

# Henlius (2696.HK) 2024 Annual Results Investor Presentation

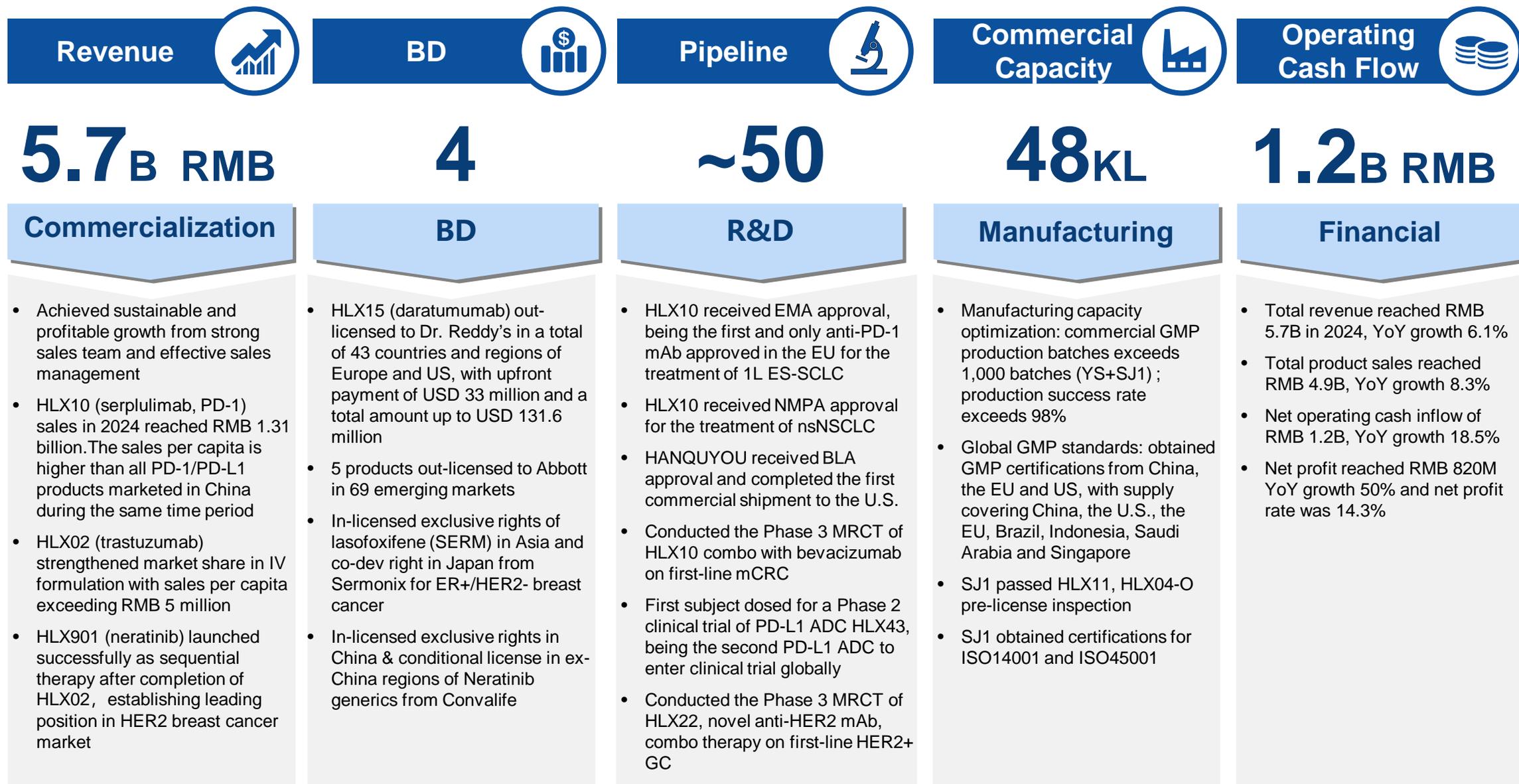
March 2025



01

# 2024 Business Highlights & Company Strategy

# Revenue Tops 5.7B RMB with Net Profit of 820M RMB



# Our Mission and Vision

Affordable Innovation  
Reliable Quality



## Biosimilars

Maximize the commercialization value in China and international markets



## Innovative Drugs

Explore new mechanisms, new technology platforms and expand the therapeutic area coverage

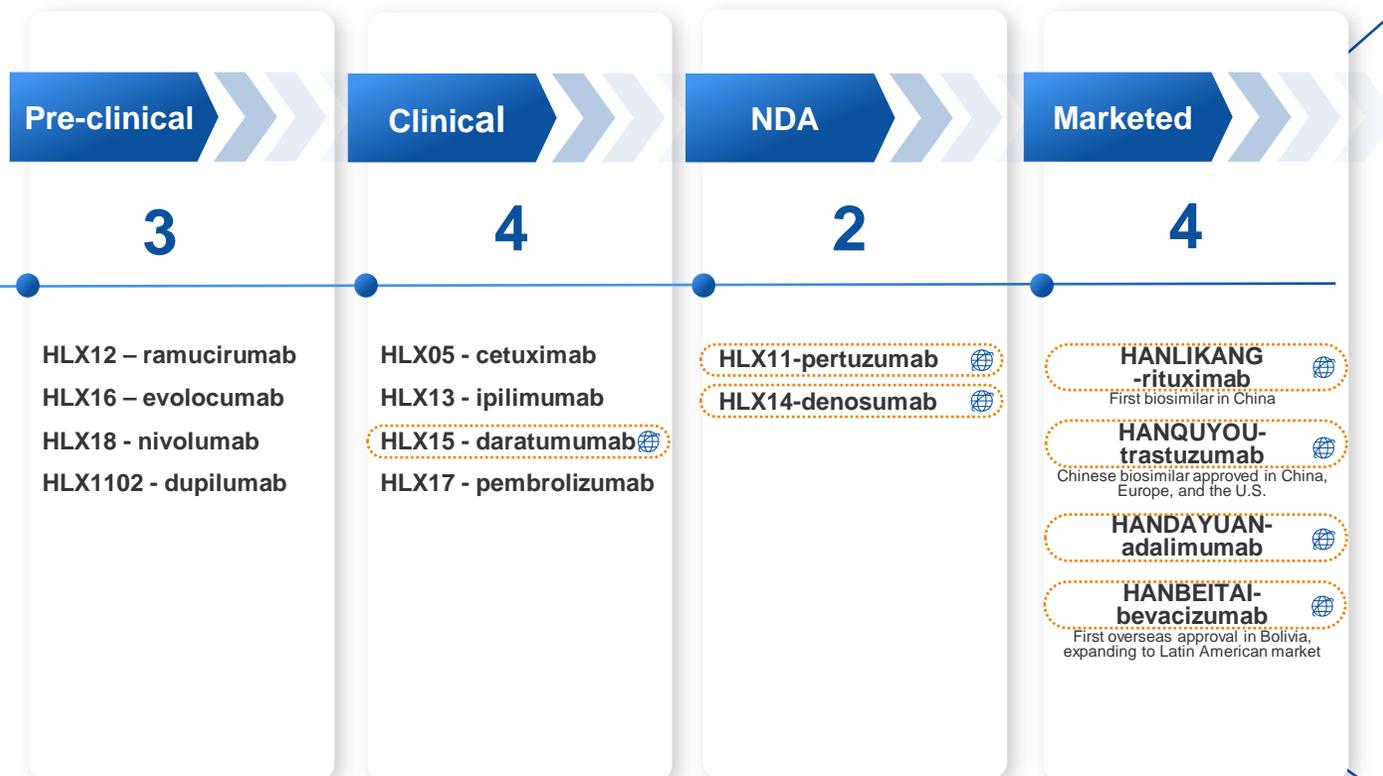


## Globalization

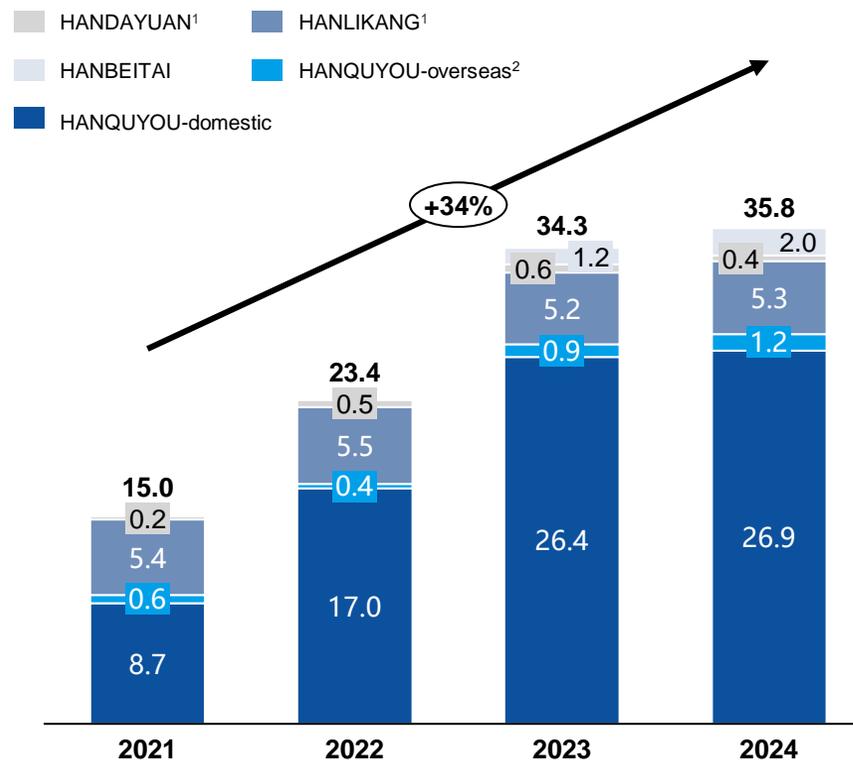
Develop towards a biopharma with global presence & scale

# Robust Biosimilar Pipeline is Aiming at Global Market

- 2024 sales revenue of biosimilars reached 3.58 billion RMB, 4.1% YoY growth. HLX11 (pertuzumab) and HLX14 (denosumab) have entered into NDA stage. The sequence biosimilar pipeline covers globally popular targets such as CTLA-4 and CD38. The Company simultaneously carries out overseas clinical trials to lay a solid foundation for the global market layout
- HANQUYOU received BLA approval in the U.S. and Canada, made the first commercial shipment to North America, being Henlius' first FDA-approved and US commercial product
- HANLIKANG received marketing approval in Peru, being Henlius' 3<sup>rd</sup> self-developed and -manufactured product breaking into global markets, accelerating the benefits to emerging market countries
- HANBEITAI received first overseas approval from Bolivia's AGEMED, being Henlius' 4<sup>th</sup> self-developed product approved overseas, accelerating the expansion of Latin American market



Sales Revenue of Marketed Biosimilars (100 million RMB)



1. Revenue recognized by Henlius  
2. Sum of revenue of trastuzumab overseas

With international out-licensing (ex-China) and clinical trials

# HLX10: Potential Best-in-class PD-1 Antibody with Global Market Opportunity

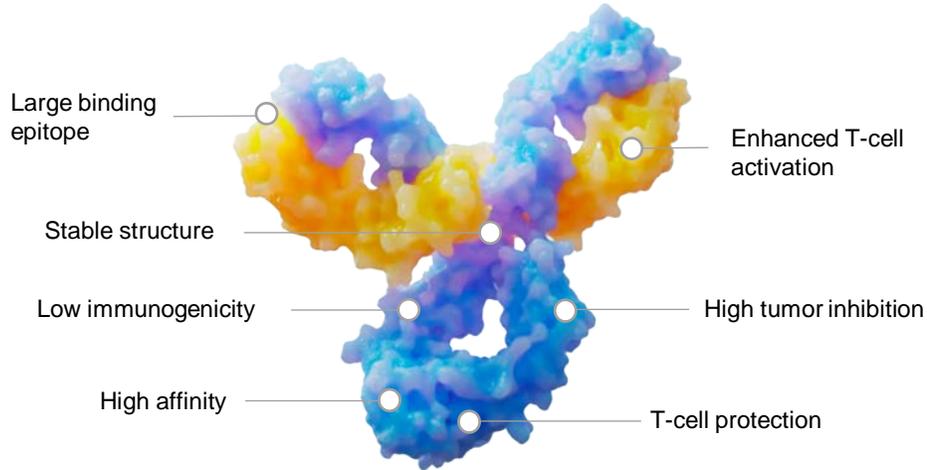
## HLX10 (PD-1) Serplulimab

HANSIZHUANG | Zerpidio® | Hetronifly®

Mar. 2022  
Launched in CN

Dec. 2023  
Launched in SEA

Feb. 2025  
Launched in EU



### Launched



Lung Cancer



Esophageal Squamous-cell Carcinoma

### Pipeline



Gastric Cancer

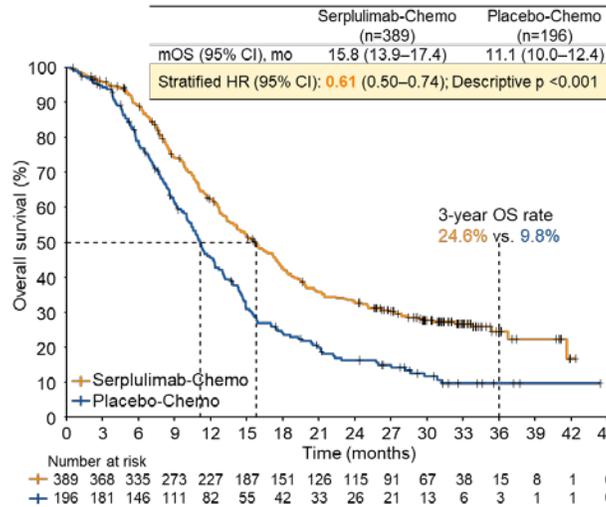


Colorectal Cancer

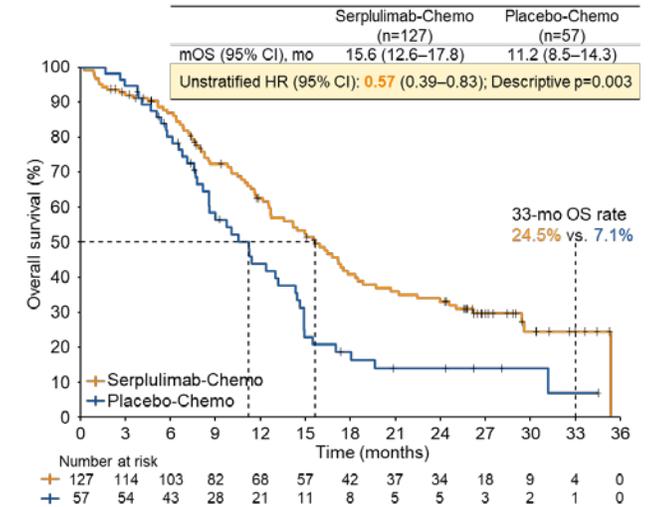
## World's first anti-PD-1 mAb for the first-line treatment of SCLC

Extended follow-up results and patient-reported outcomes from the international phase 3 ASTRUM-005 study

(A) Overall population



(B) Non-Asian (all White) patients



Data cutoff: June 13, 2023

Chemo, chemotherapy; CI, confidence interval; HR, hazard ratio; m, median; mo, month; OS, overall survival.

2024 ASCO ANNUAL MEETING

From East to West, the global launch plan will continue to advance

Brand New Territory to explore the U.S., MENA, LATAM, Japan, India, etc.



# Globalization Has Entered into Substantial Development Stage



## USA

- ✓ HANQUYOU received BLA approval and completed the first commercial shipment to the U.S.
- ✓ FDA accepted Biologics License Application (BLA) for HLX14 (denosumab) and HLX11 (pertuzumab)
- ✓ HLX22 (HER2) combo therapy received Ph 3 MRCT IND approval from the U.S. FDA
- ✓ HLX15 (daratumumab) out-licensed to Dr. Reddy's in the U.S.
- ✓ Songjiang 1<sup>st</sup> Plant obtained GMP certification from the U.S.



## Europe

- ✓ HANSIZHUANG got approval in the EU and entered UK's Innovation Licensing and Access Pathway (ILAP)
- ✓ EMA validated marketing authorization applications (MAA) for HLX14 (denosumab)
- ✓ HLX15 (daratumumab) out-licensed to Dr. Reddy's in 42 European countries and regions
- ✓ HANQUYOU marketed in around 20 countries in Europe, including UK, German, France and etc.
- ✓ Initiating clinical trials in more than 9 countries in the EU
- ✓ Xuhui Site and Songjiang 1<sup>st</sup> Plant obtained GMP certification from the EU



## Japan

- ✓ HANSIZHUANG received approval in Japan for Ph 3 MRCT on first-Line mCRC and completed first patient dosed
- ✓ HLX22 (HER2) combo therapy received Ph 3 MRCT IND approval from PMDA, and successfully holds first in-person investigator meeting in Japan
- ✓ Building in-house regulatory affairs and clinical development in Japan



## Southeast Asia

- ✓ HANSIZHUANG approved to launch in the Indonesia, Cambodia and Thailand; completed the first commercial shipment to Indonesia, being the 1<sup>st</sup> China anti-PD-1 mAb approved for marketing in Southeast Asia
- ✓ HANQUYOU approved to launch in Singapore, Philippines, Thailand, and Myanmar
- ✓ Initiating clinical trials in Southeast Asia, including Singapore, Philippines, Thailand and etc.
- ✓ Xuhui Site passed PIC/S member ANVISA GMP inspection



## Middle East

- ✓ HANQUYOU made the first commercial shipment to Saudi Arabia and became the first Chinese monoclonal antibody to enter the Middle Eastern market
- ✓ Henlius and SVAX forged strategic partnership in MENAT Market. Two parties will establish JV in Saudi Arabia to integrate Henlius' leading capabilities in the R&D, and manufacturing of biologics with SVAX's local expertise in registration, market access, and commercialization



## Latin America

- ✓ HANBEITAI received approval from Bolivia's AGEMED, being Henlius' 4<sup>th</sup> self-developed product approved overseas
- ✓ HANLIKANG received marketing approval in Peru
- ✓ HANQUYOU received marketing approval in mainstream market in South America including Argentina and Brazil
- ✓ Entered out-license agreements with Abbott and Eurofarma to accelerate commercialization in LA market
- ✓ Xuhui Site obtained GMP certification of Brazil

02

# Commercialization

# HANQUYOU (Trastuzumab): China-developed Biosimilar with The Most Approved Countries and Regions



## 2.81B RMB\*

Revenue in 2024

### World-class Quality

- First approved trastuzumab biosimilar in China
- First “China-developed” mAb biosimilar approved in Europe
- Approved in US and Canada, and becomes the “China-developed” biosimilar approved in all three regions of China, Europe, and the U.S.
- Launched in 50+ countries and regions

### Leader in BC area

- Commercial team with ~600 professionals, covering 6 major sales regions and ~3,700 hospitals in China
- Devoted in benefiting every HER2+ patient, continuously build HER2+ ecosystem by providing medical education, medical big data, HER2 testing, innovative payment
- Widely used with ample real world data, benefited over 240,000 patients

### Multiple specifications

- Tailored for HER2-positive breast cancer patients in China with flexible specs to fit with personalized dosage and reduce residual fluid waste
- No preservatives, solution preparation upon product usage to improve safety
- Improved patient medication safety and good practice for drug administration



HERCESSI™ in the U.S.  
Zercepac® in Europe

### Target: HER2

#### Indications:

- Early stage breast cancer
- Metastatic breast cancer
- Metastatic gastric cancer

#### Drug Specifications:

- 150mg/vial (China, EU, US)
- 60mg/vial (China, EU)
- 420mg/vial (EU, US)

# HANQUYOU: Unique Multiple Specifications and International Quality Brings Higher Sales Per Capita

Higher Sales Per Capita Than Domestic Peers

Sales Per Capita\*  
**>5 million RMB**  
2024

Differentiated Strategies To Address Challenges And Opportunities

## The only trastuzumab with two specifications

- 2 specifications were customized to address HER2+ breast cancer patients medical needs in China
- Solved the issue of residual liquid storage, improving drug use safety and honing product differentiation advantage

## Enhance product strengths to build competitive advantages

- Competition has become complicated when other local trastuzumab products launched, as well as trastuzumab SC and pertuzumab-trastuzumab SC included in NRDL
- With advanced planning and preparation, HANQUYOU have expanded coverage, deepened promotional activities, and developed broad market.
- Enhanced the market's recognition of the product advantages on international quality and two specifications

## Brand synergy between HANQUYOU and HANNAIJIA

- Successfully launched HANNAIJIA (neratinib), which will collaborate with HANQUYOU to make Henlius the market leader in HER2+ breast market

\* Sales per capita = Product sales / # of salesforce

# HANNAIJIA (neratinib): Product Synergy to Strengthen HER2+ Breast Cancer Pipeline



## 45M RMB

Revenue in 2024  
(Commercialized for > 3 months)



### Product Synergy

- Neratinib is a tyrosine kinase inhibitor anti-cancer medication used for the treatment of breast cancer. HANNAIJIA used as sequential therapy after completion of HANQUYOU (trastuzumab) that is self-developed by the company to further reduce the risk of recurrence for patients with early-stage HER2-positive breast cancer.
- In August 2024, Henlius reached a strategic cooperation with Convalife Pharmaceuticals. Henlius is granted an exclusive license to commercialize neratinib in China, as well as the exclusive negotiation and conditional licenses in agreed overseas countries and regions.



### Expand Commercial Layout

- Leverage HANQUYOU commercial team's market coverage and customer connection to promote awareness and adoption of extended adjuvant therapy in early BC patients more efficiently and widely, and build HANNAIJIA as the leading brand of neratinib to benefit more Chinese HER2+ patients
- Completed NRDL and tendering platform listing for all provinces in China

**Target: HER1/HER2/HER4**

**Indication:** Extended adjuvant treatment of adult patients with early-stage HER2-positive breast cancer, to follow adjuvant trastuzumab-based therapy

**Drug Strength:** 40mg/180 tablets/bottle

# HANSIZHUANG (Serplulimab): More Indications Approved Covering LC And EC

 **1.31B RMB\***  
Revenue in 2024

## Widespread recognition

- First Approved PD-1 mAb for 1L ES-SCLC
- Non-squamous NSCLC indication approved in China in December 2024
- Feb 2025, approved in EU for treatment for first line extensive SCLC patients, which is the only approved PD-1 monoclonal antibody for ES-SCLC in EU

## Differentiated strategies to grab market share

- Developed differentiated marketing strategies, strengthen leading position in SCLC market, increase market share in NSCLC and EC market, and gain customer trust
- Create more commercial value and expand overseas market with business partners

## Efforts to improve affordability

- Launched patient assistance programs to reduce patients' economic burdens, to improve adherence so as to optimize treatment outcomes
- Covered by Huiminbao (Regional Commercial Health Insurance) in 118 provinces/cities incl. Shanghai, Guangzhou, Shenzhen, Kunming, Fujian Province, Hunan Province, and Shaanxi Province, significantly enhancing its accessibility for patients

## Professional team to drive penetration

- ~600 people commercial team with strong sales experience in oncology and territories allocated
- Established efficient distribution network, strengthening the coverage of DTP pharmacies and infusion centers to maximize patients' accessibility



## Target: PD-1

- Indications:
- sqNSCLC
  - ES-SCLC
  - ESCC
  - nsNSCLC

Drug Specifications: 100mg/10ml/bottle

Hetronify® in Europe  
Zerpidio® in SEA

# HANSIZHUANG: Outstanding Commercialization Efficiency and Differentiated Strategy

First-class  
Commercialization  
Efficiency



**1.31 Billion RMB**  
2024

Sales Per Capita <sup>1</sup>  
**> 2.4 million RMB**  
2024

Differentiation  
Strategy To Tackle  
Challenges And Win  
Opportunities

## Differentiated Strategy Focus on SCLC (15-20% of lung cancer patients)

- Actively tackle with challenges from newly launched SCLC products, and accurately interpret the research results
- Effectively deliver the product's strengths to solidify our leadership in SCLC

## Develop in NSCLC Market

- The approval of non-squamous NSCLC indication expanded HANSIZHUANG's LC market
- Target brain metastatic patients to develop NSCLC potential

## Improve Share in EC

- Promote HANSIZHUANG's efficacy advantage in ESCC patients treated with immunotherapy.
- Deliver the concept of precise treatment for precise benefits to rapidly increase ESCC market share

## Plan for CRC and GC

- Prepare for the upcoming data readout of phase III pivotal studies in CRC and GC patients, and possible indication approval in the future

# HANBEITAI (Bevacizumab): Rapidly Grow In Dual-channel Market



## 197M RMB

Revenue in 2024

65% YoY growth



Acceleration on market access and penetration

### Domestic Market

- Covered by NRDL in 31 provinces, and completed tendering and procurement platform listing in 28 provinces
- Focus on the dual-channel markets, and enhance market recognition to drive sales growth
- Proactively seek for hospitals access in non-dual-channel markets
- Proactively participate in provincial VBP programs

### Overseas market

- Grant Eurofarma exclusive rights on HANBEITAI in Latin American 15 countries, including Mexico, Argentina and Chile and Eurofarma obtains a semi-exclusive right to HANBEITAI in Brazil
- Recently approved in Bolivia, the 4<sup>th</sup> self-developed product of Henlius approved overseas, further promoting the Company's globalization process

Exploration for new medication methods

- The only bevacizumab biosimilars with phase 3 clinical data on metastatic colorectal cancer in China
- Potentially can combine with HANSIZHUANG (anti-PD-1 mAb) to treating multiple tumors in a combo therapy



**Target: VEGF**

**Indications:**

- Metastatic colorectal cancer
- Advanced, metastatic or recurrent non-small cell lung cancer
- Recurrent glioblastoma
- Cervical cancer
- Epithelial ovarian cancer, fallopian tube cancer or primary peritoneal cancer

**Drug Strength:**

100mg/4ml/vial

# HANLIKANG (Rituximab): Strengthen the Market Leader Position

# HANDAYUAN (Adalimumab): Entered Autoimmune Disease Area



**528M RMB**

Revenue recognized by Henlius and licensing income in 2024



**40M RMB**

Revenue recognized by Henlius and licensing income in 2024



**First biosimilar in China**

- Approved in February 2019 as the first approved biosimilar in China, the first approved rituximab biosimilar in China
- New indication approved in February 2022: the first rituximab approved for Rheumatoid Arthritis indication in China



**Solid market leader position**

- Market leader for rituximab in China with speedy share growth since launch. Gained the largest market share for consecutive quarters, 40% in Q4 2024<sup>1</sup>
- Fosun Yaohong<sup>2</sup>, a subsidiary of Fosun Pharma, is responsible for HANLIKANG's commercialization in China



**Improve accessibility to treat more patients**

- Henlius' first autoimmune disease product
- The first phase 3 clinical study of adalimumab biosimilar for psoriasis patients in China
- Establish China's first comprehensive care platform for patients with autoimmune diseases, named "Da En Home" pioneered a collaboration with the "National Clinical Research Center for Skin and Immune Diseases" to launch the "ASSC Standardized Diagnosis and Treatment Program for Ankylosing Spondylitis"



**Work with partners on commercialization**

- Fosun Wanbang<sup>3</sup> is responsible for China local sales of HANDAYUAN. It has a sizable rheumatic immunity business unit with experienced salesforces as well as a mixed line sales team targeting at broad market.

## HANLIKANG

- **Target:** CD20
- **Indication:** NHL, CLL, RA
- **Drug Strength:** 100mg/10ml/vial, 500mg/50ml/vial



## HANDAYUAN

- **Target:** TNF- $\alpha$
- **Indication:** rheumatoid arthritis, ankylosing spondylitis, plaque psoriasis, uveitis, polyarticular juvenile idiopathic arthritis, pediatric plaque psoriasis, Crohn's disease, pediatric Crohn's disease
- **Drug Strength:** 40mg/0.8ml/vial



1. Source: Henlius internal analysis  
 2. Fosun Yaohong, formerly known as Jiangsu Fosun Pharmaceutical Sales Co., Ltd.  
 3. Fosun Wanbang, formerly known as Jiangsu Wanbang (Group) Biopharmaceutical Co., Ltd.

03

# Business Development

# Recent Major Business Development Out-licensing Products



**Abbott Products  
Operations AG.**

**Contract signing date: 2024/12/31**

## **Collaboration Expansion**

**4 key biosimilars and 1 innovative drug  
69 emerging markets in Asia, Latin America and the  
Caribbean, Middle East and Africa**

Collaboration extension from 1 country to more emerging markets.  
Resource integration and strategic cooperation.  
Broadens Access to Multiple Biologics in Emerging Markets



**Dr. Reddy's  
Laboratories SA**

**Contract signing date: 2025/02/06**

## **Out-licensing**

**HLX15 (daratumumab biosimilar)  
Exclusive commercial rights in 42 European countries  
and the United States  
\$33M upfront payment, \$131.6M deal size**

Potential 1<sup>st</sup> biosimilar of a ten-billion product with experienced  
commercial partner, to deliver high-quality and affordable treatment  
options to U.S. and European markets

# In-licensing Focus: Leverage BD to Expand Portfolio into Different Sub-types of Breast Cancer

Breast cancer products



3000+ hospitals



600+ Commercialization team

Type	HER2+	ER+/ HER2-
Perioperative period	<p>Neratinib (HANNAIJIA)</p>	Lasofoxifene (HLX78)
1L	Pertuzumab (HLX11)	
2L/2L+		<p>Lasofoxifene (HLX78)</p> <ul style="list-style-type: none"> <li>• ESR1<sup>mut</sup> BC (2L+)</li> <li>• ER+/HER2- (2L+) BC</li> </ul>

## Lasofoxifene (small molecule SERM\*):

- Lasofoxifene has tissue selectivity to the biological activities of estrogen receptor (ER); ER shows inhibitory activity in breast cancer cells while it can activate bone tissue cells
- Lasofoxifene has positive data from two phase 2 clinical trials for ESR1-mutated breast cancer; PFS reached 13.9 months in combination with Abemaciclib (Eli Lilly's CDK4/6 inhibitor), while historical PFS was ~5 months for Fulvestrant + Abemaciclib
- Lasofoxifene has less side effects such as decreased bone density and menopause symptoms compared with SERDs
- Currently, the Phase 3 MRCT (including China) of lasofoxifene is ongoing

## In-licensing deal snapshot:

- Henlius and Sermonix expanded the partnership of Lasofoxifene. Henlius obtained the additional exclusive rights of Lasofoxifene in Asia including Japan, and will co-develop Lasofoxifene with Sermonix to expedite the development progress in Japan.

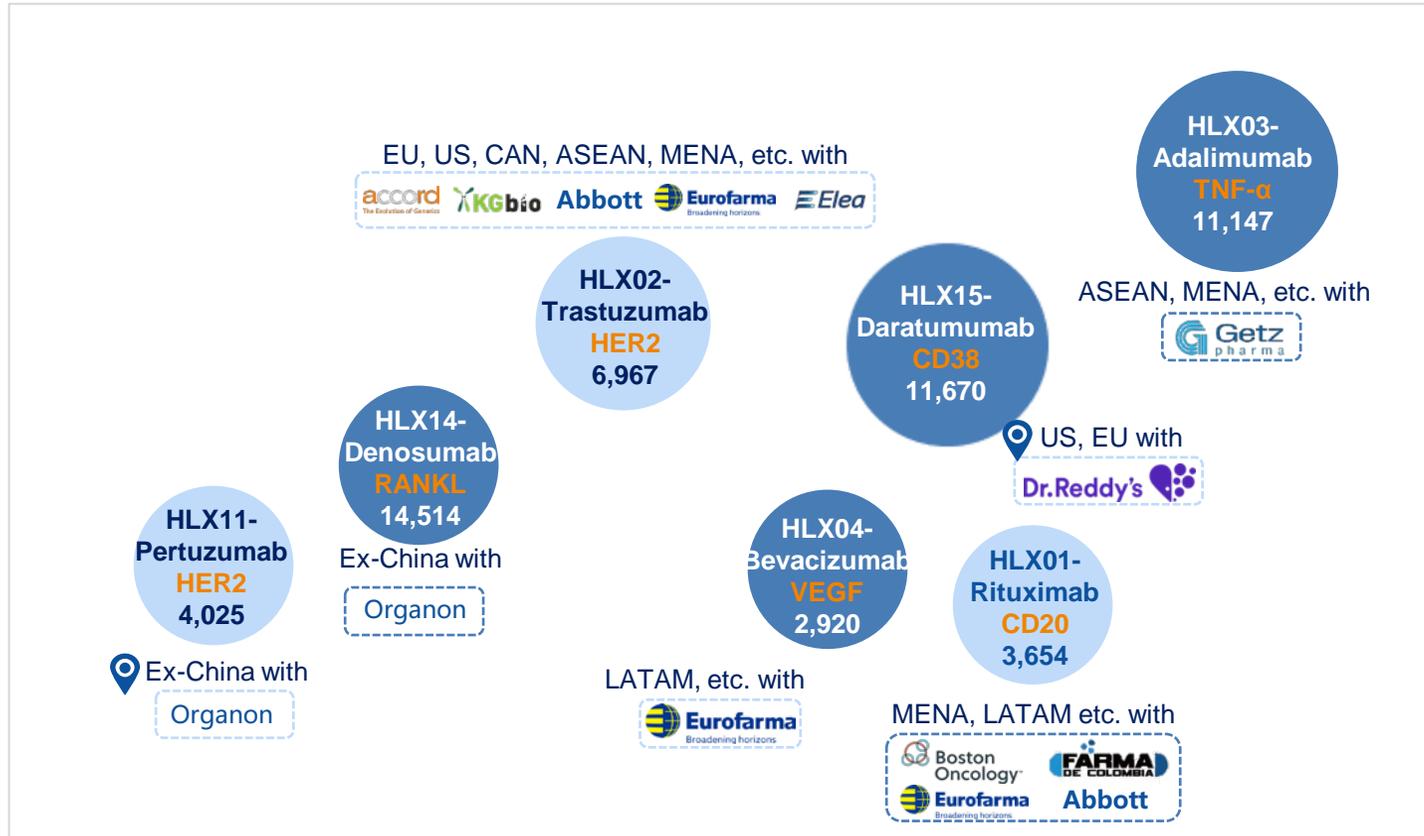
\*SERM: selective ER modulator; SERD: selective ER degraders

# Out-licensing Focus: Henlius' International Quality Biosimilars Scale up across the Globe

## Market Size of Originators and Marketed Biosimilars

### Biosimilars with existing out-licensing partners

Global sales in 2024 (M USD)

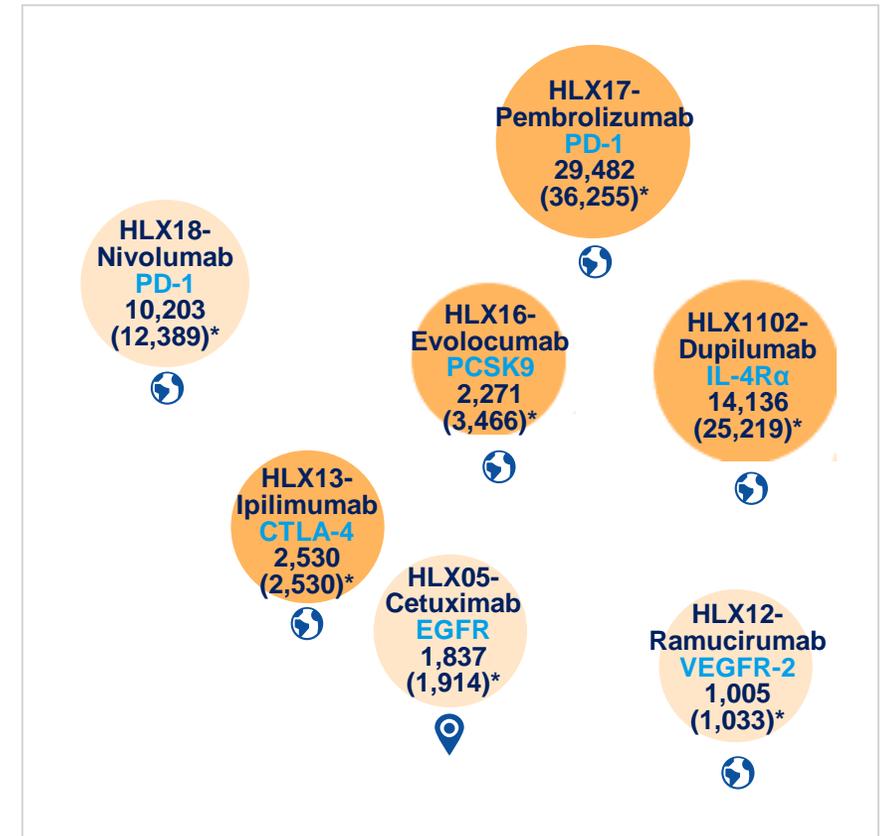


Potentially first biosimilar in EU and the U.S.

Global potentially first biosimilar

### Biosimilars to be out-licensed ex-China

Global sales in 2024 (M USD)



()\*: Potential peak sales from Global Data

04

# Research & Development

# Product Portfolio and Pipeline

Pre-IND / IND	Phase 1	Phase 2	Phase 3	NDA	In-Market
HLX79 <sup>(1)</sup> Sialidase Fc Fusion Protein Active Glomerular Diseases	HLX6018 GARP/TGF-β1 IPF	HLX10 <sup>(5)</sup> (serplulimab) + HLX07 <sup>(6)</sup> PD-1+EGFR HNSCC, NPC, sqNSCLC, etc.	HLX10 <sup>(5)</sup> (serplulimab) + Chemo PD-1 ES-SCLC 1L 	HLX14 (denosumab) <sup>(12)</sup> RANKL Osteoporosis, etc.   	HANSIZHUANG (serplulimab) <sup>(5)</sup>  PD-1 sqNSCLC, ES-SCLC, ESCC, nsNSCLC
HLX17 (pembrolizumab) PD-1 NSCLC, TNBC, etc.	HLX42 <sup>(2)</sup> EGFR ADC Solid tumours	HLX10 <sup>(5)</sup> (serplulimab) + HLX26 + Chemo PD-1+LAG-3 NSCLC 1L	HLX10 <sup>(5)</sup> (serplulimab) + Chemo PD-1 Neo/adjuvant treatment for GC	HLX11 (pertuzumab) <sup>(13)</sup> HER2 BC  	HANLIKANG (rituximab) <sup>(14)</sup>  CD20 NHL, CLL, RA <sup>(15)</sup>
HLX316 Fusion protein Solid tumor	HLX05 (cetuximab) <sup>(3)</sup> EGFR mCRC, HNSCC	HLX07 <sup>(6)</sup> EGFR Solid tumors (cSCC)	HLX10 <sup>(5)</sup> (serplulimab) + Chemo + Radio PD-1 LS-SCLC 1L 		HANQUYOU (trastuzumab) <sup>(16)</sup>  HER2 BC, mGC
HLX105 Fusion protein Solid tumor	HLX15 (daratumumab) <sup>(4)</sup> CD38 Multiple myeloma	HLX208 <sup>(7)</sup> BRAF V600E LCH/ECD, MEL, NSCLC, etc.	HLX10 <sup>(5)</sup> (serplulimab) + bevacizumab + Chemo PD-1+VEGF mCRC 1L 		HANDAYUAN (adalimumab) <sup>(17)</sup> TNF-α RA, AS, Ps, UV, pJIA, pediatric Ps, CD, pediatric CD
HLX97 KAT6A/B ERα+ Breast Cancer	HLX13 (ipilimumab) CTLA-4 Melanoma, HCC, etc.	HLX208 <sup>(7)</sup> + HLX10 <sup>(5)</sup> (serplulimab) BRAF V600E + PD-1 NSCLC	HLX04-O <sup>(9)</sup> VEGF Wet AMD 		HANBEITAI (bevacizumab) <sup>(18)</sup>  VEGF mCRC, advanced, metastatic or recurrent NSCLC, GBM, etc.
HLX48 Bispecific ADC NSCLC, CRC		HLX53 + HLX10 <sup>(5)</sup> (serplulimab) + bevacizumab TIGIT + PD-1 + VEGF HCC	HLX22 <sup>(10)</sup> + trastuzumab + Chemo HER2+HER2 GC 		HANNAIJIA (neratinib) <sup>(19)</sup> HER1/HER2/HER4 Extended adjuvant treatment of BC
HLX41 ADC BC		HLX43 <sup>(8)</sup> PD-L1 ADC Solid tumours	HLX78 (lasofoxifene) <sup>(11)</sup> SERM BC 		
HLX37 PD-L1 x VEGF Bispecific Solid tumours					
HLX3901 Trispecific SCLC					
HLX3902 Trispecific PCa					

(1) Exclusive license obtained in China. Phase 1/2 conducting in the U.S. (2) IND approvals obtained in China/the U.S. and granted FDA Fast Track Designation. (3) Business partner: Shanghai Jingze. (4) Business partner: Dr. Reddy's, etc. (5) Approved in China, the EU and several SEA countries. trade name: Hetronify® in Europe. partners: KGBio/Fosun Pharma/Intas. (6) IND approvals obtained in China/the U.S. (7) Exclusive license obtained in China. (8) IND approvals obtained in China/the U.S./Japan. (9) IND approvals obtained in China/Australia/the U.S./Singapore/EU countries, etc. Business partner: Essex. (10) IND approvals obtained in China/the U.S./Japan. (11) Exclusive license obtained in China. Phase 3 MRCT enrolling globally. IND approval obtained in China. (12) Marketing applications under review in the EU and the U.S. (13) Marketing applications under review in China and the U.S. Business partner: Organon. (14) Approved in countries such as China and Peru. The first biosimilar approved in China. Business partners: Fosun Pharma/Farma de Colombia/Eurofarma/Abbott/Boston Oncology. (15) The first rituximab approved for the indication in China. (16) Approved in 50+ countries, including China, U.S., the UK, Germany, France and Australia, trade name registered in U.S.: HERCESSI™. trade name registered in Europe: Zerocpac®. Business partners: Accord/Cipla/ Jacobson/ Elea/ Eurofarma/ Abbott/ KGBio/ Getz. (17) Business partners: Wanbang/Getz Pharma. (18) Business partner: Eurofarma. (19) Exclusive license obtained in China.

 Innovative mAb	 Innovative fusion protein	 Biosimilar mAb
 Innovative ADC	 small molecule	 Innovative multi-specific antibody
 Bridging study in U.S.	 BLA under FDA review	 MAA under EMA review
 Global MRCT	 Global MRCT	

# Clinical Pipeline Milestones: 2024 Review

2024

  
NDA/BLA/MAA  
Submission

**HLX01 HANLIKANG**  
NHL, CLL, RA (LATAM)

**HLX04 HANBEITAI**  
mCRC, advanced, metastatic or recurrent NSCLC, GBM, etc. (Uruguay)

**HLX10**  
ES-SCLC<sup>2</sup>  
1L (the Philippines, UK, Swit, Vietnam, India)

**HLX10**  
sqNSCLC  
1L (Indonesia, Thailand, Cambodia)

**HLX11**  
Breast cancer  
Neoadjuvant therapy (China, US)

**HLX14**  
PMOP<sup>1</sup>, etc.  
(EU & Canada & US)

  
NDA/BLA/MAA  
Approval

**HLX10**  
ES-SCLC<sup>2</sup>  
1L (EU, Cambodia, Thailand)

**HLX10**  
nsqSCLC  
1L (China)

**HANNAIJIA**  
HER1/HER2/HER4  
Extended adjuvant treatment of breast cancer (China)

**HLX01 HANLIKANG**  
NHL, CLL, RA  
(Nicaragua, Bolivia, Peru)

**HLX02 HANQUYOU**  
Breast cancer, mGC  
(US, Canada, Central and Southeast Asian, LATAM)

**HLX03 HANDAYUAN**  
pJIA, pediatric Ps, CD, pediatric CD  
(China)

**HLX04 HANBEITAI**  
mCRC, advanced, metastatic or recurrent NSCLC, GBM, etc.  
(Bolivia)

  
Key Clinical Data  
Readouts

**HLX10+HLX04**  
mCRC<sup>3</sup>  
1L (PoC)

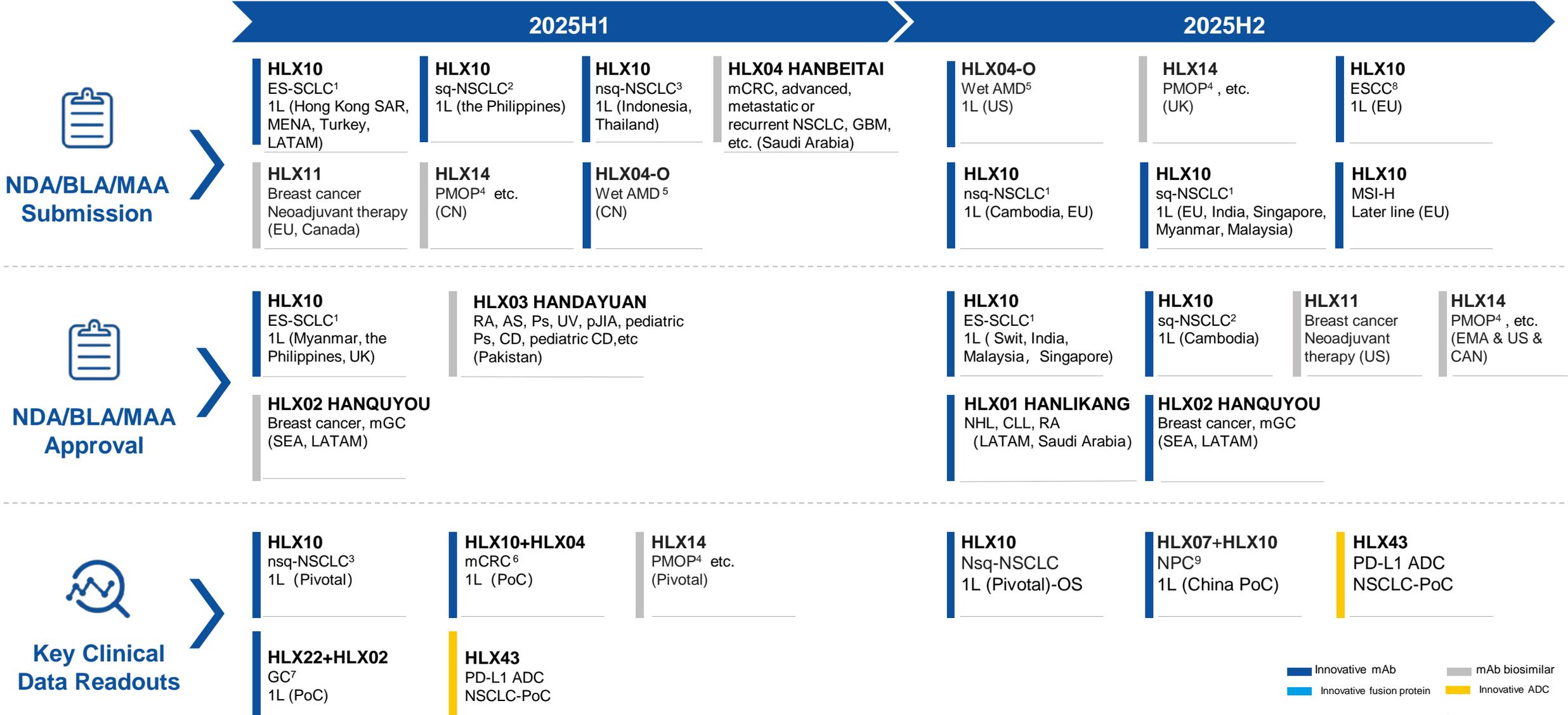
**HLX22+HLX02**  
GC<sup>4</sup>  
1L (PoC)

**HLX10**  
ES-SCLC  
1L (Follow-up&QoL)

**HLX10+HLX07**  
NPC  
1L (CN PoC)

1. Postmenopausal osteoporosis
2. Extensive stage small cell lung cancer
3. Metastatic colorectal cancer
4. Gastric cancer

# Clinical Pipeline Milestones: Expected in 2025



■ Innovative mAb    ■ mAb biosimilar  
■ Innovative fusion protein    ■ Innovative ADC

1. Extensive stage small cell lung cancer  
 2. Squamous non-small cell lung cancer  
 3. Non-squamous non-small cell lung cancer  
 4. Postmenopausal osteoporosis  
 5. Age-related macular degeneration  
 6. Metastatic colorectal cancer  
 7. Gastric cancer  
 8. Esophageal squamous cell carcinoma  
 9. Nasopharyngeal carcinoma

The Company's internal planning time is subject to the actual situation, and shareholders and potential investors of the Company are advised to exercise caution when trading the Company's shares.

# Clinical Data of HLX10-015-CRC301

Data cut-off date: 2024/6/30; median follow-up duration: 31.0 months

- The latest clinical data of the phase 2/3 results (HLX10-015-CRC301) of HANSIZHUANG (HLX10, serplulimab)+HANBEITAI (HLX04, bevacizumab)+XELOX for 1L mCRC (metastatic colorectal cancer) treatment was presented in posters at the 2025 ASCO GI
- The results of this study demonstrated that serplulimab plus bevacizumab and XELOX was safe and improved PFS as well as other efficacy endpoints compared to placebo plus bevacizumab and XELOX in patients with mCRC. The probability of  $\geq$  Grade 3 TRAEs was similar between the two treatment groups, with the most common Grade 3 and above TRAEs being neutrophil count decreased and platelet count decreased.
- Serplulimab + bevacizumab + XELOX warrants further large-scale investigation and could be a new first-line treatment option for mCRC patients. The Phase 3 part of this study in mCRC patients is currently ongoing (NCT04547166) to further evaluate serplulimab combined with bevacizumab and XELOX as a first-line treatment regimen for mCRC.

Product	Clinical Trial	Regimen	Sample Size	mPFS (months)	mOS (months)	mDOR (months)
Serplulimab +SOC	<b>HLX10-015-CRC301</b> (Ph2) <b>Data cutoff: June 30, 2024, median follow up: 31.0 months</b>	A: Serplulimab + bev + XELOX	ITT population 55 vs 57	<b>16.6</b> vs 10.7, p=0.17 HR=0.66 (95% CI, 0.37-1.19)	NA	<b>17.7</b> vs 11.3, p=0.041 HR=0.45 (95% CI, 0.20-0.98)
		B: Bev + XELOX	MSS subgroup 40 vs 50	<b>16.8</b> vs 10.1, p= 0.21 HR=0.65 (95% CI, 0.33-1.29)	<b>23.5</b> vs 20.2, p=0.40 HR=0.79 (95% CI, 0.45-1.38)	<b>19.4</b> vs 8.3, p=0.045 HR=0.39 (95% CI, 0.15-1.00)
Atezolizumab +SOC	<b>AtezoTRIBE<sup>1</sup></b> (Ph2)	A: Atezolizumab + bev + FOLFOXIRI	ITT population 145 vs 73	13.1 vs 11.5 HR=0.71, p=0.015	33 vs 27.2 HR=0.81, p=0.136	NA
		B: Bev + FOLFOXIRI	pMMR subgroup 134 vs 67	13.0 vs 11.5 HR=0.79, p=0.073	30.8 vs 26.9 HR=0.83, p=0.172	NA
Nivolumab +SOC	<b>CheckMate 9X8<sup>2</sup></b> (Ph2)	A: Nivolumab + bev + mFOLFOX6 B: Bev + mFOLFOX6	ITT population 127 vs 68	11.9 vs 11.9 HR=0.81, p=0.3 ( <b>Negative</b> )	29.2 vs NR HR=1.03, p NA	12.9 vs 9.3 HR NA, p NA
Bevacizumab (SOC)	Bev plus FOLFIRI for mCRC <sup>3</sup> (Ph3)	A: Bev + FOLFIRI B: FOLFIRI	ITT population 402 vs 411	10.6 vs 6.2 HR=0.54, p<0.001	20.3 vs 15.6 HR=0.66, p<0.001	10.4 vs 7.1 HR=0.62, p=0.001
HLX04 (bev biosimilar, SOC)	Similarity study (Ph3) <sup>4</sup>	A: HLX04 + mFOLFOX6 or XELOX B: Bev + mFOLFOX6 or XELOX	ITT population 338 vs 337	11.4 vs 12.4 HR=1.07 (95% CI, 0.83-1.37)	20.7 vs 22.4 HR=1.03 (95%CI, 0.84-1.25) <sup>5</sup>	11.1 vs 12.3 HR=1.14 (95% CI, 0.80-1.61)

<sup>a</sup> IFL, irinotecan, bolus fluorouracil, and leucovorin; bev, bevacizumab.

1. J Clin Oncol 41, 2023 (suppl 16; abstr 3500) . 2. Lenz, H-J. et al. J Clin Oncol 40, 4\_suppl.008 (2022). 3. Hurwitz, H. et al. N Engl J Med 350, 2335-2342 (2004).

# Serplulimab: Targeting Differentiated Indications



## Gastric Cancer (GC)

Neoadjuvant treatment in combination with Chemotherapy / Adjuvant with serplulimab only

- 1 According to the baseline data analysis of 649 subjects in the Checkmate, 60% advanced GC patients had CPS  $\geq$  5. The trial design had focused on PD-L1-positive patients (CPS  $\geq$  5) from the very beginning. Serplulimab aims to be **the world-leading and China's only perioperative I/O treatment for GC**
- 2 Around 2/3 of 400,000 new GC cases in China every year<sup>1,2</sup> were suitable for perioperative treatments. With the increasing penetration of gastroscopy examinations, more GC cases will be detected
- 3 Currently, the median EFS of perioperative SoC for GC is ~3 years. It is estimated that most patients can be treated with serplulimab for up to 20 treatment cycles (the maximum duration set by the trial protocol) if the trial succeeds



## Metastatic Colorectal Cancer (mCRC)

Serplulimab combined with bevacizumab & XELOX

- 1 Colorectal cancer (CRC) is one of the most common malignant cancers worldwide. According to relevant data, there were approximately over 1.9 million new cases globally in 2022, with more than 900,000 deaths<sup>3</sup>
- 2 Phase 3 MRCT, clinical layout covers mainland China, Japan, and Indonesia; the first patient has been dosed in May 2024, and as of February 2025, 558 patients have entered the clinical trial
- 3 At present, bevacizumab combined with chemotherapy is the standard first-line treatment for advanced colorectal cancer, and PD-1 has only been approved for first-line treatment of MSI-H colorectal cancer. If the trial is successful, Serplulimab is expected to become **the world's first PD-1 monoclonal antibody for the treatment of non-MSI-H advanced colorectal cancer**

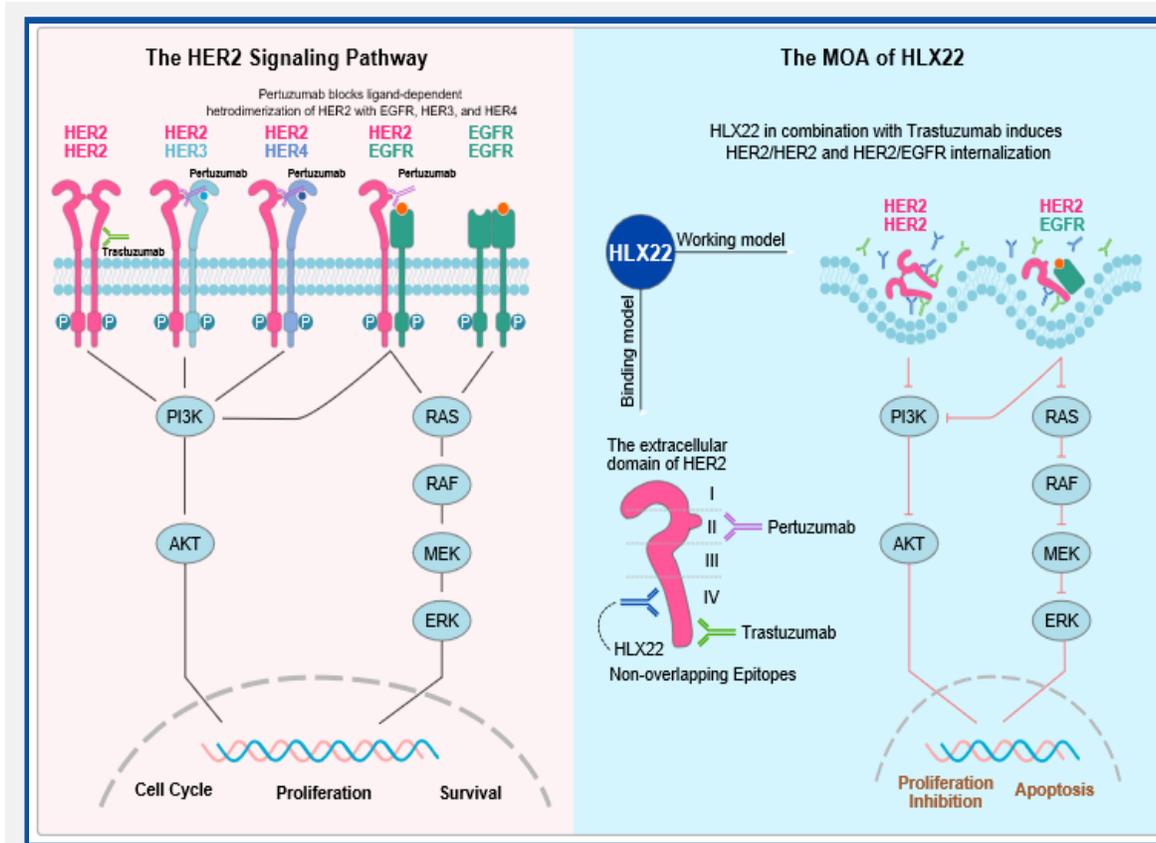
1. Zheng RS et al. 2016 China cancer prevalence analysis. Chinese Journal of Oncology, 2023, 45(3): 212-220. DOI: 10.3760/cma.j.cn112152-20220922-00647.

2. Strong, Vivian E et al. "Differences in gastric cancer survival between the U.S. and China." Journal of surgical oncology vol. 112,1 (2015): 31-7. doi:10.1002/jso.23940.

3. Bray, Freddie CA Cancer J Clin. 2024;74(3):229-263.

# HLX22: Potential to Change the SOC of 1L GC

## HLX22 (HER2)



- HLX22 targets at **different** epitopes within domain IV of Her2, the results demonstrated that HLX22 and trastuzumab (HLX02) simultaneously bind to HER2 subdomain IV, which subsequently facilitate the endocytosis of both HER2/HER2 homodimers and HER2/EGFR heterodimers, resulting in a 40-80% increase in HER2 endocytosis.
- PDx data shows HLX22 & trastuzumab combo has more advantages than trastuzumab & Pertuzumab combo in GC

- Current SOC of 1L mGC/GJC treatment trastuzumab + chemo approved in 2010: mPFS 6.7 months, mOS 13.8 months, and mDoR 6.9 months<sup>1</sup>
- Phase 2 study data shows HLX22 has clear benefits for patients, leading to great potential to change the SOC

- HLX22 has shown better efficacy and safety
- Efficacy will not be affected by the expression level of PD-L1
- No observation of severe diarrhea which was observed in other clinical trials of 1L HER2+ GC

- Phase 2 clinical data of HLX22-GC-201 has been presented in [2024 ESMO GI](#) and [2025 ASCO GI](#)
- HLX22 dual targeting of HER2 MOA and its research result have been published in *Journal of Translational Medicine*

1. Bang, Yung-Jue et al. "Trastuzumab in combination with chemotherapy versus chemotherapy alone for treatment of HER2-positive advanced gastric or gastro-oesophageal junction cancer (ToGA): a phase 3, open-label, randomised controlled trial." *Lancet* (London, England) vol. 376,9742 (2010): 687-97. doi: 10.1016/S0140-6736 (10) 61121-X; 2. Janjigian, Yelena Y et al. "The KEYNOTE-811 trial of dual PD-1 and HER2 blockade in HER2-positive gastric cancer." *Nature* vol. 600, 7890 (2021): 727-730. doi: 10.1038/s41586-021-04161-3; Zanidatamab (zani), a HER2-targeted bispecific antibody, in combination with chemotherapy (chemo) and tislelizumab (TIS) as first-line (1L) therapy for patients (pts) with advanced HER2-positive gastric/gastroesophageal junction adenocarcinoma (G/GEJC): Preliminary results from a phase 1b/2 study. Keun Wook Lee, Li-Yuan Bai, et al *Journal of Clinical Oncology* 2022 40: 16\_suppl, 4032-4032

# Clinical Data of HLX22-GC-201

Data cut-off date: 2024/6/30; median follow-up duration: 20.3 months for HLX22 group and 24.0 months for placebo group

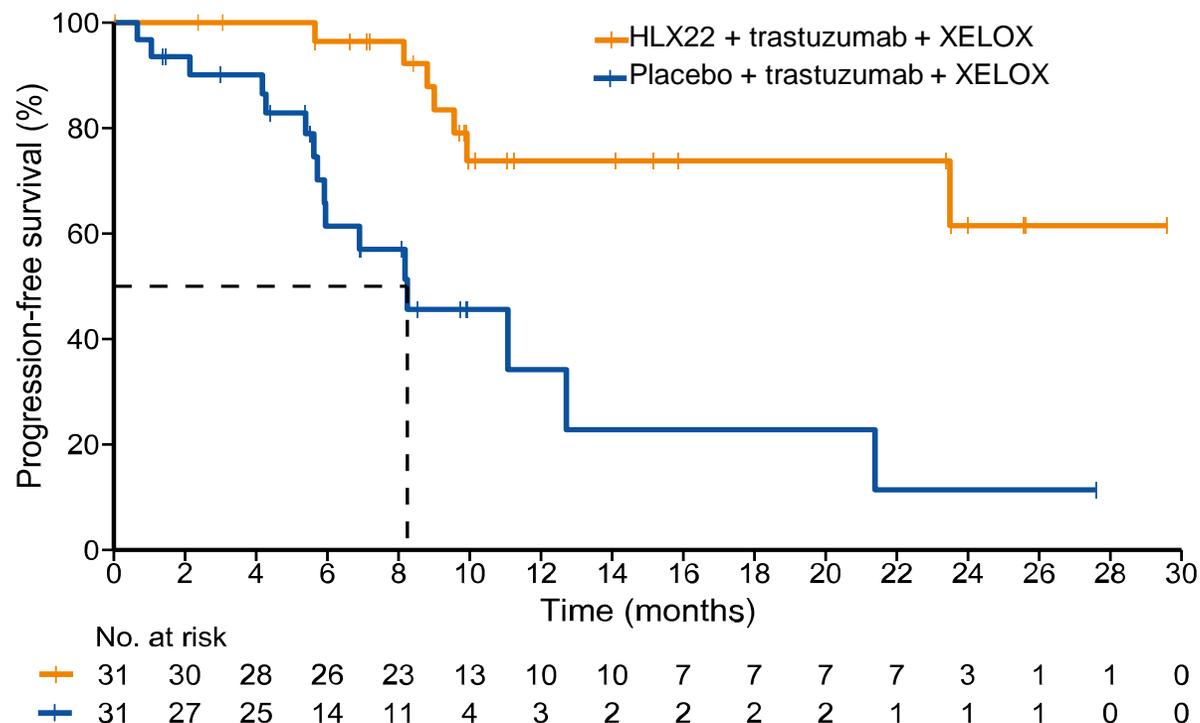
- The clinical data of Phase 2 study (HLX22-GC-201) of HLX22 (an innovative anti-HER2 mAb)+HANQUYOU (HLX02, trastuzumab)+XELOX for the 1L HER2-positive gastric/gastroesophageal junction (G/GEJ) cancer was presented in the posters at 2024 ESMO GI
- The results of this study demonstrated that adding HLX22 to trastuzumab + XELOX was safe and improved survival and antitumor response in patients with HER2-positive G/GEJ cancer in the first-line treatment. HLX22+HLX02+XELOX, as the 1L treatment for HER2-positive G/GEJ cancer also shown good tolerance, with the most common treatment-related adverse events (AEs) of neutrophil and leukocyte count decreased and anaemia
- HLX22+ trastuzumab +XELOX warrants further large-scale investigation and could be a new 1L treatment option for HER2-positive G/GEJ cancers. Currently, no similar HER2 dual-target treatment for HER2-positive GC has been approved globally

Product	Clinical Trial	Regimen	Sample Size	mPFS (months)	mOS (months)	mDOR (months)
HLX22	<b>HLX22-GC-201</b> (Ph 2) <b>Data cutoff: June 30, 2024, median follow up: 20.3 months</b>	A: HLX22 (15 mg/kg)+trastuzumab+chemo (XELOX) B: Placebo+Trastuzumab+chemo (XELOX)	ITT population 31 vs 31	NR vs 8.3 <b>HR=0.2</b> (95% CI, 0.06–0.45)	NR vs 22.0 HR=0.5 (95% CI, 0.20–1.21)	NR vs 9.7 <b>HR=0.1</b> (95% CI, 0.04–0.41)
Pembrolizumab	<b>KEYNOTE-811<sup>1</sup></b> (Ph 3) <b>EMA:</b> approved for PD-L1+ subgroup; <b>FDA:</b> expedited approved for PD-L1+ subgroup	A: Pembrolizumab+trastuzumab+chemo (CF/XELOX) B: Trastuzumab+chemo (CF/XELOX)	ITT population 350 vs 348	10.0 vs 8.1 HR=0.73 (95%CI 0.61-0.87)	20.0 vs 16.8 HR=0.80 p=0.0040	11.3 vs 9.5 HR NA, p NA
			PD-L1+ subgroup 298 vs 296	10.9 vs 7.3 HR=0.72 (95%CI 0.60-0.87)	20.1 vs 15.7 HR=0.79 (95%CI 0.66-0.95)	11.3 vs 9.5 HR NA, p NA
			PD-L1- subgroup 52 vs 52	9.5 vs 9.5 HR=0.99 (95%CI 0.62-1.56)	18.2 vs 20.4 HR=1.10 (95%CI 0.72-1.68)	NA
Trastuzumab	<b>ToGA<sup>2,3</sup></b> (Ph 3)	A: Trastuzumab+chemo (CF/CX) B: chemo (CF/CX)	Adjusted ITT population 294 vs 290	6.7 vs 5.5 HR=0.71, p = 0.0002	13.8 vs 11.1 HR=0.74, p=0.0046	6.9 vs 4.8 HR=0.54, p <0.0001
			China subgroup 36 vs 48	6.8 vs 5.5 HR=0.69, p NA	12.6 vs 9.7 HR=0.72, p <0.05	5.8 vs 4.5 HR=0.56, p NA
Pertuzumab	<b>JACOB<sup>4</sup></b> (Ph 3 <b>failed</b> )	A: Pertuzumab+trastuzumab+chemo (CF/CX) B: Trastuzumab+chemo (CF/CX)	ITT population 388 vs 392	8.5 vs 7.0 HR=0.73, p = 0.0001	17.5 vs 14.2 HR=0.84, p=0.057 ( <b>failed</b> )	10.2 vs 8.4 HR NA, p NA

CF, cisplatin and fluorouracil; CX, cisplatin and capecitabine; DOR, duration of response; G/GEJ, gastric/gastroesophageal junction; HR, hazard ratio; IA, interim analysis; ITT, intention-to-treat; m, median; NA, not available; NR, not reached; OS, overall survival; Pembro, pembrolizumab; PFS, progression-free survival; Tras, trastuzumab; XELOX, capecitabine and oxaliplatin. 1. Y.Y. Janjigian, et al. ESMO Congress 2024. 2. Bang Y-J, et al. Lancet 2010; 376 (9742): 687-97. 3. Shen L, et al. Zhonghua Zhong Liu Za Zhi 2013; 35 (4): 295-300. 4. Tabernero J, et al. Lancet Oncol 2018; 19 (10): 1372-1384.

# HLX22-GC-201 Primary Endpoint: PFS by IRRC per RECIST 1.1 and OS

June 30, 2024 (data cutoff), median follow-up 20.3 months for HLX22 group and 24.0 months for placebo group

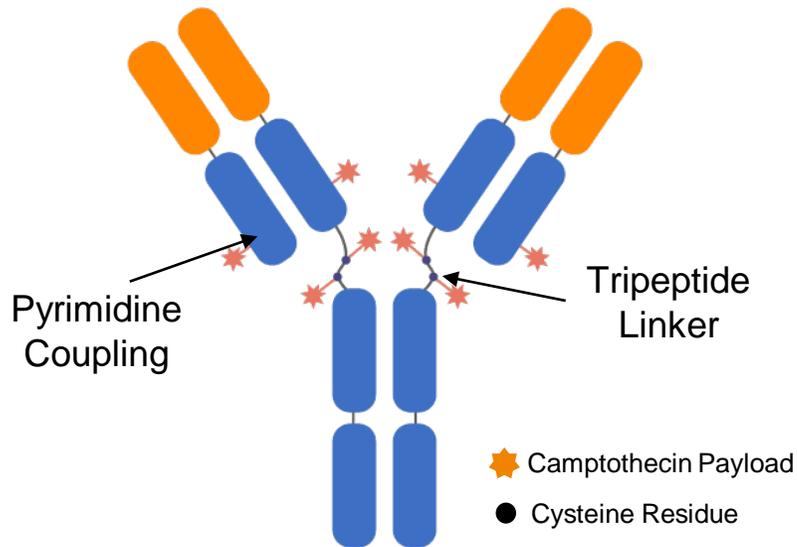


	HLX22 group (n = 31)	Placebo group (n = 31)
mPFS, months (95% CI)	NR (23.5–NE)	8.3 (5.7–12.7)
HR (95% CI)	<b>0.2</b> (0.06–0.45)	p<0.0001
12-month PFS rate (95% CI)	73.8 (50.3–87.4)	34.2 (12.0–58.1)
24-month PFS rate (95% CI)	61.5 (30.4–82.0)	11.4 (0.8–38.1)
mOS, months (95% CI)	NR (23.5–NE)	22.0 (10.6–NE)
HR (95% CI)	<b>0.5</b> (0.20–1.21)	p=0.1174

CI, confidence interval. HR, hazard ratio. NE, not evaluable. NR, not reached. PFS, progression-free survival. XELOX, oxaliplatin+capecitabine.

# HLX43, an anti-PD-L1 ADC with TMALIN\* linker and TOPO1i Payload

## Anti-PD-L1 mAb



## Key Attribute

- High binding affinity and an internalizable humanized IgG1 with clinically proved safety, IP owned
- Cleavable and **TME activable tripeptide linker**
- Highly stable linker in circulating blood
- Highly potent and low systemic half-life payload
- Toxin with strong bystander killing effects
- **IND** granted by the U.S. **FDA & CDE**
- **Mono Phase Ph2** PoCs is ongoing
- **HLX43 combo with HLX10 Phase 1b/2** IND



## Development Strategy

- PD-L1, express high in broad range of tumor and low in normal tissue, a not crowded but attractive ADC target
- The MediLink TMALIN distinguishes this type ADC from others by the unique toxin release mechanism, protease cleavable linker
- Highly potent **Topoisomerase 1 inhibitor** payload with short  $t_{1/2}$  and strong bystander killing effects
- Address unmet medical needs from patients with **PD-(L)1 resistance** or **PD-(L)1 low response**



Target: PD-L1



Modality: ADC



DAR:8

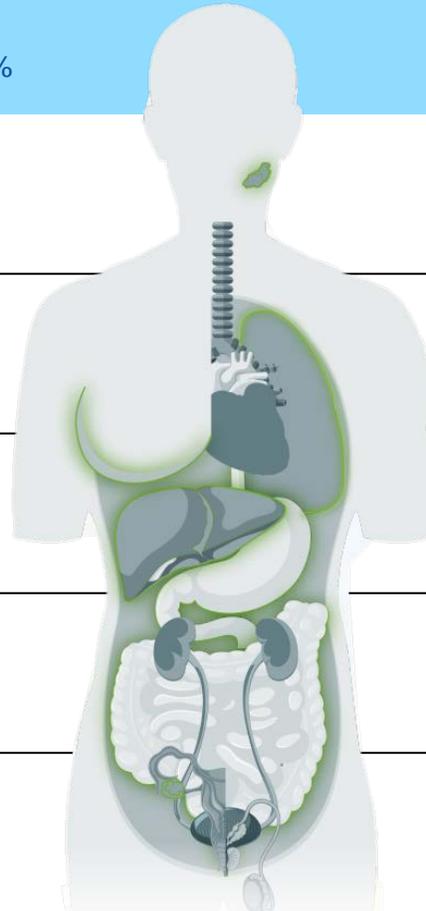
## Indications in Phase 1b/2:

- NSCLC
- HCC
- NPC
- HNSCC
- CC
- ESCC
- CRC
- GC

# PD-L1 is a Trans-membrane Protein and an Attractive Target for ADC

Expression observed in a broad spectrum of solid tumors  
 Normal tissue expression low | Limited primarily to immune cell

Epidemiology Inc. cases per year in CH/Global	Target Indication of <b>HLX43</b>	PDL1 Expression in Solid Tumors		Target Indication of <b>HLX43</b>	Epidemiology Inc. cases per year in CH/Global
		TPS >1%   ≥50%	CPS >1%		
1000k/2000k	✓	<b>Lung (NSCLC)</b> 71%   37%		<b>Gastric</b> 84%	470k/1140k
510k/1900k	✓	<b>Colon</b> 31%   5%		<b>Esophageal</b> 86%	320k/600k
70k/330k	✓	<b>Ovarian</b> 37%   4%		<b>Hepatocellular</b> ~20%	300k/799k
134k/1410k		<b>Prostate</b> 34%   10%		<b>Cervical</b> 60~70%	160k/690k
9k/330k		<b>Melanoma</b> 56%   14%		<b>HNSCC</b> ~80%	110k/800k



# HLX43 (PD-L1 ADC) Presented Excellent Preclinical Efficacy Data and Entered into Clinical Phase 2

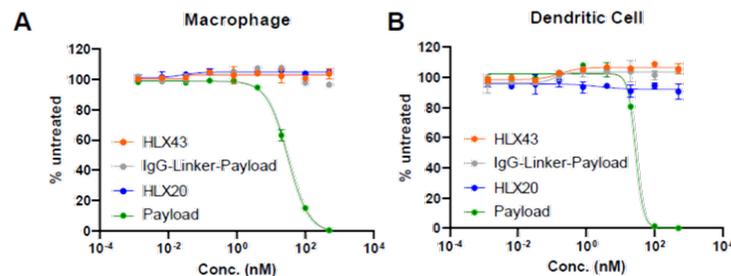
## Preclinical Results

- HLX43 shows no immunotoxicity towards PD-L1+ human APCs
- HLX43 exhibits excellent bystander effect
- In *in vivo* efficacy studies, HLX43 induced tumor regression in multiple PD-L1-positive CDX & PDX models, and was well tolerated, with no major changes in body weight of administered mice compared to control animals, across all dosing groups
  - In MDA-MB-231 model, weekly administration of HLX43 for three times induced significant tumor regression, superior over anti-PD-L1-GGFG-Dxd and anti-PD-L1-vc-MMAE at equivalent doses
  - In NSCLC PDX model, weekly administration of HLX43 at 8mg/kg for three times induced significant tumor regression, and the treatment group still had durable response in lesions after stopping dosing
  - HLX43 also induced significant tumor regression in HCC PDX model with (IHC+) or without (IHC-) PD-L1 expression, meanwhile showed strong synergy with anti-VEGF antibody
- Toxicity studies in mice and cynomolgus monkeys also demonstrated that HLX43 was well tolerated

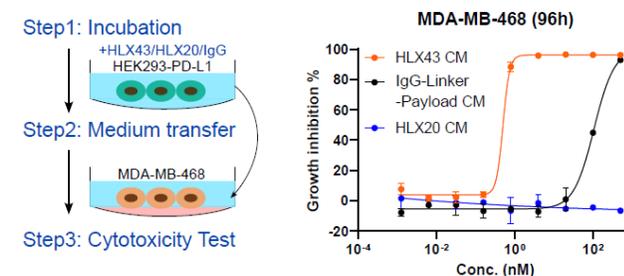
## Regulatory and Clinical Trial Progress

- IND of HLX43 for the treatment of advanced/metastatic solid tumors has been approved by China NMPA and the US FDA on Oct. and Nov., 2023, respectively.
- IND for a phase 1b/2 clinical trial of HLX43 has been approved by the China NMPA on Dec. 2024, for monotherapy or combination therapy to treat patients with advanced/metastatic solid tumours.
- IND for a phase 1b/2 clinical trial of HLX43, in combination with the company's independently developed innovative anti-PD-1 monoclonal antibody (mAb) HANSIZHUANG (serplulimab injection), has been approved by the China NMPA on Jan. 2025, for the treatment of advanced/metastatic solid tumours.
- The first patient has been dosed in clinical study of HLX43 for the treatment of recurrent/metastatic esophageal squamous cell carcinoma (ESCC) in Feb. 2025; the first patient has been dosed in clinical study of HLX43 for the treatment of recurrent/metastatic cervical cancer (CC) in Feb. 2025; the first patient has been dosed in clinical study of HLX43 for the treatment of recurrent/metastatic hepatocellular carcinoma (HCC) in Mar. 2025

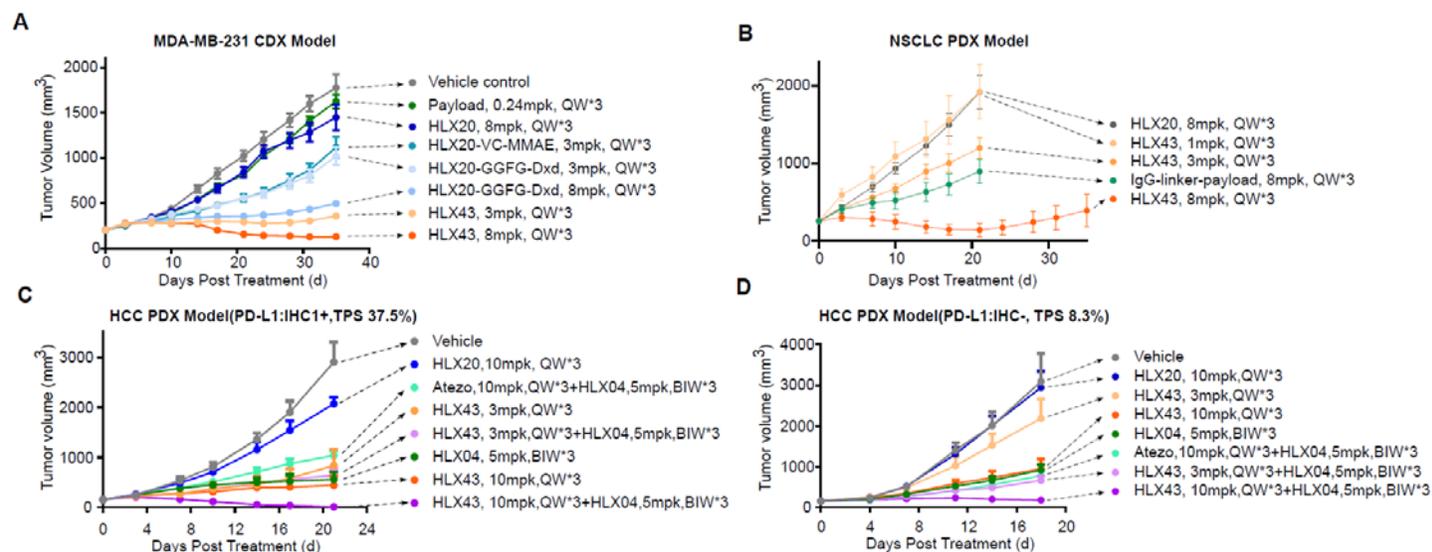
### HLX43 Shows No Immunotoxicity Towards PD-L1+ Human APCs



### HLX43 Exhibits Excellent Bystander Effect

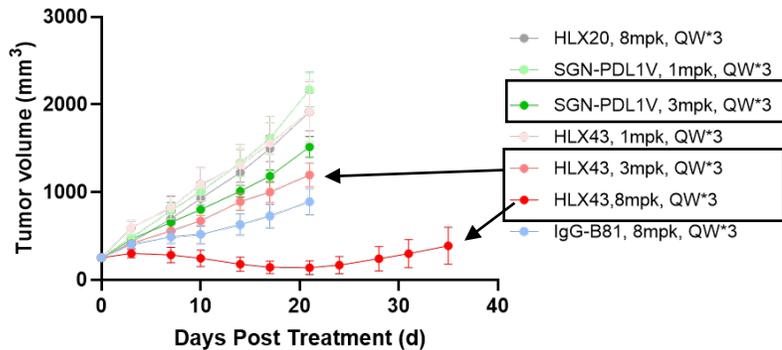


### HLX43 Exhibits Excellent Anti-tumor Efficacy *In vivo*



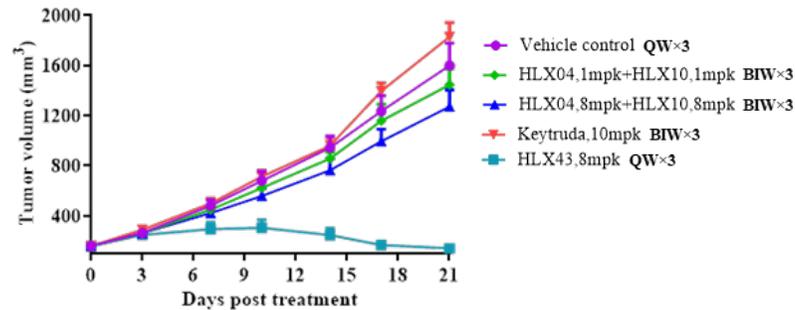
# Anti-tumor Efficacy of HLX43 in PDX & CDX

**1 LU6437 PDX model**  
(sqNSCLC PD-L1 IHC 2+, HLX10 resistant)



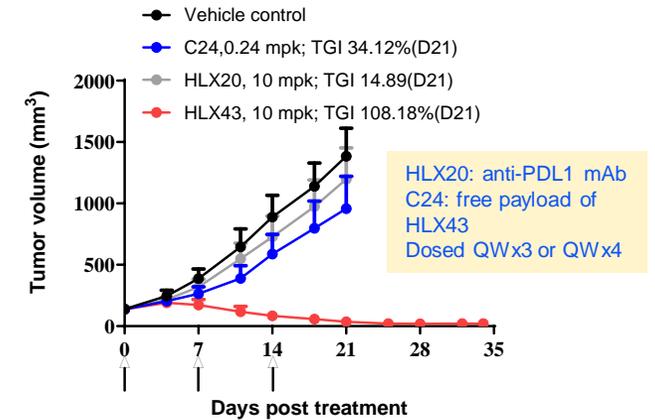
Notes: (i) HLX20, Henlius in-house anti-PDL1 mAb, the antibody of HLX43; (ii) SGN-PDL1V: Seagen's Anti-PDL1 ADC; (iii) (iv) IgG-B81: Isotype-ADC.

**2 CRC (MSI-H, Pembro resistant)**  
PD-L1 IHC 3+, TPS 80%  
Model with hPBMC reconstitution

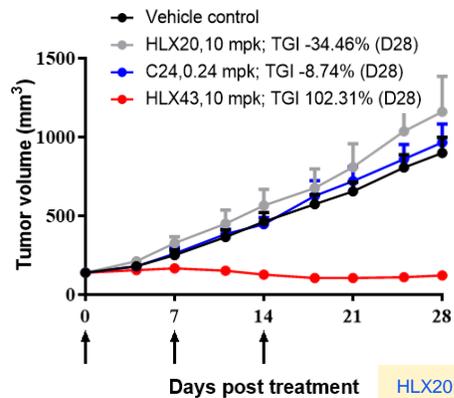


HLX04, bevacizumab biosimilar  
HLX10: Henlius in house anti-PD-1 mAb

**3 GC (treatment naïve, KRASm)**  
PD-L1 IHC 2+, TPS 70%

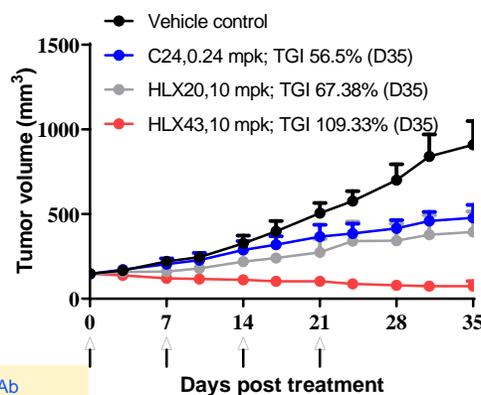


**4 HNSCC (PD-1 mAb, Chemo-R)**  
PD-L1 IHC 2+, TPS 87.5%

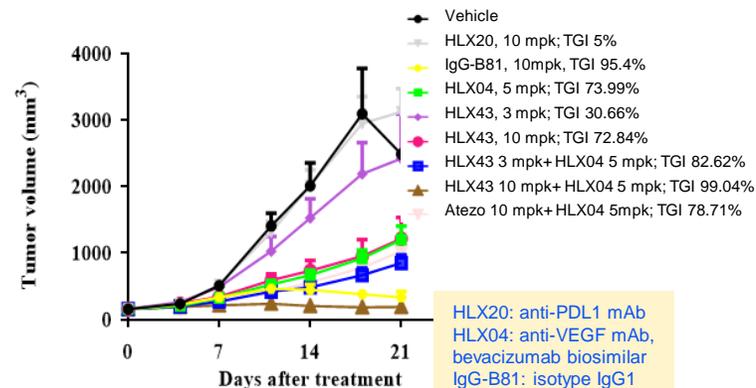


HLX20: anti-PDL1 mAb  
C24: free payload of HLX43  
Dosed QWx3 or QWx4

**5 Cervical cancer (PD-1 mAb, Anlotinib-R)**  
PD-L1 IHC1+, TPS 30%

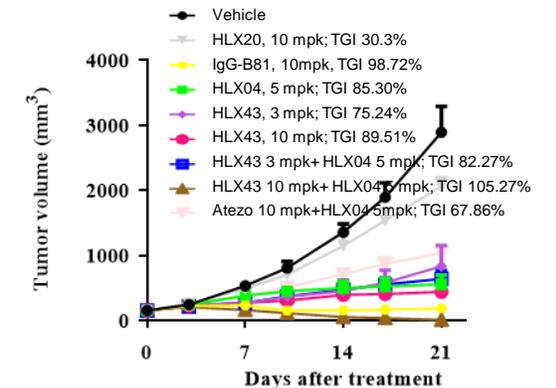


**6 HCC PDX (PD1 mAb-R, sorafenib-R)**  
PD-L1 IHC-, TPS 8.3%



HLX20: anti-PDL1 mAb  
HLX04: anti-VEGF mAb, bevacizumab biosimilar  
IgG-B81: isotype IgG1  
ADC, non-targeted control of HLX43

**7 HCC PDX (treatment-naïve)**  
PD-L1 IHC1+, TPS 37.5%

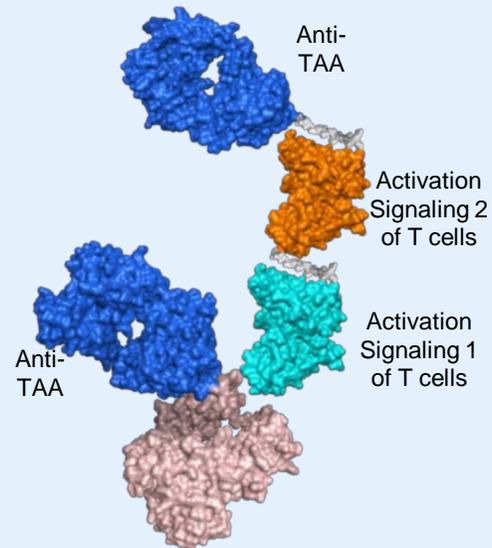


# 4.1

## Pre-clinical Assets

# Henlius Advanced Pre-clinical Platforms

## Tri-specific TCE Platform



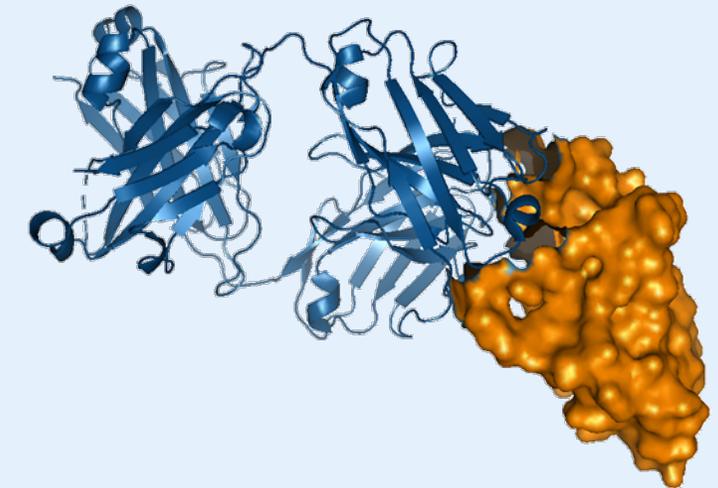
- Longer persistence of Activated T Cell
- Greater Efficacy in solid tumor treatment
- Enhanced Safety with lower CRS Risks

## Hanjugator™ ADC Platform



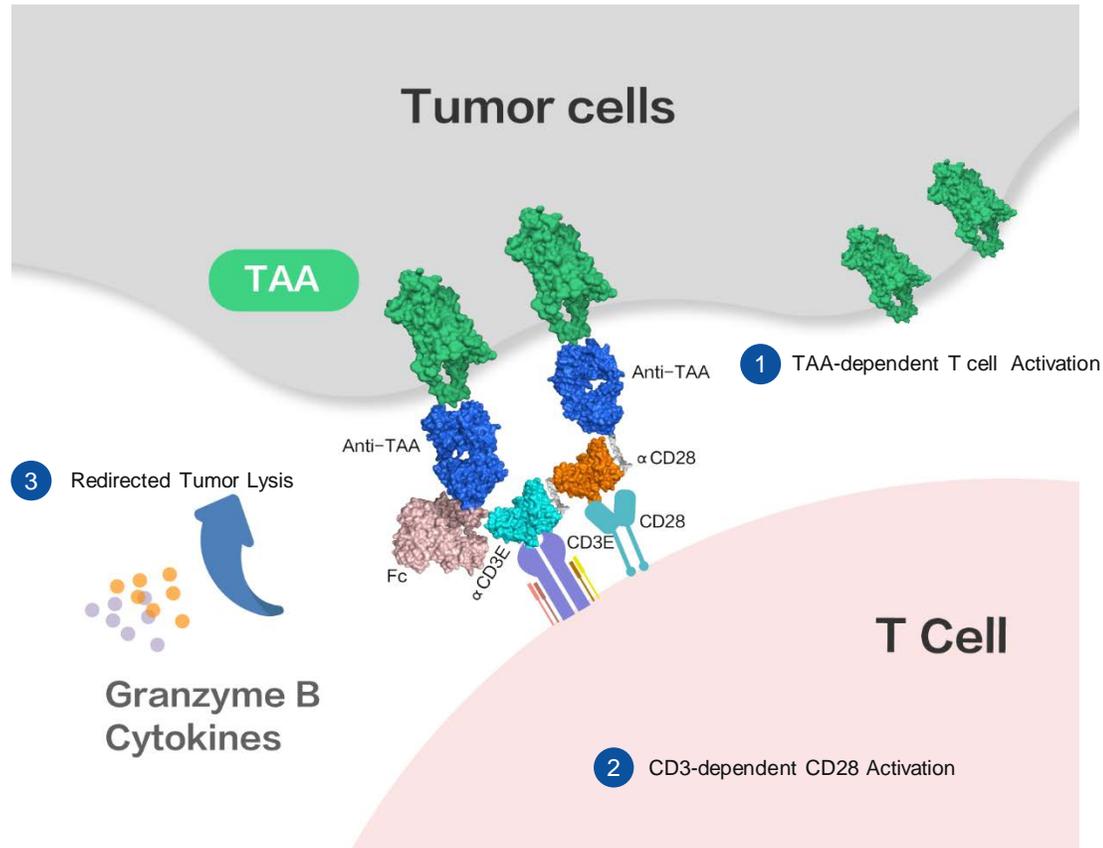
- Expanded clinical therapeutic window
- Overcome resistance to widely used payloads
- Combination of multiple payload mechanisms

## HAI Club



- Identification of Novel drug targets
- Cost-effective Research & Development
- Improved Success rate in drug discovery

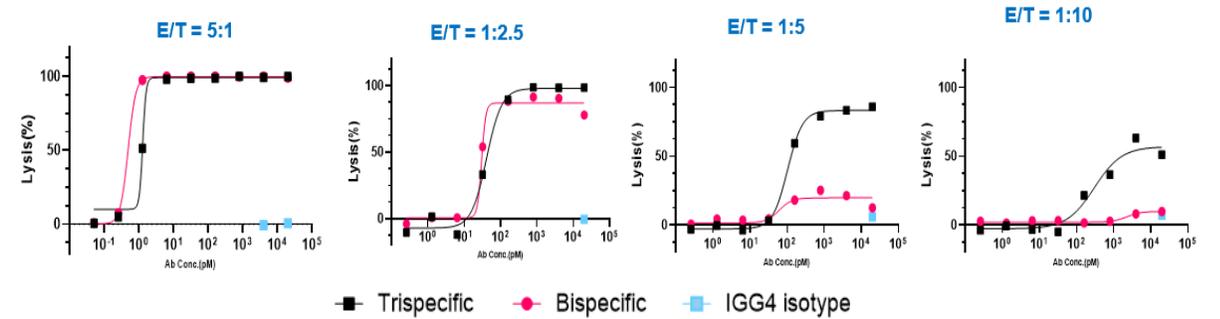
# Henlius Established a Safer and More Efficient Tri-specific T-cell Engager Platform



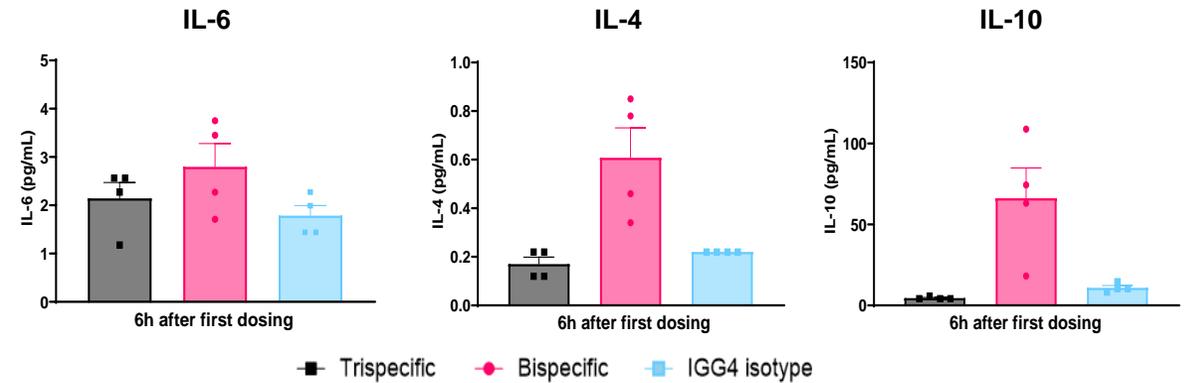
TAA: Tumor associated antigen

## Better efficacy under low T cell infiltration

Effector (PBMC)/Tumor ratios: from 5:1 to 1:10



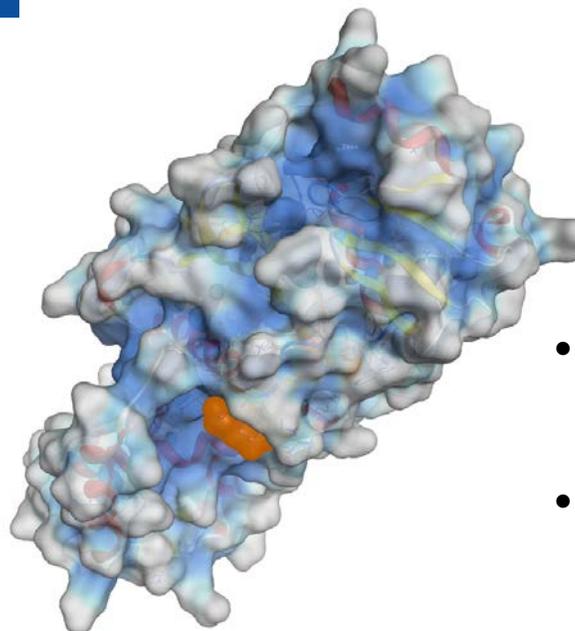
## Lower cytokine release



# HLX97: an Oral Small-Molecule Inhibitor with Best-In-Class Potential for ER $\alpha$ + Breast Cancer

## Oral Small-Molecule Inhibitor

- An emerging epigenetic target KAT6A/B
- A target with validated clinical PoC through preliminary efficacy and safety evidence
- Novel MoA enables combo strategies & resistance management
- Frontline treatment potential

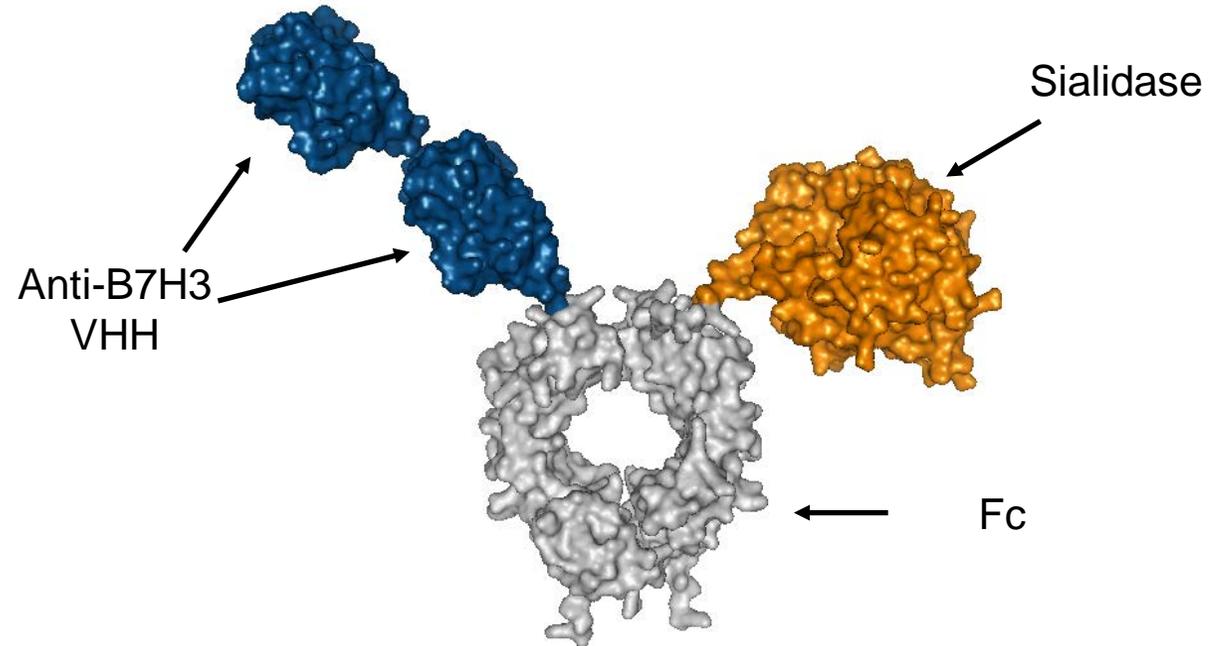


- Significantly enhanced bioactivities comparing to competitor
- Distinctive PK profile to reduce peripheral Exposure
- Favorable ADMET properties
- Mitigating on-target hematotoxicity

# HLX316: a Novel and First In Class Anti-B7H3 Sialidase for the Treatment of Solid Tumors

## Targeted Functional Molecule

- B7H3 (CD276): an emerging TAA for cancer therapy.
- Hypersialylation: excessive sialic acid on tumor cells suppresses tumor related immune responses
- HLX316: an Fc fused B7H3 targeted sialidase, can remove sialic acid on tumor and enhance immune response

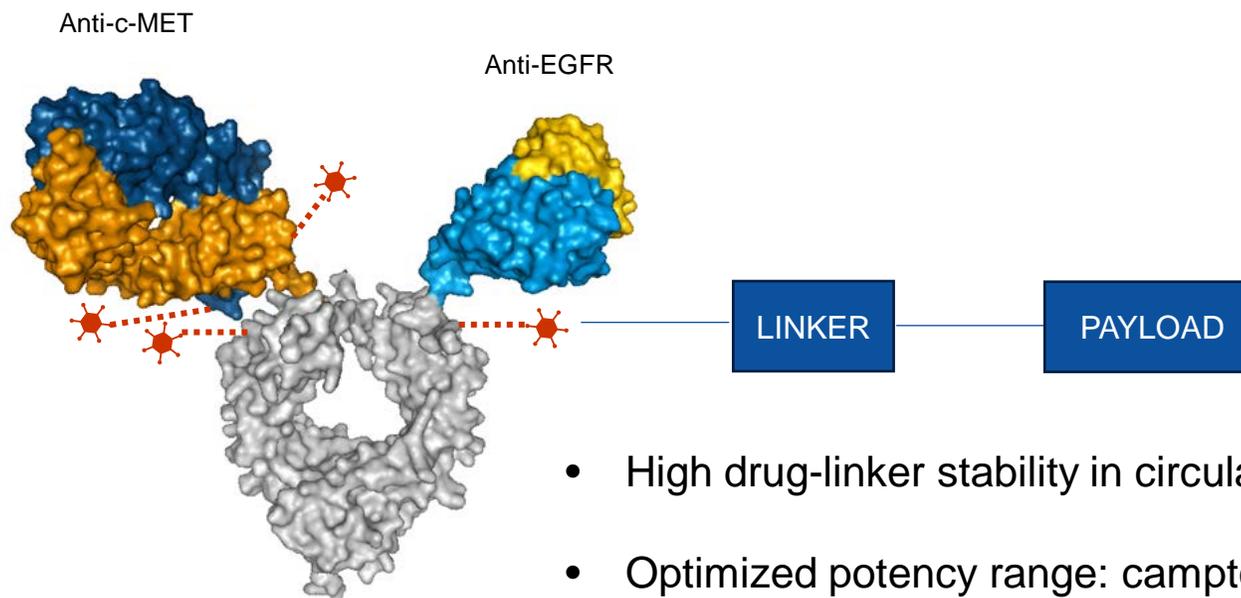


- Sialidase from Palleon EAGLE platform
- Anti-B7H3 VHH, invented by Henlius
- Novel and First In Class (FIC)

# HLX48: Best-in-class Anti-EGFRx c-MET Bispecific ADC for the treatment of NSCLC and CRC

## BISPECIFIC ANTIBODY

- Adjusted EGFR affinity for an improved safety profile.
- c-MET as the leading target to enhance dual-arm avidity
- Enhanced endocytosis and drug effect
- Antibody with tumor inhibition efficacy



- High drug-linker stability in circulation
- Optimized potency range: camptothecin
- Expanded clinical therapeutic window

05

# Manufacturing

# International Leading Capabilities on Manufacturing and Quality Management



Xuhui Site

24,000L

- **Manufacturing capacity optimization:** Commercial GMP production batches **exceeds 1,000 batches** (YS+SJ1) **Production success rate exceeds 98%**
- “Henlius Quality” with international standard: products supply cover **China, the EU, Brazil, Indonesia, Saudi Arabia and Singapore**
- Won the title of “**Quality Benchmark**” in Shanghai

Continuous Improvement



Songjiang 1<sup>st</sup> Plant

24,000L

- **Global GMP standards:** obtained GMP certifications from **China, the EU and US**
- **HLX02 (HANQUYOU)** commercial supplied to the U.S.
- **Accelerate new products to the market:** Completed GMP inspections for **HLX11 and HLX04-O** before commercialized in China

Aligned Quality & Efficiency



Songjiang 2<sup>nd</sup> Plant

36,000L+60,000L

- **Phase I of the plant will be completed soon:** Main buildings construction of the phase I has already completed, with manufacturing capacity covering **drug substance, liquid filling, pre-filled syringes, and ADC conjugation.**
- **Accelerate the manufacturing lines to achieve globalized supply**

Intelligent Drug Manufacturing

# Operation Excellence and Continuous Innovation

## Technical Innovation

### AI Empowerment

The development and testing of the manufacturing process and in-process data automatic capture and trend prediction system have been completed.

Successfully completed the automatic feedback control test of Raman spectroscopy in 200L bio-reactor

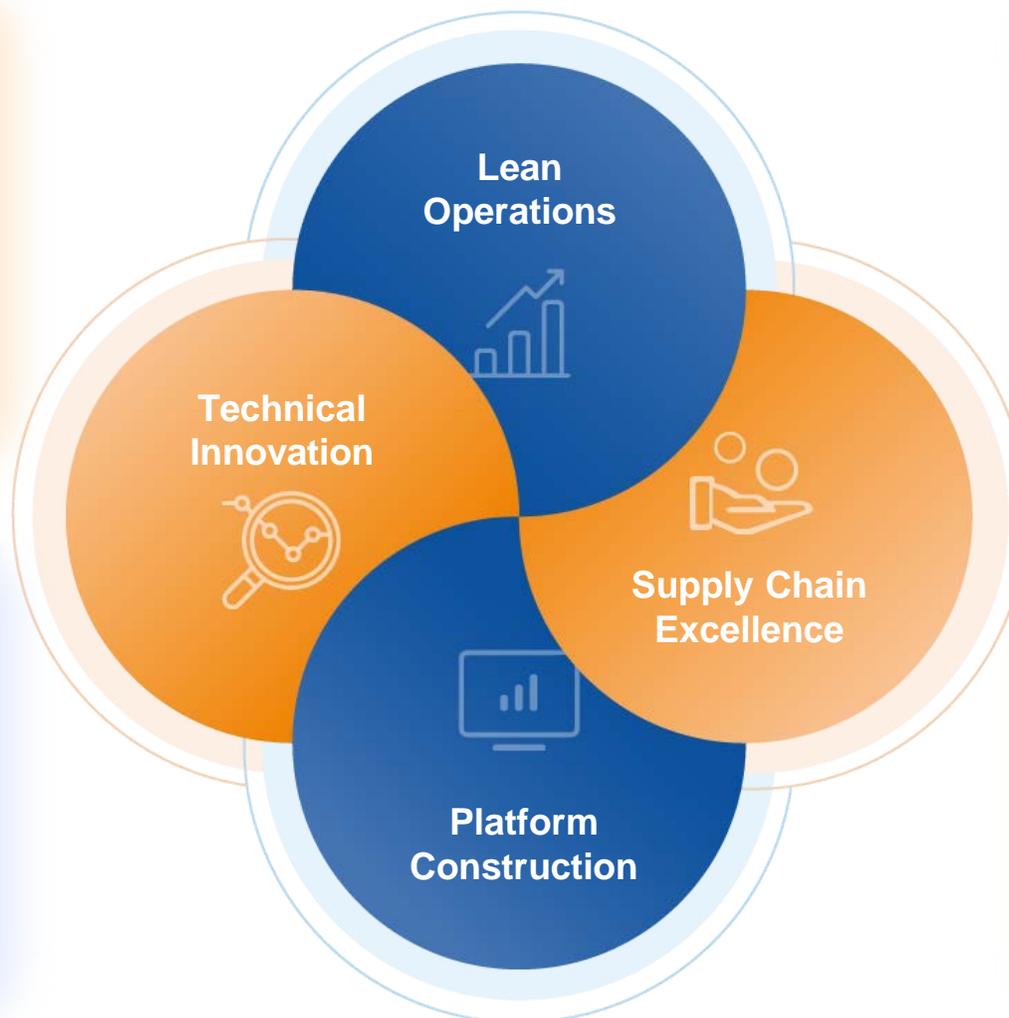
## Platform Construction

### Application of BI System

Real-time Monitoring of Key Indices in Production, Quality, and Supply Chain  
Risk Prediction Visualization

### Employee Efficiency Enhancement Platform

The proportion of multi-skilled employees exceeds 50%.



## Lean Operations

**200+ on-going lean operations projects** with ~30M RMB\* expected annualized returns

**The batch output of HLX01 (HANLIKANG) and HLX04 (HANBEITAI) increased over 10%\* YTD** through process optimization

## Supply Chain Excellence

The direct material cost was **over 10%\* lower than that in 2024**

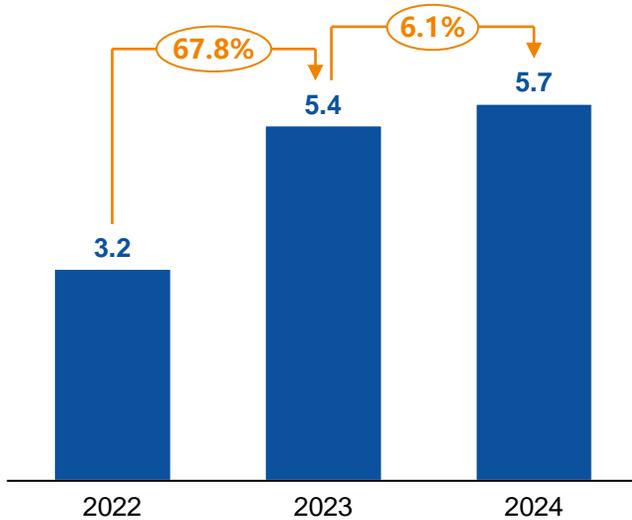
Through operational and process optimization, **the shipping cost per vial of the commercial product has decreased by over 25%\***

06

## 2024H1 Financial Review

# 2024 Revenue of RMB 5.72 Billion with 6.1% YoY

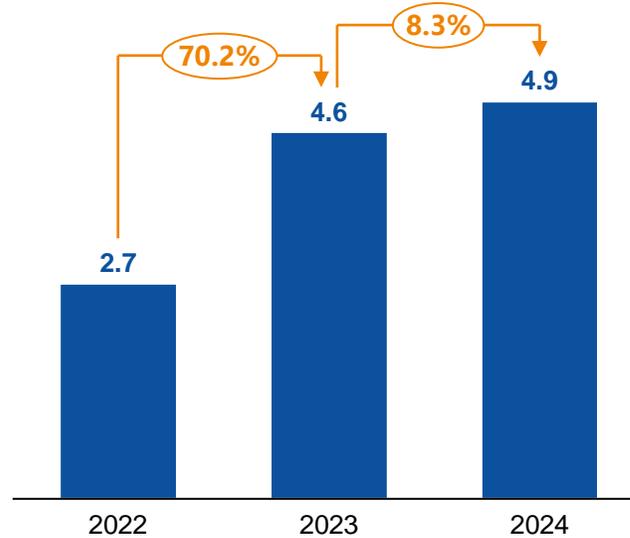
## Revenue (in Billion RMB)



### Revenue Growth

- Revenue of RMB 5.72B in 2024, 6.1% YoY growth
- Revenue growth mainly driven by: sales ramp-up of HANSIZHUANG
- Gross profit of RMB 4.18B in 2024, 6.8% YoY growth

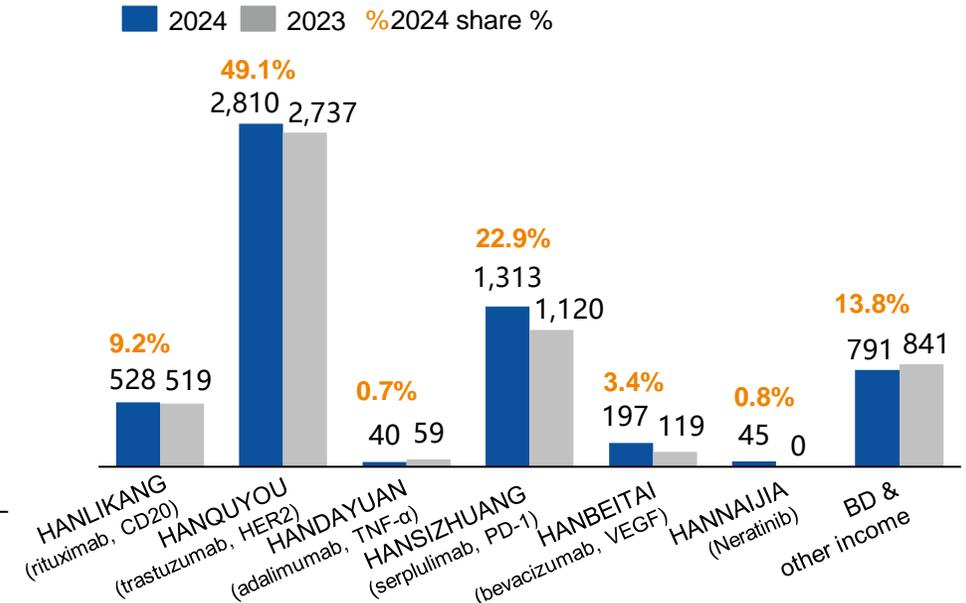
## Product Sales (in Billion RMB)



### Product Sales

- Product sales of RMB 4.93B in 2024, 8.3% YoY growth
- Product sales growth mainly from: HANQUYOU sales continue to grow year-on-year, Zercepac® sales in Europe grow steadily; HANSIZHUANG sales grow rapidly

## 2024 Revenue Breakdown (in Million RMB)

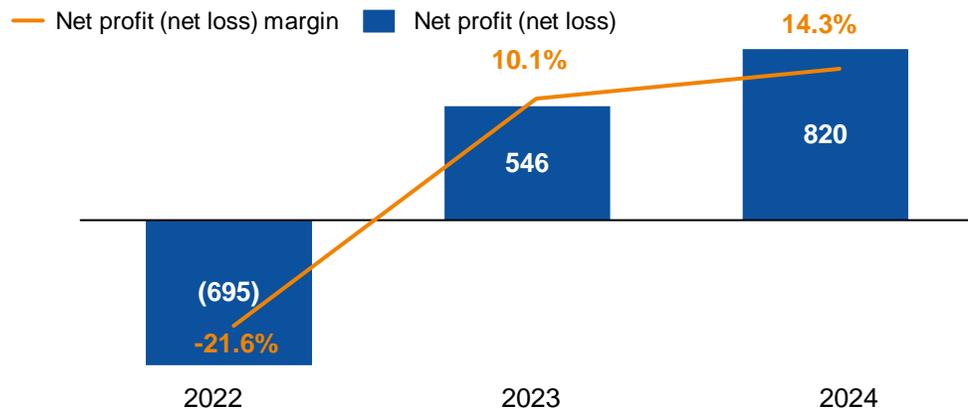


### Revenue Breakdown

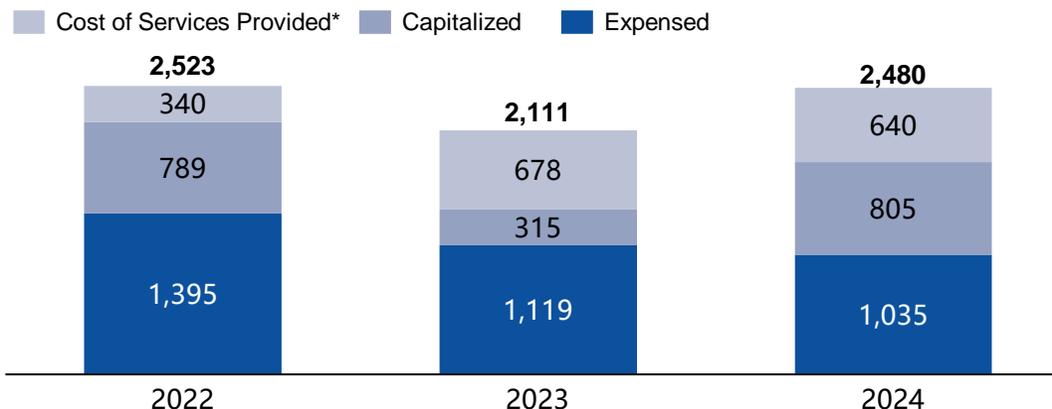
- HANQUYOU: RMB 2.81B sales\* in 2024, 2.7% YoY growth
- HANSIZHUANG: RMB 1.31B sales\* in 2024, 17.2% YoY growth
- HANLIKANG: RMB 528M sales in 2024, 1.9% YoY growth
- HANDAYUAN: RMB 40M sales in 2024, -31.6% YoY
- HANBEITAI: RMB 197M sales in 2024, 65.1% YoY growth
- HANNAIJIA: RMB 45M sales in 2024
- BD and other income: RMB 791M in 2024, -6.0% YoY

# Achieved Profitability in 2024 with RMB ~1.24B Operating CF

## Net profit (net loss): Keep profitability (in Million RMB)

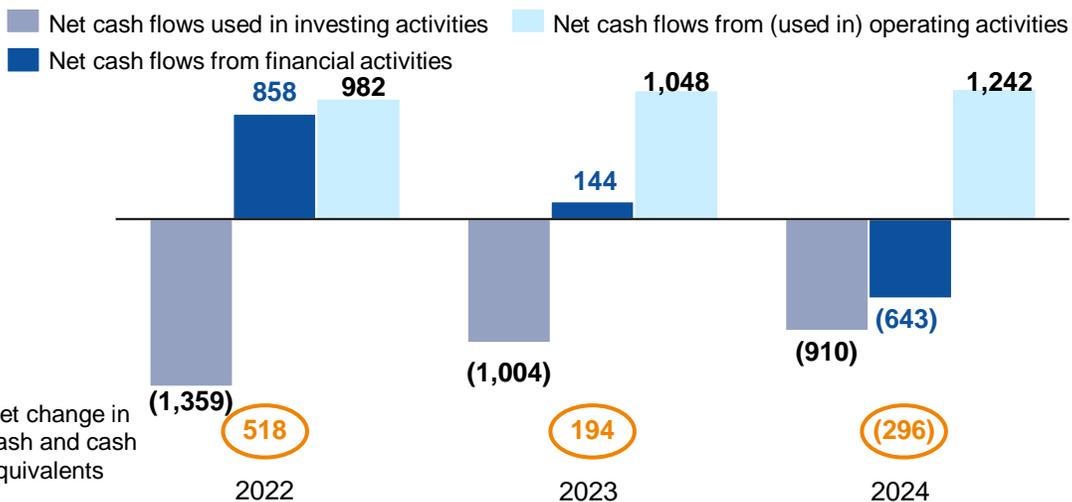


## R&D related investment (in Million RMB)

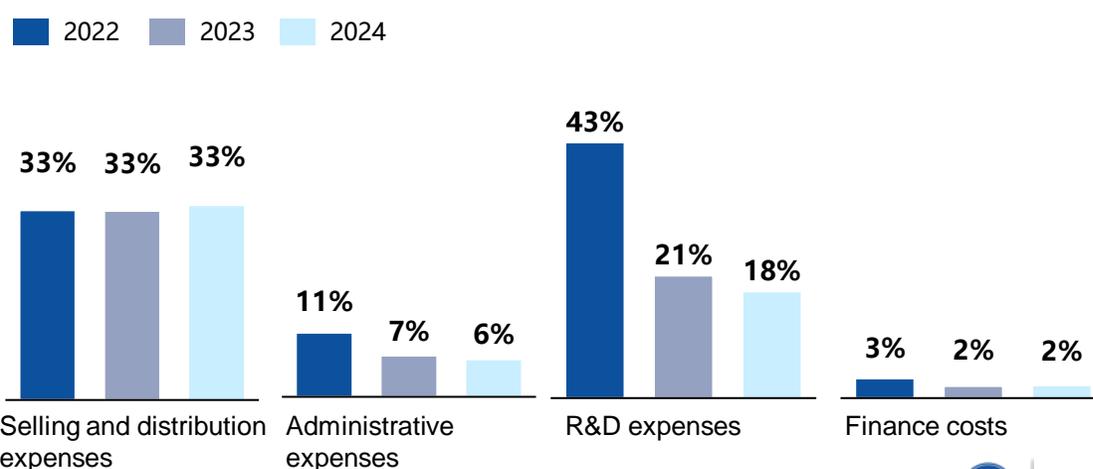


\* R&D spending related to out-licensing products accounted into cost of services provided according to accounting practices

## positive OCF (in Million RMB)



## Expense to revenue ratios : effective controls on expenses



# Financial Highlights

Financial Data (selected)	2024		2023		YoY Growth	
	Unit	In Million RMB	% of revenue	In Million RMB	% of revenue	%
<b>Revenue</b>		5,724.4	100.0%	5,394.9	100.0%	6.1%
<b>Product sales</b>		4,933.5	86.2%	4,553.5	84.4%	8.3%
<b>BD and other revenue</b>		790.9	13.8%	841.4	15.6%	(6.0%)
<b>Cost of sales</b>		(1,539.8)	(26.9%)	(1,476.1)	(27.4%)	4.3%
<b>Selling and distribution expenses</b>		(1,917.4)	(33.5%)	(1,754.2)	(32.5%)	9.3%
<b>Administrative expenses</b>		(370.8)	(6.5%)	(383.8)	(7.1%)	(3.4%)
<b>R&amp;D expenses</b>		(1,035.1)	(18.1%)	(1,118.7)	(20.7%)	(7.5%)
<b>Financial costs</b>		(122.9)	(2.1%)	(110.5)	(2.0%)	11.2%
<b>Net profit</b>		820.5	14.3%	546.0	10.1%	50.3%
<b>Cash and bank balances</b>		773.0	13.5%	987.7	18.3%	(21.7%)
<b>Net cash flows from operating activities</b>		1,241.9	21.7%	1,047.9	19.4%	18.5%

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Reliable Quality  
Affordable Innovation

