

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

March 2025





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## 2024 Business Highlights & Company Strategy



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

Revenue

BD



Pipeline



Commercial Capacity



Operating Cash Flow



**5.7**<sub>B</sub> RMB

4

~50

**48**<sub>KL</sub>

**1.2**B RMB

#### Commercialization

Achieved sustainable and profitable growth from strong sales team and effective sales

management

HLX10 (serplulimab, PD-1)
 sales in 2024 reached RMB 1.31
 billion. The sales per capita is
 higher than all PD-1/PD-L1
 products marketed in China
 during the same time period

- HLX02 (trastuzumab) strengthened market share in IV formulation with sales per capita exceeding RMB 5 million
- HLX901 (neratinib) launched successfully as sequential therapy after completion of HLX02, establishing leading position in HER2 breast cancer market

**BD** 

- HLX15 (daratumumab) outlicensed to Dr. Reddy's in a total of 43 countries and regions of Europe and US, with upfront payment of USD 33 million and a total amount up to USD 131.6 million
- 5 products out-licensed to Abbott in 69 emerging markets
- In-licensed exclusive rights of lasofoxifene (SERM) in Asia and co-dev right in Japan from Sermonix for ER+/HER2- breast cancer
- In-licensed exclusive rights in China & conditional license in ex-China regions of Neratinib generics from Convalife

#### R&D

- HLX10 received EMA approval, being the first and only anti-PD-1 mAb approved in the EU for the treatment of 1L ES-SCLC
- HLX10 received NMPA approval for the treatment of nsNSCLC
- HANQUYOU received BLA approval and completed the first commercial shipment to the U.S.
- Conducted the Phase 3 MRCT of HLX10 combo with bevacizumab on first-line mCRC
- First subject dosed for a Phase 2 clinical trial of PD-L1 ADC HLX43, being the second PD-L1 ADC to enter clinical trial globally
- Conducted the Phase 3 MRCT of HLX22, novel anti-HER2 mAb, combo therapy on first-line HER2+ GC

#### Manufacturing

- Manufacturing capacity optimization: commercial GMP production batches exceeds 1,000 batches (YS+SJ1); production success rate exceeds 98%
- Global GMP standards: obtained GMP certifications from China, the EU and US, with supply covering China, the U.S., the EU, Brazil, Indonesia, Saudi Arabia and Singapore
- SJ1 passed HLX11, HLX04-O pre-license inspection
- SJ1 obtained certifications for ISO14001 and ISO45001

#### **Financial**

- Total revenue reached RMB
   5.7B in 2024, YoY growth 6.1%
- Total product sales reached RMB 4.9B, YoY growth 8.3%
- Net operating cash inflow of RMB 1.2B, YoY growth 18.5%
- Net profit reached RMB 820M
   YoY growth 50% and net profit rate was 14.3%

## 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



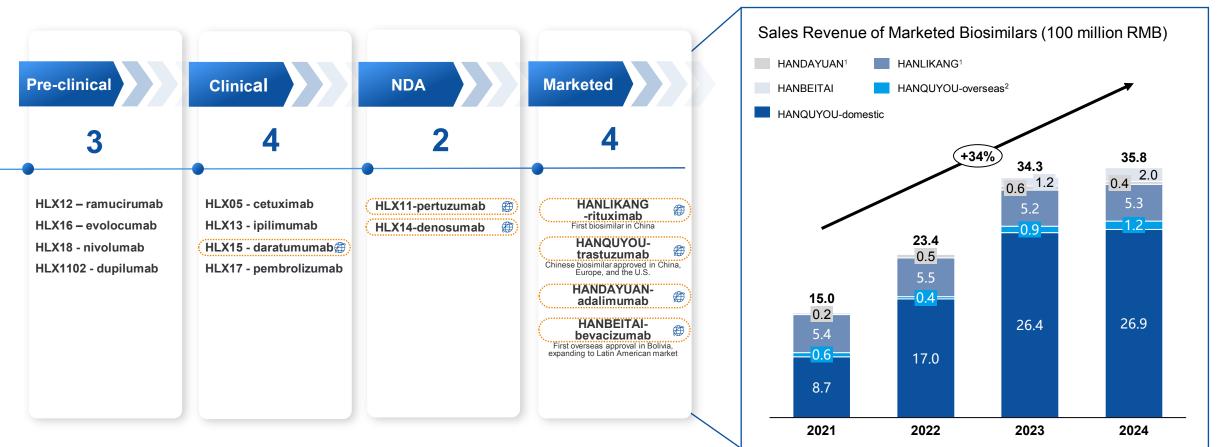
#### **Globalization**

Develop towards a biopharma with global presence & scale

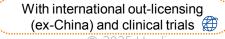


#### Robust Biosimilar Pipeline is Aiming at Global Market

- 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' 3rd 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' 4th self-developed product approved overseas, accelerating the expansion of Latin American market



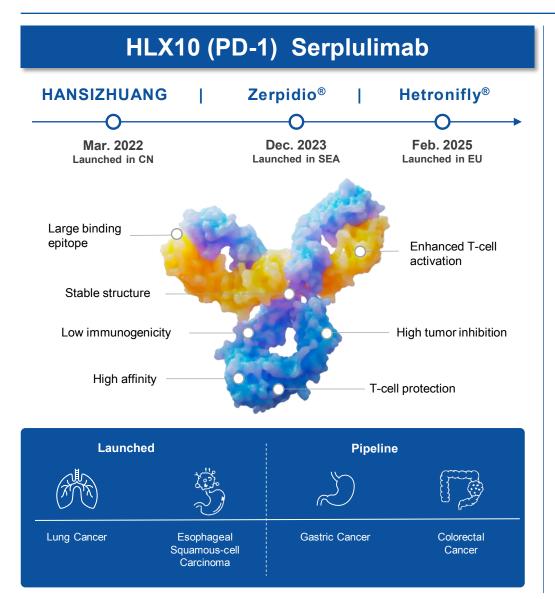
<sup>1.</sup> Revenue recognized by Henlius





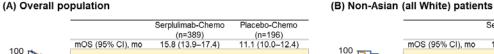
<sup>2.</sup> Sum of revenue of trastuzumab overseas

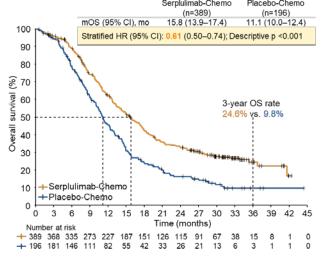
#### **HLX10: Potential Best-in-class PD-1 Antibody with Global Market Opportunity**

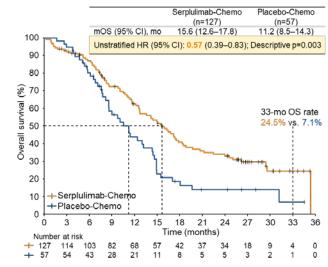


#### World's first anti-PD-1 mAb for the first-line treatment of SCLC

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







Data cutoff: June 13, 2023
Chemo, chemotherapy; CI, confidence interval; HR, hazard ratio; m, median; mo, month; OS, overall survive

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.



2024 **ASCO** 

#### 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)
- HLX15 (daratumumab) out-licensed to Dr. Reddy's in the U.S.
- Songjiang 1st 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 1st 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 1st 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



#### **Latin America**

- HANBEITAI received approval from Bolivia's AGEMED, being Henlius' 4th 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

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### 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 "Chinadeveloped" biosimilar approved in all three regions of China, Europe, and the U.S.
- Launched in 50+ countries and regions



#### 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



#### 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



#### 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

>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



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



#### **45M RMB**

Revenue in 2024 (Commercialized for > 3 months)



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#### **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



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







#### 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



#### 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



#### 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



#### 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

04110020

• ES-SCLC

• ESCC

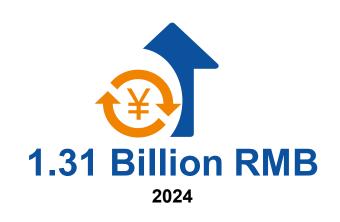
nsNSCLC

Drug Specifications: 100mg/10ml/bottle



### HANSIZHUANG: Outstanding Commercialization Efficiency and Differentiated Strategy

First-class
Commercialization
Efficiency



Sales Per Capita <sup>1</sup>

> 2.4 million RMB

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 nonsquamous NSCLC indication expanded HANSIZHUANG's LC market
- Target brain metastatic patients to develop NSCLC potential

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#### 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



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贝伐珠单抗注射流

### HANLIKANG (Rituximab): Strengthen the Market Leader Position HANDAYUAN (Adalimumab): Entered Autoimmune Disease Area



**528M 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



#### 40M RMB

Revenue recognized by Henlius and licensing income in 2024



#### 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.

POSUNPHARMA DELEGRATE

#### **HANLIKANG**

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







#### **HANDAYUAN**

- **Target**: TNF-α
- 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



- 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



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



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+



Perioperative period

2L/2L+



Neratinib (HANNAIJIA)

Pertuzumab (HLX11) Lasofoxifene (HLX78)

#### Lasofoxifene (HLX78)

- ESR1<sup>mut</sup> BC (2L+)
- ER+/HER2- (2L+) BC

#### 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 codevelop Lasofoxifene with Sermonix to expedite the development progress in Japan.

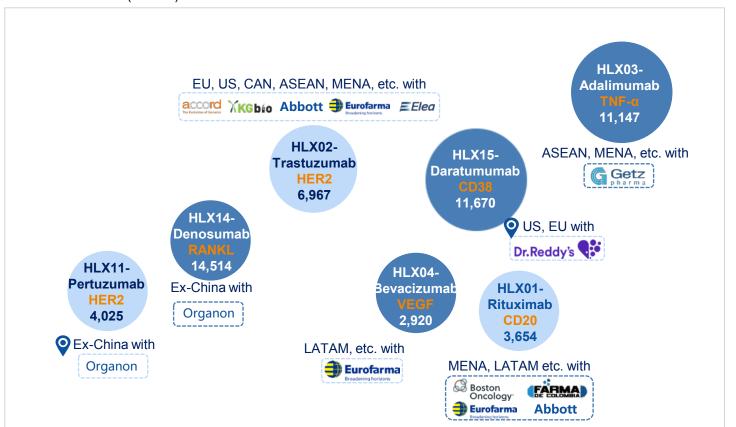


### Out-licensing Focus: Henlius' International Quality Biosimilars Scale up across the Globe

#### Market Size of Originators and Marketed Biosimilars

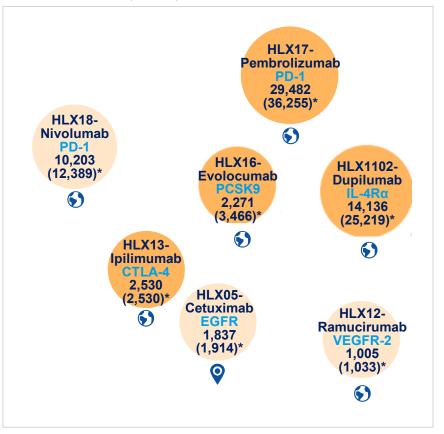
#### Biosimilars with existing out-licensing partners

Global sales in 2024 (M USD)



#### 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) (12) RANKL Osteoporosis, etc.	HANSIZHUANG (serplulimab) (5) 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) (13) HER2 BC	HANLIKANG (rituximab) (14) CD20 NHL, CLL, RA(15)	
HLX316 Fusion protein Solid tumor	HLX05 (cetuximab) (3) 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) (16) 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) (17) 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) (18) 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) (19) HER1/HER2/HER4 Extended adjuvant treatment of BC	
HLX41 ADC BC		HLX43 <sup>(8)</sup> PD-L1 ADC Solid tumours	HLX78 (lasofoxifene) (11) SERM BC			
HLX37 PD-L1 x VEGF Bispeciifc Solid tumors		a. Phase 1/2 conducting in the U.S. (2) IND approvals obta	ined in China/the U.S. and granted FDA Fast Track Design		novative fusion protein Biosimilar mAb	
HLX3901 Trispecific SCLC	in Europe, partners: KGbio/Fosun Pha in China/the U.S. (9) IND approvals ob China/the U.S./Japan. (11) Exclusive I under review in the EU and the U.S. (1	. (4) Business partner: Dr. Reddy's, etc. (5) Approved in Chirma/Intas. (6) IND approvals obtained in China/the U.S. (7) I vatained in China/Australia/the U.S./Singapore/EU countries, icense obtained in China. Phase 3 MRCT enrolling globally. (3) Marketing applications under review in China and the U.S.	Exclusive license obtained in China. (8) IND approvals obtate. Business partner: Essex. (10) IND approvals obtained IND approval obtained in China. (12) Marketing applications. (14) Approved in countries s. Business partner: Organon. (14) Approved in countries s.	ained Innovative ADC si si sons	mall molecule Innovative multi-specific a	
HLX3902 Trispecific PCa	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 <sup>™</sup> . trade name registered in Europe: Zercepac®. 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.					

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#### **Clinical Pipeline Milestones: 2024 Review**







**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

PMOP1, etc. (EU & Canada & US)



#### HLX10

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

#### HLX10

nsaSCLC 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)





#### HLX10+HLX04

mCRC3 1L (PoC)

#### HLX22+HLX02

GC<sup>4</sup> 1L (PoC)

#### HLX10

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

#### HLX10+HLX07

NPC 1L (CN PoC)

- Postmenopausal osteoporosis
- Extensive stage small cell lung cancer
- Metastatic colorectal cancer
- Gastric cancer









#### **Clinical Pipeline Milestones: Expected in 2025**

2025H1 2025H2 HLX10 HLX10 HLX10 **HLX04 HANBEITAI** HLX14 HLX10 HLX04-O FSCC8 FS-SCLC1 sa-NSCLC<sup>2</sup> nsa-NSCLC3 mCRC, advanced, Wet AMD5 PMOP4 . etc. 1L (Hong Kong SAR. 1L (the Philippines) 1L (Indonesia. metastatic or 1L (US) (UK) 1L (EU) MENA, Turkey, recurrent NSCLC, GBM, Thailand) etc. (Saudi Arabia) LATAM) HLX11 HLX14 HLX04-O HLX10 HLX10 HLX10 NDA/BLA/MAA Wet AMD 5 PMOP4 etc. nsg-NSCLC1 sa-NSCLC1 MSI-H Breast cancer Neoadjuvant therapy **Submission** (CN) (CN) 1L (Cambodia, EU) 1L (EU, India, Singapore, Later line (EU) (EU. Canada) Myanmar, Malaysia) HLX14 HLX10 HLX10 HLX10 HLX11 **HLX03 HANDAYUAN** ES-SCLC1 sq-NSCLC<sup>2</sup> RA, AS, Ps, UV, pJIA, pediatric ES-SCLC1 Breast cancer PMOP4, etc. 1L (Myanmar, the Ps, CD, pediatric CD, etc 1L (Swit, India, 1L (Cambodia) Neoadjuvant (EMA & US & Philippines, UK) therapy (US) CAN) (Pakistan) Malaysia, Singapore) **HLX02 HANQUYOU HLX01 HANLIKANG HLX02 HANQUYOU** NDA/BLA/MAA NHL. CLL. RA Breast cancer, mGC Breast cancer, mGC (SEA, LATAM) (LATAM, Saudi Arabia) (SEA, LATAM) **Approval** HLX10 HLX10+HLX04 HLX14 HLX10 HLX07+HLX10 HLX43 mCRC<sup>6</sup> NPC9 nsa-NSCLC3 PMOP4 etc. Nsa-NSCLC PD-L1 ADC 1L (Pivotal) 1L (PoC) (Pivotal) 1L (Pivotal)-OS 1L (China PoC) NSCLC-PoC **Key Clinical** HLX22+HLX02 HLX43 Innovative mAb mAb biosimilar  $GC^7$ PD-L1 ADC **Data Readouts** Innovative ADC Innovative fusion protein 1L (PoC) NSCLC-PoC

23

Extensive stage small cell lung cancer Squamous non-small cell lung cancer

Postmenopausal osteoporosis Age-related macular degeneration

Metastatic colorectal cancer

Esophageal squamous cell carcinoma Nasopharvngeal carcinoma

- 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 ≥ 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)
Serpulimab	HLX10-015-CRC301 (Ph2) Data cutoff: June 30, 2024, median follow up: 31.0 months	A: Serplulimab + bev + XELOX B: Bev + XELOX	ITT population 55 vs 57	16.6 vs 10.7, p=0.17 HR=0.66 (95% CI, 0.37-1.19)	NA	17.7 vs 11.3, p=0.041 HR=0.45 (95% CI, 0.20-0.98)
			MSS subgroup 40 vs 50	<u>16.8</u> vs 10.1, p= 0.21 HR=0.65 (95% CI, 0.33-1.29)	23.5 vs 20.2, p=0.40 HR=0.79 (95% CI, 0.45-1.38)	19.4 vs 8.3, p=0.045 HR=0.39 (95% CI, 0.15-1.00)
Atezolizumab	AtezoTRIBE¹ (Ph2)	A: Atezolizumab + bev + FOLFOXIRI B: 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
+SOC			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	CheckMate 9X8 <sup>2</sup> (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>&</sup>lt;sup>a</sup> IFL, irinotecan, bolus fluorouracil, and leucovorin; bev, bevacizumab.



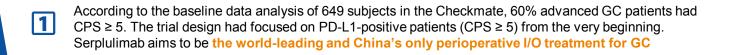
<sup>1.</sup> J Clin Oncol 41, 2023 (suppl 16; abstr 3500) . 2. Lenz, H-J. et al. J Clin Oncol 40, 4\_suppl.008 (2022). 3. Hurwitz, H. et al. N Engl J Med 350, 2335-2342 (2004).

#### **Serplulimab: Targeting Differentiated Indications**



### Gastric Cancer (GC)

Neoadjuvant treatment in combination with Chemotherapy / Adjuvant with serplulimab only



- 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
- 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)

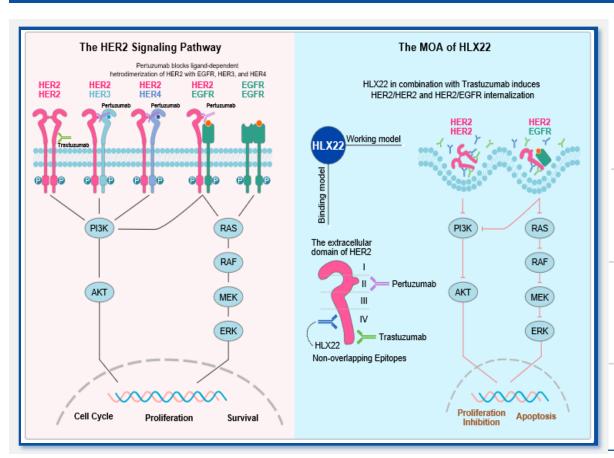
Serplulimab combined with bevacizumab & XELOX

- 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>
- 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
- 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 Oncololgy, 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



- 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

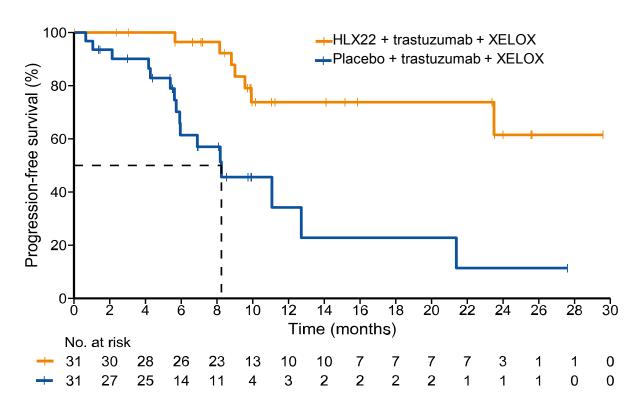
Product	Clinical Trial	Regimen	Sample Size	mPFS (months)	mOS (months)	mDOR (months)
HLX22	HLX22-GC-201 (Ph 2) Data cutoff: June 30, 2024, median follow up: 20.3 months	A: HI X// (15 mg/kg)+frastuzuman+chemo	ITT population 31 vs 31	NR vs 8.3 <u>HR=0.2</u> (95% CI, 0.06–0.45)	NR vs 22.0 HR=0.5 (95% CI, 0.20–1.21)	NR vs 9.7 <u>HR=0.1</u> (95% CI, 0.04–0.41)
	KEYNOTE-811¹ (Ph 3  EMA: approved for  PD-L1+ subgroup;  Pembrolizumab	)	ITT population 350 vs 348	10.0 vs 8.1 HR=0.73 (95%Cl 0.61-0.87)	20.0 vs 16.8 HR=0.80 p=0.0040	11.3 vs 9.5 HR NA,p NA
Pembrolizumat		A: Pembrolizumab+trastuzumab+chemo (CF/XELOX)	PD-L1+ subgroup 298 vs 296	10.9 vs 7.3 HR=0.72 (95%Cl 0.60-0.87)	20.1 vs 15.7 HR=0.79 (95%Cl 0.66-0.95)	11.3 vs 9.5 HR NA,p NA
FDA: expediated approved for PD-L1+ subgroup	B: Trastuzumab+chemo (CF/XELOX)	PD-L1- subgroup 52 vs 52	9.5 vs 9.5 HR=0.99 (95%Cl 0.62-1.56)	18.2 vs 20.4 HR=1.10 (95%CI 0.72-1.68)	NA	
Tracturumah	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
masluzumab 10			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	JACOB <sup>4</sup> (Ph 3 failed)	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



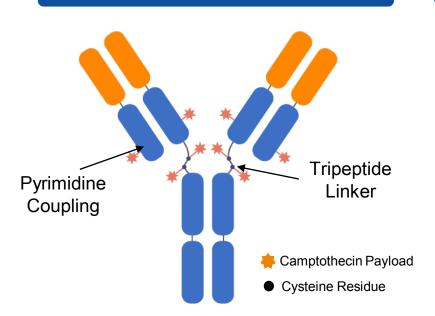
	HLX22 group (n = 31)	Placebo group (n = 31)
mPFS, months (95% CI)	NR (23.5-NE)	8.3 (5.7–12.7)
HR (95% CI)	<b>0.2</b> (0.06–0.45)	p<0.0001
12-month PFS rate (95% CI)	73.8 (50.3–87.4)	34.2 (12.0–58.1)
24-month PFS rate (95% CI)	61.5 (30.4–82.0)	11.4 (0.8–38.1)
mOS, months (95% CI)	NR (23.5–NE)	22.0 (10.6–NE)
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<sub>1/2</sub> 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
- CC
- HCC
- ESCC
- NPC
- CRC
- HNSCC
- 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 Exp	pression in Solid	Target Indication of <b>HLX43</b>	Epidemiology Inc. cases per year in CH/Global			
1000k/2000k	<b>√</b>	Lung (NSCLC) 71%   37%		Gastric 84%	J	470k/1140k		
510k/1900k	•	<b>Colon</b> 31%   5%		Esophageal 86%	J	320k/600k		
70k/330k	<b>√</b>	<b>Ovarian</b> 37%   4%		Hepatocellular ~20%	J	300k/799k		
134k/1410k		Prostate 34%   10%	6-25	Cervical 60~70%	J	160k/690k		
9k/330k		Melanoma 56%   14%		HNSCC ~80%	J	110k/800k		



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

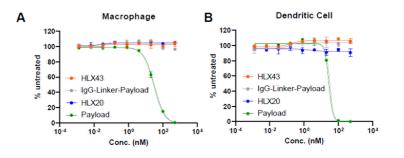
#### Preclinical Results

- 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
- II. 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
- III. HLX43 also induced significant tumor regression in HCC PDX model with (IHC1+) 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

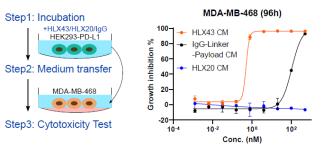
#### Regulatory and Clinical Trial Progress

- 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

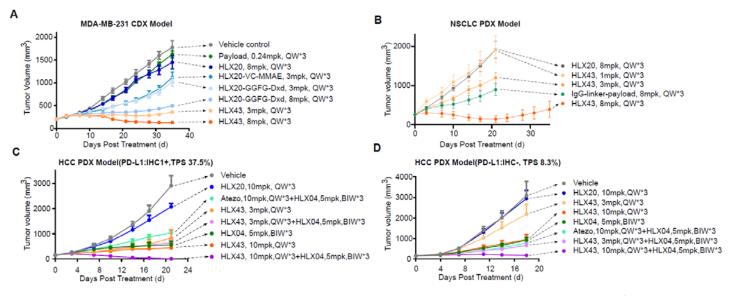
#### HLX43 Shows No Immunotoxicity Towards PD-L1+ Human APCs



#### HLX43 Exhibits Excellent Bystander Effect



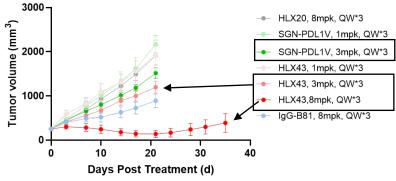
#### HLX43 Exhibits Excellent Anti-tumor Efficacy In vivo





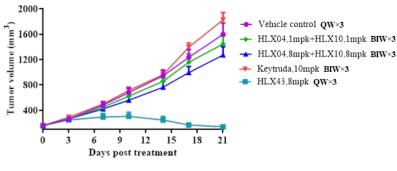
#### **Anti-tumor Efficacy of HLX43 in PDX & CDX**

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

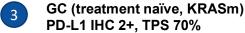


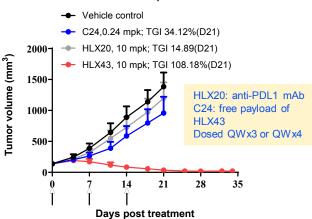
Notes: (i) HLX20, Henlius in-house anti-PDL1 mAb, the antibody of HLX43; (ii) SGN-PDL1V: Seagen's Anti-PDL1 ADC; (iii) (iv) IgG-B81: Isotype-ADC.

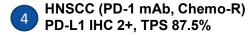
**CRC (MSI-H, Pembro resistant)** PD-L1 IHC 3+, TPS 80% Model with hPBMC reconstitution

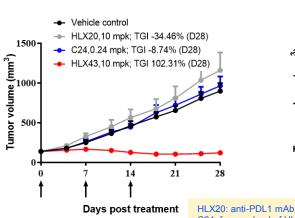


HLX04, bevacizumab biosimilar HLX10: Henlius in house anti-PD-1 mAb

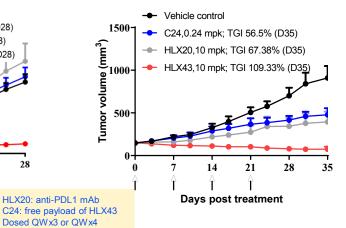




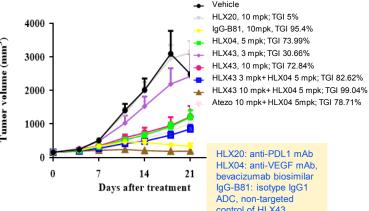




Cervical cancer (PD-1 mAb, Anlotinib-R) **PD-L1 IHC1+. TPS 30%** 

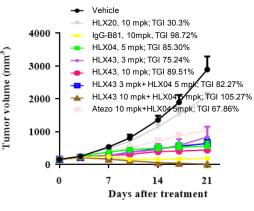


HCC PDX (PD1 mAb-R, sorafenib-R) **PD-L1 IHC-. TPS 8.3%** 



control of HLX43

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





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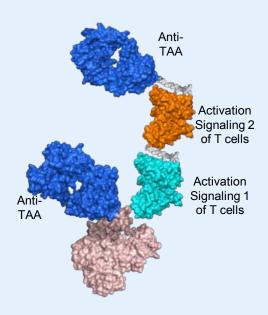
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### **Pre-clinical Assets**



#### **Henlius Advanced Pre-clinical Platforms**

#### **Tri-specific TCE Platform**



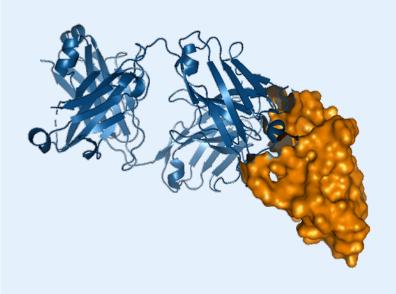
- Longer persistence of Activated T Cell
- Greater Efficacy in solid tumor treatment
- Enhanced Safety with lower CRS Risks

#### Hanjugator<sup>™</sup> ADC Platform



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

#### **HAI Club**

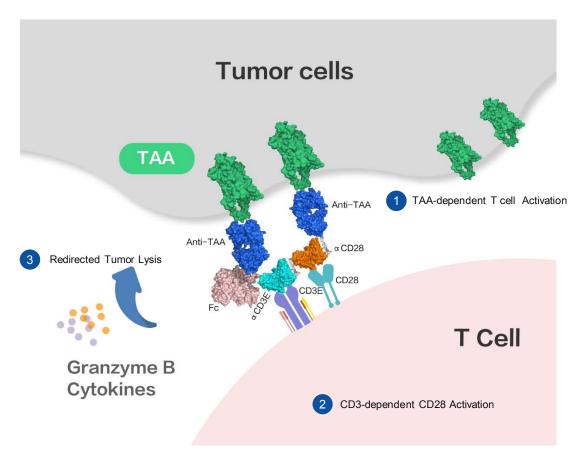


- Identification of Novel drug targets
- Cost-effective Research & Development
- Improved Success rate in drug discovery



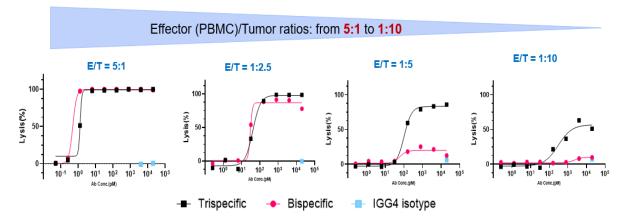
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### Henlius Established a Safer and More Efficient Tri-specific T-cell Engager Platform

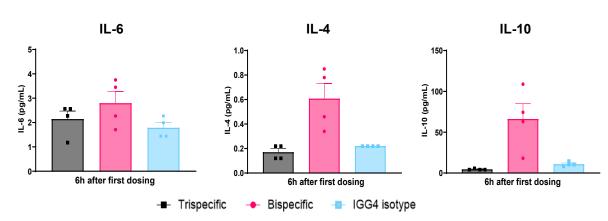


TAA: Tumor associated antigen

#### Better efficacy under low T cell infiltration



#### Lower cytokine release

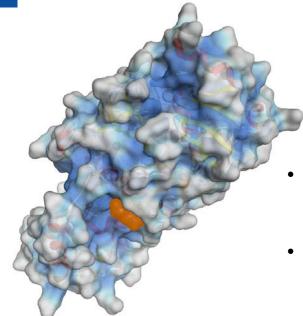




#### HLX97: an Oral Small-Molecule Inhibitor with Best-In-Class Potential for ERα<sup>+</sup> Breast Cancer

#### **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



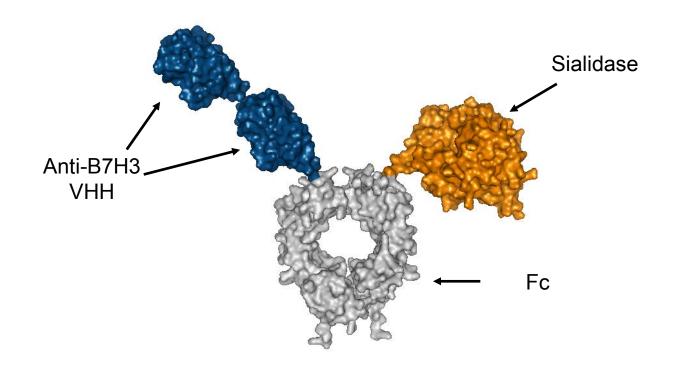
- Significantly enhanced bioactivities comparing to competitor
- Distinctive PK profile to reduce peripheral Exposure
- Favorable ADMET properties
- Mitigating on-target hematotoxicity



#### 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



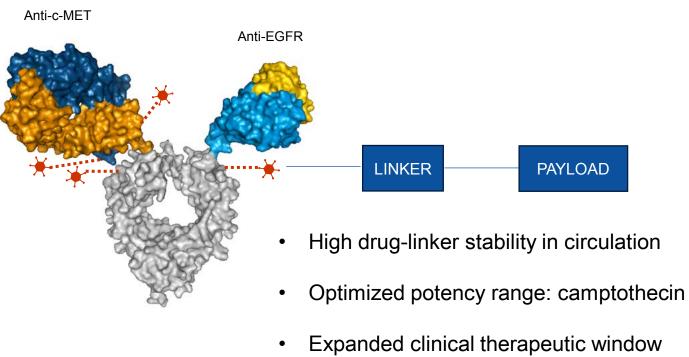
- Sialidase from Palleon EAGLE platform
- Anti-B7H3 VHH, invented by Henlius
- Novel and First In Class (FIC)



#### 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







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### Manufacturing



#### International Leading Capabilities on Manufacturing and Quality Management



- 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

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- 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



- 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



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#### **Operation Excellence and Continuous Innovation**

#### **Technical Innovation**

#### **Al 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

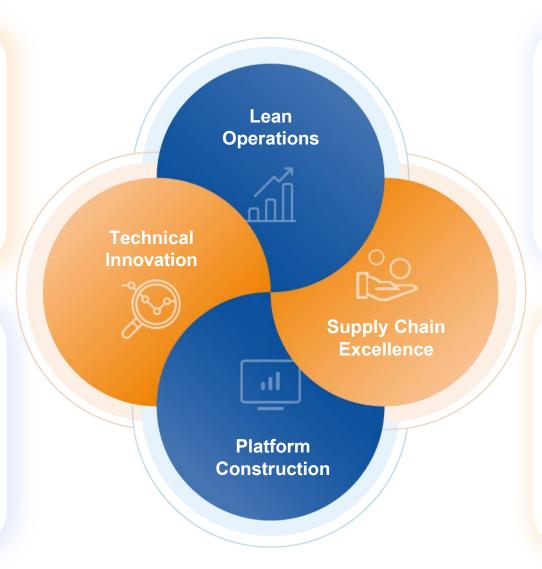
#### **Platform Construction**

#### **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%\*



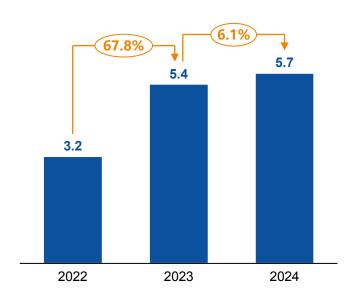
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### 2024H1 Financial Review



#### 2024 Revenue of RMB 5.72 Billion with 6.1% YoY

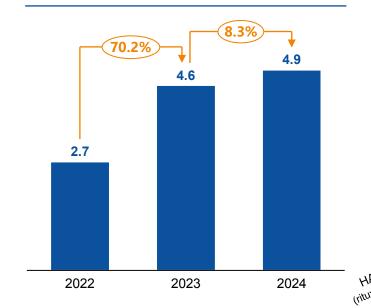
#### Revenue (in Billion RMB)



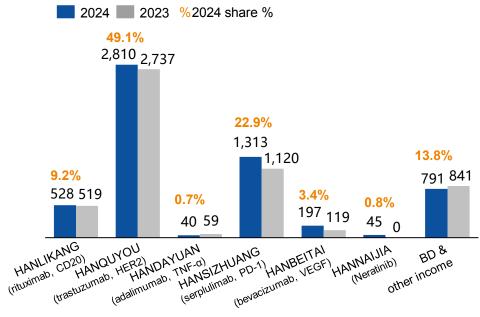
#### Revenue Growth

- 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)



#### 2024 Revenue Breakdown (in Million 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<sup>®</sup> sales in Europe grow steadily; HANSIZHUANG sales grow rapidly

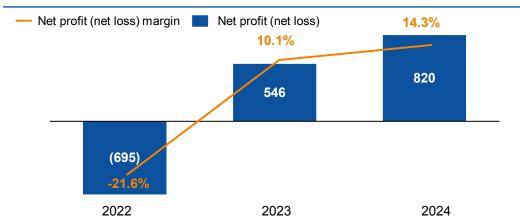
#### Revenue Breakdown

- 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

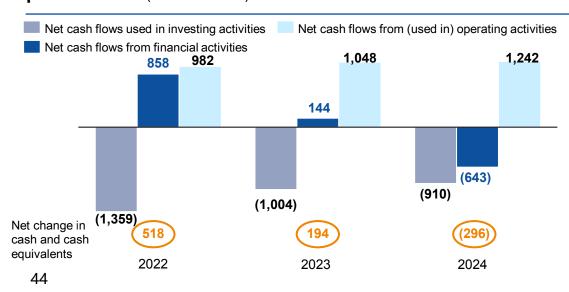


#### Achieved Profitability in 2024 with RMB ~1.24B Operating CF

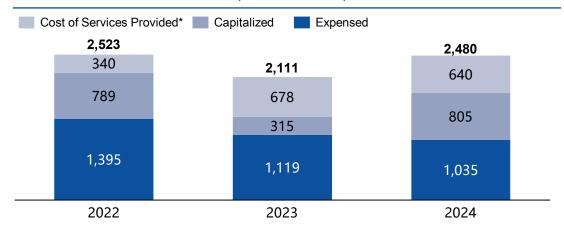
#### Net profit (net loss): Keep profitability (in Million RMB)



#### positive OCF (in Million RMB)

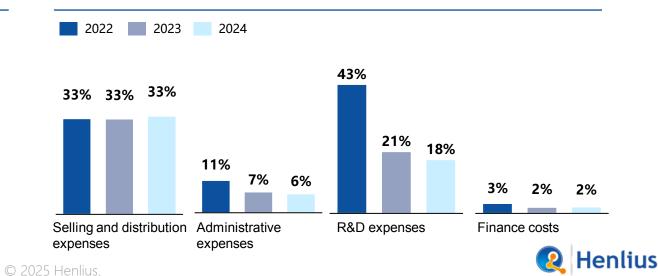


#### **R&D related investment** (in Million RMB)



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

#### Expense to revenue ratios : effective controls on expenses



#### **Financial Highlights**

Financial Data (selected)	2024		202	YoY Growth	
Unit	In Million RMB	% of revenue	In Million RMB	% of revenue	%
Revenue	5,724.4	100.0%	5,394.9	100.0%	6.1%
Product sales	4,933.5	86.2%	4,553.5	84.4%	8.3%
BD and other revenue	790.9	13.8%	841.4	15.6%	(6.0%)
Cost of sales	(1,539.8)	(26.9%)	(1,476.1)	(27.4%)	4.3%
Selling and distribution expenses	(1,917.4)	(33.5%)	(1,754.2)	(32.5%)	9.3%
Administrative expenses	(370.8)	(6.5%)	(383.8)	(7.1%)	(3.4%)
R&D expenses	(1,035.1)	(18.1%)	(1,118.7)	(20.7%)	(7.5%)
Financial costs	(122.9)	(2.1%)	(110.5)	(2.0%)	11.2%
Net profit	820.5	14.3%	546.0	10.1%	50.3%
Cash and bank balances	773.0	13.5%	987.7	18.3%	(21.7%)
Net cash flows from operating activities	1,241.9	21.7%	1,047.9	19.4%	18.5%

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# Reliable Quality Affordable Innovation

