# Investor Relations

## 3Q 2025

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# Forward-Looking Statements

- The financial information in this document are consolidated earnings results based on K-IFRS.
- This document is provided for the convenience of investors only, before the external audit on our Q1 2025 financial results is completed. The audit outcomes may cause some parts of this document to change. Please note that Hanmi will not be responsible for individual investment decisions sole based on this material. In addition, Hanmi will not be responsible for update of this material which based on current business results.
- This presentation contains forward-looking statements with respect to the financial condition, results of operations and businesses of Hanmi Pharmaceutical Company. By their nature, forward-looking statements and forecasts involve risk and uncertainty because they relate to events and depend on circumstances that will occur in the future. There are a number of factors that could cause actual results and developments to differ materially from that expressed or implied by these forward-looking statements. These factors include, among other things, the loss or expiration of patents, marketing exclusivity or trade marks; exchange rate fluctuations; the risk that R&D will not yield new products that achieve commercial success; the impact of competition, price controls and price reductions; taxation risks; the risk of substantial product liability claims; the impact of any failure by third parties to supply materials or services; the risk of delay to new product launches; the difficulties of obtaining and maintaining governmental approvals for products; the risk of failure to observe ongoing regulatory oversight; the risk that new products do not perform as we expect; and the risk of environmental liabilities.

- **Consolidated subsidiaries (K-IFRS)**
  : Beijing Hanmi Pharmaceutical Co., Ltd 73.68%, Hanmi Fine Chemical Co., Ltd 63.00%

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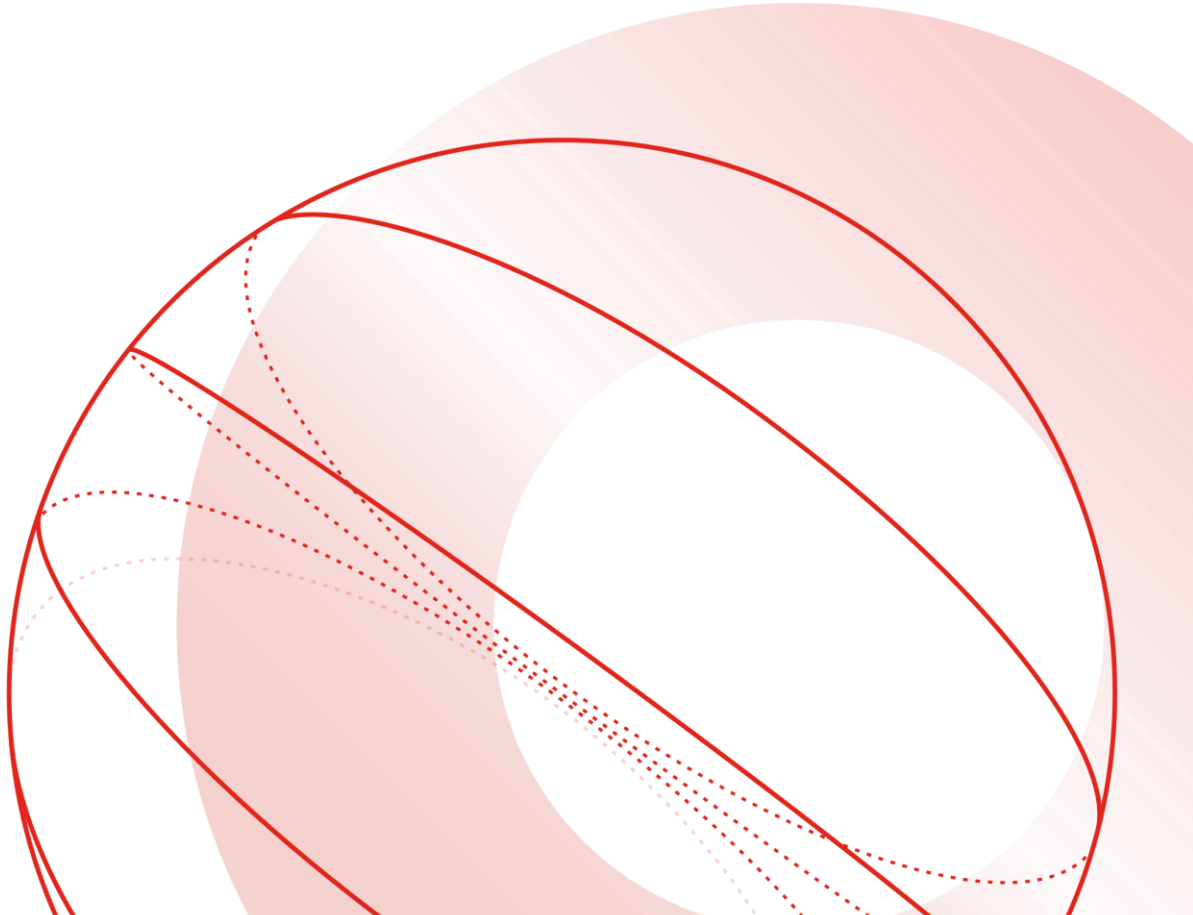
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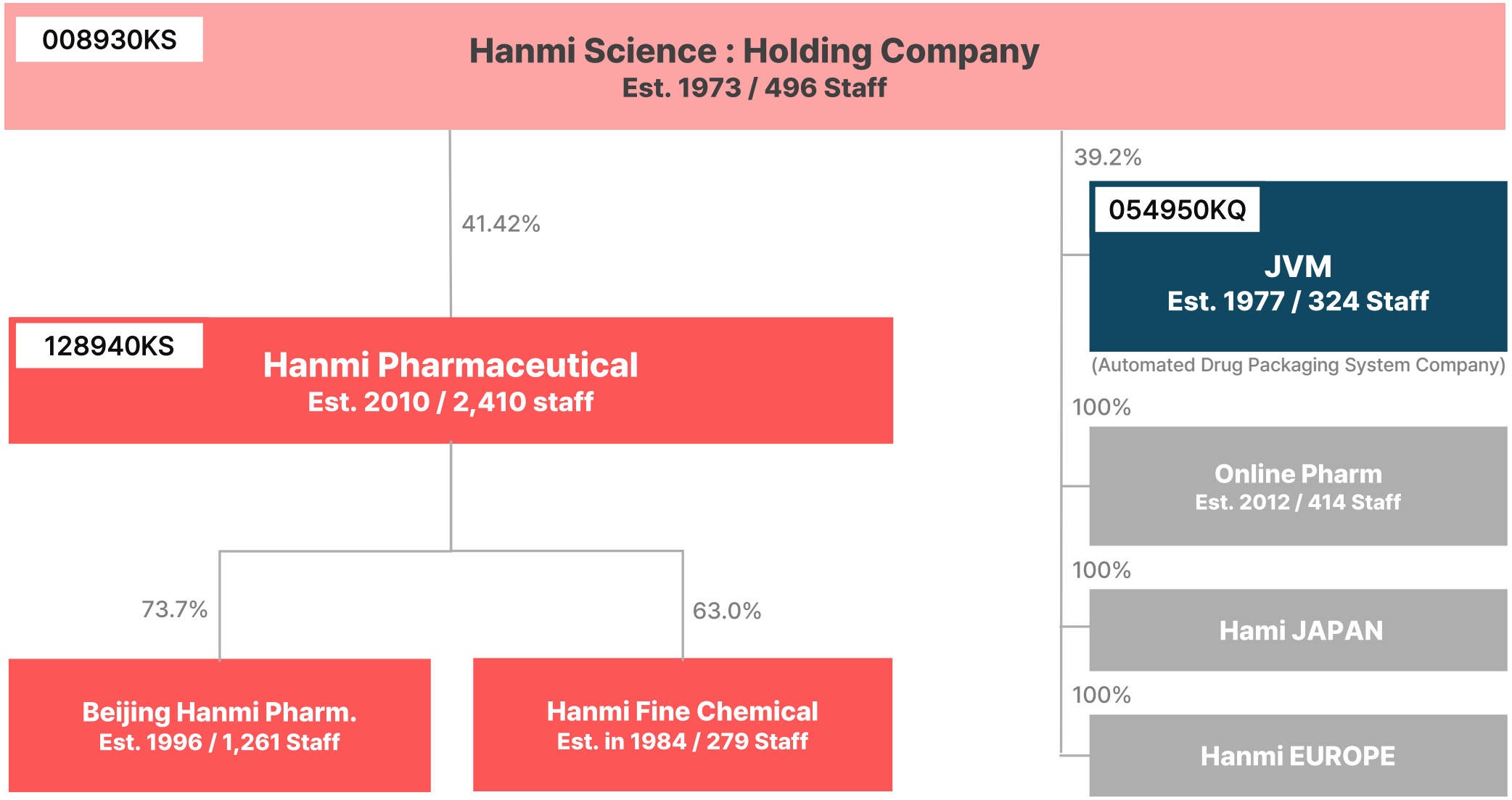



# Company Overview



# Corporate Governance

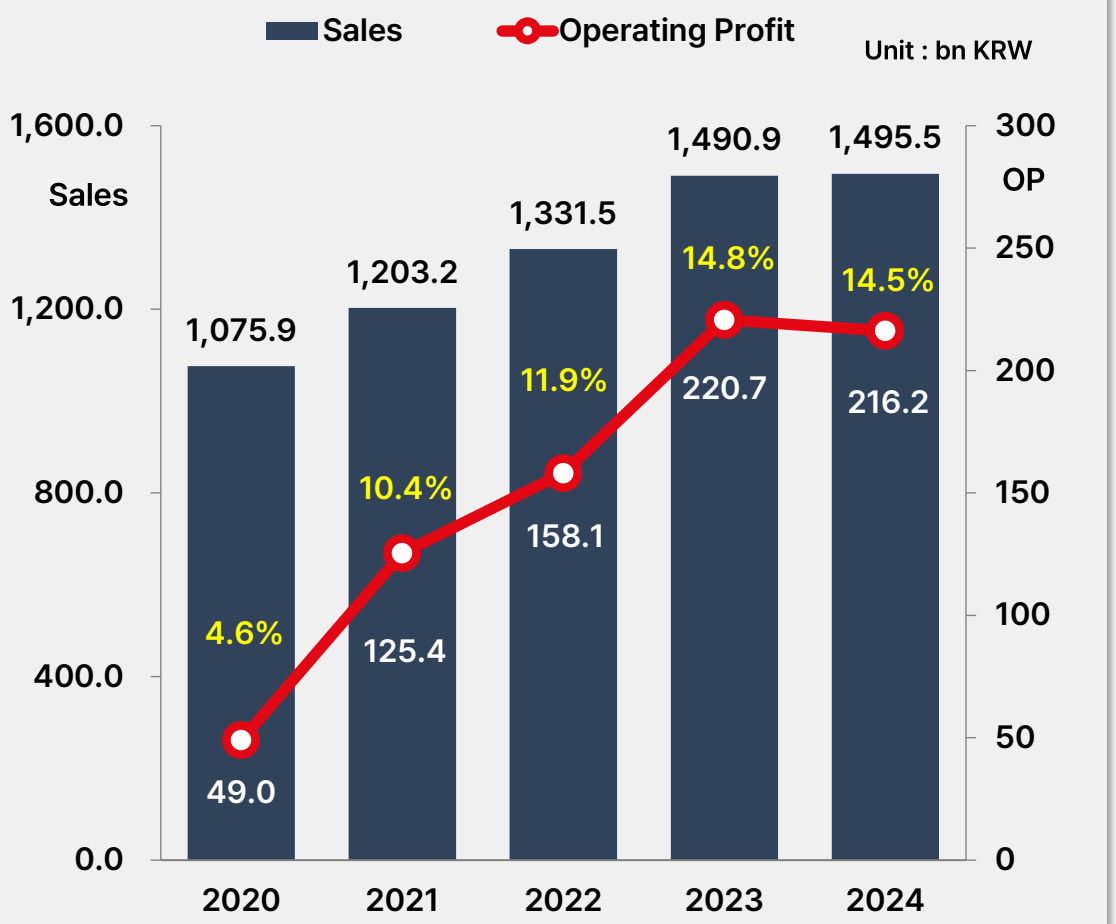
(As of Jun 2025)



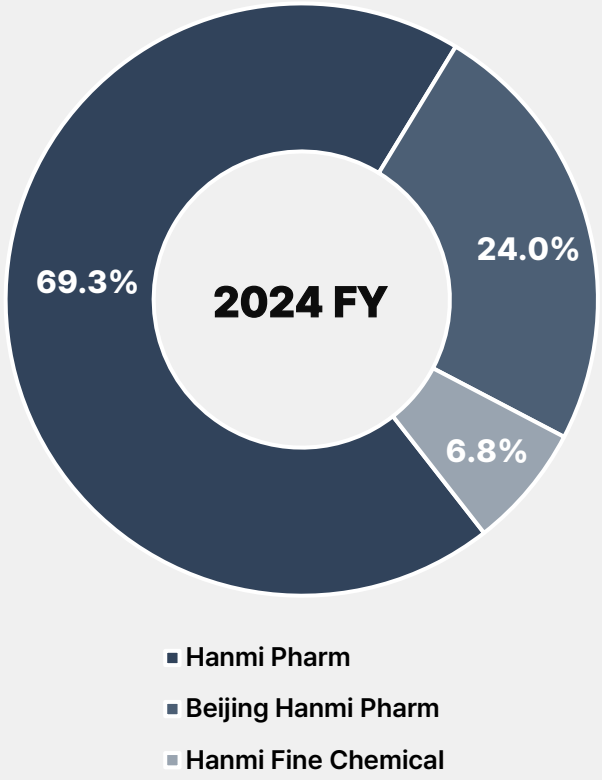
# 5-year Performance Trend Consolidated Business Results

- **2024 annual sales KRW 1,495.5bn, +0.3% YoY. OP KRW 216.2bn, -2.0% YoY**

## 5-year Performance Trend



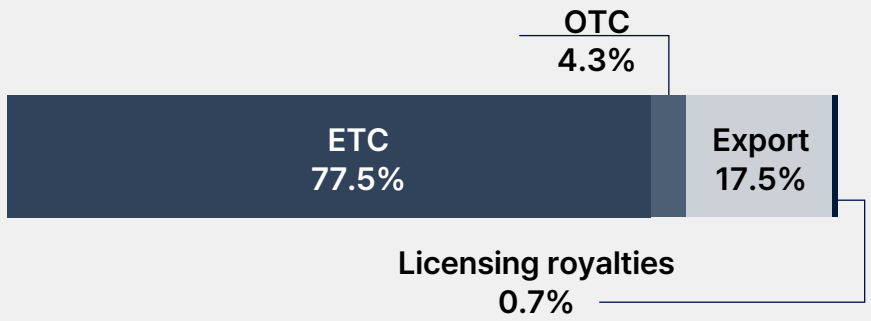

## Sales Breakdown*




*% based on the aggregated sales of Hanmi Pharm & its subsidiaries before eliminating internal transactions

# Hanmi Pharmaceutical Sales Analysis

## 2024 Sales Breakdown



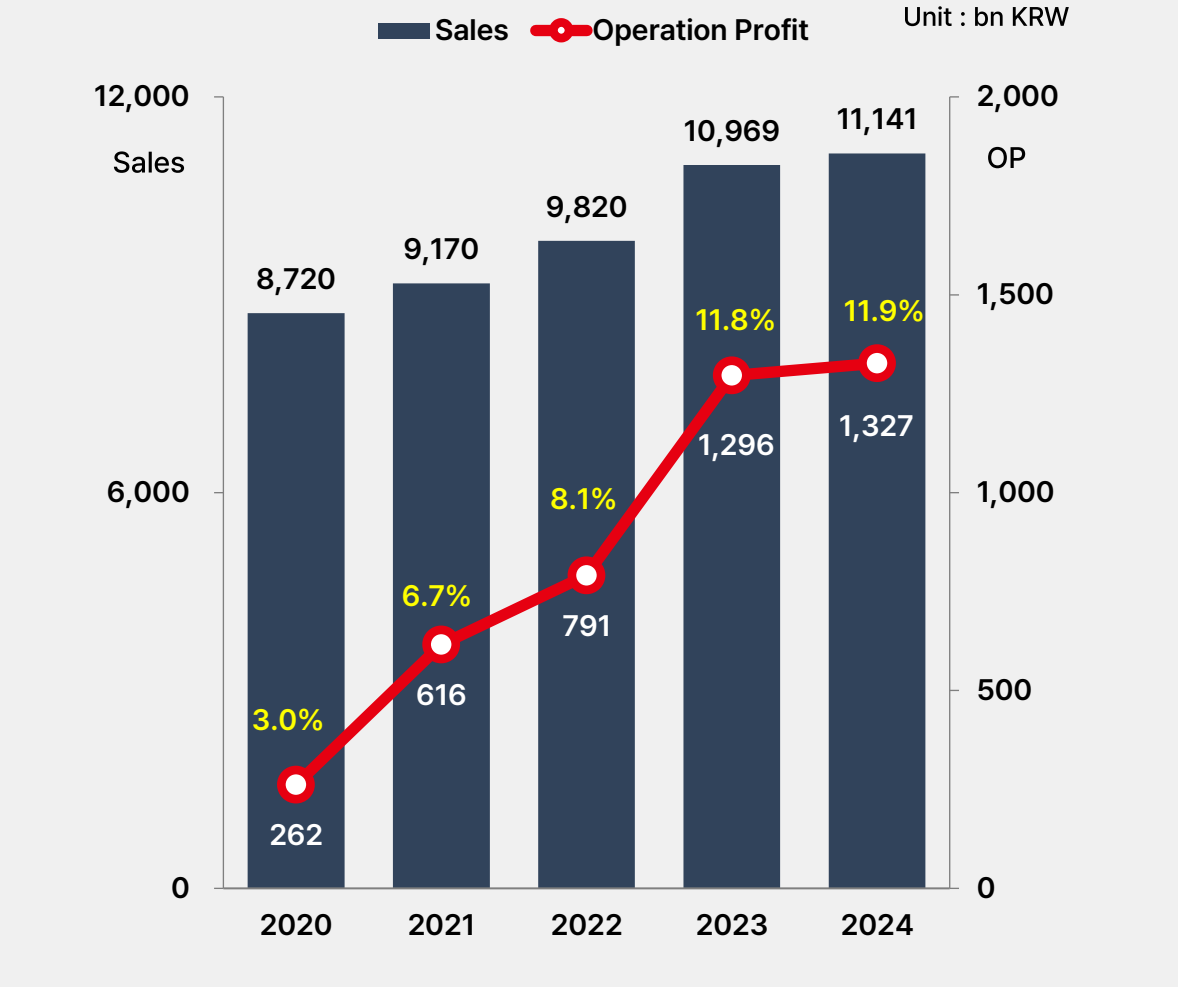

## Top ETC Products *(Outpatient prescription Sales)*

Unit: bn KRW

| Category | Product | 2024 | Sales(%) | YoY |
|---|---|---|---|---|
| Cardiovascular | Rosuzet | 210.3 | 19.6% | 17.6% |
| Cardiovascular | Amosartan Family | 146.7 | 13.7% | 3.3% |
| Gastrointestinal | Esomezol Family | 65.2 | 6.1% | 1.5% |
| Urology | Hanmi Tams/OD | 45.6 | 4.3% | 12.7% |
| Urology | Pal Pal | 42.1 | 3.9% | -0.8% |
| Cardiovascular | Naxozol | 25.8 | 2.4% | -3.9% |
| NSAIDs | Amodipin | 25.4 | 2.4% | 2.2% |
| Urology | Gugu | 23.5 | 2.2% | 8.3% |
| Total Sales | | 1,070.9 | 100% | 6.6% |

(* Source: UBIST data)

## “Double-digit OPM sustained by strong product growth”



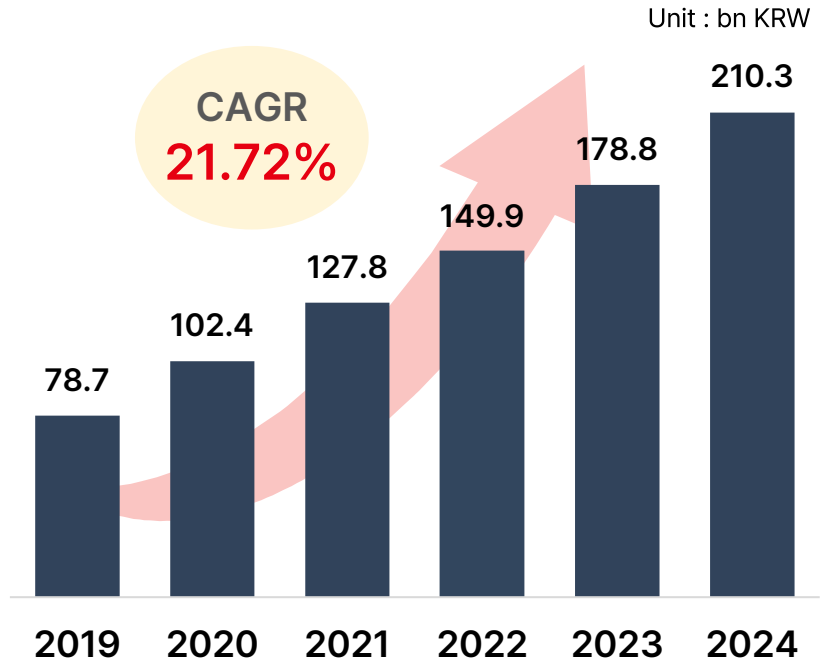
# Core Value-added product Rosuzet (Hypercholesterolemia treatment)

## Achieved No.1 in domestic outpatient prescriptions, Rosuzet

- ✓ Robust domestic growth led by evidence-oriented marketing
- ✓ Expanding efficacy & safety profile through multiple Real World Data
- ✓ Building physician trust through data-driven engagement



## Annual sales of Rosuzet




(* Source: UBIST data)

## Rosuzet's RACING Study results were published in the Lancet

| THE LANCET '22.07.18 | European Heart Journal '22.12.19 | JACC JOURNALS '23.04.03 |
|---|---|---|
| **[RACING Study]** Long-term efficacy and safety of moderate-intensity statin with ezetimibe combination therapy versus high-intensity statin monotherapy in patients with ASCVD | **[The 1st sub-analysis of RACING Study]** Moderate-intensity statin with ezetimibe vs. high-intensity statin in patients with diabetes and ASCVD | **[The 2nd sub-analysis of RACING Study]** Combination Moderate-Intensity Statin and Ezetimibe Therapy for Elderly Patients With Atherosclerosis |
| eClinicalMedicine Part of THE LANCET Discovery Science '23.04.04 | JAMA Cardiology '23.08.02 | CARDIO VASCULAR DIABETOLOGY '24.11.05 |
| **[The 3rd sub-analysis of RACING Study]** Efficacy and safety of moderate-intensity statin with ezetimibe combination therapy in patients after percutaneous coronary intervention | **[The 4th sub-analysis of RACING Study]** Moderate-Intensity Statin With Ezetimibe Combination Therapy vs High-Intensity Statin Monotherapy in Patients at Very High Risk of ASCVD | **[NODM Big Data Study]** Efficacy and diabetes risk of moderate intensity statin plus ezetimibe versus high intensity statin after percutaneous coronary intervention |

# Beijing Hanmi 5-year Performance Trend

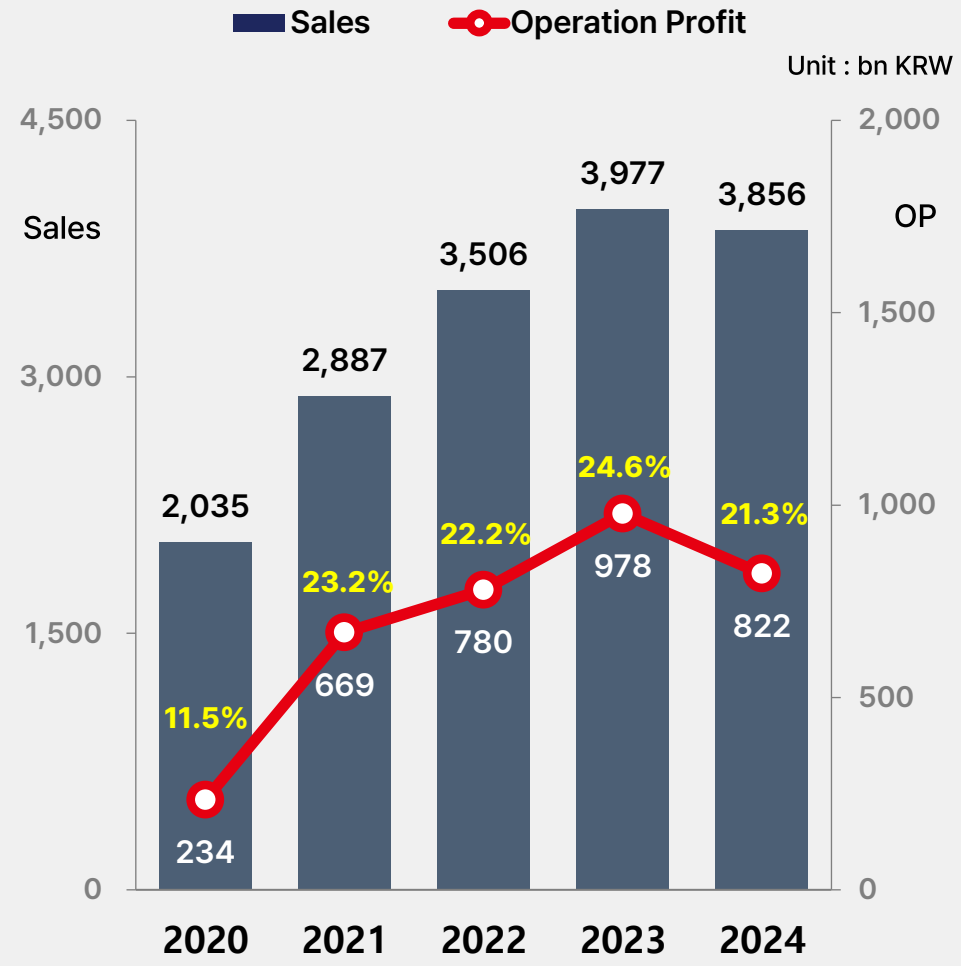
- Est.1996. Full Value Chain (R&D to commercialization)
- 2024 annual sales KRW 385.6bn -3.0% YoY
  operating profit KRW 82.2bn -16.0% YoY

## Flagship Products

Unit : 1,000 RMB

| Product | Indication | 2024 | Sales(%) | YoY |
|---|---|---|---|---|
| Itanjing | Antitussive expectorants | 708,592 | 34.7% | -8.6% |
| Li Dong | Constipation | 573,785 | 28.1% | 18.1% |
| Mami Ai | Probiotics for infants | 297,030 | 14.6% | -29.8% |
| Mechangan | Probiotics for adults | 162,487 | 8.0% | 15.8% |
| Yianping | Antitussive expectorants | 138,954 | 6.8% | -10.9% |
| Total Sales | | 2,040,093 | 100% | -5.5% |

## 5-year Performance Trend



# Hanmi R&D

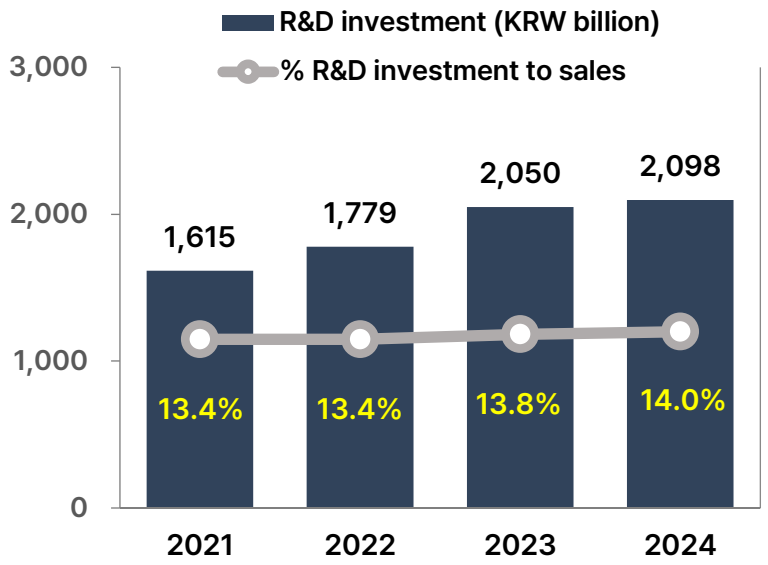


# R&D Overview

**R&D Pipeline**
**25 Candidates**
(2025.06.)

**R&D investment**
**14%** ('24)
**on revenue basis**

**Total R&D Staff**
**671***
(2025.06.)




| Partners | Pipeline | Progress Status | Date of Agreement | Out-Licensing Value | Amount Achieved |
|---|---|---|---|---|---|
| Assertio (U.S.) | Rolvedon®/Rolontis® | Launched in the U.S. and S.Korea | 2012.01.31 | Not disclosed | Not disclosed |
| | Poziotinib (pan-HER) | Preparing for global phase 3 trial | 2015.02.27 | | |
| MSD (U.S.) | efinopegdutide (LAPSGLP/GCG agonist) | Global phase 2 | 2020.08.04 | US$870M | Upfront Payment : US$10M<br>Milestone : US$14M |
| Health Hope Pharma (HK) | ORASCOVERY™ | Submitted MAA to UK MHRA** | 2011.12.16 | US$42.44M | Not disclosed |
| Genentech (U.S.) | belvarafenib (pan-RAF) | Global and S. Korea phase 1 trial | 2016.09.28 | US$910M | Upfront Payment : US$80M<br>Milestone : Not disclosed |
| Aptose (U.S./Canada) | tuspetinib (MKI) | Global and S. Korea Phase 1 trial | 2021.11.04 | US$420M | US$12.5M |
| AffaMed Therapeutics (China) | Luminate® (ALG-1001) | Preparing for phase 3 in China (for AMD) | 2021.12.31 | US$145M | US$6M |
| NOBO Medicine (Korea) | poseltinib (Multi-TEC) | S. Korea phase 2 trial | 2024.06.03 | Not disclosed | Not disclosed |

* Consolidated basis, Hanmi Pharm R&D Staff: 434, ** Medicines and Healthcare products Regulatory Agency

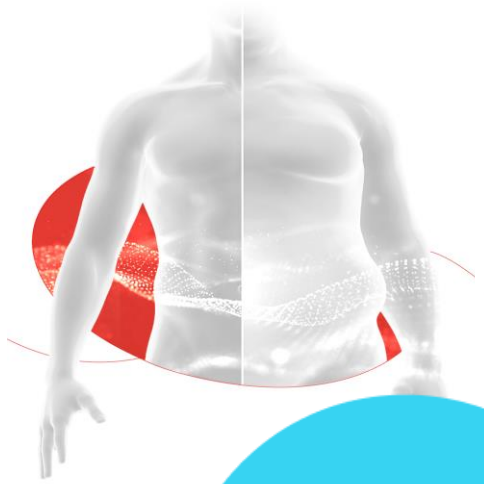
# R&D Pipeline

| | Pre-clinical | Phase 1 | Phase 2 | Phase 3 | Approved |
|---|---|---|---|---|---|
| Obesity/ Metabolism | **Efpegerglucagon+Efpeglenatide**<br>[LAPS Glucagon Combo]<br>Obesity/Metabolic disease | **HM15275**[1)]<br>[LA-GLP/GIP/GCG]<br>Obesity, Completion of Phase 1 | **Efinopegdutide**<br>[LAPS GLP/GCG agonist]<br>MASH, formerly NASH — MSD | **Efpeglenatide**<br>[LAPS Exd4 Analog]<br>T2DM/Obesity | |
| | **HM17321**<br>[LA-UCN2]<br>Obesity | | **Efocipegtrutide**<br>[LAPS Triple agonist]<br>MASH, formerly NASH | | |
| Oncology | **HM1012071**<br>[SOS1]<br>Solid tumors | **Rolvedon®**<br>[Eflapegrastim]<br>Chemotherapy-induced Neutropenia (Same Day Administration) — Assertio | **Belvarafenib**<br>[pan-RAF Inhibitor]<br>BRAF mutant/fusion solid tumor — Roche | **Poziotinib**<br>[pan-HER Inhibitor]<br>HER2 exon 20-mutated NSCLC (2nd line) — Assertio | **Rolvedon®**<br>[Eflapegrastim]<br>Chemotherapy-induced Neutropenia — Assertio |
| | **HM100714**<br>[sHER2]<br>Non-small cell lung cancer | **Belvarafenib**<br>[pan-RAF Inhibitor]<br>Solid tumors (melanoma) — Genentech | **Tivumecirnon**<br>[FLX475]<br>Gastric cancer — RAPT | **Oraxol®**<br>[Encequidar+Paclitaxel]<br>Solid tumors (breast cancer) — Health Hope Pharma | |
| | | **BH2950** B<br>[PD-1/HER2 BsAb]<br>Solid tumors — Innovent | **Poseltinib**<br>[multi-TEC]<br>B-cell lymphoma — NOBO Medicine | | |
| | | **Tuspetinib**<br>[MKI]<br>Acute Myeloid Leukemia — Aptose | | | |
| | | **HM97662**<br>[EZH1/2 Inhibitor]<br>Solid tumors, hematologic cancers | | | |
| | | **BH3120** B<br>[PD-L1/4-1BB BsAb]<br>Solid tumors, Combination with 'KEYTRUDA' | | | |
| | | **HM16390**<br>[LAPS IL-2 analog]<br>Solid tumors | | | |
| Rare Diseases/ Other | **Efocipegtrutide**<br>[LAPS Triple agonist]<br>Idiopathic Pulmonary Fibrosis | **HM15421**<br>[LA-GLA]<br>Fabry disease — GC | **Efpegerglucagon**<br>[LAPS Glucagon analog]<br>Congenital Hyperinsulinism | | **Synojoynt®**<br>[Sodum hyaluronate]<br>Pain in osteoarthritis of the knee — Arthrex |
| | | | **sonefpeglutide**<br>[LAPS GLP-2 analog]<br>Short Bowel Syndrome | | |
| | | | **Efpegsomatropin**<br>[LAPS hGH]<br>Growth Hormone Deficiency | | |
| | | | **Luminate®**<br>Dry Age-related Macular Degeneration — Allegro AffaMed | | |

B Beijing Hanmi

Updates 1) Entering Part B of Phase 1 → Completion of Phase 1

# H.O.P Project (Hanmi Obesity Pipeline) – Full Cycle Chain for obesity treatment

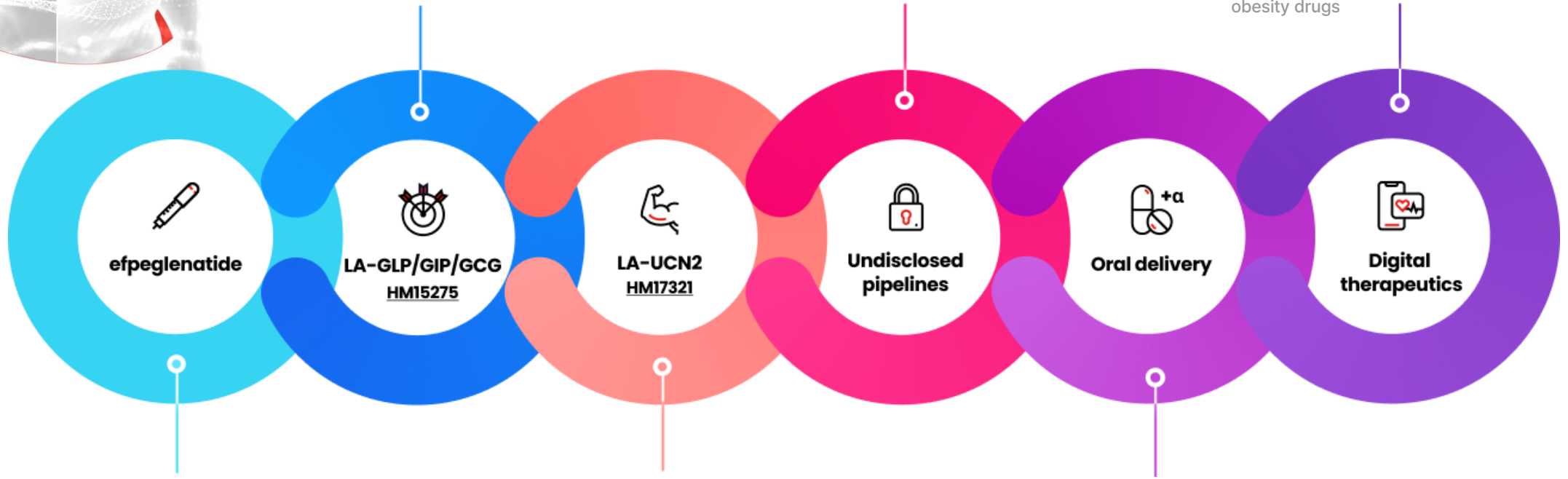


## Research on Building a Patient-centric Portfolio for the Entire Obesity Lifecycle: Treatment, Post-Weight Loss Management, and Comprehensive Care

- Best-in-class drug for severe obesity patients in global market

- Regulate eating disorders both for acquired & congenital obesity
- Muscle preservation and gain

- Development of digital platform to guide patients' lifestyle and to improve drug adherence
- Further improvement in efficacy/safety profiles of obesity drugs




- Optimized GLP-1 obesity drug for populations with low prevalence of severe obesity, such as Koreans
- Best-in-class protective efficacy for cardiovascular disease among GLP-1s

- First-in-class obesity drug with AI and structural modeling technology that enables simultaneous weight loss and muscle gain
- An obesity drug that can be used in combination with incretins as well as alone for high quality weight management

- Development of next generation formulation technology for oral delivery
- Maximize dosing convenience with patch and monthly formulation

# Obesity: Efpeglenatide (LAPSExd4 analog)

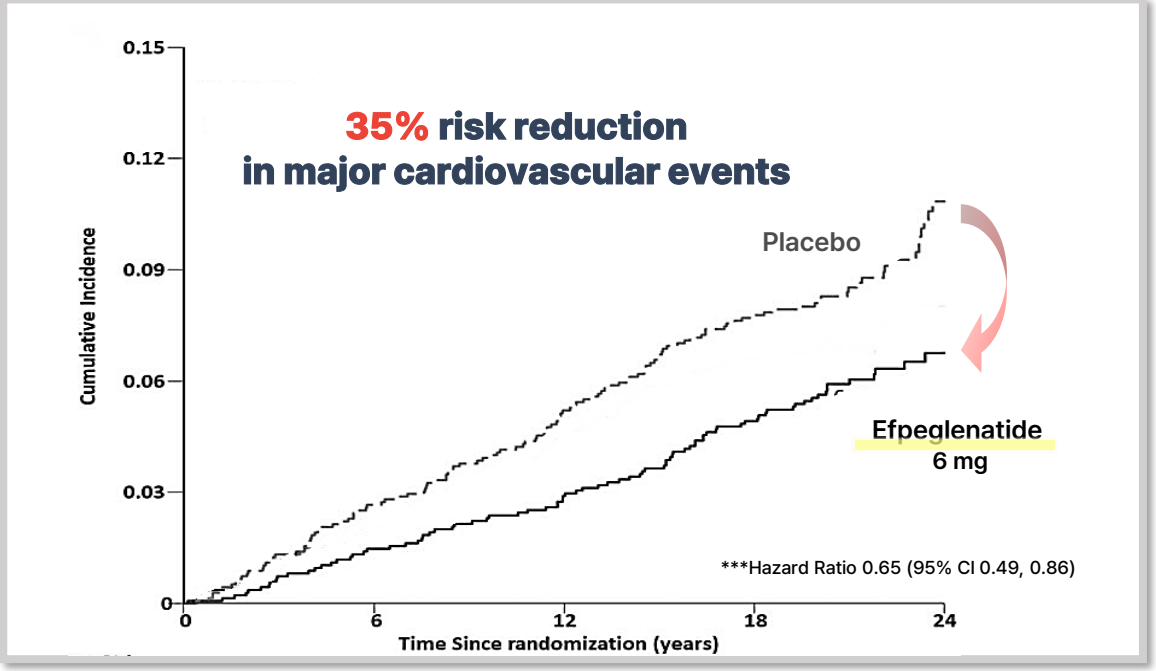
Phase 3

## GLP-1 Obesity Treatment Optimized for Korean Patients with a Low Prevalence of Severe Obesity

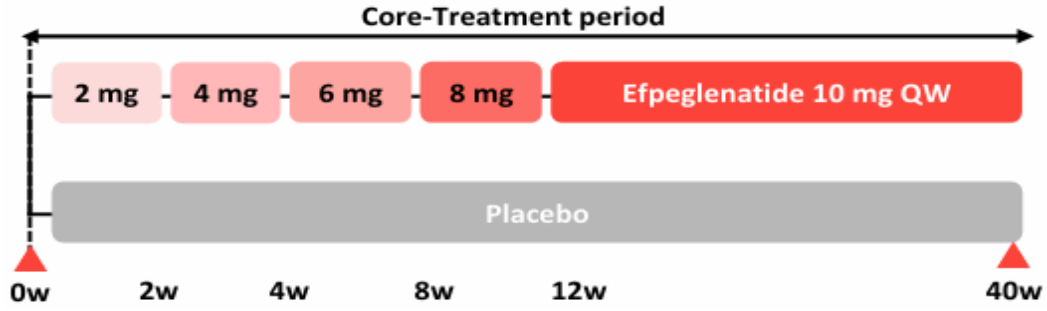
efpeglenatide

- Hanmi's LAPSCOVERY™ Platform and Improved gastrointestinal tolerability through slow absorption
- Superior Cardiovascular and Renal Protection Among GLP-1 incretin-based therapies[1)]
- Affordable Pricing and Stable Supply can resolve shortage issues of obesity treatment products
- Phase 3 Patient Enrollment Completed, Targeting market launch by 2H of 2026

### Reduction in 3-point MACE* (CV death, MI, stroke)[2)]




### Study Design of Phase 3




**[Primary Endpoint]**
- Percent Change in Body Weight [Time Frame: Baseline to 40 Weeks]
- Percentage of Patients ≥5% body weight reduction [Time Frame: Week 40]

**[Inclusion Criteria]**
- BMI ≥30 kg/m² or 27 kg/m2 ≤ BMI < 30 kg/m2 with at least 1 of the following comorbidities: hypertension, dyslipidemia, sleep apnea or cardiocerebrovascular disease

1) N Engl J Med 2021;385:896-907, 2) 2022 Korean Statistical Information Service, 2017-2018 National Health and Nutrition Examination Survey (NHANES)
**LAPSCOVERY:** Long Acting Protein / Peptide Discovery Platform Technology

# Obesity: HM15275 (LA-GLP/GIP/GCG) Phase 1

## Triple Agonist for Obesity with Best-in-Class Potential

LA-GLP/GIP /GCG

- Demonstrated Potential for Weight Reduction Comparable to Surgical Methods(≥ 25% anticipated)
- Potential of Improved Weight Loss Quality Compared to existing obesity treatments has been confirmed
- Favorable Safety and Tolerability in Phase 1 with Confirmed Weight Loss at Week 4 in the Highest Dose Group
- Phase 2 Trial Planned for 2H 2025 with Long-Term Dosing Including High Doses (≥8 mg)

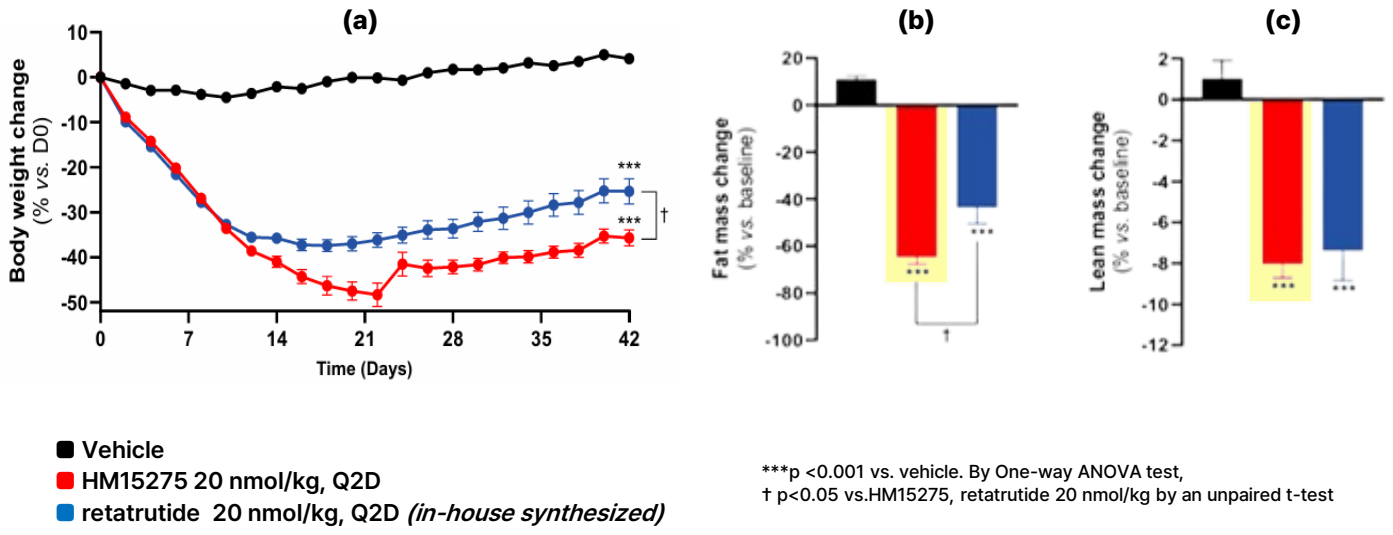
### Safety/Tolerability and Weight Loss in Obese Patients[1)]

| Subject with any (n, %) | MAD HM15275 (mg) 0.5/0.5/0.5/0.5 (N=8) | 1.0/1.0/1.0/1.0 (N=8) | 0.5/0.5/2.0/2.0 (N=8) | 0.5/1.0/2.0/4.0 (N=8) | 0.5/2.0/4.0/8.0 (N=8) | Pooled Placebo (N=10) |
|---|---|---|---|---|---|---|
| TEAE | 7 (87.5) | 7 (87.5) | 7 (87.5) | 6 (75.0) | 8 (100.0) | 10 (100.0) |
| TRAE | 3 (37.5) | 7 (87.5) | 7 (87.5) | 4 (50.0) | 6 (75.0) | 5 (50.0) |
| Maximum Severity | | | | | | |
| Grade 1 | 2 (25.0) | 5 (62.5) | 6 (75.0) | 1 (12.5) | 5 (62.5) | 3 (30.0) |
| Grade 2 | 1 (12.5) | 2 (25.0) | 1 (12.5) | 3 (37.5) | 1 (12.5) | 2 (20.0) |
| Grade 3 | 0 | 0 | 0 | 0 | 0 | 0 |
| Serious TEAE | 0 | 0 | 0 | 0 | 0 | 0 |
| TEAE leading to study discontinuation | 0 | 1 (12.5)[b] | 1 (12.5)[c] | 0 | 0 | 0 |

- Placebo-adjusted D29 % Change from baseline

| Dose (mg) | HM15275 0.5/0.5/0.5/0.5 | HM15275 1.0/1.0/1.0/1.0 | HM15275 0.5/0.5/2.0/2.0 | HM15275 0.5/1.0/2.0/4.0 | HM15275 0.5/2.0/4.0/8.0 |
|---|---|---|---|---|---|
| Mean (SD) | -2.12 (0.87) | -3.65 (1.41) | -2.96 (0.96) | -2.70 (1.03) | -4.81 (1.01) |

### Comparison of (a) Body Weight, (b) Fat Mass, and (c) Lean Mass in Obese Mice[2)]




***p <0.001 vs. vehicle. By One-way ANOVA test,
† p<0.05 vs.HM15275, retatrutide 20 nmol/kg by an unpaired t-test

**MAD:** Multiple ascending dose

1) Marcus Hompesch, et al. ADA 2025, Jun 22, 2025, 2) Sang Hyun Park, et al. ADA 2025, Jun 22, 2025

# Obesity: HM17321 (LA-UCN2)

Preclinical

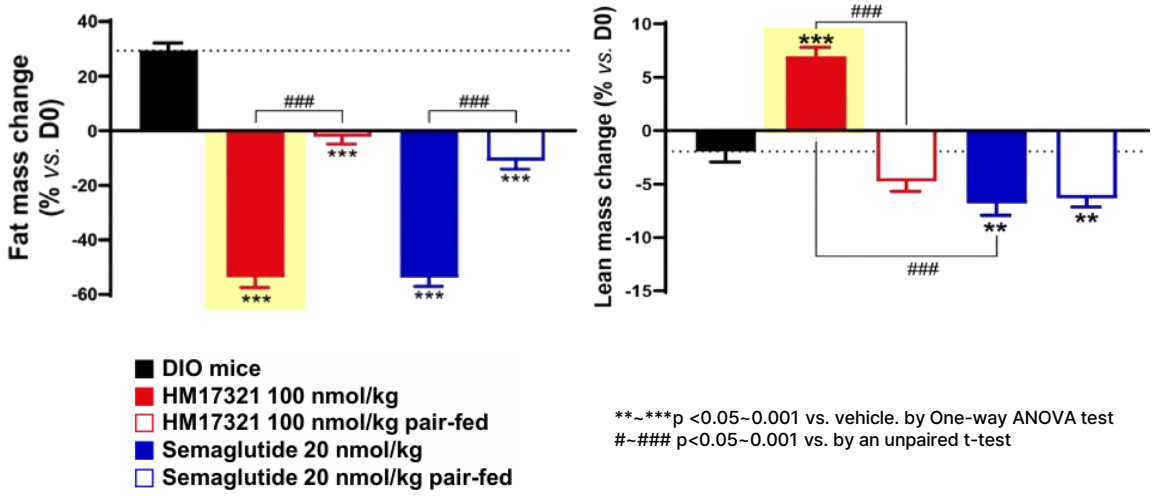
## First-in-Class Obesity Treatment Achieving Both Weight Loss and Muscle Gain (Monotherapy)

LA-UCN2

- Preclinical Data Presented at ADA 2025 → Demonstrated Weight Loss and Body Composition Effects, Confirmed in Primates[1)]
- Achieves Targeted Pharmacological Effects (Fat ↓, Muscle ↑) through AI/SAR (HARP*)-Based Drug Design
  → Accelerates Development Timeline
- Enter Phase 1 clinical trial in the 2H25

### Body Composition Analysis vs. Semaglutide in Obese Mice

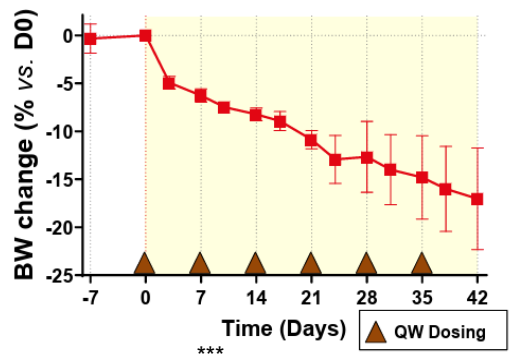
(a) Change in body composition from BL**



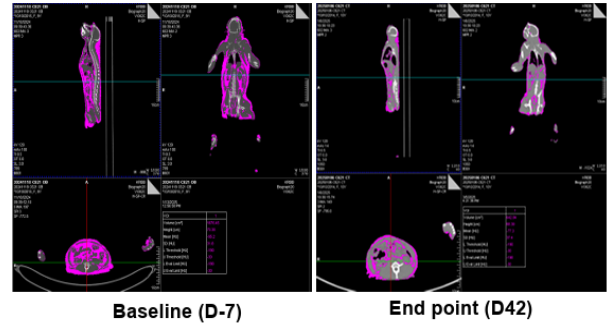

**~***p <0.05~0.001 vs. vehicle. by One-way ANOVA test
#~### p<0.05~0.001 vs. by an unpaired t-test

### Weight Loss and Body Composition Analysis in NHP Model

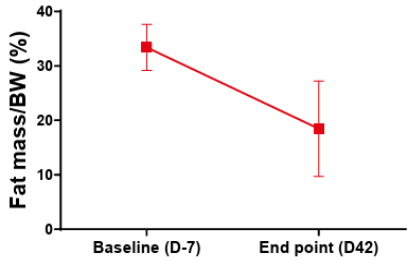
(a) Change in Body weight from BL



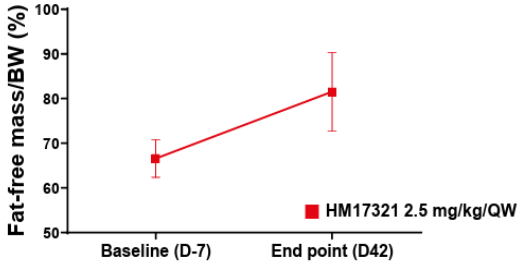

(b) Representative CT images




(c) Change in FM*** relative to BW




(d) Change in FFM**** relative to BW

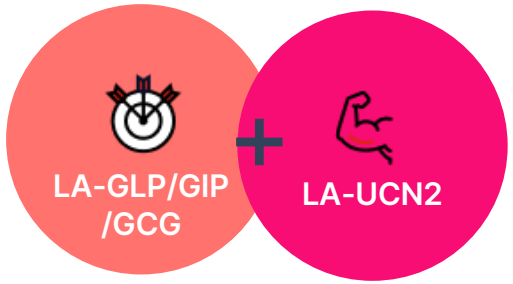



***HARP**: Hanmi AI-driven research platform, ****BL**: Baseline, *****FM**: Fat mass, ******FFM**: Fat free mass,
1) Seon Myeong Lee, et al. ADA 2025, Jun 22, 2025

# Obesity: HM15275 (LA-GLP/GIP/GCG) + HM17321 (LA-UCN2) Combo

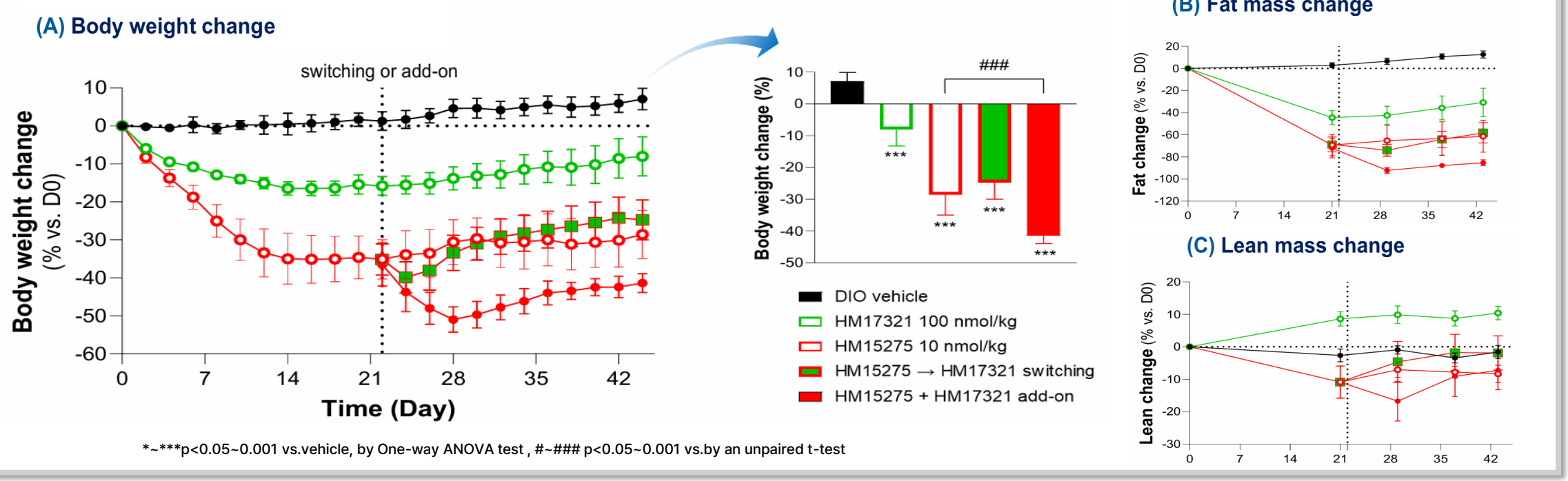
Preclinical

## A Game Changer in High-Quality Weight Management Suitable for all patients from overweight to severe obesity




- Product Characteristics: Once weekly, SC formulation
- Maximized Weight Loss Efficacy and Improved Quality of Life For Patients with Severe Obesity (BMI ≥ 40)
- Functional and Metabolic Benefits of HM17321 via Muscle Gain Confirmed at ADA 2025[1)]
- Facilitates Optimal Combination Therapy Development through a common modality applied to both drugs

### HM17321 Switch/Add-On in Obese Mice: Comparison of (A) Body Weight, (B) Fat Mass, and (C) Lean Mass




*~***p<0.05~0.001 vs.vehicle, by One-way ANOVA test , #~### p<0.05~0.001 vs.by an unpaired t-test

1) Hyunjoo Kwon, et al. ADA 2025, Jun 22, 2025

# H.O.P Project (Hanmi Obesity Pipeline)

- Global pharmaceutical companies **are building portfolios covering the entire obesity lifecycle**
- H.O.P **differentiates itself from global pharmaceutical companies** with a competitive pipeline spanning the entire obesity lifecycle, including **game-changing therapies**

| | | N Pharm. | L Pharm. | Hanmi |
|---|---|---|---|---|
| **"Entire Obesity Lifecyle"** Incretin-Based Injectable Therapies | **Overweight / Obesity** WL <25% | Saxenda® / Wegovy® **-5.4% / -14.4%** | Tirzepatide **-20.1%** | efpeglenatide **Semaglutide-Level Weight Loss + Superior Cardiovascular and Renal Protection** |
| | **Severe Obesity** WL >25% | CagriSema (P3) **-22.7%** (Did not meet the predefined weight loss target) | Retatrutide (P3) **-24%** (Less than 40% of Patients Achieved ≥25% Weight Loss,10.9% Reduction in Lean Mass) | HM15275 **Expected Weight Loss of Over 25% + Minimal Lean Mass Reduction** |
| **"Maximize Dosing Convenience"** Oral GLP-1RA & DDS | | Oral semaglutide (NDA submission) **Peptide-Based with Cost Burden** | orforglipron (P3) **Small Molecule Compound** | HM101460 **Small Molecule Compound** HM15275, HM17321 **Patch, Once-Monthly Formulation** |
| **"Prevention of Muscle Loss and High-Quality Weight Management"** Game changer through novel mechanism | | LX9851 (Pre-Clinical) **Combination therapy or maintenance therapy after weight loss** | bimagrumab (P2) **Not Suitable for Monotherapy (Combination Only) Preservation of Muscle Mass** | HM17321 **Suitable for Both Monotherapy and Combination with Incretins** Weight Loss (Fat Reduction) + Muscle Mass Gain |
| **"Digital Healthcare"** | | None | LillyDirect™ **Home Delivery Service** (Aiming to Reduce Drug Costs) | Development of Digital Platform (Bagel Labs) **Lifestyle Modification for Patients Improvement of Medication Adherence** |

**WL:** Weight loss, **DDS:** Drug delivery system, **RA:** Receptor agonist

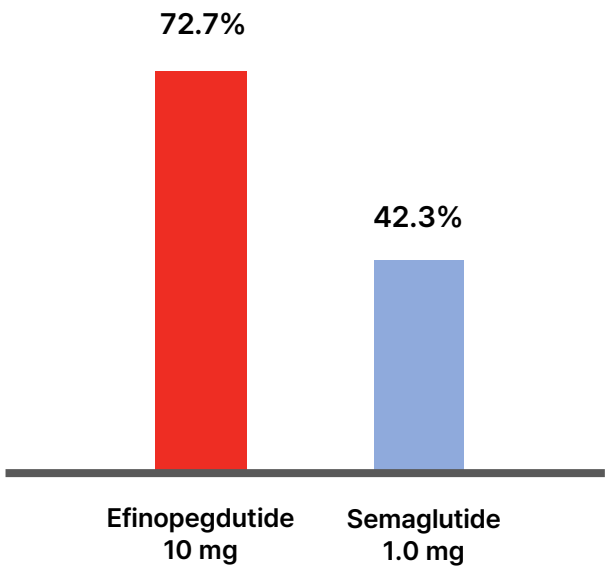
# MASH : Efinopegdutide ($^{LAPS}$GLP/GCG agonist)

Phase 2

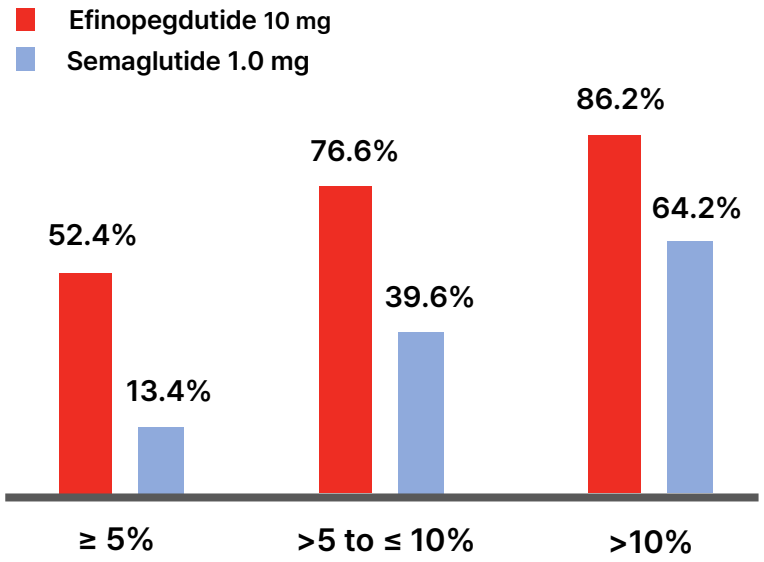
## Once-Weekly Subcutaneous GLP/GCG Dual Agonist for MASH Treatment

- Phase 2a: 72.7% liver fat reduction at Week 24, showing superior efficacy vs. semaglutide
- Stage : Phase 2b, Study Completion: DEC 2025

### Relative Reduction from Baseline in LFC at Week 24[1)]

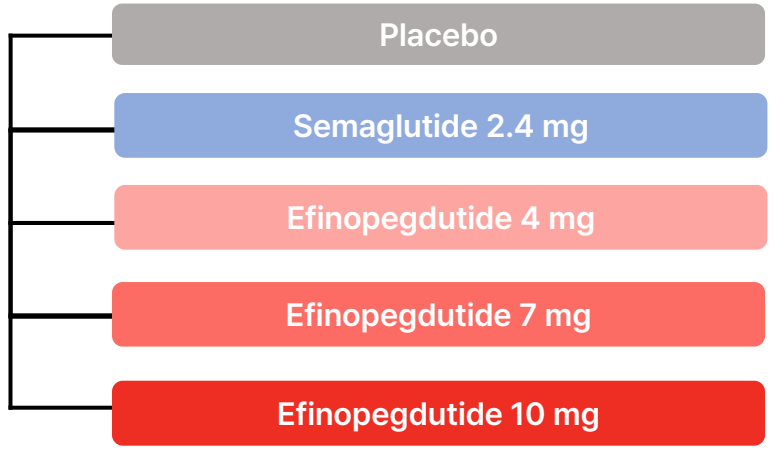



### Percent Reduction from Baseline in BW at Week 24[1)]




### Study Design of Phase 2b

- 52-week study in F2-F3 MASH patients (N=360)
- Primary Outcome: NASH Resolution Without Worsening of Fibrosis & Adverse Events
- Secondary Outcome: ≥1 Stage Improvement in Fibrosis Without Worsening of Steatohepatitis & Change from Baseline in BW




1) Romero-Gome M, et al. J Hepatol . 2023 Jun 5;S0168-8278(23)00342-2.

# Oncology: HM97662 (EZH1/2)

Phase 1

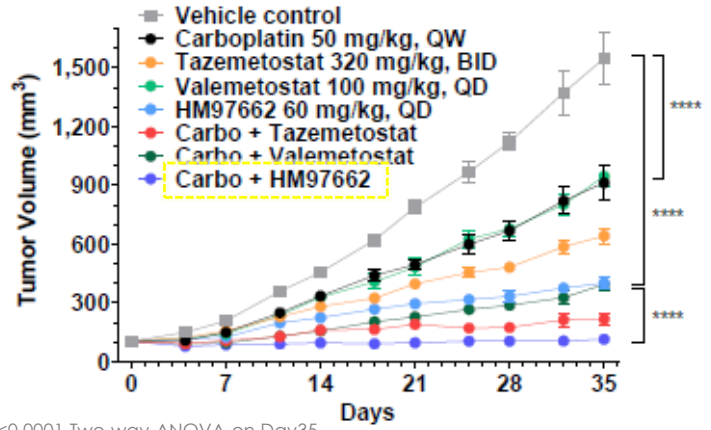
## Next-generation Oral EZH1/2 Dual Inhibitor

- Ongoing Phase 1 [1)] trial to assess the safety, tolerability, PK, and preliminary efficacy in patients with advanced or metastatic solid tumors
- Enrollment: 170 (Part 1, Dose escalation: 40 / Part 2, Dose determination: 30 / Part 3, Dose expansion: 100)
  - Primary Endpoints: Safety, Tolerability, MTD, RP2D
  - Secondary Objective: PK, Preliminary anti-tumor activity (ORR by RECIST 1.1)
- **Interim Phase 1 results to be presented in Q4 2025;** study expected to complete in June 2028

### Anti-tumor efficacy in solid tumor models (mono/chemo combo)[2)]

- **Synergy with platinum-based SoC***

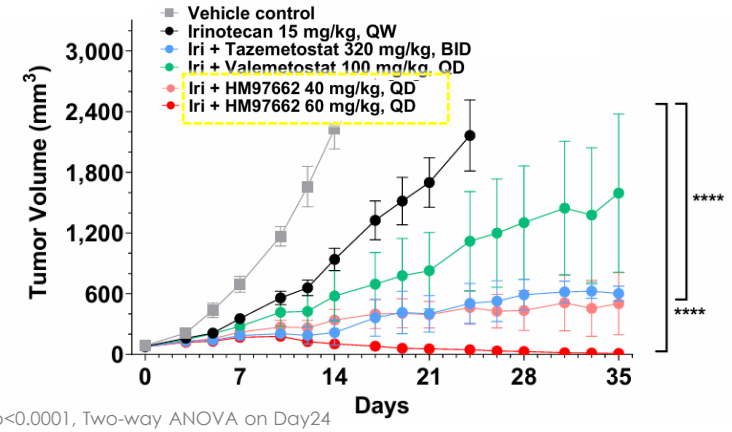
Ovarian cancer, HM97662+Carboplatin
: HSA=10.1, 2× efficacy vs. valemetostat




**** p<0.0001 Two-way ANOVA on Day35

- **Synergy with TOP1 inhibitor**

SCLC, HM97662+Irinotecan
: Superior to EZH2 inhibitors with combo synergy

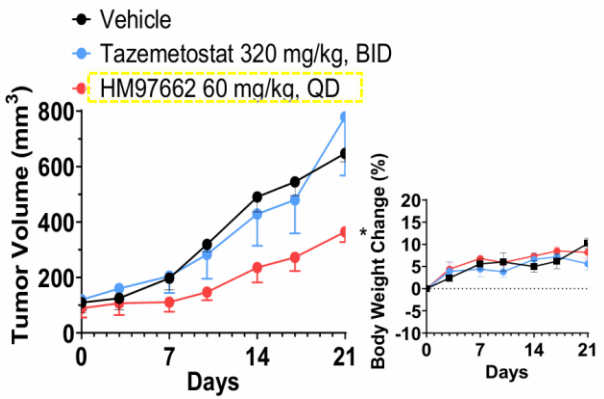



**** p<0.0001, Two-way ANOVA on Day24

### Anti-tumor efficacy & resistance-overcoming potential in hematologic cancer models[3)]

- **Resistance-overcoming potential**

HM97662 monotherapy in Tazemetostat-resistant hematologic models:
Anti-tumor activity in Taz-resistant models




**Superior efficacy and resistance-overcoming potential vs. EZH2 inhibitor — both as monotherapy and with chemo**

1) NCT05598151, 2) Seung Hyun Jung Hyun, et al. AACR Apr. 2025, 3) Young Su Noh, et al. ICML Jun. 2025 ***SoC**: Standard of Care

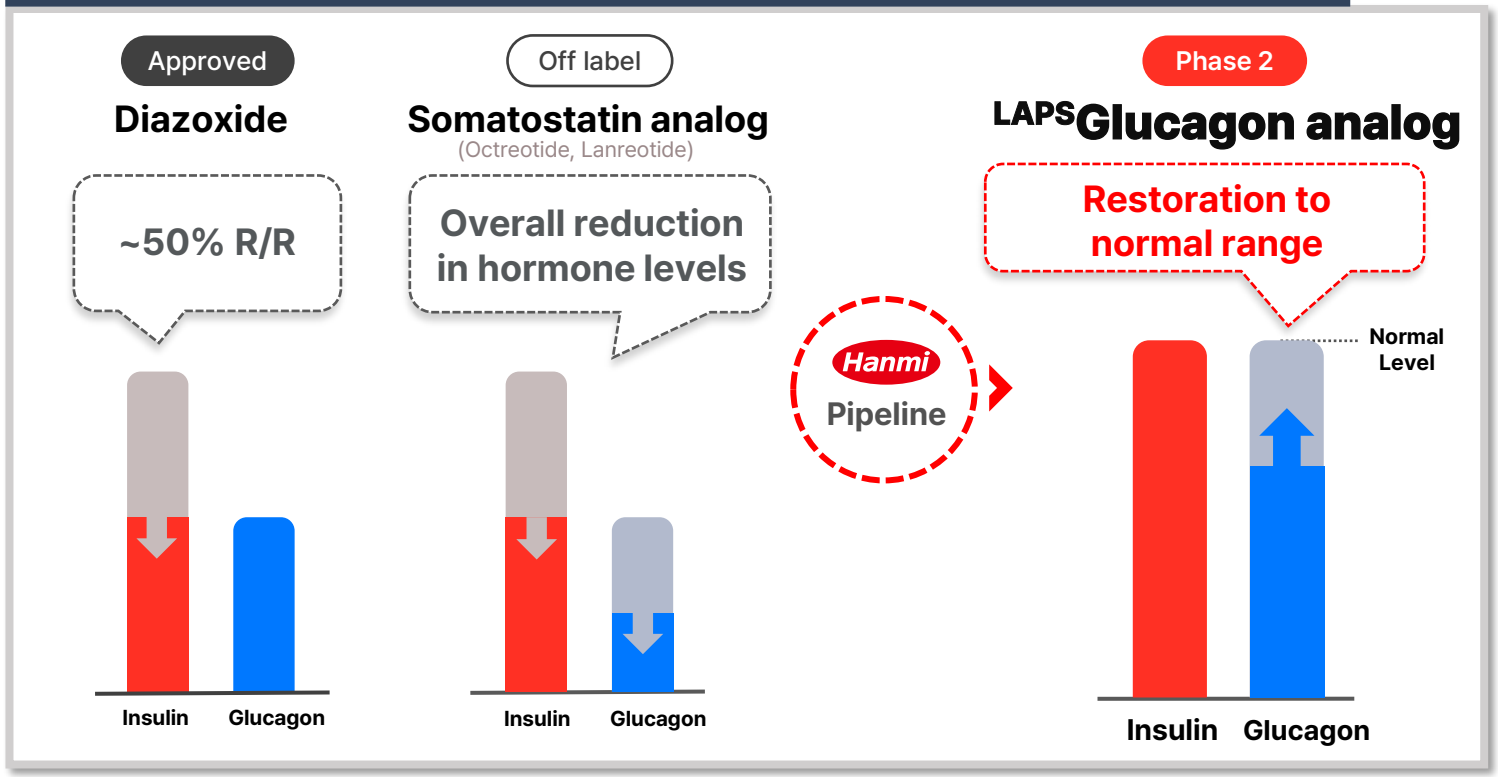
# Rare Disease: efpegerglucagon (LAPSGlucagon analog)

Phase 2

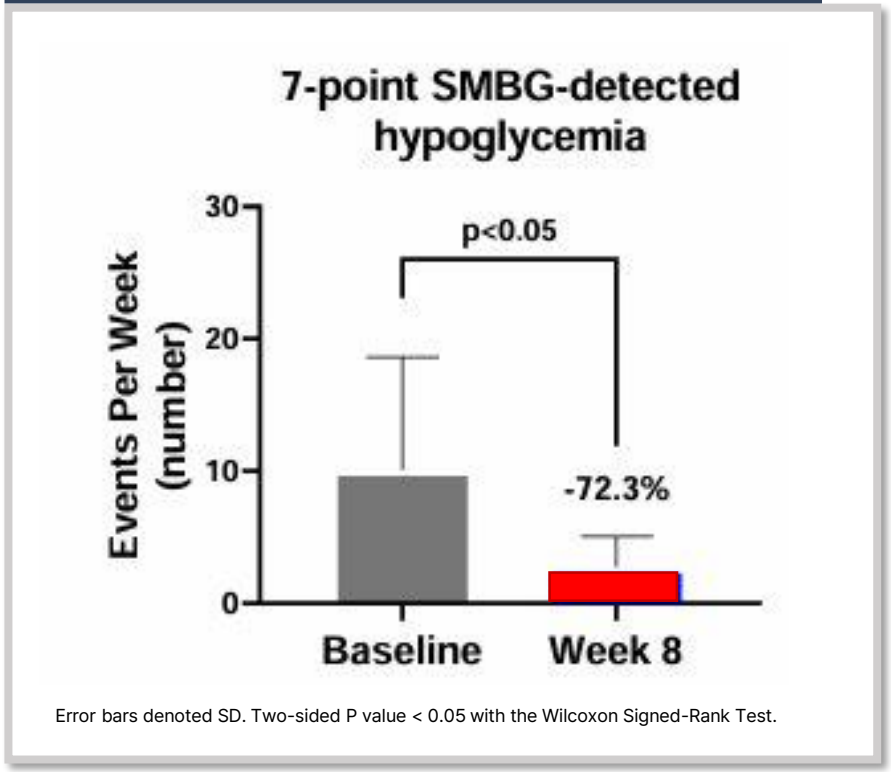
## First-in-class glucagon receptor agonist with once-weekly dosing

- Orphan drug designation: FDA, EMA, MFDS (2018) | FDA Rare Pediatric Disease Designation (2020)
- Phase 2 interim: –72.3% reduction in frequency & duration of hypoglycemia (<70mg/dL) and severe hypoglycemia
- Phase 2 'ACHIEVE' trial in congenital hyperinsulinism (CHI) patients is ongoing, with results expected in H1 2026

### Enhanced PK and physicochemical profile vs. Diazoxide (only approved drug)

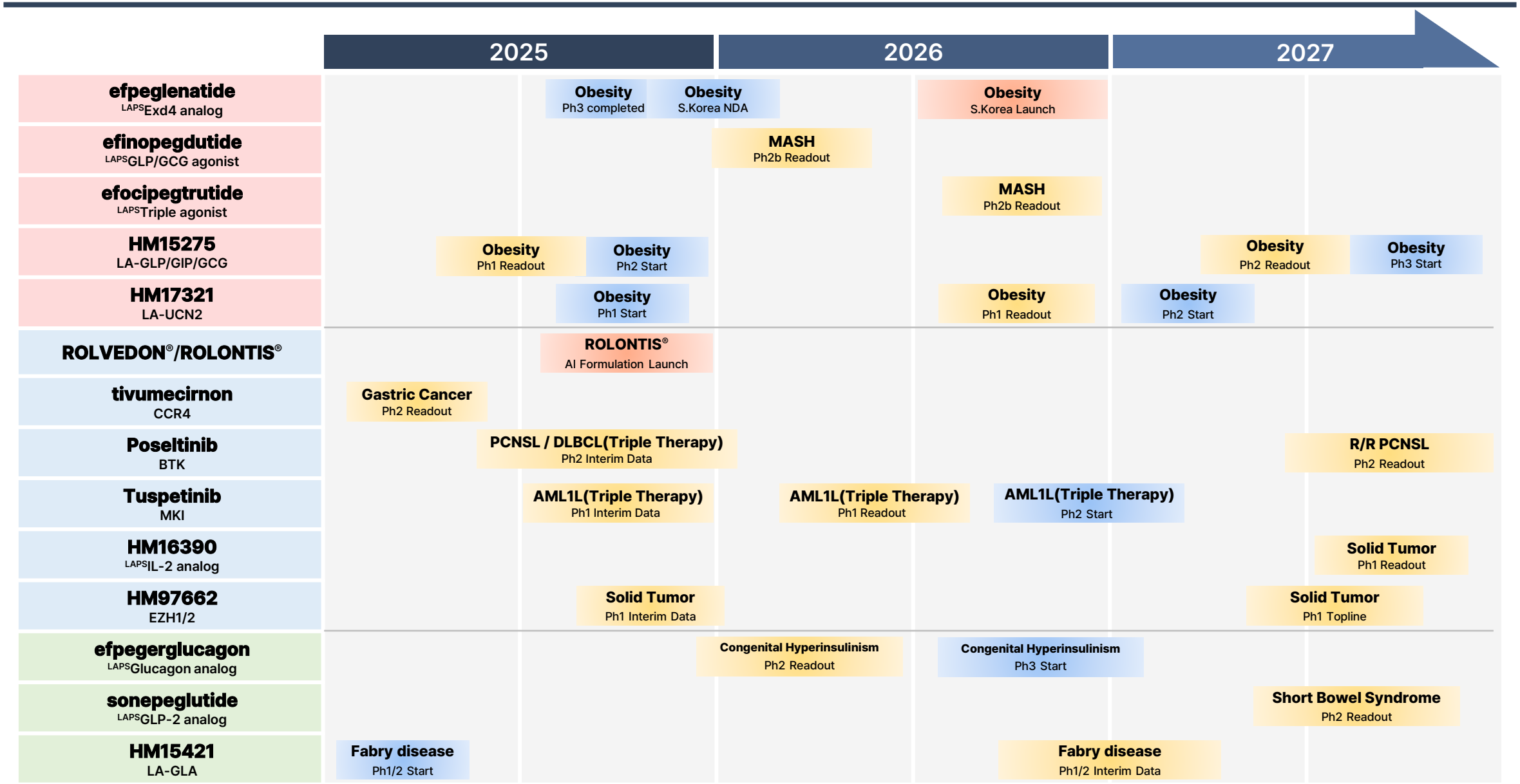



### Phase 2 interim results: Hypoglycemia based on 7-point SMBG* measurements[1)]



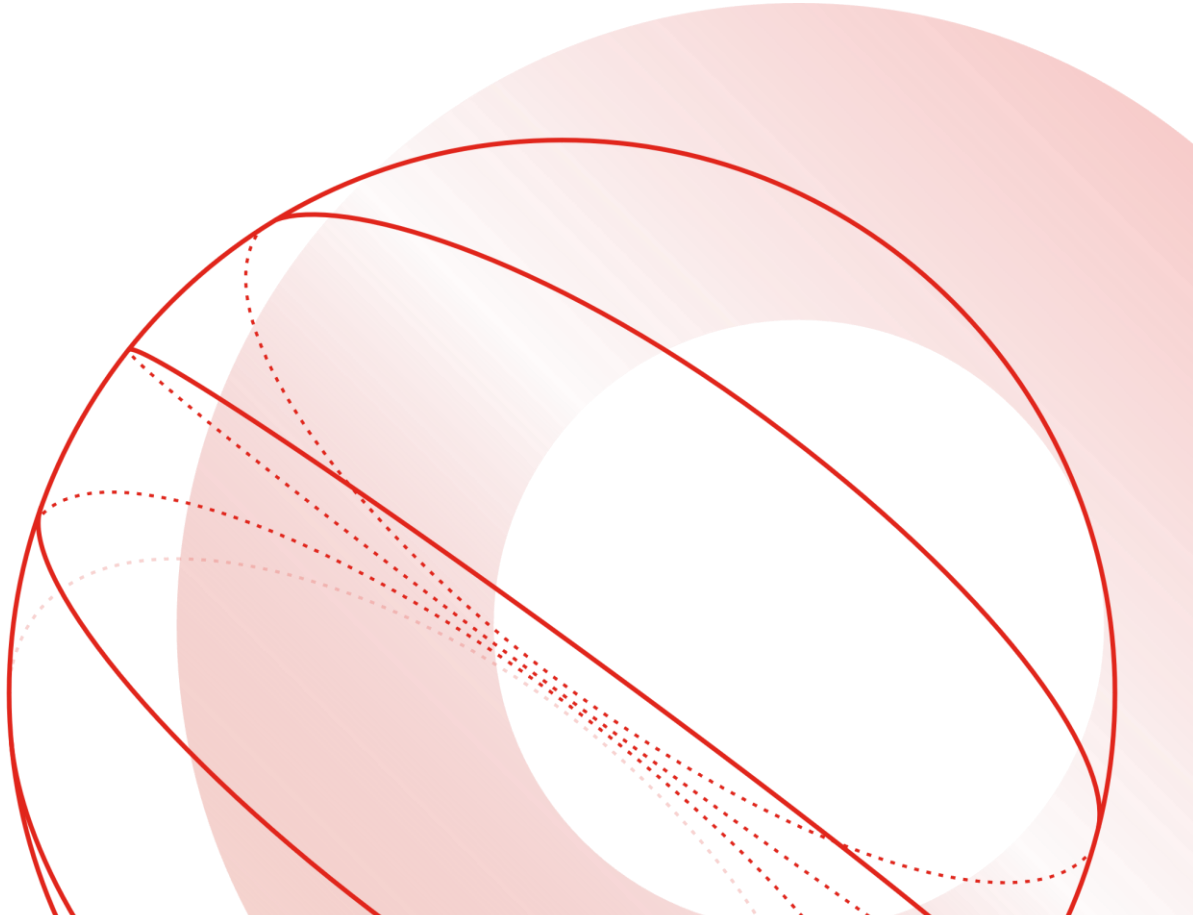

1) A. Dastamani. ESPE/ESE joint congress 2025 ***7-point SMBG**: self-monitored blood glucose

# R&D Key Milestones




**LAPS**: LAPSCOVERY™, **LA**: Long-acting, **MASH**: Metabolic dysfunction-associated steatohepatitis, **PCNSL**: Primary central nerve system lymphoma, **R/R**: relapsed/refractory, **AML**: Acute myeloid leukemia

# Financial Performance



# Financial Results Consolidated Business Results

- ▶ 2Q25 Sales KRW 361.3bn, -4.5% YoY
- ▶ Operating profit KRW 60.4bn, Net profit KRW 43.0bn
- ▶ OP delivered +4.0% YoY growth driven by solid performance of value-added products and expansion in high-margin segments

Unit: Billion KRW

| Category | 2025 2Q | 2024 2Q | YoY | 2025 1Q | QoQ |
|---|---|---|---|---|---|
| Sales | 361.3 | 378.1 | -4.5% | 390.9 | -7.6% |
| Operating Profit (%) | 60.4 (16.7%) | 58.1 (15.4%) | 4.0% | 59.0 (15.1%) | 2.4% |
| Pre-tax Profit (%) | 49.6 (13.7%) | 54.0 (14.3%) | -8.2% | 53.2 (13.6%) | -6.8% |
| Net Profit (%) | 43.0 (11.9%) | 47.1 (12.4%) | -8.6% | 44.7 (11.4%) | -3.7% |

# Financial Results Hanmi Pharmaceutical

- ▶ 2Q25 Sales KRW 276.4bn, -1.9% YoY, -6.3% QoQ
- ▶ Operating profit KRW 43.5bn, Net profit KRW 28.0bn
- ▶ Sales breakdown: Finished products 84%, Merchandise 12%, Royalties/Milestones 0.8%
- ▶ Despite decline in overseas API exports, OP grew by 35.3% YoY, supported by strong domestic business-driven growth

Unit: Billion KRW

| Category | 2025 2Q | 2024 2Q | YoY | 2025 1Q | QoQ |
|---|---|---|---|---|---|
| Sales | 276.4 | 281.8 | -1.9% | 295.0 | -6.3% |
| Finished products | 233.1 | 228.0 | 2.2% | 257.4 | -9.4% |
| Merchandise | 33.5 | 49.7 | -32.6% | 31.1 | 7.8% |
| Upfront/Milestones | 2.2 | 1.9 | 17.7% | 1.5 | 47.8% |
| Others | 7.6 | 2.3 | 236.6% | 5.1 | 48.3% |
| Operating Profit (%) | 43.5 (15.7%) | 32.1 (11.4%) | 35.3% | 47.0 (15.9%) | -7.5% |
| Pre-tax Income (%) | 32.9 (11.9%) | 37.4 (13.3%) | -11.8% | 50.3 (17.0%) | -34.5% |
| Net Income (%) | 28.0 (10.1%) | 32.5 (11.5%) | -14.0% | 40.9 (13.9%) | -31.6% |

# Sales Analysis Outpatient Prescription Sales of Key Brands (UBIST data)

- ‘Rosuzet’ continues to grow by recording +9.5% YoY at KRW 56.0 bn
- ‘Amosartan Family’ KRW 36.0 bn, ‘Esomezol Family’ KRW 15.7 bn, ‘Hanmi Tams/OD’ KRW 11.3 bn maintain solid performance
- Sales of new diabetes product ‘Daparon Family’ achieved +52.4% YoY growth

Unit: Billion KRW

| Product | 2025 2Q | 2024 2Q | YoY | 2025 1Q | QoQ |
|---|---|---|---|---|---|
| Rosuzet | 56.0 | 51.1 | 9.5% | 54.3 | 3.1% |
| Amosartan family | 36.0 | 36.2 | -0.5% | 36.1 | -0.3% |
| Esomezol family | 15.7 | 15.5 | 1.0% | 16.0 | -2.3% |
| Hanmi Tams/OD | 11.3 | 11.2 | 1.0% | 11.1 | 1.5% |
| Pal Pal | 9.4 | 10.5 | -10.2% | 9.5 | -1.3% |
| Amodipin | 6.3 | 6.5 | -3.4% | 6.0 | 3.4% |
| Naxozol | 6.1 | 6.3 | -2.3% | 6.2 | -1.4% |
| Gugu | 5.6 | 5.8 | -3.4% | 5.6 | -0.2% |
| Pidogul | 5.1 | 5.1 | -0.8% | 5.0 | 0.6% |
| Monterizine | 4.7 | 4.8 | -2.5% | 4.3 | 9.2% |

(Source: UBIST)

# Sales Analysis Domestic & Export Sales

## ▶ 2Q25 exports* KRW 39.9bn, -30.9% YoY due to weak overseas API sales

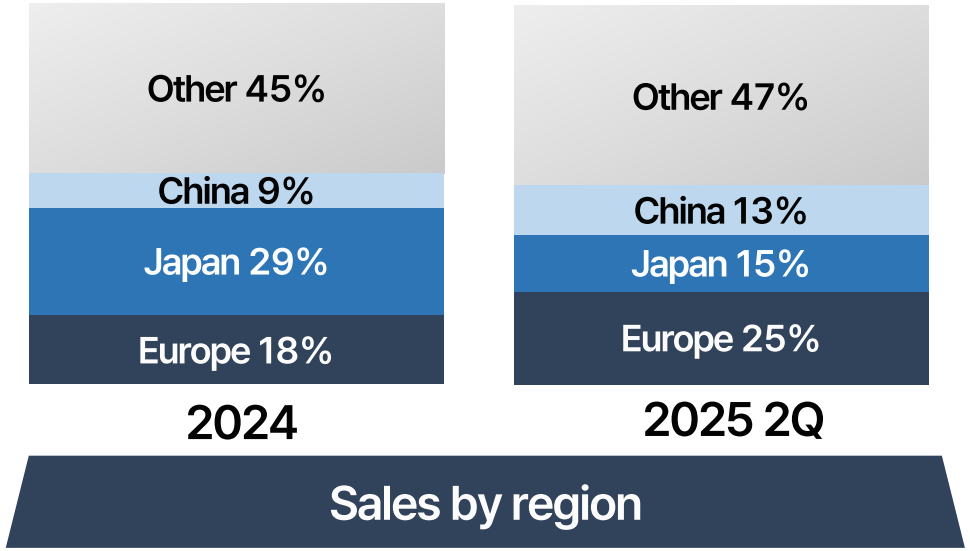
Unit : Billion KRW

| | 2025 2Q | 2024 2Q | YoY | 2025 1Q | QoQ |
|---|---|---|---|---|---|
| Domestic | 234.3 | 222.1 | 5.5% | 225.4 | 3.9% |
| Export* | 39.9 | 57.8 | -30.9% | 68.2 | -41.4% |

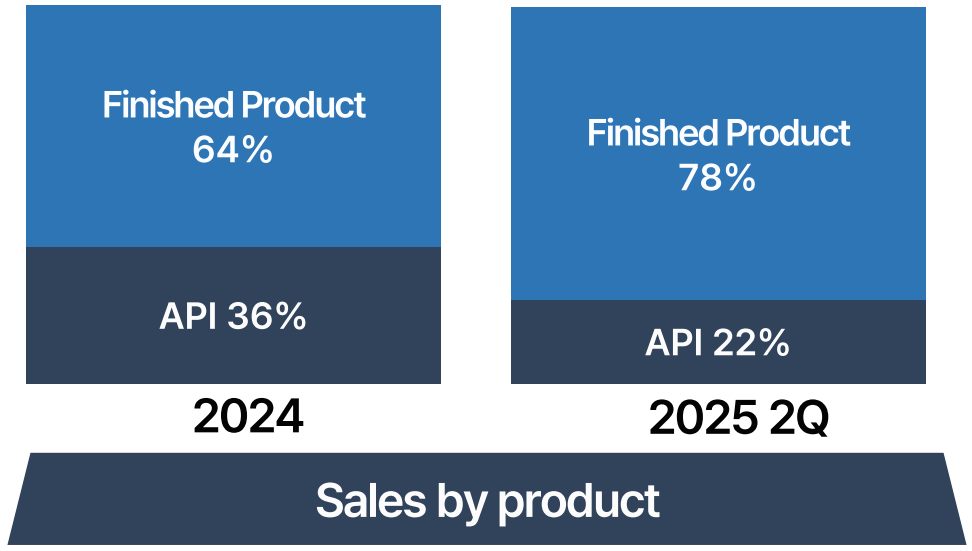
*Excludes milestone payments

## ▶ Export details

*Japan and China API export declined*




*Finished Product proportion increased*



# Financial Results Beijing Hanmi

▶ 2Q25 Sales KRW 86.7bn, -12.2% YoY, -10.2% QoQ

▶ ETC sales declined due to intensified impact of China's Volume-Based Procurement(VBP)

▶ OP recovered QoQ, driven by continued inventory reduction and improved operational efficiency

Unit : Billion KRW

| Unit | Category | 2025 2Q | 2024 2Q | YoY | 2025 1Q | QoQ |
|---|---|---|---|---|---|---|
| Billion KRW | Sales | 86.7 | 98.7 | -12.2% | 96.5 | -10.2% |
| | Operating Profit (%) | 16.7 (19.3%) | 25.2 (25.5%) | -33.7% | 11.3 (11.8%) | 47.1% |
| | Pre-tax Income (%) | 16.8 (19.4%) | 25.7 (26.1%) | -34.8% | 11.7 (12.2%) | 43.0% |
| | Net Income (%) | 15.5 (17.9%) | 23.2 (23.5%) | -33.2% | 9.9 (10.3%) | 56.3% |
| 1,000 RMB | Sales | 447,440 | 520,777 | -14.1% | 483,994 | -7.6% |
| | Operating Profit | 85,690 | 132,487 | -35.3% | 56,927 | 50.5% |
| | Pre-tax Income | 86,215 | 135,314 | -36.3% | 58,917 | 46.3% |
| | Net Income | 79,612 | 122,280 | -34.9% | 49,791 | 59.9% |

# Financial Results Hanmi Fine Chemical

▶ 2Q25 Sales KRW 23.0bn, -32.9% YoY, +1.0% QoQ

▶ OP turnaround driven by CDMO growth, despite weak API from cephalosporin competition

Unit : Billion KRW

| Category | 2025 2Q | 2024 2Q | YoY | 2025 1Q | QoQ |
|---|---|---|---|---|---|
| Sales | 23.0 | 34.3 | -32.9% | 22.8 | 1.0% |
| Operating Profit (%) | 2.0 (8.6%) | 1.8 (5.2%) | 10.8% | -1.9 (-8.5%) | TTB |
| Pre-tax Income (%) | 1.6 (7.1%) | 1.2 (3.4%) | 38.1% | -2.5 (-10.9%) | TTB |
| Net Income (%) | 1.6 (7.1%) | 1.4 (4.1%) | 16.4% | -2.5 (-10.9%) | TTB |

# Cost Analysis

▶ 2Q25 R&D investment (revenue basis) : KRW 50.4bn, 14.0% of revenue

▶ Optimized SG&A through market-friendly policy adjustment following inventory clearance at Beijing Hanmi in 1H

Unit : Billion KRW

| Category | | 2025 2Q | 2024 2Q | YoY | 2025 1Q | QoQ |
|---|---|---|---|---|---|---|
| Consol. | SG&A | 100.9 | 103.0 | -2.0% | 109.1 | -7.5% |
| | R&D Investment | 50.4 | 52.3 | -3.5% | 55.3 | -8.7% |
| Hanmi Pharm | SG&A | 66.6 | 63.2 | 5.4% | 64.6 | 3.1% |
| | R&D Investment | 42.9 | 44.2 | -2.9% | 46.0 | -6.7% |
| Beijing Hanmi | SG&A | 32.3 | 38.0 | -14.8% | 42.3 | -23.6% |
| | R&D Investment | 5.9 | 6.1 | -1.8% | 7.2 | -17.7% |
| Hanmi Fine Chem | SG&A | 2.0 | 2.0 | 2.5% | 2.2 | -8.0% |
| | R&D Investment | 1.6 | 2.0 | -21.4% | 2.0 | -21.8% |

*R&D Investment = Ordinary development expense(clinical trials + formulation research) + capitalized development costs (intangible assets)

# Income Statement Consolidated Business Results

Unit: Billion KRW

| Category | 2025 2Q | 2024 2Q | YoY | 2025 1Q | QoQ |
|---|---|---|---|---|---|
| Sales | 361.3 | 378.1 | -4.5% | 390.9 | -7.6% |
| COGS | 156.5 | 171.5 | -8.7% | 177.4 | -11.8% |
| % | (43.3%) | (45.3%) | | (45.4%) | |
| SG&A | 100.9 | 103.0 | -2.0% | 109.1 | -7.5% |
| % | (27.9%) | (27.2%) | | (27.9%) | |
| Ordinary development expense | 43.4 | 45.5 | -4.6% | 45.5 | -4.5% |
| % | (12.0%) | (12.0%) | | (11.6%) | |
| Operating profit | 60.4 | 58.1 | 4.0% | 59.0 | 2.4% |
| % | (16.7%) | (15.4%) | | (15.1%) | |
| Pre-tax income | 49.6 | 54.0 | -8.2% | 53.2 | -6.8% |
| % | (13.7%) | (14.3%) | | (13.6%) | |
| Net income | 43.0 | 47.1 | -8.6% | 44.7 | -3.7% |
| % | (11.9%) | (12.4%) | | (11.4%) | |

# Balance Sheet Consolidated Business Results

Unit: Billion KRW

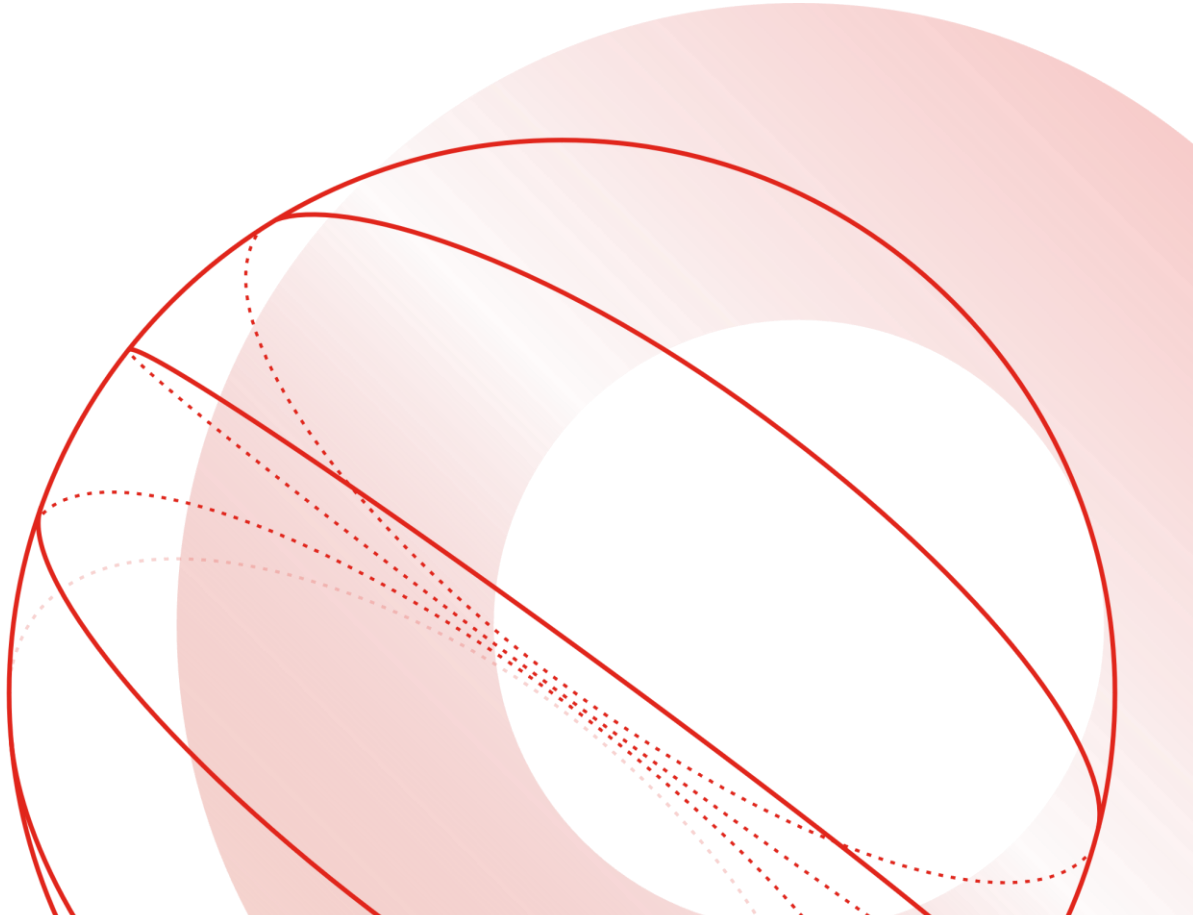
| Category | As of Jun 2025 | As of Dec 2024 | Growth rate |
|---|---|---|---|
| Current Asset | 736.8 | 746.3 | -1.3% |
| Non-Current Asset | 1,226.3 | 1,274.5 | -3.8% |
| *Total Asset* | *1,963.1* | *2,020.8* | *-2.9%* |
| Current Liability | 596.3 | 682.8 | -12.7% |
| Non-Current Liability | 87.1 | 97.3 | -10.6% |
| *Total Liability* | *683.4* | *780.1* | *-12.4%* |
| *Total Equity* | *1,279.7* | *1,240.8* | *3.1%* |

# Income Statement – Hanmi Science Consolidated Business Results

Unit: Billion KRW

| Category | 2025 2Q | 2024 2Q | YoY | 2025 1Q | QoQ |
|---|---|---|---|---|---|
| Sales | 338.3 | 309.1 | 9.4% | 332.2 | 1.8% |
| COGS | 322.5 | 300.9 | 7.2% | 325.0 | -0.8% |
| Operating profit | 34.6 | 26.5 | 30.7% | 27.1 | 27.9% |
| Pre-tax income | 31.5 | 21.9 | 44.2% | 26.7 | 18.3% |
| Net income | 28.3 | 20.3 | 39.2% | 24.5 | 15.8% |

# Business Review Appendix



# Key Events

## ✓ Key Updates

| Category | Month | Details |
|---|---|---|
| R&D | MAY | ▪ Signed a supply agreement with MSD for the combination trial of IL-2 immunotherapy candidate 'HM16390' with Keytruda<br>▪ Presented interim Phase 2 results of efpeglenatide at the ESPE/ESE Joint Congress |
| | JUN | ▪ Presented six posters at ADA 2025, including Phase 1 results of 'HM15275' and non-clinical findings of 'HM17321'<br>▪ Presented non-clinical data of 'HM97662 (EZH1/2)' for blood cancers at ICML 2025 |
| Products | JUN | ▪ Received MFDS approval in Korea for low-dose triple antihypertensive, 'Amoprel' |
| | JUL | ▪ Co-launched the Prolia biosimilar 'Obodence' in partnership with Samsung Bioepis |
| Subsidiaries | MAY | ▪ Hanmi Fine Chemical signed a CDMO contract with LegoChem Biosciences for the production of intermediates for the ADC platform 'ConjuAll |

## ✓ 4 New products launched

| Category | Month | Details |
|---|---|---|
| ETC | MAY | ▪ Mosazal SR Tab, mosapride citrate extended-release prokinetic for gastric motility |
| | JUN | ▪ Hanmi Ginkgo Tab (80 mg), ginkgo biloba leaf extract for venous insufficiency |
| OTC | APR | ▪ Mujonal Max Solution, terbinafine topical solution for onychomycosis |
| | JUN | ▪ Magne-B Speed Solution, magnesium plus B-vitamin supplement |

# Our Business

## Strong Strategic Alliances around the Globe *"We value our partners and our innovation"*

### Hanmi HQ
- Clinical
- Regulatory
- Sales & Marketing

### Beijing Hanmi
- R&D
- Manufacturing
- Sales & Marketing
- PENTAMBODY Platform (BsAb)

*Chemical, Biologics*




### Hanmi R&D Center
- R&D, Nonclinical
- LAPSCOVERY Platform

*Chemical, Biologics*

### Fine Chemical
- R&D
- Manufacturing

*APIs (Nucleotide, Peptide, PEG)*

### Paltan
- R&D
- Manufacturing

*Oral Dosage Finished Product*

### Bioplant
- R&D
- Manufacturing
- LAPSCOVERY Platform

*Biologics (RNA, DNA, Protein)*

# "Global Standard Quality & Specification"



## Paltan Plant – FPP Manufacturing Sites

- ODM Partnership with global partners : MSD, Sanofi, etc
- The New Global Smart Plant completed and received operation approval in Dec 2016
- Annual capsule production capacity : 2B → max. 10B



## Pyeongtaek Plant – Bio Plant

- Production of investigational new biologics for global studies
- Second Bio Plant construction completed in 4Q 2018 for global clinical trials and commercialization of LAPSCOVERY based new biologics
- Certified by PIC/S



## Hanmi Fine Chem – API Business

- 30% M/S of European cephalosporin antibiotics API market
- FDA(US), BSG(GER), TGA(AUS), PMDA(JPN), EDQM(EU), MHRA(GB) GMP received

# Company Overview Beijing Hanmi

Beijing R&D center | Manufacturing | Sales & Marketing

## R&D Staff 68 (PhD. 3, MS. 36)

Focused Areas

- Bispecific Antibody Biopharmaceutical Research
- PENTAMBODY™



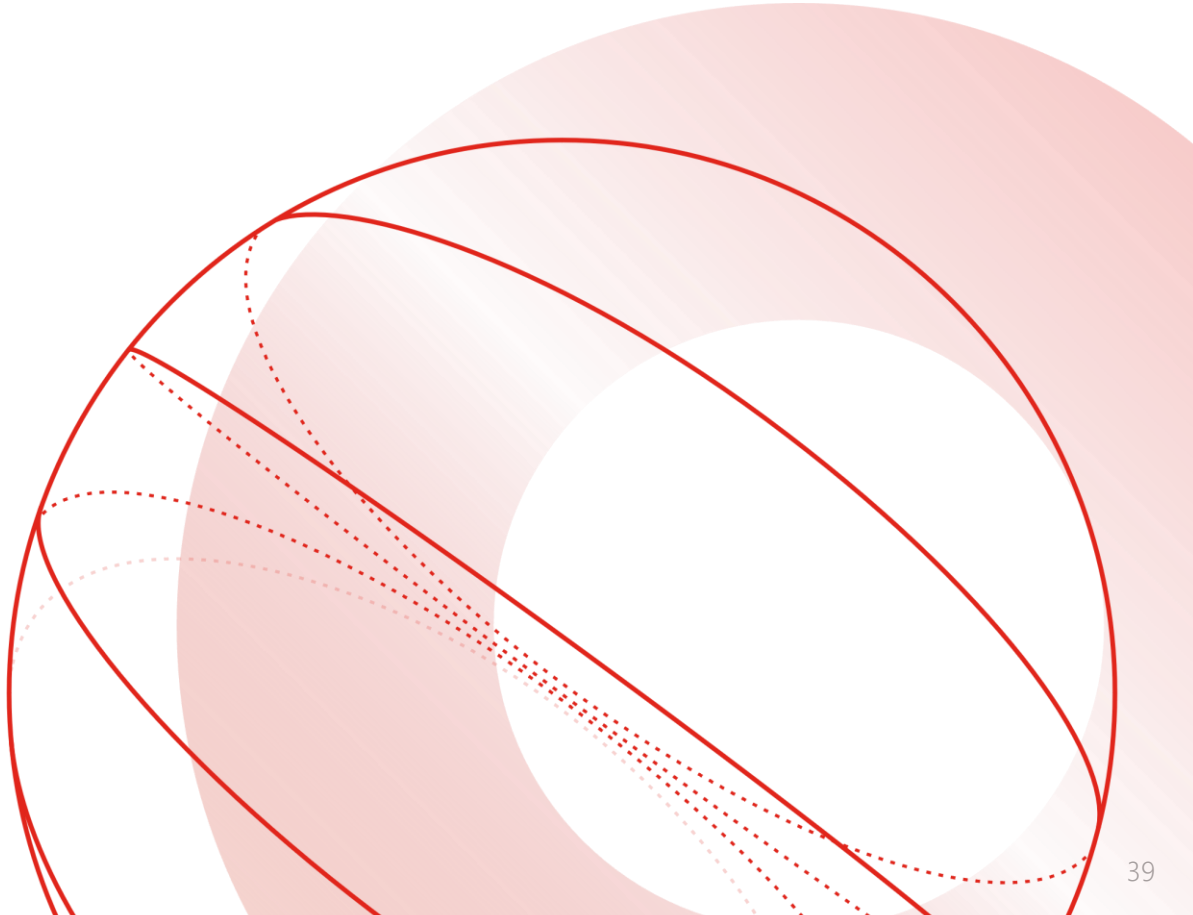

## Sales force 1,000+

About 70% : Doctors and Pharmacists Directly covering 9,000 hospitals

Unit : 1,000 RMB

| Product | Indication | 2Q25 | YoY | 1Q25 | QoQ | 1Q24 | 2Q24 | 3Q24 | 4Q24 | 2024 |
|---|---|---|---|---|---|---|---|---|---|---|
| Mami Ai | Probiotics for infants | 37,775 | -65.4% | 77,320 | -51.1% | 110,069 | 109,332 | 49,900 | 27,729 | 297,030 |
| Itanjing | Antitussive expectorants | 143,336 | -8.8% | 118,356 | 21.1% | 296,329 | 157,103 | 126,556 | 128,604 | 708,592 |
| Li Dong | Constipation | 137,838 | -4.0% | 161,541 | -14.7% | 163,097 | 143,519 | 152,043 | 115,127 | 573,785 |
| Mechangan | Probiotics for adults | 49,448 | 17.0% | 48,610 | 1.7% | 41,259 | 42,252 | 44,980 | 33,995 | 162,487 |
| Yianping | Antitussive expectorants | 39,278 | 28.7% | 45,349 | -13.4% | 35,598 | 30,527 | 38,332 | 34,497 | 138,954 |

# R&D Appendix



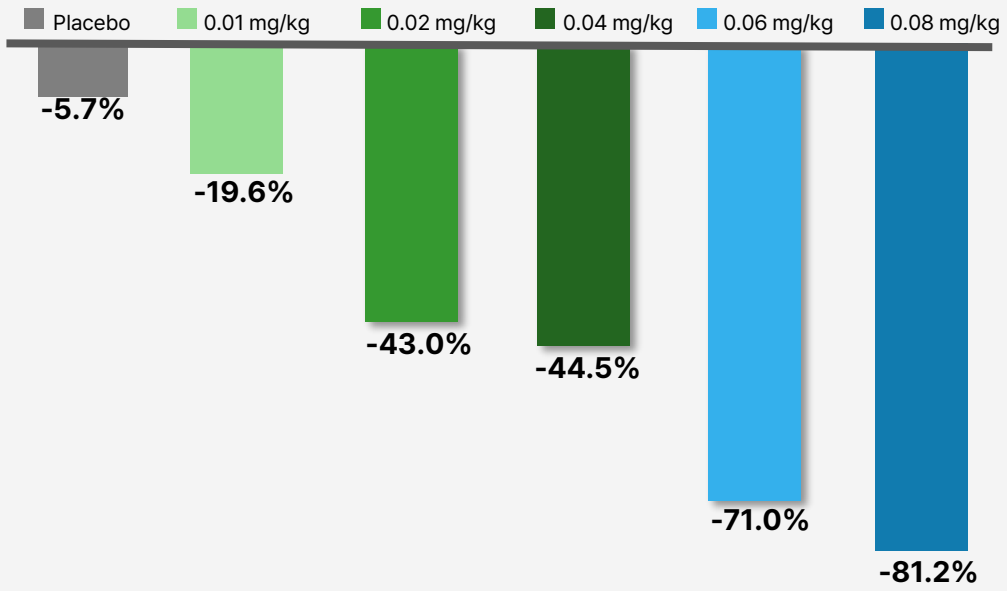
# MASH: Efocipegtrutide (LAPS Triple agonist)

Phase 2

## GCG/GIP/GLP-1 triple agonist with liver-specific distribution and optimized efficacy

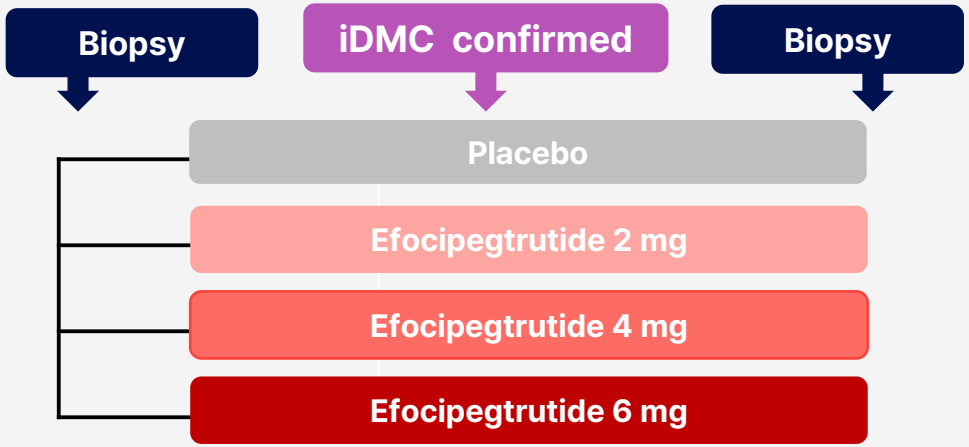
- Multiple modes of action in liver are employed to manage inflammation, fibrosis, and steatosis resolution
- Progress: Phase 2b in biopsy-confirmed NASH patients, Estimated Completion: 2H 2026

### Relative Liver Fat Changes after 12 Weeks[1)]




### Phase 2b Design[2)]

- Biopsy-Confirmed NASH Fibrosis (F1~F3) with or without Type 2 diabetes
- Enrollment: 240
- Study Duration: 52 weeks
- Primary Endpoint: resolution of steatohepatitis on overall histopathological reading and no worsening of liver fibrosis




1) Manal F. Abdelmalek. EASL 2020 2) NCT04505436
**MRI-PDFF:** Magnetic resonance imaging derived proton-density-fat-fraction, **iDMC:** Independant Data-Monitoring Committee

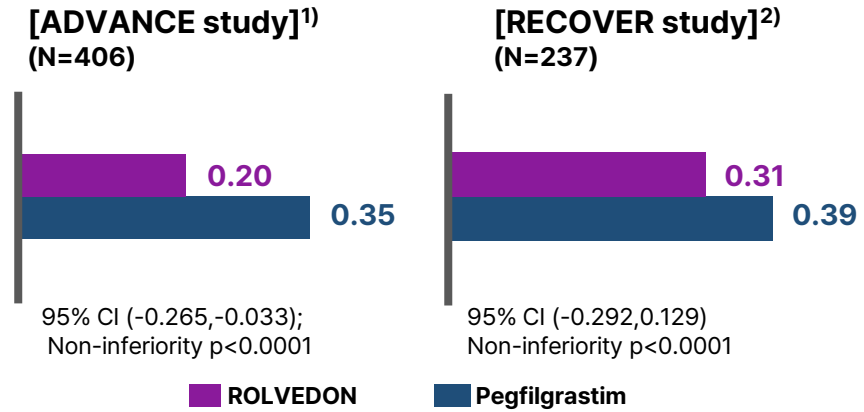
# Oncology: ROLONTIS®/ROLVEDON® (Eflapegrastim)

Launched

## The First novel long-acting G-CSF (granulocyte-colony stimulating factor) analog with the LAPSCOVERY platform technology

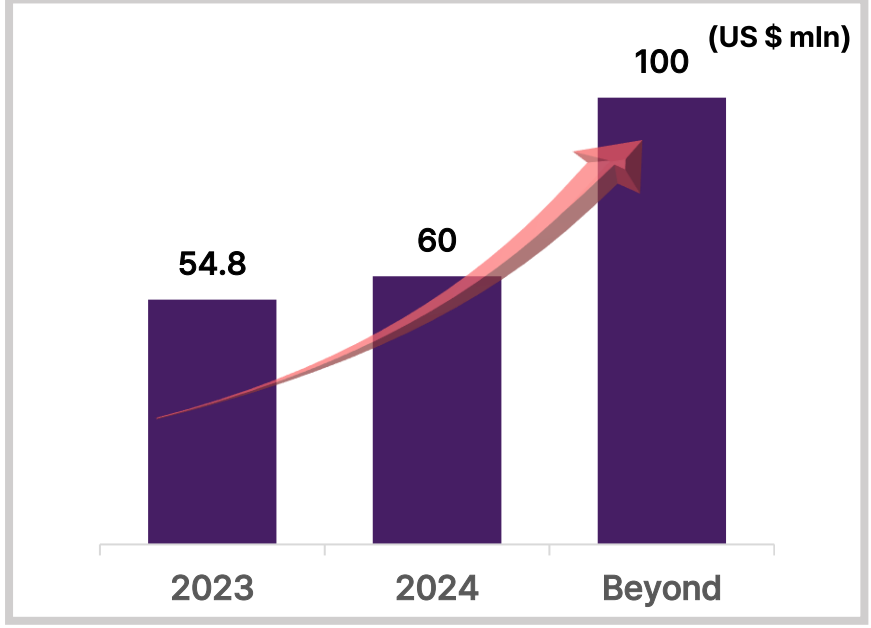
- Approved in 2021 by MFDS (South Korea) under the name of ROLONTIS® and in 2022 by FDA (U.S.) under the name of ROLVEDON® as a treatment for chemotherapy-induced neutropenia
- ROLVEDON® was added to NCCN* Guidelines in oncology for Hematopoietic Growth Factors as an appropriate option for cancer patients who are at risk for febrile neutropenia and received permanent J-Code (J1449)
- Open-Label, Phase 1 Study on same day dosing, 30 minutes after the patient's chemotherapy treatment, confirming efficacy and safety

### Mean Duration of Severe Neutropenia (Days) in Cycle 1




**In two global phase 3 trials, met the primary endpoint of noninferiority (p<.0001) and noninferiority was maintained throughout the four treatment cycles (P<.0001 in all cycles)**

### ROLVEDON® Net sales3)




1) Schwartzberg LS, et al. Oncologist. 2020 Aug;25(8):e1233-e1241. 2) Cobb PW, et al. Cancer Med . 2020 Sep;9(17):6234-6243. 3) Spectrum Pharmaceuticals, Assertio Holdings
* **NCCN:** National Comprehensive Cancer Network

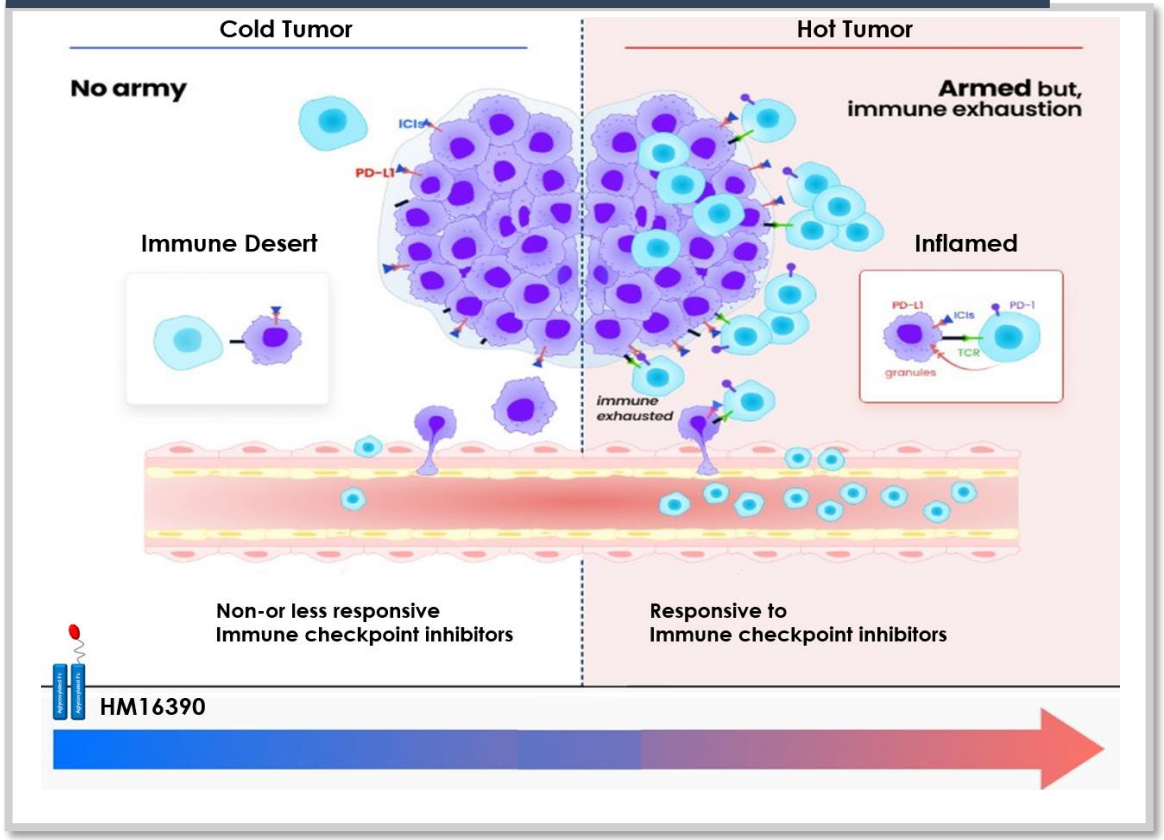
# Oncology: HM16390 ($^{LAPS}$IL-2 analog)

Phase 1

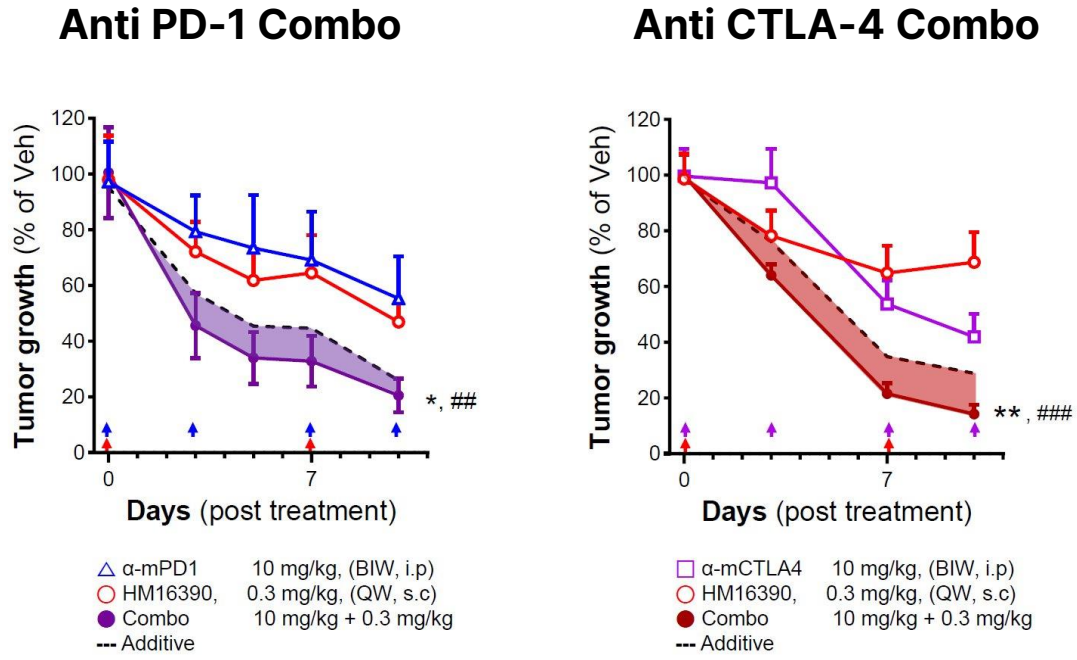
## Next-generation long-acting IL-2 analog with optimized dosing schedule for cancer therapy

- CD122 (IL-2Rβ) binding for 'best-in-class' anti-tumor efficacy, with optimized CD25 (IL-2Rα) affinity to minimize adverse effects
- Potent anti-tumor activity as monotherapy and in combination with immune checkpoint inhibitors(ICI) in preclinical studies[1)]
- Phase 1 clinical trial is currently ongoing to assess pharmacokinetics and efficacy, with a planned combination study with KEYTRUDA®

### Cold-to-Hot tumor conversion to enhance ICI




### Combinatorial efficacy with multiple ICIs in melanoma models




**p<0.01, *p<0.05 vs. Immune checkpoint inhibitor mono; ###p<0.001, ##p<0.01 vs. HM16390 mono by unpaired t-test.

1) Jinyoung Kim, et al. SITC Nov. 2024, 2) NCT06724016

# Oncology: HM16390 ($^{LAPS}$IL-2 analog)

Phase 1

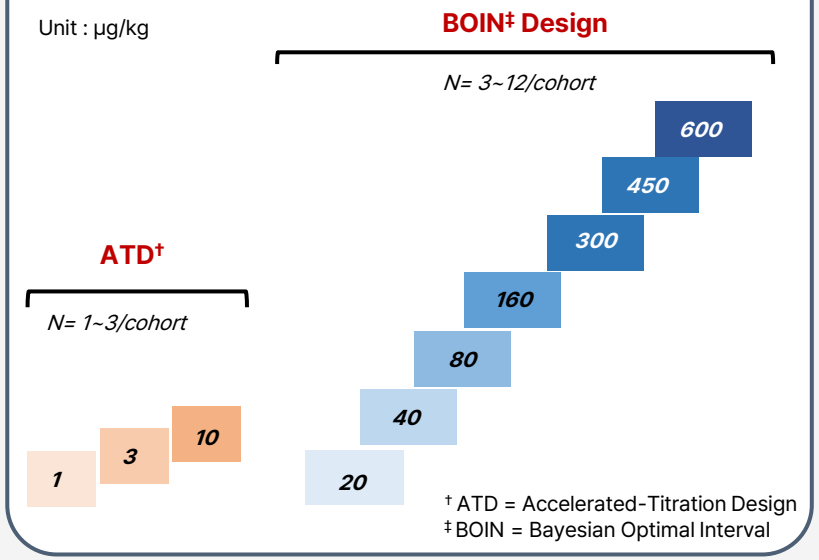
- **Title: A Phase 1, Open-Label, Multicenter, Dose Escalation and Expansion Study of HM16390 in Patients with Advanced or Metastatic Solid Tumor**
- **Primary objective: Safety and tolerability of HM16390 administered subcutaneously (SC), as a single agent and in combination with pembrolizumab**
- **Secondary objective: Maximum tolerated dose (MTD) or recommended Phase 2 dose (RP2D), pharmacokinetics (PK), anti-tumor effect (ORR by RECIST v1.1) of HM16390, as a single agent and in combination with pembrolizumab**
- **Estimated clinical completion: Study Completion 2030 1H**

- **Estimated enrollment: 215**
- **Participation Criteria**
  - **Key inclusion criteria: advanced metastatic solid tumor, age of 18 or older**
  - **Key exclusion criteria: prior treatment with agent targeting the IL-2, IL-7, and IL-15**

*Keytruda® combination trial planned per CTCSA*

## Dose Escalation Part

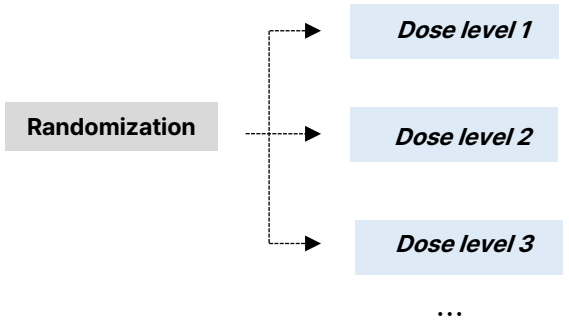
**→ To establish the MTD or Recommended Dose (RD)**




† ATD = Accelerated-Titration Design
‡ BOIN = Bayesian Optimal Interval

## Dose-Ranging Part

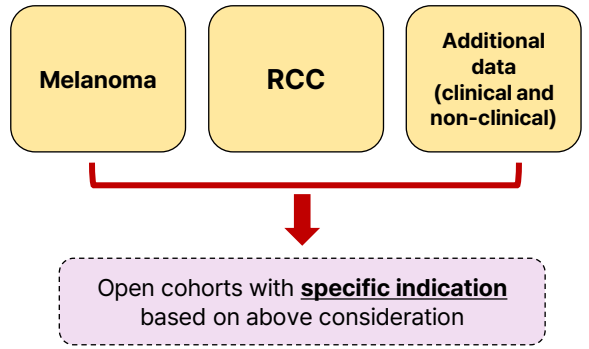
**→ To determine the potential RP2D**




- *No. of doses (at least 2 doses) to be randomized will be determined based on a comprehensive review of the results from the Dose-Escalation Part*
- *n = 20 per arm (dose level); TBD*

## Dose-Expansion Part

**→ To assess the potential efficacy in indication-specific cohorts**



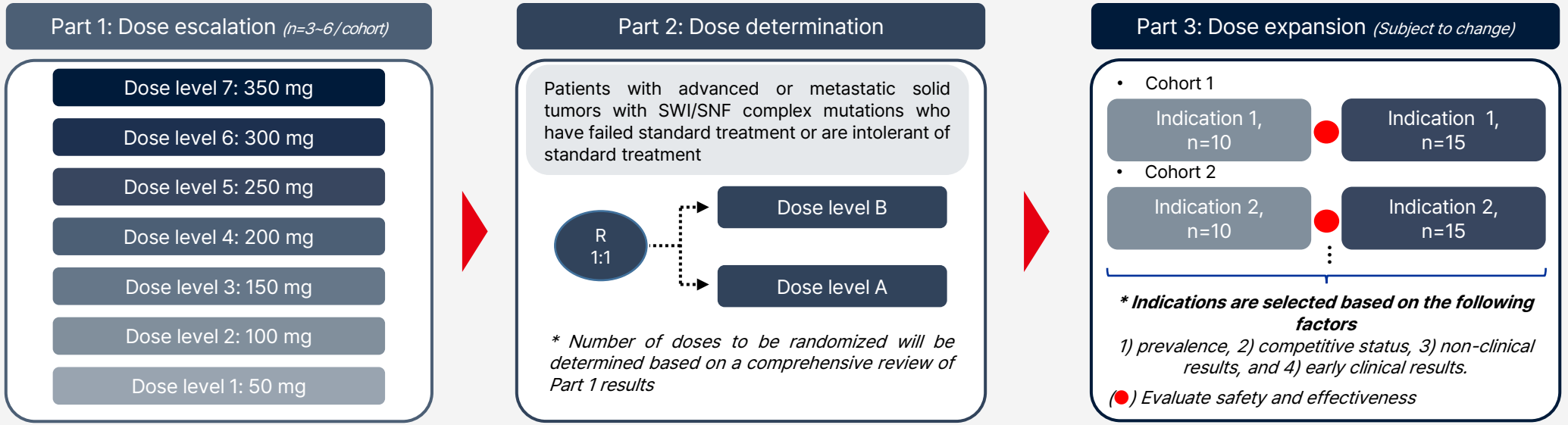

***Indication will be selected based on :***
*1) Initial clinical results from Dose-Escalation/-Ranging Part*
*2) Prevalence and competitive landscape of the indication*
*3) Additional pre-clinical results*

# Oncology : HM97662 (EZH1/2)

Phase 1

- **Title:** Dose Escalation and Expansion Study of HM97662 in Advanced or Metastatic Solid Tumors
- **Primary endpoints:** Safety and tolerability (DLT, adverse event evaluation), determination of maximum tolerated dose (MTD) and recommended phase 2 dose (RP2D)
- **Secondary endpoints:** Pharmacokinetics (PK), preliminary anticancer effect (ORR by RECIST 1.1)
- **Estimated clinical completion: Interim results 2025 2H (dose escalation/dose determination/dose expansion), Study Completion 2028 1H**

- **Enrollment: 170**
- **Duration of treatment: about 5yrs**
- **Participation Criteria**
  **- For patients with advanced or metastatic solid tumors who have failed or are intolerant of Standard of Care**
  **- For patients who have not received prior EZH1/2 dual inhibitor therapy, have an ECOG* performance status of 0 or 1, and adequate hematologic, renal, and hepatic function**




1) NCT05598151 * **ECOG**: Eastern Cooperative Oncology Group

# Oncology: Tuspetinib (MKI)

Phase 1

## Tuspetinib (TUS) is a potent, once-daily oral kinase inhibitor targeting SYK, FLT3, JAK1/2, RSK1/2, and mutant KIT kinases that drive dysregulated proliferation in AML

- **Title**: Tuspetinib Oral Myeloid Kinase Inhibitor Safety and Efficacy as Monotherapy and Combined with Venetoclax (VEN) in Phase 1/2 Trial of Patients with Relapsed or Refractory (R/R) Acute Myeloid Leukemia (AML)[1)]
- Tuspetinib shows excellent safety and broad efficacy across genetic subgroups, including TP53, RAS/MAPK, and FLT3 mutants, both alone and with VEN
- **TUS/VEN/Azacitidine(AZA)** triplet is being developed as well tolerated and mutation agnostic 1L therapy for newly diagnosed AML

### [ TUS monotherapy (n=93) ]

- **42% CRc and 50% ORR** was observed in VEN naïve & FLT3MUT harboring patients

**TUS Single Agent (40, 80, 120, 160mg)**

| R/R AML | VEN-Naïve | |
|---|---|---|
| | CRc | ORR |
| **All Comers** | 30% (9/30) | 33% (10/30) |
| FLT3$^{MUT}$ | **42% (5/12)** | **50% (6/12)** |
| FLT3$^{WT}$ | 22% (4/18) | 22% (4/18) |
| TP53$^{MUT}$ | 67% (2/3) | 67% (2/3) |
| N/KRAS$^{MUT}$ | 67% (2/3) | 67% (2/3) |
| Prior-FLT3i | 67% (2/3) | 67% (2/3) |

### TUS PK in TUS/VEN/AZA: Relative to TUS Single Agent

- 40% ORR was observed in FLT3MUT patients. Among these 83% (5/6) had failed prior-VEN and 50% (3/6) had failed both Prior VEN & FLT3i treatment

**80mg TUS + 400mg VEN**

| R/R AML | CRc | ORR |
|---|---|---|
| **All Comers** | 19% (12/65) | 25% (18/65) |
| FLT3$^{MUT}$ | **27% (4/15)** | **40% (6/15)** |
| FLT3$^{WT}$ | 16% (8/49) | 25% (12/49) |
| TP53$^{MUT}$ | 18% (3/17) | 18% (3/17) |
| N/KRAS$^{MUT}$ | 9% (1/11) | 27% (3/11) |
| Prior-VEN | 19% (9/48) | 27% (13/48) |
| Prior-FLT3i | 26% (5/19) | 32% (6/19) |

1) Naval G.Daver, et al. EHA 2024, Data Cut APR 26, 2024 * MKI: myeloid kinome inhibitor, CRc: Composite Complete Remission, DLT: Dose Limiting Toxicity

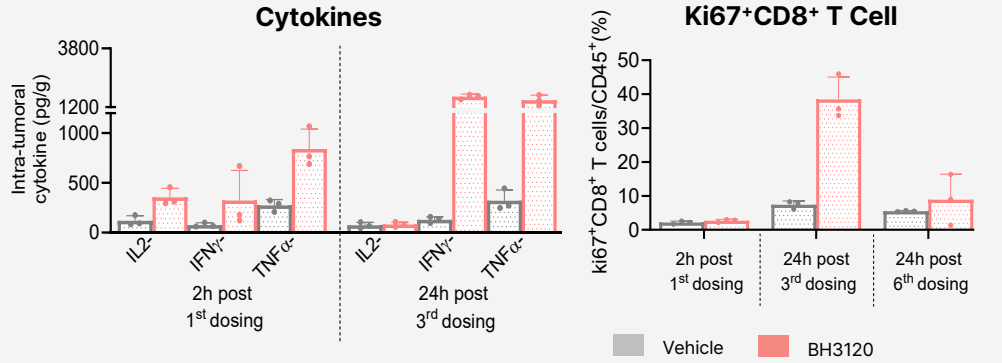
# Oncology: BH3120 (4-1BB x PD-L1 BsAb)

Phase 1

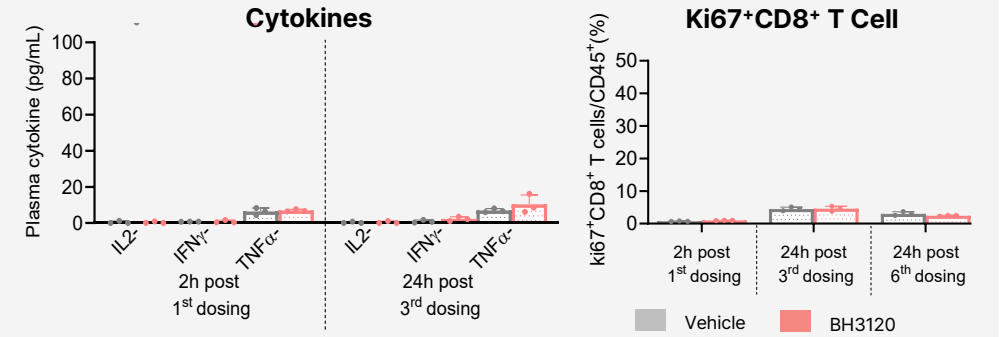
## PD-L1/4-1BB Bispecific Antibody

- its high 4-1BB Kd **lowers the risk of liver toxicity** seen with earlier 4-1BB drugs.[1)]
- It activates 4-1BB only in PD-L1-positive tumours, boosting local immunity while sparing normal tissue.
- **A global Phase 1**[2)], open-label dose-escalation study is under way, testing **BH3120 alone and with KEYTRUDA® (pembrolizumab)** in advanced solid tumours.

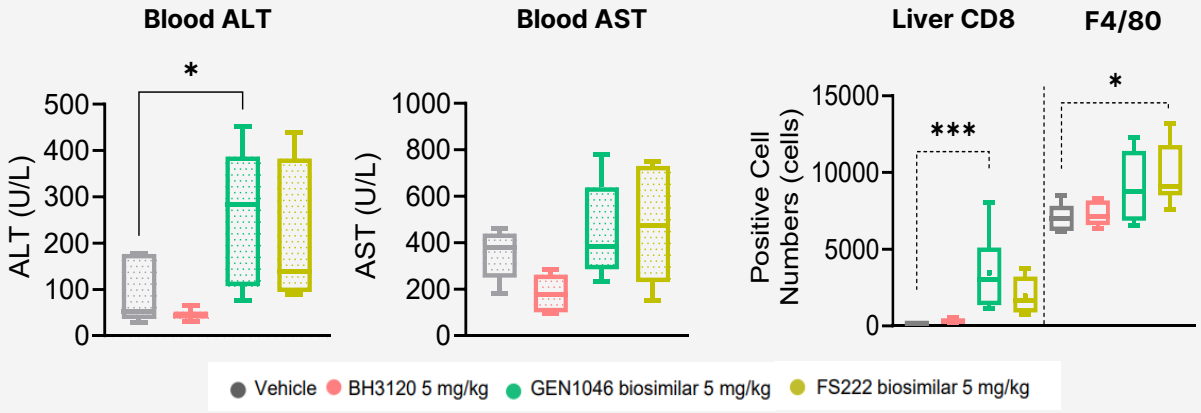
### Tumor microenvironment

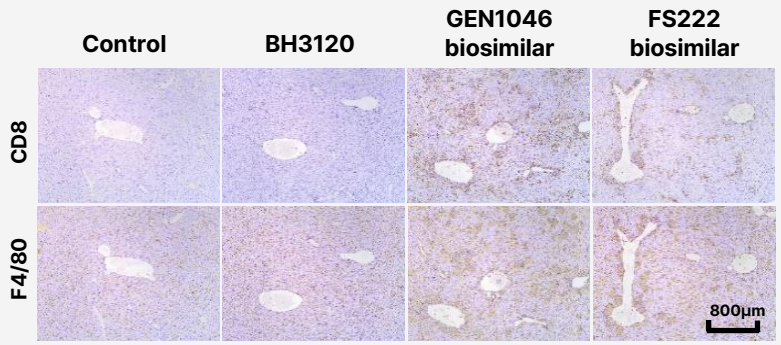



### Blood




### Liver toxicity




1) Wang.J., et al. Cancer Res (2023), 2) NCT06234397

# Fast Track Designation Status by Country

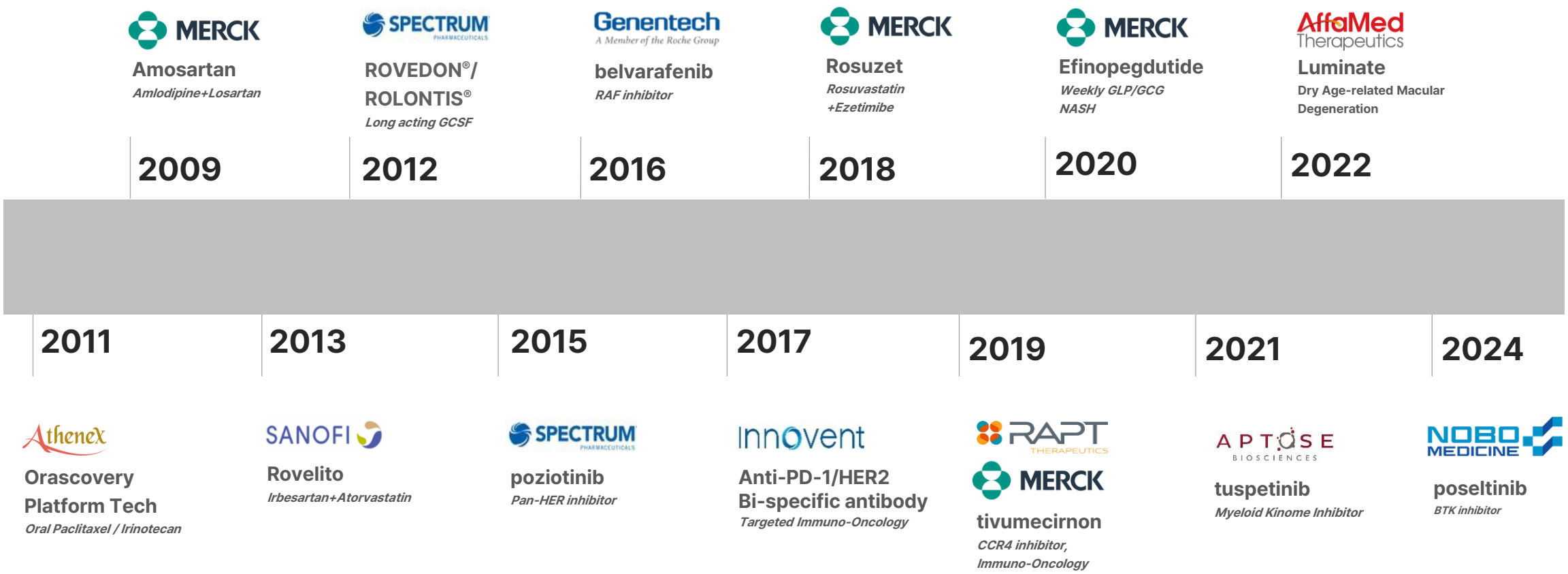
| | FDA | | EMA | MFDS | Others |
|---|---|---|---|---|---|
| **Efocipegtrutide** ([LAPS]Triple agonist) | • Orphan Drug<br>- Primary Biliary Cholangitis<br>- Primary Sclerosing Cholangitis<br>- Idiopathic Pulmonary Fibrosis | • Fast Track<br>-NASH | • Orphan Drug<br>- Primary Biliary Cholangitis<br>- Primary Sclerosing Cholangitis<br>- Idiopathic Pulmonary Fibrosis | | |
| **Efinopegdutide** ([LAPS]GLP/GCG agonist) | | • Fast Track<br>-NASH | | | |
| **Efpegerglucagon** ([LAPS]Glucagon analog) | • Orphan Drug<br>- Congenital Hyperinsulinism<br>• Rare Pediatric Disease:<br>- Congenital hyperinsulinism | | • Orphan Drug<br>- Congenital Hyperinsulinism<br>- Autoimmune Insulin Syndrome | • Orphan Drug<br>- Congenital Hyperinsulinsm | |
| **Sonefpeglutide** ([LAPS]GLP-2 analog) | • Orphan Drug<br>- Short Bowel Syndrome<br>• Rare Pediatric Disease<br>- Short Bowel Syndrome | • Fast Track<br>- Short Bowel Syndrome | • Orphan Drug<br>- Short Bowel Syndrome | • Orphan Drug<br>- Short Bowel Syndrome | |
| **Oraxol®** | • Orphan Drug<br>- Angiosarcoma | | • Orphan Drug<br>- Soft Tissue Sarcoma | | • Promising Innovative Medicine<br>- M. Breast Cancer in the UK MHRA |
| **Poziotinib** (pan-HER) | | • Fast Track<br>- NSCLC | | | |
| **Poseltinib** (BTK) | | | | • Orphan Drug<br>- Primary Central Nervous System Lymphoma (PCNSL) | |
| **Tuspetinib** (MKI) | • Orphan Drug<br>- Acute Myeloid Leukemia | • Fast Track<br>- Relapsed/Refractory AML with FLT3 mutation | | • Orphan Drug<br>- Acute Myeloid Leukemia | |
| **Efpegsomatropin** ([LAPS]hGH) | | | • Orphan Drug<br>- Growth Hormone Deficiency | | |
| **HM15421** (LA-GLA) | • Orphan Drug<br>- Fabry disease | | | • Orphan Drug<br>- Fabry disease | |

*Orphan Drug Designation grants fee waivers and review support. In the U.S., it provides 7 years of market exclusivity post-approval; in Europe, 10 years.
In Korea, no separate market exclusivity exists, but protection is offered via Data Exclusivity for approval data.
*Fast Track (U.S. FDA) supports accelerated development and approval of drug candidates addressing serious diseases with unmet medical needs.
Benefits: Enables frequent FDA consultations during clinical development to mitigate risks early; eligible drugs can receive Priority Review, shortening review time from 10 to 6 months.
*UK MHRA designates promising innovative therapies for serious or limited treatment options diseases. Benefits: Allows early use before approval and streamlined regulatory processes, including linkage to Priority Review for faster approval.

# R&D Partnership

## "Largest domestic tech export, ongoing global partnerships"

**Over the past 10 years, cumulative contracts related to new drugs total approximately KRW 10 trillion, with upfront payments and milestone receipts around KRW 1 trillion.**



# Thank you