USD mn)



## **Strategic Partnership**

## Maximizing synergy through joint co-promotion between Korean Top-Class novel drugs







## Introduction of 4 types of Kanarb family from Boryung

- Kanarb, Korean 15<sup>th</sup> novel drug
   (Component : Fimasartan trihydrate)
- Introduction items : Kanarb, Dukaro, Dukarb,
   Dukarb Plus
- Prescription performance

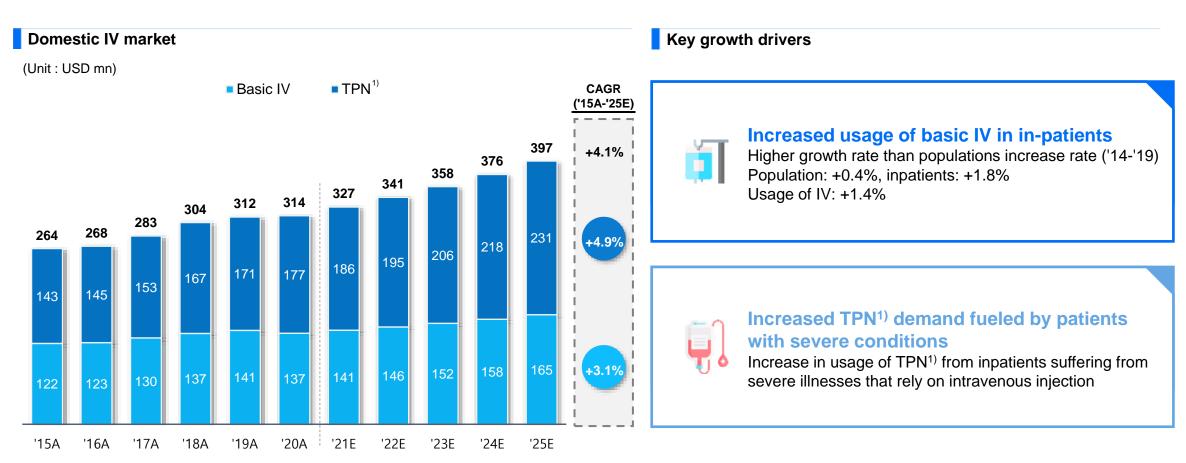
## Co-Promotion Strategy

- Strengthening hypertension/dyslipidemia portfolios
- Expanding the prescription range for chronic diseases
- Maximizing growth potential between two novel drug by sharing blockbuster development capabilities

: USD 90mn in 2022 → USD 101mn in 2023

## **Domestic IV Market Forecast**

# Sturdy 4% CAGR and steady demand fueled by in-patients and patients with severe conditions

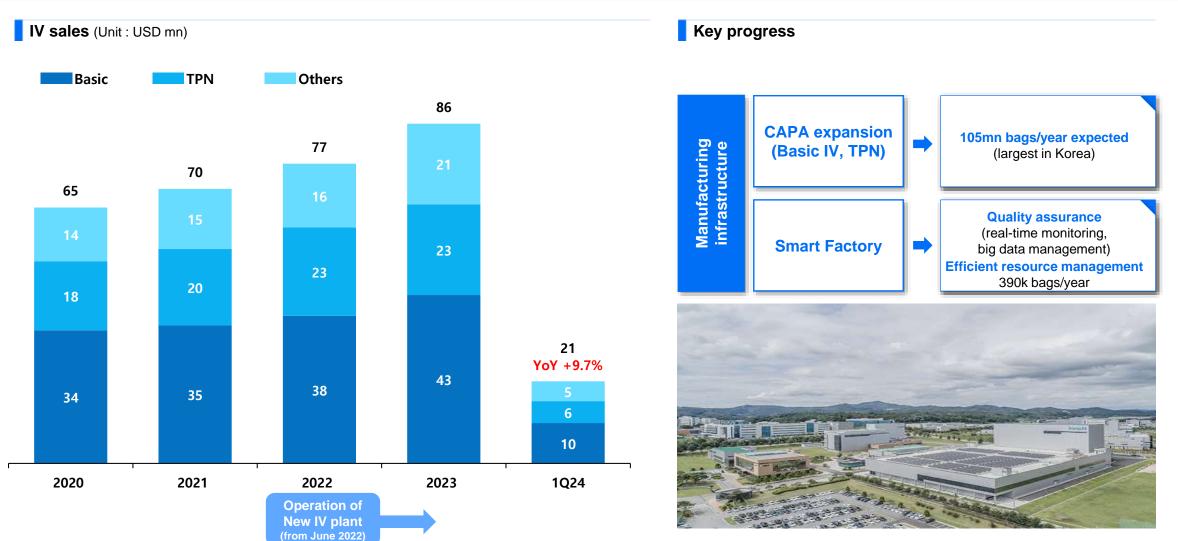


Source: BCC Research Note: 1) Total parenteral nutrition

## **IV Business**

Note: 1) Twist-Off Protector

# Strengthen competitiveness via capacity expansion, TOP¹) implementation and development of new TPN



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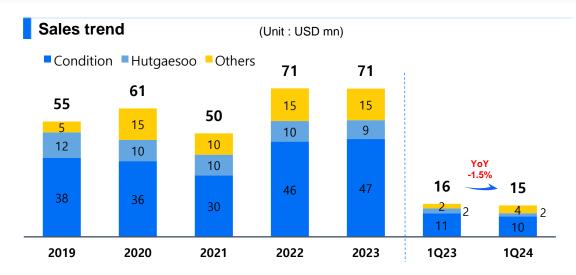
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**Company Overview** 

Core Business - ETC / H&B / R&D

## H&B (Health & Beauty) – Business Status

## Well balanced portfolio consisting products with high profits (hangover relieving drink) & new business (beauty)





## Major achievements



## **Hangover relieving drink (Condition)**

- Sales increase(recovery) after lifting of social distancing restrictions
- Expansion of M/S of ND(Non-Drink : stick, hwan) product



## **Healthcare** beverage

- Constant growth via release of new products and expansion of distribution networks
- Hutgaesoo, barley tea, carbonated water(REFREZ), liquid tea(tealog)



## **Beauty**

- Lineup: 'bewants' eye serum stick, shampoo(Scalpmed)
- Expansion of bewants brand lineup
- Expansion of distribution network
  - : H&B Store on/off channel(1,300 stores), Amazon US

## **Condition, No.1 Hangover Relieving Drink**

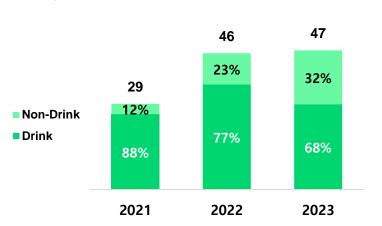
# Condition - #1 in market share New Market generation and market expansion with the launch of "Condition Stick"

Quarterly sales (Unit : USD mn)

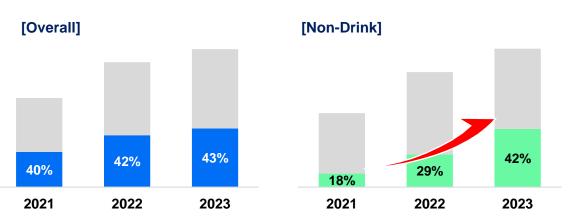




## Yearly sales (Unit: USD mn)



## **Condition M/S(Domestic)**



Source : Company data, Neilsen IQ Korea data

## **H&B\_Other Beverage**

## Tealog (Zero calorie iced tea)

• Launched in 2023

• Sales in 2023: USD 7mn



## Hutgaesoo (Liquid tea for thirst)

• Launched in 2010 / Sales in 2023: USD 9mn



## Saessakbori (Liquid tea)

• Launched in 2015 / Sales in 2023: USD 2mn



## **H&B** - Synergy with Kolmar

Swift entry into derma cosmetics market via accumulated pharmaceutical know-how and partnership with Kolmar (cosmetics ODM¹))



Kolmar -> inno.N

Supply of the best beauty products

Brand launch through inno.N's sales force

inno.N

Accumulated expertise in pharmaceuticals

## **Synergy with Kolmar**

## Continuous portfolio diversification with aggressive branding

# ScalpMed Hair-loss prevention "Microbiome" technologies



## **Growth strategies**

## Product line-up expansion

major brands

ScalpMed Be+wants

strategic development

## **Channel expansion**

 Expanding various channel networks such as H&B Store (on/off), Amazon US, etc

## Selective market penetration

- Prevention of hair loss
- Slow-aging Basic Line

Source: BCC Research

Note: 1) Original design development

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**Company Overview** 

Core Business - ETC / H&B / R&D

## R&D – Key pipeline

Operating R&D pipelines for synthetic new drugs, antibodies, and cell therapy in the areas of gastrointestinal, diabetes/obesity, autoimmune, infection, and oncology

Development stage	Candidate	Pre-clinical	P1	P2	P3	Launch
Gastrointestinal	Best-in-class First-in-class		B IN-114199 CIC <sup>1)</sup>	F FM-101 MASH <sup>2)</sup>		C K-CAB  GERD <sup>3</sup> , Gastric Ulcer, H. Pylori eradication
Diabetes/Obesity					Ecnoglutide GLP-1 Receptor Agonist	
Autoimmune	B 22ND01 TYK2 inhibitor		B IN-115314  AD <sup>4</sup> ), Psoriasis, Rheumatoid arthritis		B IN-115314 Pet Atopic Dermatitis	
Infection		B IN-B00001 Smallpox				
Oncology	F IN-B00003 CAR-T/CAR-NK	B IN-119873 Next gen. EGFR <sup>5)</sup> inh.	B IN-B00004 CD56 NK (AML, MM)			
Oncology	F IN-B00002 HLA-G MAB					

Source: Company data

## **Ecnoglutide: Long-lasting Weekly Injection of GLP-1 Receptor Agonist**

## Significant decrease in HbA1C and body weight with comparable efficacy to semaglutide and tirzepatide

Overview of Ecnoglutide		
Target Indications	Type 2 Diabetes, Obesity, MASH <sup>1)</sup>	
Dosage & Administration	Once a Week, Subcutaneous(SC) Injection	
Development Status	P3 Clinical Studies for T2D/Obeisty in China are ongoing  * P1 in AUS / P2 in China and AUS/NZ / P3 in China conducted  * P3 for T2D/Obesity planned in KR	
Remarks	<ul> <li>Clinically proven efficacy and safety         which is comparable with semaglutide &amp; tirzepatide</li> <li>Better cost-effectiveness than current competitors in market</li> <li>Potential development opportunity for FDC<sup>2</sup>/oral formulation</li> </ul>	



#### Paradigm of T2D Treatment: GLP-1 RA<sup>3)</sup> is a Next-Generation Drug

GLP-1 RA



## Market Trends

- GLP-1 agonist market: reaching a global market size of \$105B in 2029
- ❖ Big pharmas are moving to combination of amylin analogue or DCRA<sup>4</sup>) as well as dual/triple agonist of incretin mimetics in clinical developments

**Clinical Information** | HbA1c reduction (P2 in China) Up to -2.39% HbA1c change at the end of treatment(134 Day) HbA1c change from HbA1c over time baseline at end of treatment ◆ 0.4 mg 
◆ 1.2 mg O 0.8 mg -O- Placebo 0.4 mg 0.8 mg 1.2 mg placebo Ecnoglutide HbA1c change from baseline over time and at end of treatment (least squares mean and standard error). Mean difference from placebo and 95% confidence interval are shown at end of treatment (Day 134). | Body weight reduction at 26weeks(P2 in AUS/NZ) Up to 14.7% BW loss after 26weeks of once-weekly dosing Percent body weight Percent body weight change over time change at 26 weeks 8 2 4 8 8 16 12 14 16 18 1 1.2 mg Eprogluside 3 2.4 mg Eprogluside 1.8 mg Ecnoglutide 33 mg Lineglutide

Source: Company internal data, GlobalData, DataMonitor, ADA 2023 poster

Note: 1) Metabolic dysfunction-associated steatohepatitis 2) Fixed-Dose Combination 3) Glucagon-like Peptide 1

4) Dual amylin and calcitonin receoptor agonist

## IN-115314: New topical JAK inhibitor for treatment of atopic dermatitis (AD)

## Efficacy GLP-Tox Phase 1 Phase 2 Phase 3

Selectivity
AD DNCB Model

ADME

2/4/13 week repeat Tox

(Rat, Monkey)

8 week topical repeat

Tox (Minipig) Genetoxicity

Local Tox (Dermal, Eye)

## I Phase 1: First-in-Human (Topical) study ongoing

	Phase la		Phase lb
	Single Ascending Dose (SAD)	Multiple Ascending Dose (MAD)	
Target	Healthy volunteer (Korean)	Healthy volunteer (Korean)	Patient (Korean, mild to moderate AD)
Investigational product	IN-115314 ointment (5 doses) Placebo	IN-115314 ointment (2 doses) Placebo	IN-115314 ointment (2 doses) Elidel cream
No. of subjects	32	24	24
Endpoint	<ul><li>Safety</li><li>Exposure</li></ul>	Safety     Exposure	<ul><li> Efficacy</li><li> PK/PD parameters</li><li> Safety</li></ul>
Duration	4M	4 M	7 M



SAD: Completion, MAD: Ongoing; Adevrse effect not reported

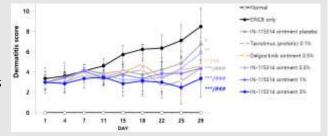
## Efficacy and safety of topical IN-115314 (pre-clinical)

## Growth of the global atopic dermatitis market: \$16B+ by 2027

- \$10B by 2019, CAGR 13% / Topical market: 25~30%
- 1st topical JAK inhibitor (Opzelura®): market sale \$400M by 2022.
  - → Topical market approx. doubles (US) / predicted peak sales \$1.8B
  - → Safety concerns by systemic exposure

## In vivo efficacy in mouse AD model

- DNCB-induced mouse AD model, Topical administration BID for 28 days
- ~50% improvement in dermatitis score and other skin parameters



: IN-115314 ointment 3% ≥ tacrolimus 0.1% (TCI), delgocitinib 0.5% (JAKi)

## Topical JAK inhibitor, improves safety by minimzing systemic exposure

- No significant adverse effect was observed in Minipig 8-week repeated toxicity study.
- Compared to Opzelura®, improved safety by minimzing systemic exposure (Best in Class).

Day	Dose	AUC <sub>0-24hr</sub> (ng*h/mL)	Remark
Ruxolitinib crea	am (Opzelura)		
Day 296	1.0% QD	79	WBC↓
	1.0% BID	146	WBC↓ (dermal NOAEL)
	1.5% BID	198	WBC↓
IN-115314 oin	tment		
Day 56	1% QD	1.44	-
	3% QD	3.96	-
	5% QD	21.97	- (NOAEL)

# IN-115314: New JAK inhibitor for treatment of canine atopic dermatitis (Pet HealthCare)

## **Efficacy**

**GLP-Tox** 

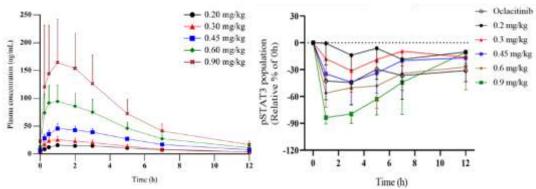
Phase 1

Phase 2 Phase 3

Selectivity
AD HDM Model
(mice)
AD DNCB Model
(mice)

PK-PD study in healthy dogs 13-week repeated tox study in dogs Genotoxicity study Safety pharmacology study HDM induced AD model in dogs IL-31 induced pruritus model in dogs

## PK/PD study in dogs



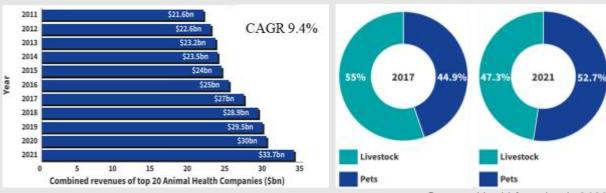
- Dose-dependent increase in exposure from 0.2 to 0.9 mg/kg.
- Dose-related PD effects on JAK1-related biomarker were confirmed.
- Effective dose of IN-115314 is considered to be similar to Apoquel®.

## **Efficacy study in dogs**

- HDM induced AD model in dogs: on-going
- IL-31 induced pruritus model in dogs: on-going

## **Animal Health Sector Revenue Growth**

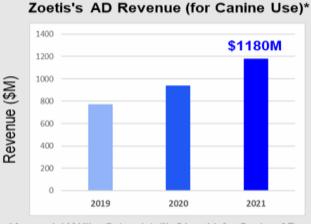




Source: Healthforanimals 2022

## JAK inhibitor as a Good Treatment Option for Canine Atopic Dermatitis

- Apoquel® (JAK inhibitor of Zoetis) sales was \$800 million in 2022.
- Skin disease including atopic dermatitis is the most common Vet visits (18%, CAGR 9% in Korea)



\*Apoquel (JAKi) + Cytopoint (IL-31 mab) for Canine AD

# IN-119873: Allosteric EGFR inhibitor, the best partner of Tagrisso® The 4th Gen EGFR TKI for the treatment of L858R EGFR+NSCLC



Selectivity
in vitro efficacy
-L858R, L858R/T790M,
L858R/C797S, L858R/T790M/C797S
CDX model
PDX model
Brain metastasis in vivo model

## I Competitive differentiation in the EGFR TKI Market

### The first allosteric EGFR inhibitor

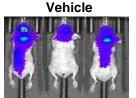
- Excellent kinase selectivity without EGFR wild type activity
- Synergistic effect with osimertinib by unique allosteric binding mode
- Provide treatment options to Tagrisso® resistance patients.

## Great antitumor efficacy in patient derived xenograft

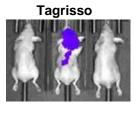
- High potential for demonstrating strong efficacy in human tumors

## Excellent antitumor efficay in brain metastasis model

- Enhanced Competitiveness through improved antitumor efficacy in brain







# Development of 4<sup>th</sup> generation EGFR inhibitor compatible with 3<sup>rd</sup> generation TKI osimertinib combination

#### Unmet medical needs

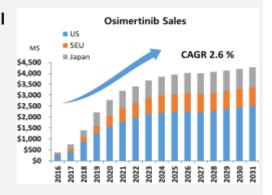
- Despite the approval of 3<sup>rd</sup>-generation EGFR inhibitors, patients with the L858R mutation exhibit a more unfavorable prognosis.
- There is currently no established standard 2<sup>nd</sup> line therapy following osimertinib treatment.
- The next-generation EGFR TKIs should address osimertinib resistance effectively, while avoiding EGFR WT activity to reduce issues like skin problems and cardiotoxicity.

## Development strategy

- Enhancing efficacy and minimizing through combination with 3<sup>rd</sup> generation EGFR TKI
- 4<sup>th</sup> generation EGFR inhibitor as the 2<sup>nd</sup> line treatment for non-responder to 3<sup>rd</sup> generation EGFR TKI drugs

## Forecast global market growth of EGFR TKI

- Growing and to reach \$6.8B by 2029 at CAGR 11%
- Global market growth of Osimertinib \$4.3B by '29 at CAGR 2.6 %
- The synergistic effect with osimertinib is expected to lead to the expansion of the market, potentially increasing the osimertinib market share.



## Global partnering opportunity