

# **Investor Relations**

1Q 2024



- 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 Q4 2023 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 daims; 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%







# **Company Overview**





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✓ 2023 annual sales KRW 1,490.9bn, +12.0% YoY. OP KRW 220.7bn, +39.6% YoY



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

# Hanmi Pharmaceutical Sales Analysis





Unit : bn KRW

(Source: UBIST data)



- ✓ Sustaining growth of core products in Korea based on solid evidence-oriented marketing
- ✓ Expanding efficacy & safety profile through multiple Real World Data



2018-2023 Annual sales of Rosuzet

# Unit : bn KRW Rosuzet's RACING Study results were published

Article Title	Journal Name	Date
[RACING Study] Long-term efficacy and safety of moderate-intensity statin with ezetimibe combination therapy versus high-intensity	THE LANCET	'22.07.18
[The 1st sub-analysis of RACING Study] Moderate-intensity statin with ezetimibe vs. high-intensity statin in patients with diabetes and ASCVD	European Heart Journal	'22.12.19
[The 2nd sub-analysis of RACING Study] Combination Moderate-Intensity Statin and Ezetimibe Therapy for Elderly Patients With Atherosclerosis	I JACCE	'23.04.03
[The 3rd sub-analysis of RACING Study] Efficacy and safety of moderate-intensity statin with ezetimibe combination therapy in patients after Percutaneous coronary intervention	eClinicalMedicine Part of THE LANCET Discovery Science	'23.04.04
[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	JAMA Cardiology	'23.08.02

 RACING Study is a large-scale clinical trial conducted on 3,780 patients with ASCVD in Korea

(Source: UBIST data)



✓ 2023 annual sales KRW 397.7bn, +13.4% YoY. OP KRW 97.8bn, +25.4% YoY



Flagship I	Products		Unit : 1,0	00 RMB
Product	Indication	2023	Sales(%)	YoY
Itanjing	Antitussive expectorants	775,565	35.9%	8.1%
Li Dong	Constipation	485,782	22.5%	13.2%
Mami Ai	Probiotics for infants	423,052	19.6%	18.8%
Mechangan	Probiotics for adults	140,303	6.5%	16.1%
Yianping	Antitussive expectorants	155,876	7.2%	<b>97.8</b> %
Total Sales		2,158,799	100%	<b>17.9%</b>

(Average Exchange rate: 1 RMB= 184.22 KRW)



# Hanmi R&D

### **R&D** Investment 5-year trend





# **R&D** Pipeline



	Pre-clinical	Phase 1	Phase 2	Phase 3	Registration	Approved
Obesity/	LAPS Glucagon Combo [HM15136+Efpeglenatide] Obesity/Metabolic disease		LAPSGLP/GCG [Efinopegdutide] MASH, formerly NASH	LAPS Exd4 Analog [Efpeglenatide] T2DM/Obesity		
Metabolism	LA-GLP/GIP/GCG [HM15275] Obesity		LAPSTriple Agonist [Efocipegtrutide] MASH, formerly NASH			
	SOS1 [HM99462] Solid tumors	Rolvedon <sup>®</sup> Assertic= [Eflapegrastim] Chemotherapy-induced Neutropenia (Same Day Administration)	Belvarafenib] BRAF mutant/fusion solid tumor	Pan-HER Inhibitor [Poziotinib] HER2 exon 20-mutated NSCLC (2 <sup>nd</sup> line)	Oraxol <sup>®</sup> [Paclitaxel+Encequidar] Solid tumors (breast cancer)	Rolvedon <sup>®</sup> ASSERTION [Eflapegrastim] Chemotherapy-induced Neutropenia
	LAPSIL-2 Analog [HM16390] Solid tumors	Genentech pan-RAF Inhibitor [Belvarafenib] Solid tumors (melanoma)	CCR4 Antagonist [FLX475] Solid tumors			
Oncology		PD-1/HER2 BSAb [BH2950] Solid tumors Innovent	BTK [Poseltinib] B-cell lymphoma			
Oncology		MKI APTOSE [Tuspetinib] Acute Myeloid Leukemia				
		<b>EZH1/2 Inhibitor</b> [HM97662] Solid tumors, hematologic cancers				
		BD-L1/4-1BB BsAb [BH3120] Solid tumors				
	LAPS <b>Triple Agonist</b> [HM15211] Idiopathic Pulmonary Fibrosis		LAPSGlucagon Analog [HM15136] Congenital Hyperinsulinism			Synojoynt <sup>®</sup> Arthrex [Sodum hyaluronate] Pain in osteoarthritis of the knee
Rare Diseases/ Other	Long-acting GLA (HM15421) Fabry disease		LAPSGLP-2 Analog [HM15912] Short Bowel Syndrome			
			LAPS <b>hGH</b> [Efpegsomatropin] Growth Hormone Deficiency			
			Luminate® [ALG-1001] Dry Age-related Macular Degeneration			
B Beijing Hanmi	: Approved from the	ne FDA				12

- > Establishing patient-centric portfolio for the entire period from obesity prevention, treatment and management
- +750 million people are living with obesity, which causes 5% of deaths globally, according to World Health Organization estimates. <u>Global market for obesity drugs</u> are expected to reach <u>\$77 billion by 2030<sup>1</sup></u>



1) Morgan Stanley 'Obesity Drugs Boost Pharma's Growth Outlook'



- Long-acting exendin-4 analog as a GLP-1 receptor agonist with the LAPSCOVERY platform technology
- In phase 3 clinical trials, Efpeglenatide not only shows robust glycemic control efficacy, but also provides improvement effects on cardiovascular outcomes in patients with type 2 diabetes mellitus (T2DM)
- Progress: Phase 3 multicenter, randomized, double-blind study to evaluate efficacy and safety in adult obesity patients without diabetes mellitus, <u>Estimated Study Completion: 2026</u>

#### 2022 Korea Obesity treatment sales<sup>1)</sup>

Korea Obesity treatment market size by 2030 KRW 305.9 bn



### • Dose Escalation Schedule of Efpeglenatide in Phase 3 Study • Enrollment: 420



#### • 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/m<sup>2</sup> or 27 kg/m<sup>2</sup> ≤ BMI < 30 kg/m<sup>2</sup> with at least 1 of the following comorbidities: hypertension, dyslipidemia, sleep apnea or cardiocerebrovascular disease



### Study Design<sup>1)</sup>

Phase IIa, randomized, active-comparator-controlled, parallel-group, open-label study. Participants with an LFC of ≥ 10% at screening were randomized 1:1 to efinopegdutide(n=72) 10 mg or semaglutide(n=73) 1 mg, both administered subcutaneously once weekly for 24 weeks.



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

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### Subgroup Results<sup>1)</sup>

Efficacy and safety of efinopegdutide in patients with nonalcoholic fatty liver disease and type 2 diabetes: results from an activecomparator-controlled study. Among 145 randomized subjects in Phase IIa, <u>48 had T2DM (</u>24 in each treatment group)





- Title: A Phase 2b Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Efinopegdutide (MK-6024) in Adults With Precirrhotic Nonalcoholic Steatohepatitis
- > 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 Body Weight
- Study Completion: 2025 2H



- Duration: 52 wks
- Inclusion Criteria

 Histological confirmation of NASH, defined as NAFLD Activity Score (NAS) ≥4 with a score ≥1 point in each component (steatosis, ballooning, and lobular inflammation) AND NASH clinical research network (CRN) fibrosis score of Stage 2 or 3

 No history of T2DM OR a history of T2DM with an A1C ≤9% that is controlled by diet or stable doses of antihyperglycemic agents



Study

Design

- Title: Tuspetinib (TUS) 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)<sup>1)</sup>
- > TUS single agent was more active in VEN-naïve R/R AML [TUS 80-160mg: Overall CRc=29%, 80mg: Overall CR/CR<sub>h</sub>=36%]
- > TUS/VEN doublet was well tolerated and active across broad populations of R/R AML [CRc 25% in all patients]
- TUS/VEN/HMA triplet will be studied in 1L newly diagnosed AML patients

#### [TUS monotherapy (n=68)]

- **Safety:** Mild AEs and no DLTs up to 160 mg/day, no drug discontinuations from drug related toxicity
- Recommended Phase 2 Dose = 80 mg once daily

TUS Response Rate Analysis	5 (ITT)
TUS in VEN Naïve AML (80-160mg)	CRc
Overall	<mark>29%</mark> (n=8/28)
FLT3-Mutated	42% (n=5/12)
FLT3-Unmutated (Wildtype)	19% (n=3/16)
TUS in VEN Naïve AML at 80mg RP2D	CR/CR <sub>h</sub> *
Overall	<mark>36%</mark> (n=5/14)
FLT3-Mutated	50% (n=3/6)
FLT3-Unmutated (Wildtype)	25% (n=2/8)

\*CRh: Complete Remission with partial hematologic recovery

1) Naval G.Daver, et al. ASH 2023, Data Cut Oct 23, 2023

#### [TUS/VEN Combination Therapy (n=49)]

- TUS 80mg + VEN 200mg with 36 evaluable patients (13 patients too early to assess)
- TUS/VEN is active in VEN-Naïve and Prior-VEN R/R AML
- TUS/VEN is active in FLT3<sup>WT</sup>, representing ~70% of AML patients

composite complete Kennission (CKC) in Evaluable Patients (II–30)									
FLT3 Status	ALL	VEN-Naïve VEN-Pri		FLT3i-Prior					
ALL	25% (9/36)	43% (3/7)	21% (6/29)						
FLT3 <sup>₩T</sup>	20% (5/25)	33% (2/6)	16% (3/19)						
FLT3 <sup>MUT</sup>	36% (4/11)	100% (1/1)	30% (3/10)	44% (4/9)					



# **R&D** Timeline







# **Financial Performance**

# **Quarterly Results** Consolidated Business Results



- ► 4Q23 Sales KRW 422.4bn, +20.3% YoY
- Operating profit KRW 70.1bn, Net profit KRW 30.3bn
- OP delivered +80.5% YoY growth thanks to solid growth in domestic and Beijing Hanmi and increased milestone payments

	2023 4Q	2022 4Q	YoY	2023 3Q	QoQ
Sales	422.4	351.2	20.3%	364.6	15.8%
Operating Profit (%)	70.1 (16.6%)	<b>38.8</b> (11.1%)	80.5%	57.5 (15.8%)	21.9%
Pre-tax Profit (%)	56.9 (13.5%)	<b>20.7</b> (5.9%)	175.4%	56.3 (15.4%)	1.1%
Net Profit (%)	30.3 (7.2%)	<b>22.6</b> (6.4%)	34.4%	60.5 (16.6%)	-49.9%

# **Quarterly Results Hanmi Pharmaceutical**

Hanmi

- ► 4Q23 Sales KRW 320.9bn, +20.3% YoY, +18.0% QoQ
- Operating profit KRW 53.6bn, Net profit KRW 20.4bn
- Sales breakdown: Finished products 77%, Merchandise 15%, Royalties/Milestones 6%

	2023 4Q	2022 4Q	YoY	2023 3Q	QoQ	
Sales	320.9	266.7	20.3%	272.1	18.0%	
Finished products	247.9	221.7	11.9%	228.4	8.5%	
Merchandise	46.7	37.4	24.9%	37.1	25.8%	
<b>Upfront/Milestones</b>	19.7	3.0	545.0%	2.2	776.7%	
Others	6.6	4.6	44.0%	4.3	54.4%	
<b>Operating Profit</b>	53.6	25.4	111 10/	32.5	CA 70/	
(%)	(16.7%)	(9.5%)	(12.0%)		04.1%	
Pre-tax Income	47.3	7.8		20.1	125 00/	
(%)	(14.8%)	(2.9%)	509.0%	(7.4%)	155.0%	
Net Income	20.4	11.8	72 50/	27.9	26.00/	
(%)	(6.4%)	(4.4%)	/3.3%	(10.3%)	-20.9%	

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

- 'Rosuzet', 'Amosartan family' maintained total revenue above KRW 100bn for
   4 consecutive years
- 'Rosuzet' reached all-time high sales of KRW 178.8bn

2023 4Q 2023 3Q Product 2023 2022 YoY QoQ Rosuzet 178.8 149.9 19.3% 47.9 45.5 5.3% **Amosartan family** 141.9 135.4 4.8% 36.2 35.2 2.8% **Esomezol family** 64.2 3.0% 16.5 62.4 15.9 3.7% Pal Pal 42.5 40.6 11.0 10.6 3.9% 4.5% Hanmi Tams/OD 40.5 10.9 10.3 35.6 13.7% 5.9% **ETC** 26.8 Naxozol 25.9 3.5% 6.7 6.7 0.1% Amodipin 24.8 24.6 1.1% 6.2 6.2 1.2% Gugu 21.7 18.9 14.7% 5.9 5.5 8.4% Hyalu Mini 20.3 17.8 13.9% 6.1 4.8 25.9% Pidogul 6.5% 17.7 16.3 8.9% 4.8 4.5



### 2023 exports\* KRW 186.1bn, +17.5% YoY

**Unit : Billion KRW** 

	2023	2022	YoY	2023 4Q	2023 3Q	QoQ
Domestic	885.3	820.2	7.9%	255.3	225.6	13.2%
Export	186.1	158.4	17.5%	45.9	44.2	3.9%

### **Export details**

#### Similar Sales proportion by region



#### Maintained Proportion of product sales







- ► 4Q23 Sales KRW 103.3bn, +22.5% YoY, +10.7% QoQ
- OP rose +69.6% YoY thanks to respiratory products growth due to outbreak of M.

pneumoniae, while decline -26.8% QoQ due to increased R&D and SG&A expenses

		2023 4Q	2022 4Q	YoY	2023 3Q	QoQ
	Sales	103.3	84.3	22.5%	93.3	10.7%
Billion KRW	Operating Profit (%)	19.1 (18.4%)	11.2 (13.3%)	69.6%	26.0 (27.9%)	- <b>26.8</b> %
	Pre-tax Income (%)	6.6 (6.4%)	11.7 (13.8%)	-43.4%	<b>27.3</b> (29.2%)	- <b>75.8</b> %
	Net Income (%)	6.2 (6.0%)	<b>10.0</b> (11.9%)	-37.6%	<b>23.8</b> (25.5%)	-73.8%
	Sales	565,626	442,173	<b>27.9</b> %	516,795	9.4%
1,000	<b>Operating Profit</b>	104,756	59,150	77.1%	144,036	-27.3%
RMB	Pre-tax Income	37,208	61,354	-39.4%	150,750	-75.3%
	Net Income	35,088	52,678	-33.4%	131,667	-73.4%

## **Quarterly Results Hanmi Fine Chemical**



- ► 4Q23 Sales KRW 33.6bn, +13.5% YoY, +56.0% QoQ
- Profitable CDMO leads to sales increase, resulting in a shift to QoQ profitability

	2023 4Q	2022 4Q	YoY	2023 3Q	QoQ
Sales	33.6	29.6	13.5%	21.6	56.0%
Operating Profit (%)	<b>1.6</b> (4.9%)	<b>1.3</b> (4.3%)	30.4%	-1.5 (-6.9%)	ттв
Pre-tax Income (%)	1.3 (3.8%)	<b>1.2</b> (3.9%)	11.0%	-1.3 (-6.2%)	ттв
Net Income (%)	1.4 (4.1%)	<b>0.9</b> (3.1%)	47.8%	-1.4 (-6.3%)	ттв

# **Cost Analysis**



- 2023 R&D investment KRW 205.0bn, 13.8% of revenue
- 4Q23 R&D investment : KRW 68.7bn (16.3% of revenue)

		2023	2022	YoY	2023 4Q	2023 3Q	QoQ
Concol	SG&A	426.8	406.1	5.1%	113.8	101.3	12.3%
Consol.	R&D Investment	205.0	177.9	15.2%	68.7	45.1	52.5%
Hanmi	SG&A	251.6	241.6	4.1%	68.5	63.8	7.3%
Pharm	R&D Investment	164.9	138.6	18.9%	49.7	37.8	31.4%
Beijing Hanmi	SG&A	169.1	158.7	6.6%	44.5	35.9	23.8%
	R&D Investment	32.3	33.9	-4.7%	16.9	5.4	212.2%
Hanmi	SG&A	7.7	7.1	8.5%	1.9	1.7	8.0%
Chem	R&D Investment	7.8	5.4	44.8%	2.2	1.8	18.5%



	2023	2022	YoY	2023 4Q	2023 3Q	QoQ
Sales	1,490.9	1,331.5	12.0%	422.4	364.6	15.8%
COGS %	<b>661.6</b> 44.4%	<b>613.0</b> 46.0%	<b>7.9</b> %	<b>179.2</b> 42.4%	<b>165.8</b> 45.5%	<b>8.1</b> %
SG&A %	<b>426.8</b> 28.6%	<b>406.1</b> 30.5%	5.1%	<b>113.8</b> 26.9%	101.3 27.8%	12.3%
Operating profit %	<b>220.7</b> 14.8%	<b>158.1</b> 11.9%	39.6%	<b>70.1</b> 16.6%	<b>57.5</b> 15.8%	21.9%
Pre-tax income %	<b>194.0</b> 13.0%	<b>121.0</b> 9.1%	60.3%	<b>56.9</b> 13.5%	<b>56.3</b> 15.4%	1.1%
Net income %	159.3 10.7%	<b>101.6</b> 7.6%	5 <b>6.8</b> %	<b>30.3</b> 7.2%	<b>60.5</b> 16.6%	-49.9%



	As of Dec 2023	As of Dec 2022	ΥοΥ
Current Asset	730.6	694.2	5.3%
Non-Current Asset	1,161.5	1,230.4	-5.6%
Total Asset	1,892.2	1,924.6	-1.7%
Current Liability	704.3	676.7	4.1%
Non-Current Liability	93.8	238.6	-60.7%
Total Liability	798.0	915.4	-12.8%
Total Equity	1,094.1	1,009.2	8.4%

# Income Statement - Hanmi Science Consolidated



	2023	2022	YoY	2023 4Q	2023 3Q	QoQ
Sales	1,247.9	1,046.1	19.3%	331.9	309.4	7.3%
COGS	1,190.9	1,017.9	17.0%	313.8	297.2	5.6%
Operating profit	125.1	67.6	85.0%	31.6	35.8	-11.6%
Pre-tax income	132.1	73.2	80.6%	46.8	33.1	41.4%
Net income	115.8	69.0	67.8%	35.3	30.8	14.6%



# **Business Review Appendix**



# Key Updates

- **NOV** Presented 2 poster presentations of <sup>LAPS</sup>IL-2 Analog(HM16390) at SITC
  - Presented a poster presentation on the LAPS Triple agonist in a liver inflammation and fibrosis animal model at AASLD
  - Merck announced 2 sub-analysis results of Phase 2a of LAPS Dual agonist at AASLD
- DEC Oral presentation of advanced data on phase 1/2 of AML treatment 'Tuspetinib(HM43239)' at ASH
- JAN Enrolled 1<sup>st</sup> patient in phase 3 trial of Korean GLP-1 Obesity Treatment, Efpeglenatide
  - Hanmi Pharm-AIGEN SCIENCE signed an MOU on 'R&D of New Anti-Cancer Drugs Using AI'

# Significant events

- Compliance Program (CP) AAA rating granted by the Fair Trade Commission for 5 consecutive years



# **Our Business**

### Strong Strategic Alliances around the Globe

### "We value our partners and our innovation"





### "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 · Cepha 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**





### Sales force 1,000+

About 70% : Doctors and Pharmacists Directly covering 9,000 hospitals and over 150,000 doctors, keeping the No.1 position in pediatric drug market

Unit : 1,000 RMB

Product	Indication	4Q23	4Q22	YoY	3Q23	QoQ	2023	2022	ΥοΥ
Mami Ai	Probiotics for infants	98,179	64,619	51.9%	81,559	20.4%	423,052	355,964	18.8%
Itanjing	Antitussive expectorants	244,537	200,049	22.2%	167,921	45.6%	775,565	717,409	8.1%
Li Dong	Constipation	102,657	98,336	4.4%	133,237	-23.0%	485,782	429,245	13.2%
Mechangan	Probiotics for adults	31,713	22,488	41.0%	40,525	-21.7%	140,303	120,809	16.1%
Yianping	Antitussive expectorants	41,568	19,412	114.1%	32,708	27.1%	155,876	78,805	97.8%



# **R&D** Appendix



### Mechanism of Action: GCG/GIP/GLP-1 Triple agonism



### Phase 1b/2a Study Design and Results

- Patient: Obese with NAFLD, N=60
- Duration: 12 weeks

#### Study Design

#### • Primary Endpoint:

- Liver Fat and biochemistry (Reduction of liver fat determined by MRI-PDFF
- Safety and Tolerability
- PK profile



- Unique and differentiated activity features (<u>glucagon centric</u>) are originally designed and optimized for fibrotic diseases such as NASH and IPF
- > Multiple modes of action in liver are employed to manage inflammation, fibrosis, and steatosis resolution
- FDA granted <u>'Fast Track'</u> designation for the treatment of NASH (Jul. 2020)
- <u>Progress:</u> Phase 2b in biopsy-confirmed NASH patients, IDMC recommended to continue without any changes to the dosing plan. <u>Estimated Completion: 2H 2025</u>



Biopsy-Confirmed NASH Fibrosis (F1~F3) w/ or w/o T2DM (N=217)
Study Duration: 52 weeks



• Primary Endpoint: resolution of steatohepatitis on overall histopathological reading and no worsening of liver fibrosis







### [Head to head phase 2 study design]



# [Body weight change] I ally Liraglutide -7.5% Weekly Dual -9.8% Weekly Dual -9.8% Weekly Dual -11.8% Weekly Dual -11.8%

### The first Weekly Dual agonist,

### "Benefits Proven in Human<sup>1</sup>"

- Obesity: Causing severe comorbidities that are life-threatening and costly for the society.
  - Achieved Double digit Weight Loss
    - ✓ Superior to daily GLP-1 obesity treatment
  - 40% of patients achieved ≥ 10% weight loss in 26 weeks
  - Improved metabolic profiles to reduce CV risk
    - ✓ Improved blood lipid profile
    - ✓ Clinically meaningful blood pressure reduction
  - Tolerable safety profile



- 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<sup>®</sup> and in 2022 by FDA (U.S.) under the name of ROLVEDON<sup>®</sup> as a treatment for chemotherapy-induced neutropenia
- ROLVEDON<sup>®</sup> was added to <u>NCCN Guidelines</u> in oncology for Hematopoietic Growth Factors as an appropriate option for cancer patients who are at risk for febrile neutropenia and received <u>permanent J-Code (J1449)</u>
- Undergoing an Open-Label, Phase 1 Study on same day dosing, 30 minutes after the patients chemotherapy treatment



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) Evaluate pharma, Assertio Holding's SEC filings

### Study Results<sup>1)</sup>

- Title: Anti-Tumor Activity of Belvarafenib(Belva) in combination with Cobimetinib(Cobi) in patients with metastatic solid tumors harboring BRAF fusions or BRAF class II/III mutation
- > The combination of Belvarafenib with Cobimetinib showed promising anti-tumor activity as well as durable responses with BRAF fusion/indel regardless of cancer type [ORR 66.7%, mDOR 12.0 mo, mPFS 13.7 mo]
- Safety in this population is consistent with total pt population enrolled in study. Most common TRAEs: dermatitis, acneiform, skin rash, diarrhea and CPK increased

### Phase 1b Study Design

- Open-label, multicenter, dose escalation and expansion trial
- Primary Objective: Safety, tolerability, MTD, RP2D
- Secondary Objective: PK, PD, anti-tumor activity

Dose Escalation Part (N=19) Belva 100mg~300mg BID Confirmed, locally Cobi 20mg~40gmg QD advanced, or metastatic solid Dose Expansion Part (N=114) tumors with RAS- or RD1 (N=24) RAF-mutation (N=133) Belva 200mg BID+Cobi 20mg QD RD2 (N=90) Belva 300mg BID+Cobi 20mg QOD

- Class unknown BRAF mutation was included in a basket cohort, and excluded from the sub-cohort analysis
- Safety data cut: 31 Jan 2023, Efficacy data cut: 02 Jun 2023
- RD: recommended dose, BID: twice a day, QD: once a daily, QOD: every other day

#### BRAF class II, III including fusion solid tumors (N=23)

Sub-cohort Analysis

	SC-A : BRAF fusion/indel (N=15)	SC-B : BRAF Point mutation (N=8)
ORR, n (%)	10 (66.7)	0
cPR, n (%)	10 (66.7)	0
SD, n (%)	4 (26.7)	4 (50.0)
PD, n (%)	1 (6.7)	4 (50.0)
NE, n (%)	0	0
DCR*, n (%) *CR+PR+SD	14 (93.3)	4 (50.0)
mDOR (month)	12.0	NA
mPFS (month)	13.7	2.1

In SC-A

: BRAF fusion type (N=10), BRAF indel (N=5)

Melanoma (10), NSCLC (3), CRC (1), Pancreatic cancer (1)



# **R&D Pipeline** Regulatory Designations

	FDA	EMA	Others
LAPS Triple Agonist	<ul> <li>Orphan Drug         <ul> <li>Primary Biliary Cholangitis</li> <li>Primary Sclerosing Cholangitis</li> <li>Idiopathic Pulmonary Fibrosis</li> </ul> </li> <li>Fast Track         <ul> <li>NASH</li> </ul> </li> </ul>	<ul> <li>Orphan Drug</li> <li>Primary Biliary Cholangitis</li> <li>Primary Sclerosing Cholangitis</li> <li>Idiopathic Pulmonary Fibrosis</li> </ul>	
LAPS Dual Agonist	• Fast Track - NASH		
LAPS Glucagon Analog	<ul> <li>Orphan Drug:</li> <li>Congenital Hyperinsulinism</li> <li>Rare Pediatric Disease:</li> <li>Congenital hyperinsulinism</li> </ul>	<ul> <li>Orphan Drug</li> <li>Congenital Hyperinsulinism</li> <li>Autoimmune Insulin Syndrome</li> </ul>	<ul> <li>Orphan Drug         <ul> <li>Congenital Hyperinsulinsm             in S. Korea MFDS</li> </ul> </li> </ul>
LAPSGLP-2 Analog	<ul> <li>Orphan Drug         <ul> <li>Short Bowel Syndrome</li> </ul> </li> <li>Rare Pediatric Disease         <ul> <li>Short Bowel Syndrome</li> </ul> </li> <li>Fast Track         <ul> <li>Short Bowel Syndrome</li> </ul> </li> </ul>	• Orphan Drug - Short Bowel Syndrome	<ul> <li>Orphan Drug         <ul> <li>Short Bowel Syndrome             in S. Korea MFDS</li> </ul> </li> </ul>
Oraxol	Orphan Drug     Angiosarcoma	Orphan Drug:     Soft Tissue Sarcoma	• Promising Innovative Medicine - M. Breast Cancer in the UK MHRA
Poziotinib	• Fast Track - NSCLC		
Tuspetinib	<ul> <li>Orphan Drug         <ul> <li>Acute Myeloid Leukemia</li> </ul> </li> <li>Fast Track         <ul> <li>Relapsed/Refractory AML with FLT3 mutation</li> </ul> </li> </ul>		<ul> <li>Orphan Drug         <ul> <li>Acute Myeloid Leukemia             in S. Korea MFDS</li> </ul> </li> </ul>
LAPS		Orphan Drug     Growth Hormone Deficiency	

Hanmi



### **Major R&D Achievements**

### History of Global Collaborations with partners

"The Way to Sustain Innovation and

Immuno-Oncology

Growth"

MERCK       SPECTRUM         Amosartan       Rolontis®         Amlodipine+Losartan       Long acting GCSF		Genentech A Member of the Roche Group Belvarafenib RAF inhibitor	Genentech A Member of the Roche GroupMERCKBelvarafenib RAF inhibitorRosuzet Rosuvastatin +Ezetimibe		MERCK pegdutide GLP/GCG	AffaMed Therapeutics Luminate Dry Age-related Macular Degeneration	
2009	2012	2016	2018	202	20	2022	
2011	2013	2015	2017	2019	20	)21	
Athenex Orascovery Platform Tech Oral Paclitaxel / Irinoted	SANOFI <b>SANOFI</b> Rovelito Irbesartan+Atorvastatin	SPECTRUM Poziotinib Pan-HER inhibitor	Anti-PD-1/HER2 Bi-specific antiboo Targeted Immuno-Oncology	dy	CK HM43 Myeloid	CIENCES 239 Kinome Inhibitor	

# **R&D** Platform Technology



#### LAPSCOVERY<sup>TM</sup>: Long-Acting Protein/Peptide Discovery



#### **Longer Duration**

- Monomeric form leads to a reduction receptor-mediated clearance
- FcRn binding reduces recycling and renal filtration

#### Efficacy & Safety ↑

- Flexible linker minimizes loss of intrinsic activity
- Increases solubility and bioavailability
- Reduces immunogenicity

### **PENTAMBODY<sup>TM</sup>: Penta** amino acid **m**utated bispecific antibody

Discovered by Beijing Hanmi with immunotherapy & targeted therapy



#### Next generation bispecific antibody platform technology

- Maximizes therapeutic synergies
- Targets immunotherapy and targeted therapy
- Enhances stability and manufacturability

#### Seeking collaboration opportunities

- PENTAMBODY + Novel target
- PENTAMBODY Platform Tech Licensing







**Incrementally modified Drugs** 

Controlled Realease

ER for 12hr CR for 24hr Dual release (IR+ER) Dosage Form Change

> ⊙ OD tablet

Chewable tablet Solution Fixed-Dose Combination

 $\odot$ 

Multi-layered coating FDC Double-layered FDC PolyCap Absorption Enhancement

 $\odot$ 

Microemulsion Fused solid dispersion Spray drying New Salt Formation

 $\odot$ 

Salt Solvate Complex

# **Thank You**

