

# Henlius (2696.HK) 2025 Interim Results Investor Presentation






August 2025



01

# 2025 1H Business Highlights & Company Strategy

# Revenue Tops 2.8B RMB with Net Profit of 386M RMB

Revenue 	BD Contract Cash Inflow 	Pipeline 	Global Commercial Capacity 	Overseas Product Profit 
2.8B RMB	>1B RMB	~50	> 1,150	>200% (YoY Growth)
Commercialization	BD	R&D	Manufacturing	Financial
<ul style="list-style-type: none"><li>Achieved sustainable and profitable growth from strong sales team and effective sales management</li><li>HANSIZHUANG sales in 2025H1 reached RMB 0.6 billion. Continuously strengthen in SCLC market and lay out market preparations for CRC and GC.</li><li>Five years since HANQUYOU's global approval. Till now HANQUYOU has been launched in over 50 countries and regions worldwide.</li><li>HANNAIJIA and HANQUYOU have achieved sequential therapy, with their synergistic promotion benefiting more Chinese patients with HER2-positive breast cancer.</li></ul>	<ul style="list-style-type: none"><li>The BD contract cash inflow of RMB &gt;1B in 2025 H1, a 280% YoY growth</li><li>HLX13 (Ipilimumab) out-licensed to Sandoz with upfront payment of USD 31 million and a total amount up to USD 300 million</li><li>HLX15 (daratumumab) out-licensed to Dr. Reddy's with upfront payment of USD 33 million and a total amount up to USD 131.6 million</li><li>HANSIZHUANG (serplulimab) out-licensed to Lotus in South Korea with upfront payment for USD 5 million and a total amount up to USD 112 million</li><li>In-licensed exclusive rights to develop, manufacture and commercialize novel SIRPα-Fc fusion protein in June 2025</li><li>In-licensed the right to develop, and the exclusive right to commercialize HER2 ADC GQ1005 in August 2025</li></ul>	<ul style="list-style-type: none"><li>Serplulimab approved to launch in Europe, UK, India, Singapore and Malaysia</li><li>HLX43 has 10 clinical Ph 1/2 studies of 9 different indications ongoing in China and worldwide, including NSCLC, CC, ESCC, etc.</li><li>HLX22 (novel epitope HER2) has initiated the MRCT phase 3 for 1L treatment of HER2-positive GC, head-to-head comparison vs pembrolizumab. HLX22 receives ODD from EU and US in GC</li><li>HLX26 (LAG3) has completed patient enrollment for Phase 2 clinical trial in first-line NSCLC.</li><li>The novel anti-EGFR antibody HLX07 has completed Phase 2 clinical trial for first-line squamous NSCLC, 1000mg dosage group has a mPFS of 17.4 months</li></ul>	<ul style="list-style-type: none"><li>Commercial GMP production batches &gt; 1,150 batches (YS+SJ1); production success rate exceeds 98%. Product supply covers China, EU, Brazil, Indonesia, Singapore, etc.</li><li>Henlius received the GMP Certificate for HLX14 (denosumab) and HLX11 (pertuzumab)</li><li>Certificated by ISO 14004 Environment Management System and ISO 45001 Occupational Health &amp; Safety Management System</li></ul>	<ul style="list-style-type: none"><li>Total revenue reached RMB 2.8B in 2025 1H, a 2.7% YoY growth</li><li>Total product sales reached RMB 2.6B, a 3.1% YoY growth</li><li>Net operating cash inflow of RMB 770M, a 207% YoY growth, continuing positive operating cash inflow</li><li>Net profit reached RMB 386M, and the net profit rate was 13.8%</li></ul>

# Our Mission and Vision

**Affordable Innovation**  
**Reliable Quality**



## Innovative Drugs

Explore new mechanisms, new technology platforms and broader therapeutic areas.



## Globalization

Develop into a biopharma with global presence & scale



## Biosimilars

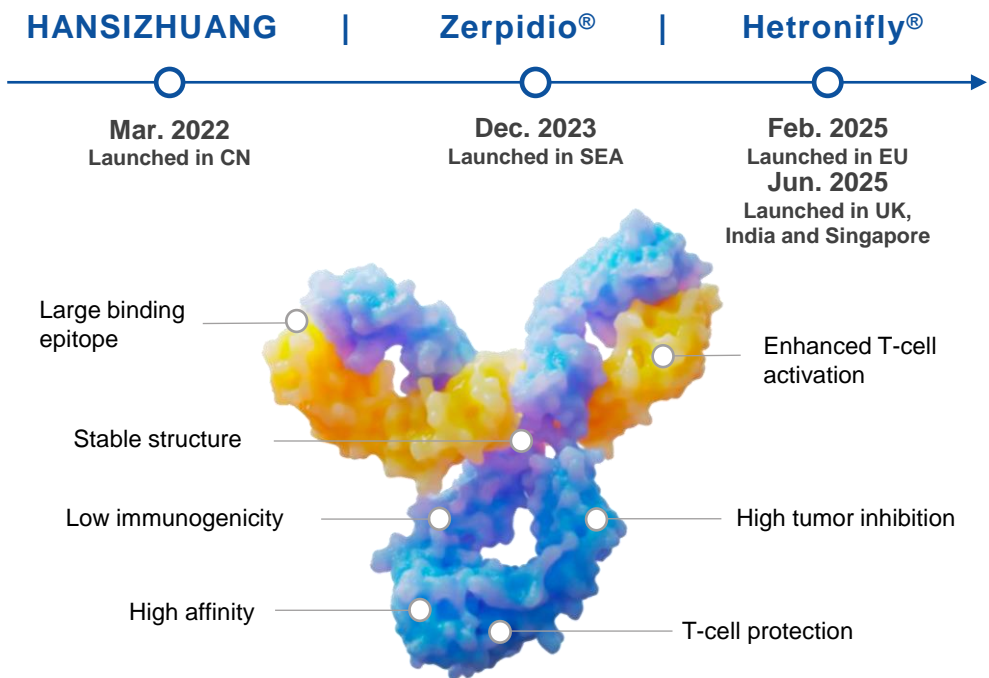
Maximize the commercialization value in China and international markets



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

2025 ASCO  
ANNUAL MEETING

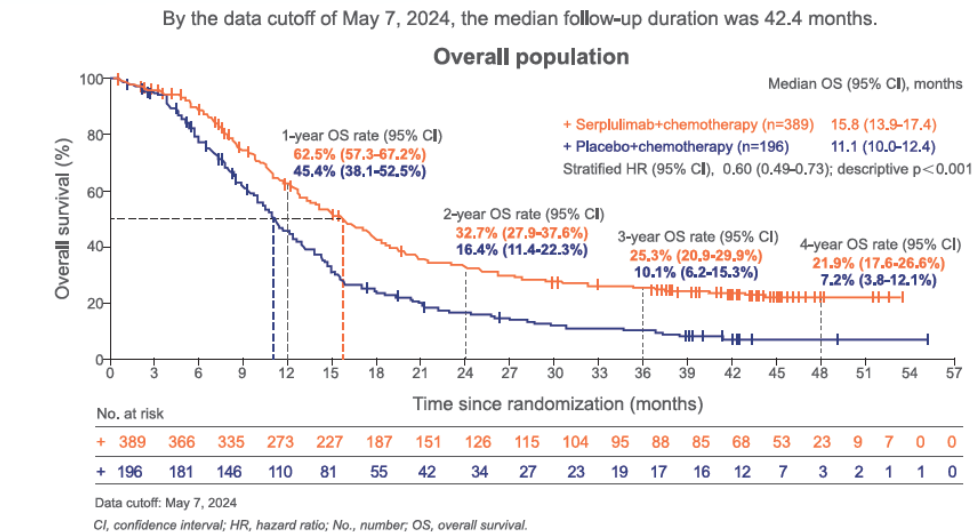
## HLX10 (PD-1) Serplulimab



Launched		Pipeline	
Esophageal Squamous-cell Carcinoma	Lung Cancer	Colorectal Cancer	Gastric Cancer

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

Long-term results and patient-reported outcomes from the ASTRUM-005 study, first published 4-year OS rate: 21.9%



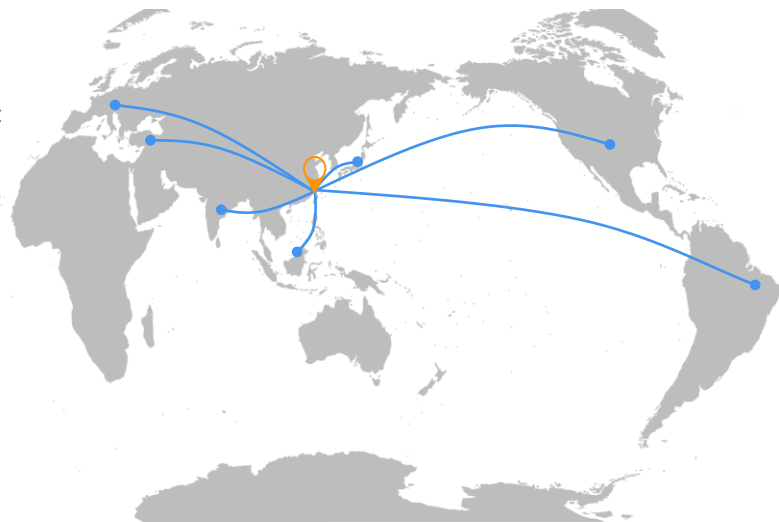
### From East to West, the global launch plan will continue to advance

#### Differentiated Indications:

- Patient enrollment has been completed for clinical trials in LS-SCLC, CRC, and neoadjuvant therapy for GC.

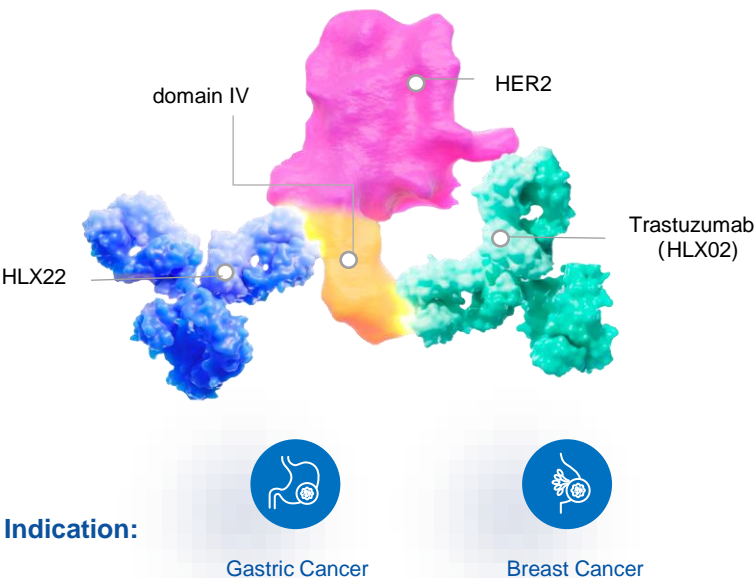
#### New Markets Expansion:

- **U.S.:** For ES-SCLC, >100 clinical sites have been activated, with 183 patients enrolled as of August 2025; FDA BLA submission is planned in 2026 for LS/ES-SCLC
- **Japan:** Completed first patient dose in the Japanese bridging study for SCLC



# HLX22: HER2 Monoclonal Antibody Poised to Succeed KEYNOTE-811

## HLX22 (novel epitope HER2)



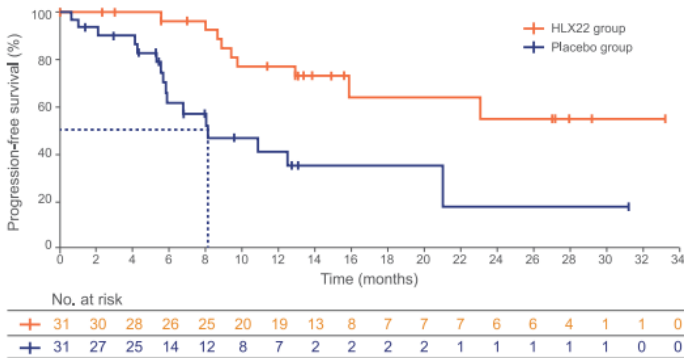
- Granted ODDs by the U.S. FDA and the EU in GC
- Dual-epitope HER2 therapy boosts HER2 internalization by 40–80%, with the potential to break 1L treatment barriers in HER2+ GC
- Phase 2 shows sustained PFS/OS benefit and 80% reduction in the risk of progression or death with >2-year follow-up
- Phase 3 MRCT: head-to-head comparison vs 1L SOC (trastuzumab + chemotherapy ± pembrolizumab)
- Ongoing trial in HER2-low, HR+ breast cancer; exploratory potential in other cancers

**HLX22 has significantly prolonged PFS and OS, and holds the potential to change the current first-line SOC for GC with >2-year follow-up (median follow-up period of 28.5 months).**

Median overall survival was not reached (95% CI 16.2 months–NE) for HLX22 group and 16.4 months (95% CI 10.7–NE) for placebo group (hazard ratio [95%], 0.6 [0.28–1.21]).

	HLX22 group (n = 31)	Placebo group (n = 31)
mPFS, months (95% CI)	NR (16.2–NE)	8.3 (5.7–21.4)
HR (95% CI)	0.2 (0.09–0.54)	p=0.0003
12-month PFS rate (95% CI)	77.1 (56.0–89.0)	40.8 (20.4–60.4)
24-month PFS rate (95% CI)	54.8 (27.3–75.7)	17.5 (1.6–48.0)
mOS, months (95% CI)	NR (16.2–NE)	16.4 (10.7–NE)
HR (95% CI)	0.6 (0.28–1.21)	p=0.1471
Subsequent anti-HER2 therapy, n (%)	3 (9.7)	14 (45.2)
Antibody-drug conjugate	3 (9.7)	8 (25.8)
Monospecific antibody	1 (3.2)	3 (9.7)
Bispecific antibody	0	3 (9.7) <sup>a</sup>

Median progression-free survival was not reached (95% CI 16.2 months–NE) and 8.3 months (95% CI 5.7–21.4) for respective groups (hazard ratio [95% CI], 0.2 [0.09–0.54]).

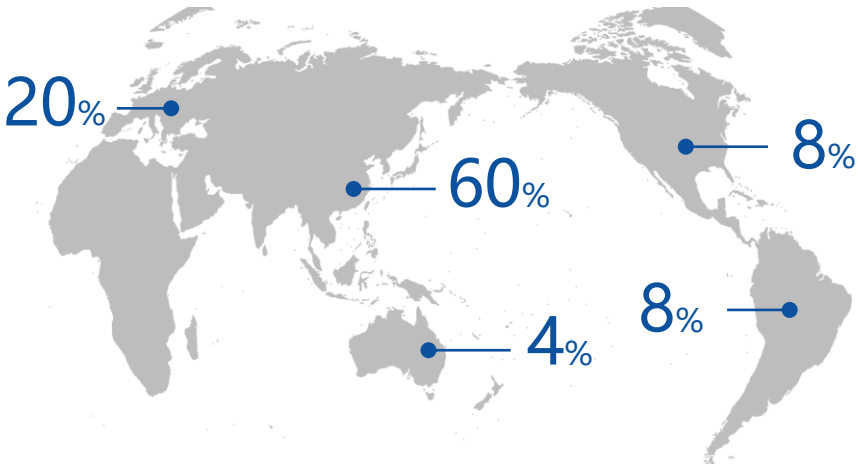


## HLX22-GC301 MRCT led by top global clinical researchers

**Dr. Shen Lin**  
Beijing Cancer Hospital  
CSCO GC Chair

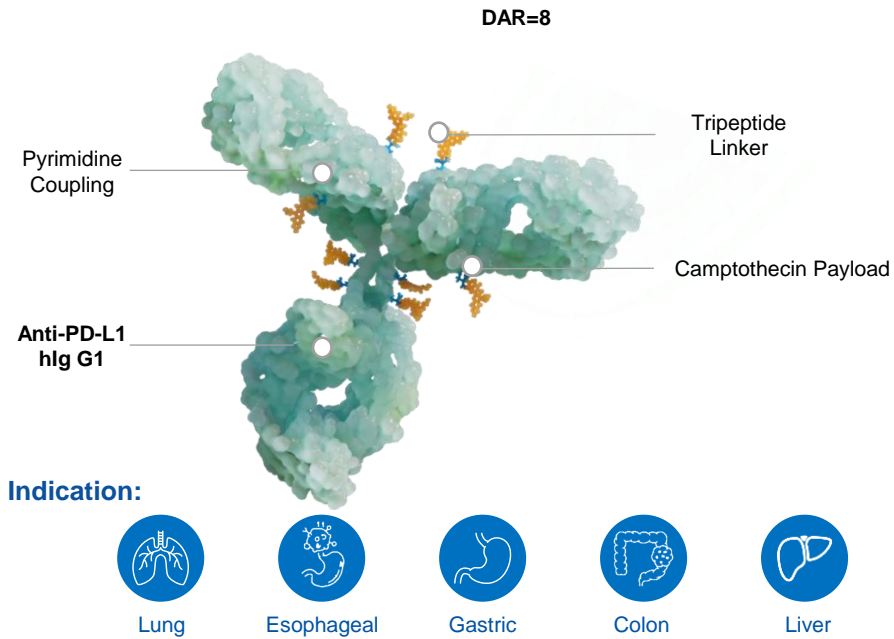
**Dr. Jaffer A. Ajan**  
M.D Anderson  
NCCN GC Chair

**Dr. Ken Kato**  
NCCN



# HLX43: a PD-L1 ADC Entering Global Ph 2 with High Efficacy, Low Toxicity, and I/O Functionality

## HLX43 (PDL-1 ADC)



- A broad-spectrum anti-tumor ADC with both ADC and IO efficacy, potential for full population coverage (not limited to PD-L1-positive patients).
- Phase 1 shows, showcasing excellent preliminary efficacy with impressive results in NSCLC and thymic squamous cell carcinoma.
- Obtained approvals in China, the U.S., Australia, and Japan to initiate Phase 2 MRCT for advanced NSCLC, the first Chinese PD-L1 ADC entering Phase 2
- Development in multiple tumor types and the exploration of various combination therapies, including combining it with Serplulimab

HLX43 was well tolerated with no new safety signals across different doses and exhibited encouraging preliminary efficacy in patients with advanced solid tumors, including those with NSCLC and TSCC, who had failed standard therapies, which warrants further investigation.

2025 ASCO  
ANNUAL MEETING

Tumor response per RECIST v1.1 <sup>a</sup>	Phase 1b 2.0 mg/kg (n = 21)
CR, n (%)	0
PR, n (%)	8 (38.1)
SD, n (%)	9 (42.9)
PD, n (%)	4 (19.0)
NE, n (%)	0
ORR, % (95% CI)	38.1 (18.1–61.6)
Confirmed ORR, % (95% CI)	33.3 (14.6–57.0)
ORR in patients who had ≥3 prior lines of therapy, %	38.5 (5/13)
DCR, % (95% CI)	81.0 (58.1–94.6)
mDOR, months (95% CI)	NR (1.4–NE)
mPFS, months (95% CI)	5.4 (4.0–6.3)
mOS, months (95% CI)	NR (6.7–NE)

Subgroup analysis of tumor response per RECIST v1.1 <sup>a</sup>	ORR % (95% CI)	DCR % (95% CI)
NSCLC subtype		
Squamous (n = 15)	40.0 (16.3–67.7)	73.3 (44.9–92.2)
Confirmed response	33.3 (11.8–61.6)	73.3 (44.9–92.2)
Nonsquamous (n = 6)	33.3 (4.3–77.7)	100 (54.1–100)
Confirmed response	33.3 (4.3–77.7)	100 (54.1–100)
Used docetaxel		
Yes (n = 9)	33.3 (7.5–70.1)	77.8 (40.0–97.2)
No (n = 12)	41.7 (15.2–72.3)	83.3 (51.6–97.9)
Brain metastasis		
Yes (n = 6)	33.3 (4.3–77.7)	100 (54.1–100)
No (n = 15)	40.0 (16.3–67.7)	73.3 (44.9–92.2)
Liver metastasis		
Yes (n = 3)	33.3 (0.8–90.6)	66.7 (9.4–99.2)
No (n = 18)	38.9 (17.3–64.3)	83.3 (58.6–96.4)
PD-L1 expression		
CPS ≥ 1 (n = 16)	37.5 (15.2–64.6)	81.3 (54.4–96.0)
CPS < 1 (n = 5)	40.0 (5.3–85.3)	80.0 (28.4–99.5)

### A Broad Therapeutic Effects

Outstanding efficacy across multiple tumor types, including TSCC, heavily treated NSCLC:

- TSCC ORR: 75% (vs. historical 25%)
- 2.0mg/kg Cohort ≥ 4L NSCLC ORR: 38.5%
- DCR in NSCLC patients with brain metastasis: 100%
- **EGFR wt nsqNSCLC ORR: 47.4%**

### B Biomarker Independent

Efficacy in various types of NSCLC

- Squamous, non-squamous
- EGFR mutant and EGFR wild-type
- With or without brain/liver metastasis
- PD-L1 positive and negative

### C Favorable Safety Profile

2.0 mg/kg: low hematologic toxicity\*, supporting future expansion into 1L therapy and combination regimens

- Anemia 14.3%
- Lymphocyte count decreased 14.3%
- Platelet count decreased 0%
- neutrophil count decreased 0%

\*Grade ≥ 3 treatment-related adverse events

# 2025H1 The key milestones of globalization



## North America

- ✓ HLX13 (Ipilimumab) out-licensed to Sandoz in the U.S., and Canada
- ✓ HLX15 (daratumumab) out-licensed to Dr. Reddy's in the U.S.
- ✓ US FDA accepts Biologics License Application (BLA) for HLX11
- ✓ PD-L1 ADC HLX43 in NSCLC received Ph 2 MRCT IND approval from the U.S. FDA
- ✓ HLX22 (novel epitope HER2) completed first patient dosed in the U.S. for Ph 3 MRCT
- ✓ FDA granted Orphan Drug Designation (ODD) for HLX22 (novel epitope HER2) for the treatment of gastric cancer.



## Japan

- ✓ First Japanese patient dosed in Ph 3 MRCT of HLX22 (novel epitope HER2)
- ✓ HLX13 (Ipilimumab) out-licensed to Sandoz in Japan
- ✓ HANSIZHUANG completed first patient dosed in Japanese SCLC bridging study
- ✓ PD-L1 ADC HLX43 on NSCLC received Ph 2 MRCT IND approval from Japan's PMDA



## Europe

- ✓ Serplulimab (trade name in Europe: Hetronify®) has been approved in UK and EU
- ✓ HLX13 (Ipilimumab) out-licensed to Sandoz in a total of 42 countries and regions of Europe
- ✓ HLX15 (daratumumab) out-licensed to Dr. Reddy's in 42 European countries and regions
- ✓ European Commission has granted ODD for HLX22 (novel epitope HER2)
- ✓ HLX22 (novel epitope HER2) receives clinical approval in EU for Ph 3 MRCT
- ✓ European Medicines Agency (EMA) validates HLX11 (pertuzumab); HLX14 (Denosumab) receives positive opinion for EMA.
- ✓ HLX14 (denosumab) and HLX11 (pertuzumab) received new EMA GMP Certification

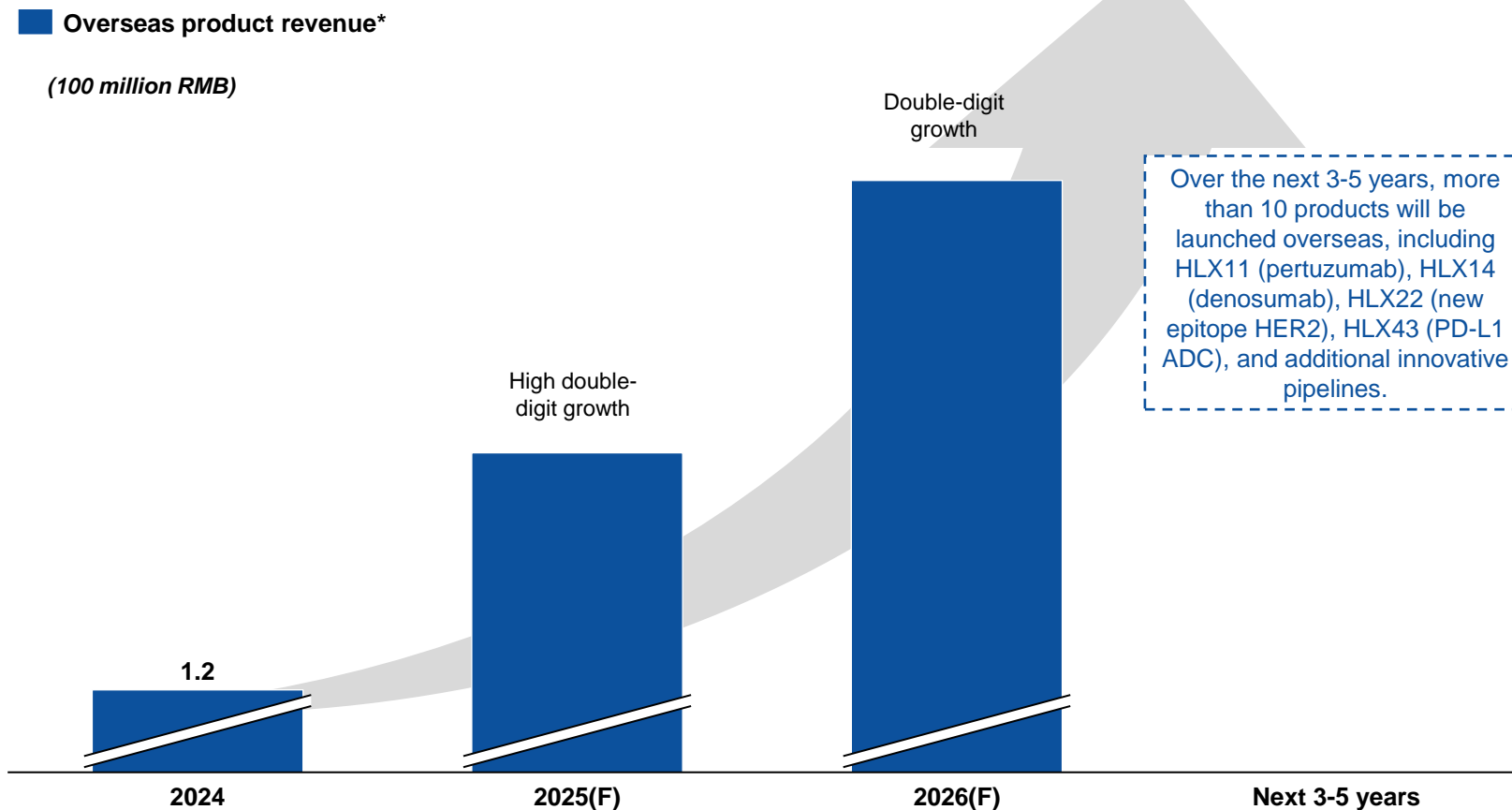


## Other countries in Asia Pacific

- ✓ HANSIZHUANG approved to launch in Singapore and Malaysia. New indications of HANSIZHUANG approved in Indonesia and Thailand
- ✓ HANSIZHUANG approved to launch in India for the first-line treatment of extensive-stage small cell lung cancer (ES-SCLC)
- ✓ Henlius and Lotus forged a strategic partnership in South Korea for Serplulimab for several indications, including ES-SCLC. Serplulimab receives ODD in South Korea
- ✓ In-licensed exclusive rights to develop novel SIRPα-Fc fusion protein, in China and certain countries and regions in Southeast Asia



# Henlius' Products Hit Global Markets such as the US, UK, and India: Revenue and Profits Set to Surge



## 2024

The 4 key products have been approved for sale overseas and are shipped to Europe, the Middle East, Latin America, and other regions.

## 2025

HANQUYOU U.S. market ramp-up to drive significant full-year growth in overseas product revenue and profit

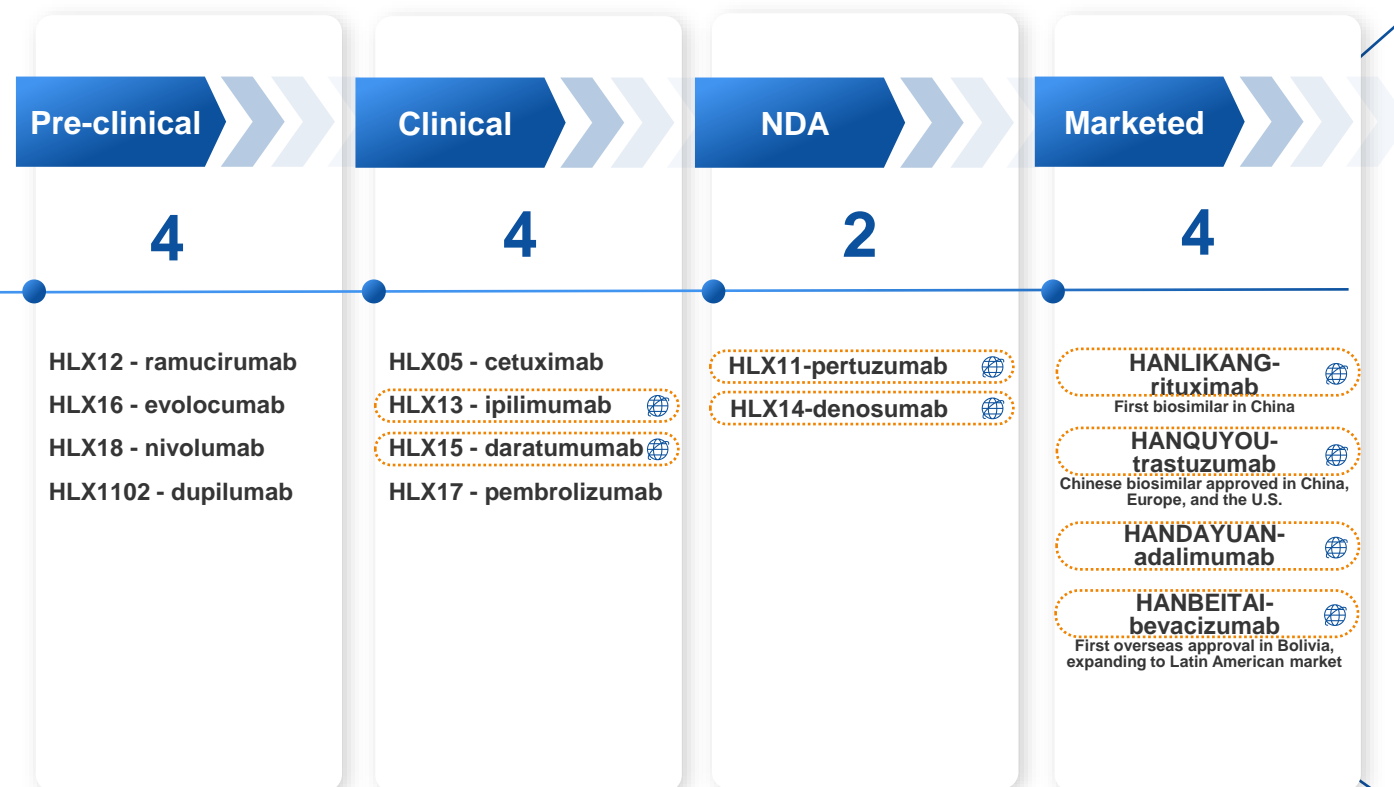
## 2026~Next 3-5 years

Growing overseas product sales of HANQUYOU and HANSIZHUANG in U.S. / Europe / India to elevate Henlius' international product revenue proportion and profit contributions

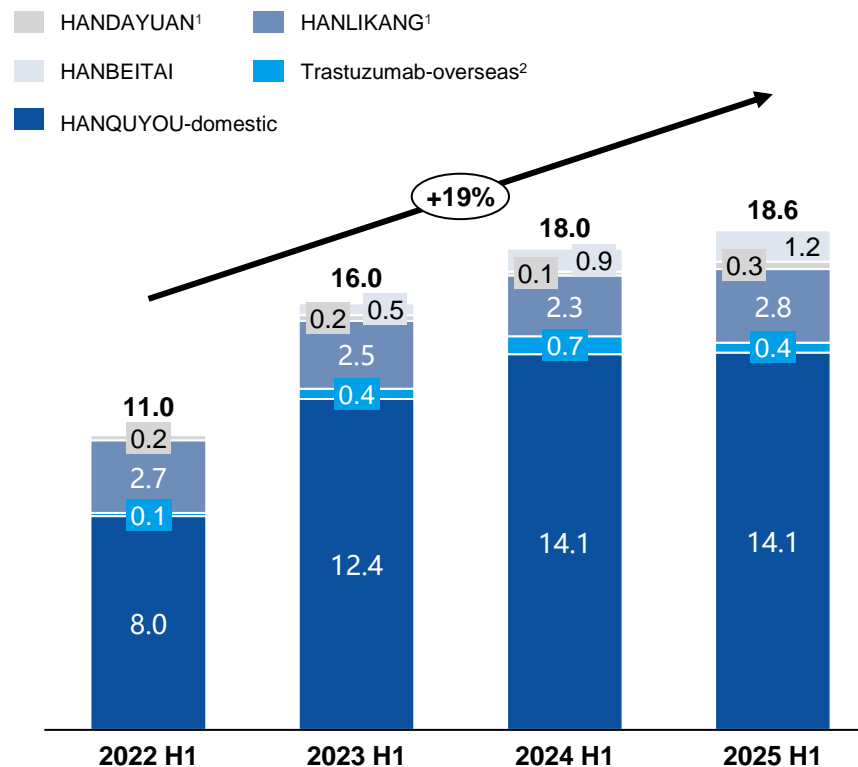
\*Overseas product revenue includes product supply revenue + royalties

# Robust Biosimilar Pipeline is Aiming at Global Market

- 2025H1 sales revenue of biosimilars reached 1.86 billion RMB. HLX11 (pertuzumab) and HLX14 (denosumab) received new EMA GMP Certification. The biosimilar pipeline covers global 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 is a China-developed mAb biosimilar approved in China, Europe, and U.S. It has approved in over 50 countries and regions, benefiting over 260,000 patients.
- HANLIKANG has been on the market for 6 years. Driven by the dual engines of "independent R&D + accessibility", it has benefited over 350,000 Chinese patients cumulatively.
- 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

02

# Business Development

# Recent Major Out-licensing Products, Contribute Cash Inflow ~670 million RMB in 1H25



**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, \$132M deal size

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



**Alvogen Korea  
Co., Ltd.**  
(wholly-owned  
subsidiary of Lotus)

**Contract signing date: 2025/04/25**

## **Out-licensing**

### **HANSIZHUANG (Serplulimab)**

South Korea  
\$5M upfront payment, \$112M deal size

By synergizing complementary strengths, aim to deliver high-quality, affordable innovative therapies to Korean patients and further solidify our strategic footprint across Asians



**Sandoz AG**

**Contract signing date: 2025/04/29**

## **Out-licensing**

### **HLX13 (Ipilimumab biosimilar)**

Exclusive commercial rights in United States, 42 European countries and regions, Japan, Canada, and Australia  
\$31M upfront payment, \$301M deal size

Potential 1<sup>st</sup> biosimilar of a billion product with an experienced biosimilar leader, to deliver high-quality and affordable treatment options to global markets

# Recent In-licensing Deal - Actively Introduce Next-Generation IO Pipeline

## In-licensing



**FBD Biologics Limited**

(License signing date: 2025/06/30)

### In-licensing

**HCB101, SIRP $\alpha$ -Fc fusion protein**

**Exclusive rights in China (including HK, MC), designated countries in Southeast Asia, etc.**

**Bringing in Next-Gen, better safty IO Therapy with synergy values**

**HCB101 (SIRP $\alpha$ -Fc fusion protein) is a fusion protein with differentiated design, fused with engineered SIRP $\alpha$  and IgG4 Fc**

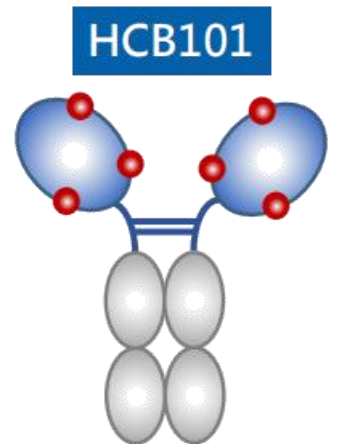
- High binding affinity to CD47 on tumor cells, and low binding affinity to CD47 on erythrocytes;
- Effectively activate macrophage phagocytosis of tumors by utilizing IgG4 Fc;
- Specifically binds to CD47 on tumor cells compared to first-generation anti-CD47 antibodies;
- Significantly enhances the affinity to CD47 compared to second-generation wild-type SIRP $\alpha$  fusion proteins<sup>1</sup>.

**Preliminary clinical data displayed good safety profiles and positive efficacy signal**

- Up to date, 10 doses have been explored, and the safety profile has been confirmed by the Safety Audit Committee (SRC).
- Mono therapy has shown tumor response to solid tumors, and the preliminary efficacy of combo therapy is significant, and PR has been observed in solid tumors such as HNSCC and TNBC

**The cornerstone of next-generation IO therapy**

- With dual mechanisms of activating both innate immunity (macrophages) and adaptive immunity (T cells), there're broad opportunities in combination therapies with various therapeutic medicines (e.g. PD-1/L1 mAb, chemotherapy, ADCs, etc. ).



1. The affinity of HCB101 to CD47 is 100-fold higher than that of wild-type SIRP $\alpha$  under specific animal models (such as Raji).  
2. It's observed that HCB101 could activate both innate immunity (macrophages) and adaptive immunity (T cells) under specific animal models.



# 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+	HR+/ HER2-
Perioperative period	 Trastuzumab	 Neratinib
1L	HER2 ADC (HLX87)	Pertuzumab (HLX11)
2L/2L+	HER2 ADC (HLX87)	Lasofoxifene (HLX78) <ul style="list-style-type: none"> <li>• ESR1<sup>mut</sup> BC (2L+)</li> <li>• HR+/HER2- (2L+) BC</li> </ul>

## HLX87/GQ1005 (HER2 ADC):

- HLX87/GQ1005 is an innovative HER2 ADC, developed based on GeneQuantum (GQ)'s proprietary enzymatic site-specific conjugation technology, under Phase 3 development for HER2+ breast cancer.
- Utilizing GQ's proprietary stabilized cleavable linker, GQ1005 demonstrated superior stability, and consequently superior safety and comparable anti-tumor activity to T-Dxd in preclinical studies.
- At AACR 2024, phase 1 clinical data of GQ1005 for the treatment of HER2-expressing or mutated advanced solid tumors were released. GQ1005 exhibited excellent safety in phase 1 study, with much less  $\geq$ Grade 3 TRAE\* than other HER2 ADCs, and comparable efficacy to T-Dxd.

## In-licensing deal snapshot:

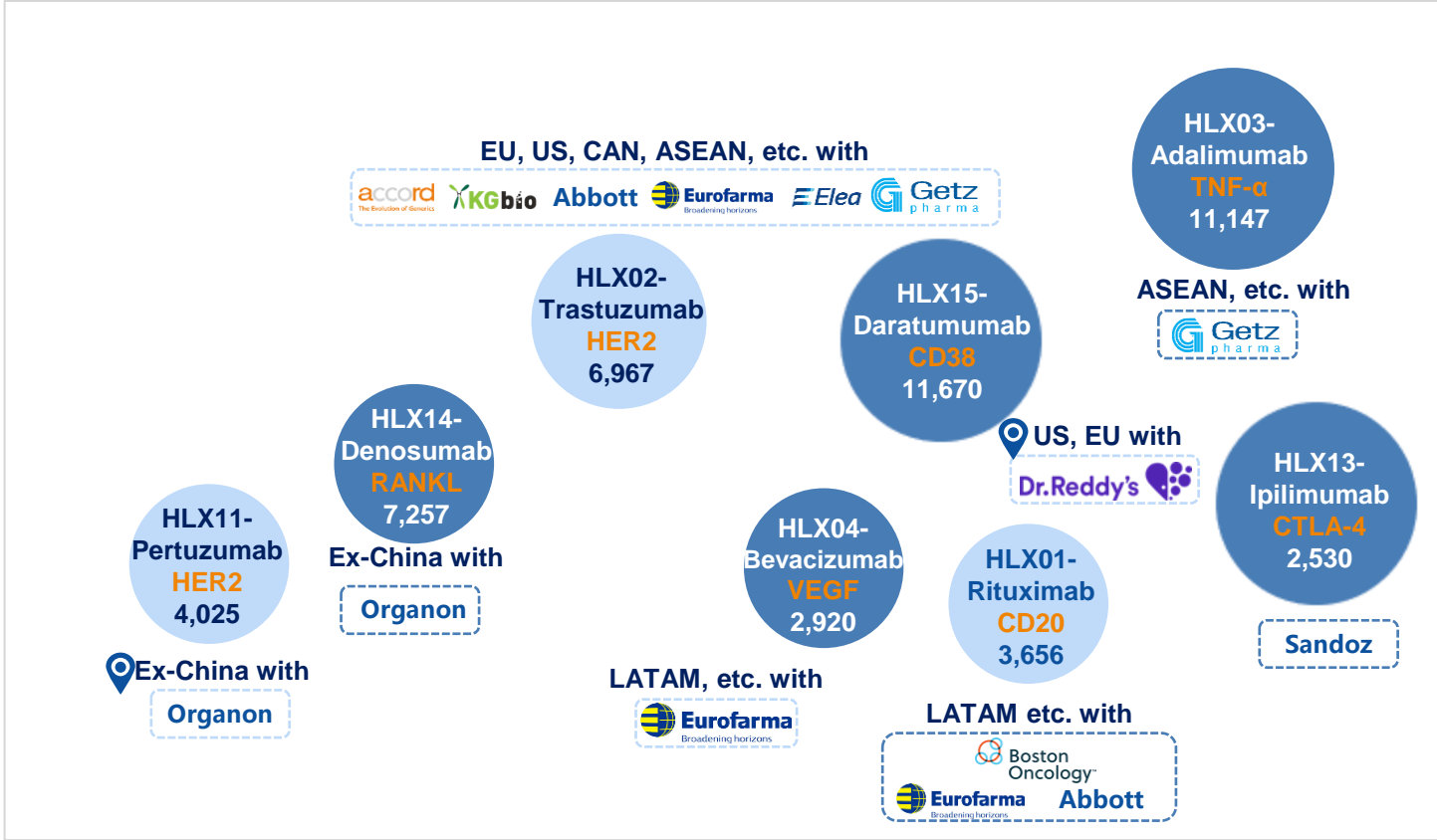
- Henlius and GeneQuantum established strategic partnership on GQ1005. Henlius obtained the right to develop and the exclusive right to commercialize the product in China and designated countries and regions out of China.

# Out-licensing Focus: Henlius' International Quality Biosimilars Provide Stable Cash Flow and Support Innovative Pipelines

## Market Size of Originators and Marketed Biosimilars

### Biosimilars with existing out-licensing partners

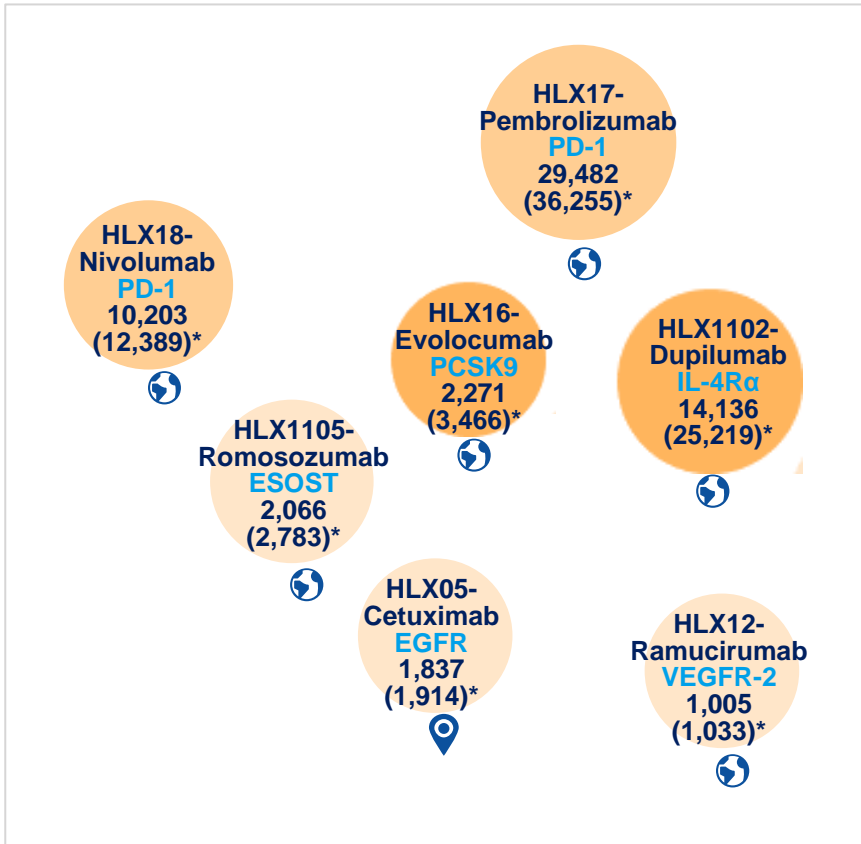
Global sales in 2024 (M USD)



Potentially first biosimilar in EU and the U.S.  
 Global potentially first biosimilar

### Biosimilars to be out-licensed US/EU Market

Global sales in 2024 (M USD)



()\*: Potential peak sales from Global Data

03

## Pre-clinical Innovative Assets

# Strategic Planning of Early Research: Leveraging Core Strengths to Align with Henlius Overall Strategy

## Major Modality: Antibody and Antibody-Derivatives



**Antibody: mAb, bispecific, multi-specific**



**ADC: single payload, multiple payloads**



**Fusion Protein: antibody fused with functional protein**



**Small Molecule**

## Key Indications: Oncology, Autoimmune Disease



**Tier1 Cancer: breast cancer, lung cancer, colon cancer**



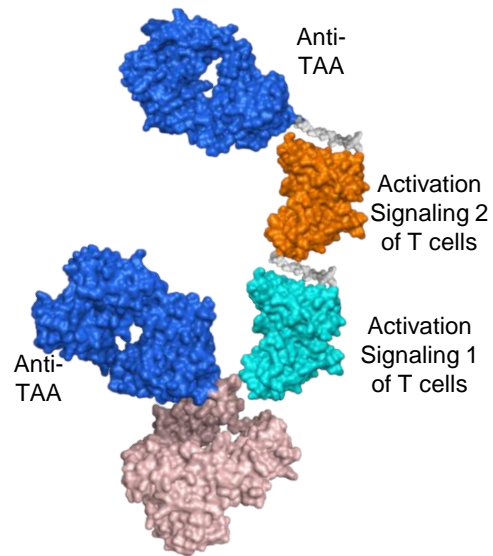
**Autoimmune disease: IBD, SLE, atopic dermatitis, asthma, etc.**



**Tier2 Cancer: HCC, GC, PDAC, prostate cancer, etc.**

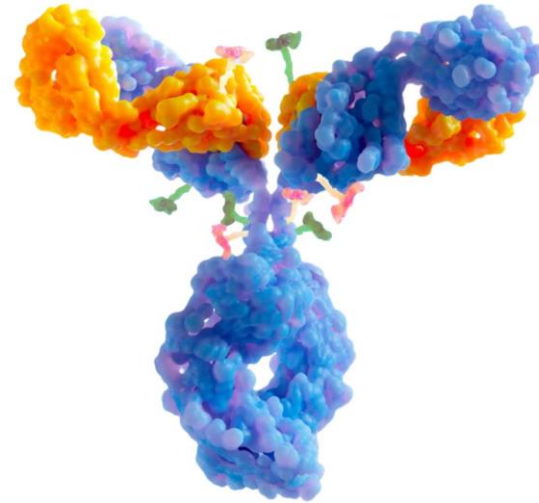
# Three Major Technology Platforms Support Mid-to-Long-Term Pipeline Development

## Tri-specific T cell engager



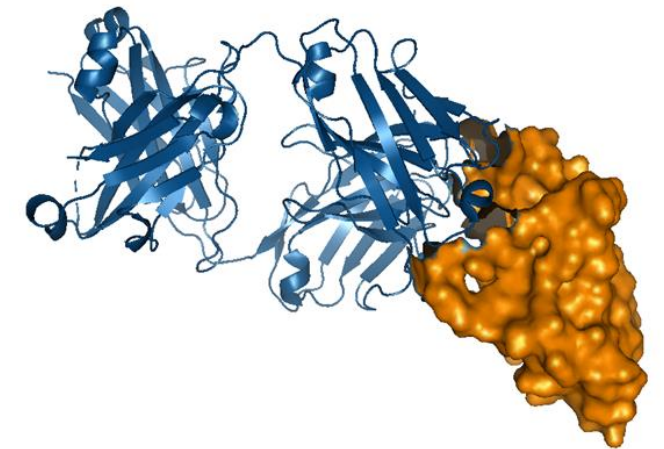
- Persistent specific T-cell activation effect
- Better efficacy in tumor microenvironment with low immune cell infiltration
- Reduced occurrence of CRS

## Hanjugator™ ADC platform



- Expand the therapeutic window
- Overcome drug resistance to widely used toxins
- Combination of toxins with multiple MOA

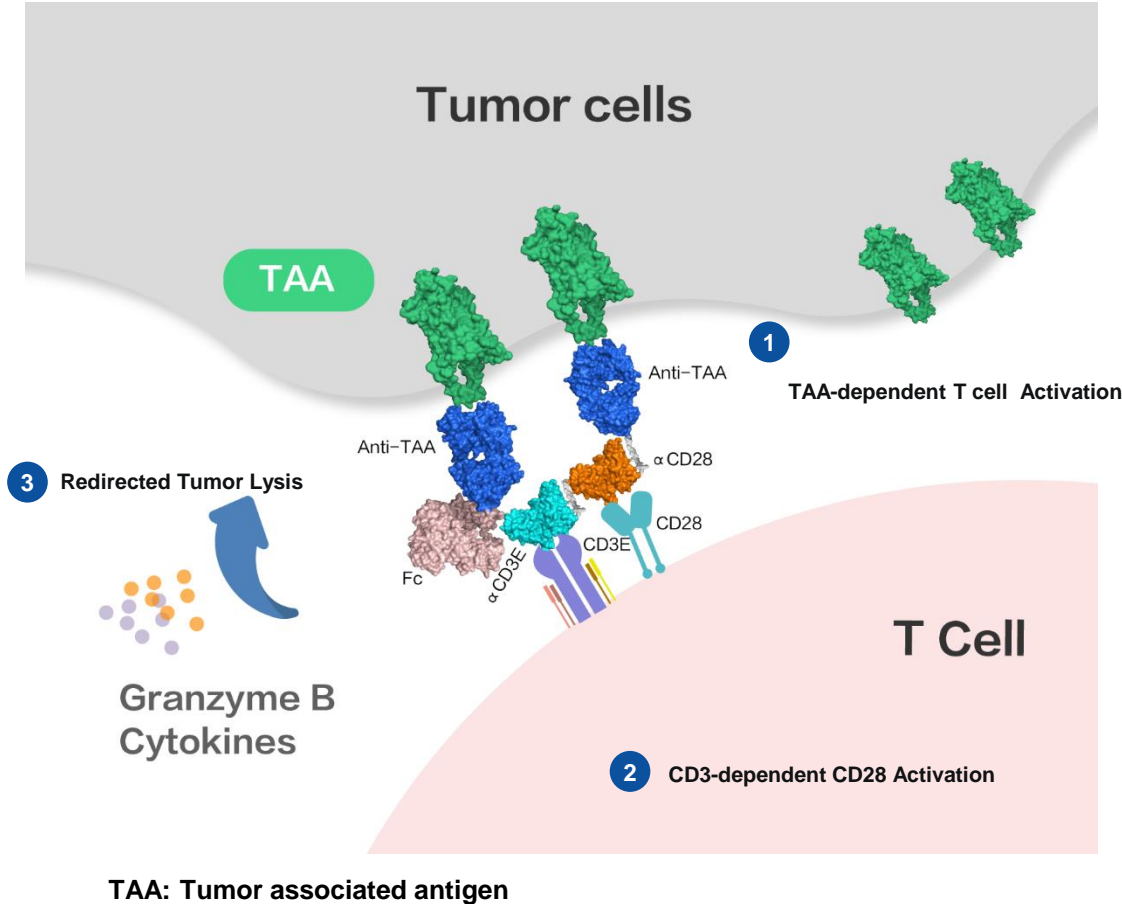
## HAI Club platform



- Searching for new drug targets
- Cost reduction and efficiency improvement in research and development
- Increasing the success rate of drug discovery

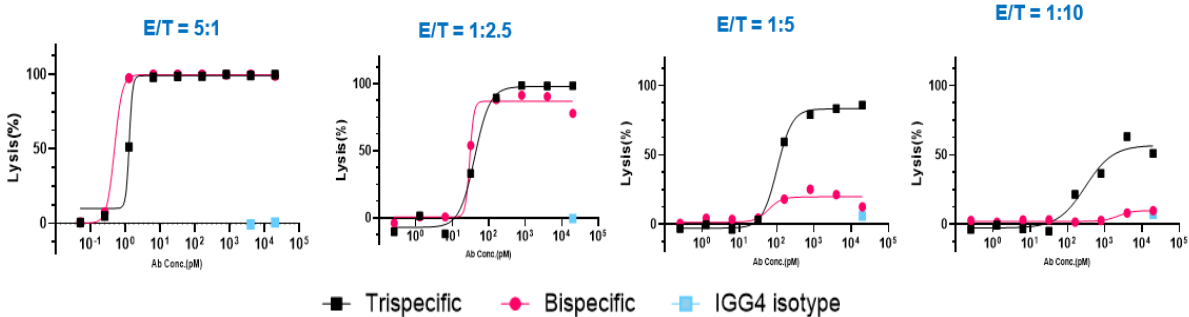


# A Safer and More Effective TAAxCD3xCD28 TCE Tri-specific Platform

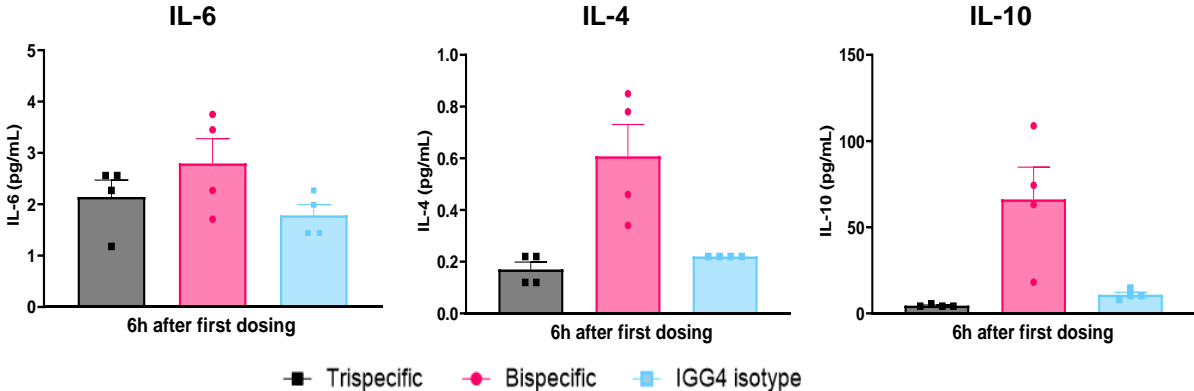


## Efficacy: better in lower E/T ratio

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

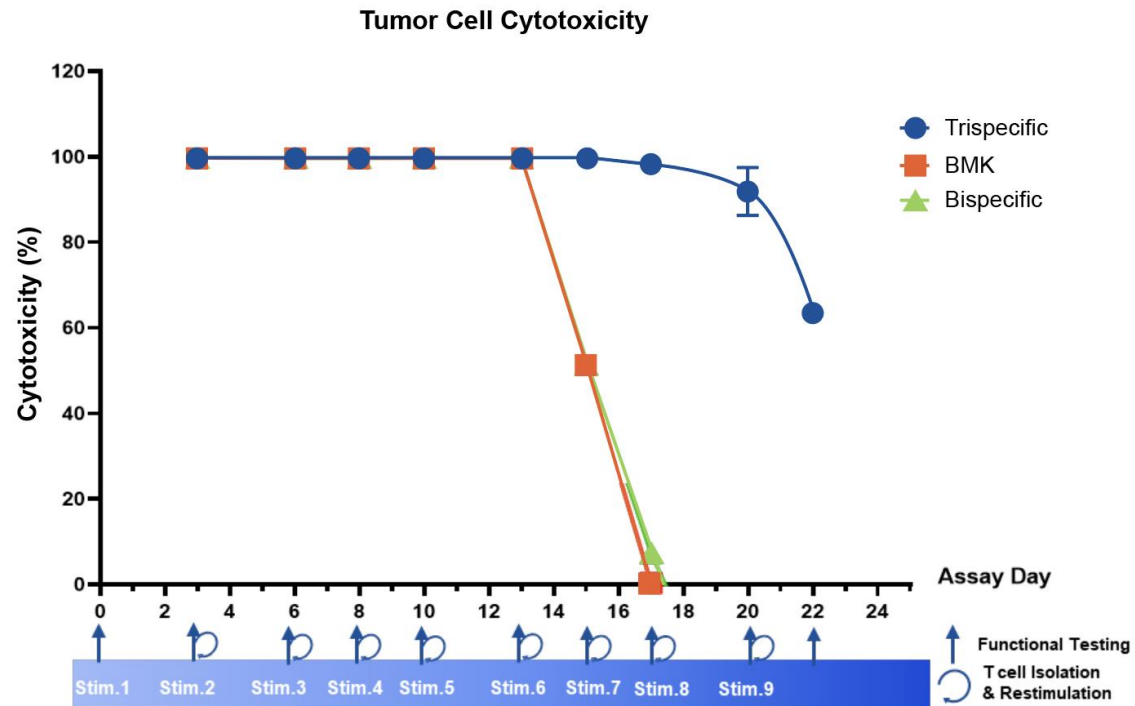


## Safety: Lower CRS

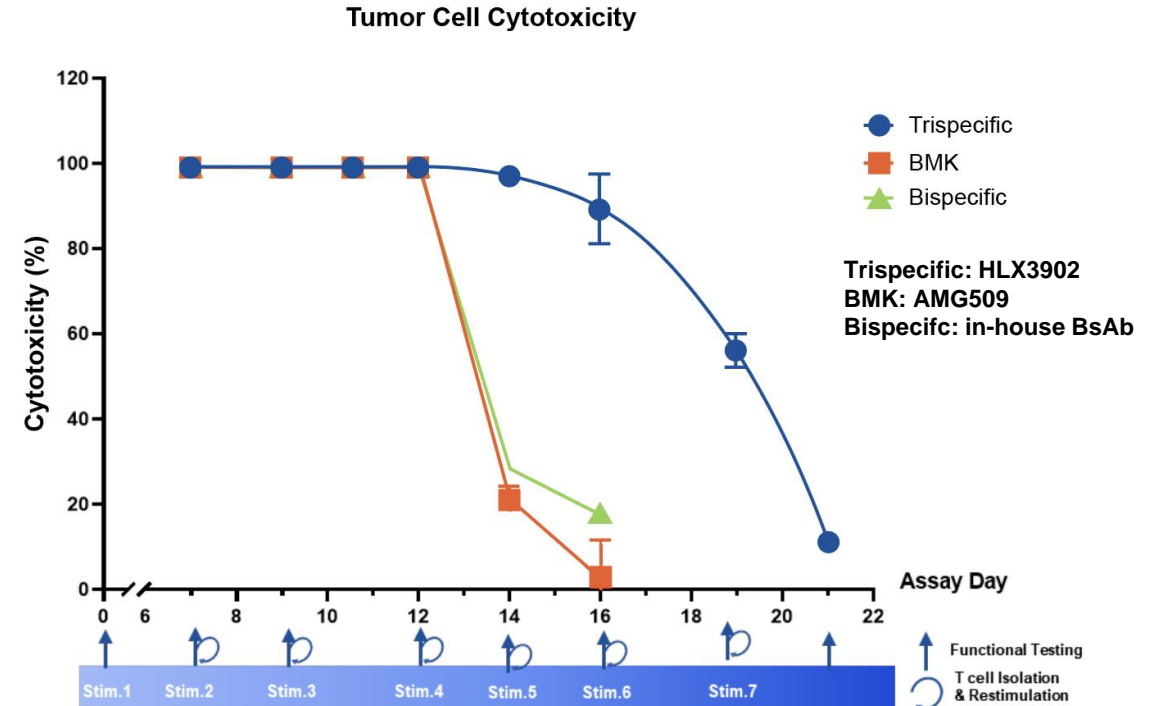


# HLX3902: A Potential “Best-In-Class” Anti-STEAP1 Tri-specific Ab

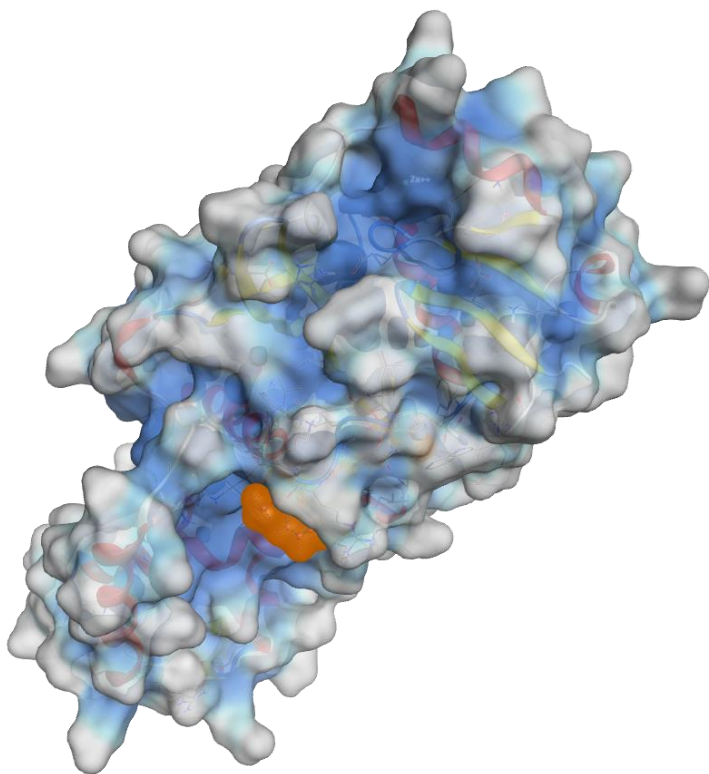
Effector (T cells): Tumor (TAA<sup>pos</sup>) = high



Effector (T cells): Tumor(TAA<sup>pos</sup>) = low

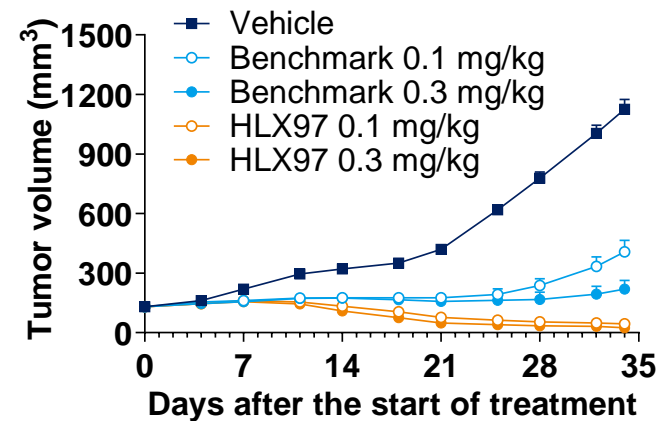


# HLX97: A Potential “Best-In-Class” KAT6A/B inhibitor



- Broad cancer indications including BrCa, CRPC, and NSCLC
- Superior *in vitro* and *in vivo* efficacy compared to competitors
- Unique pharmacokinetic properties address accumulation issues and on-mechanism hematologic toxicity
- Favorable ADMET\* properties

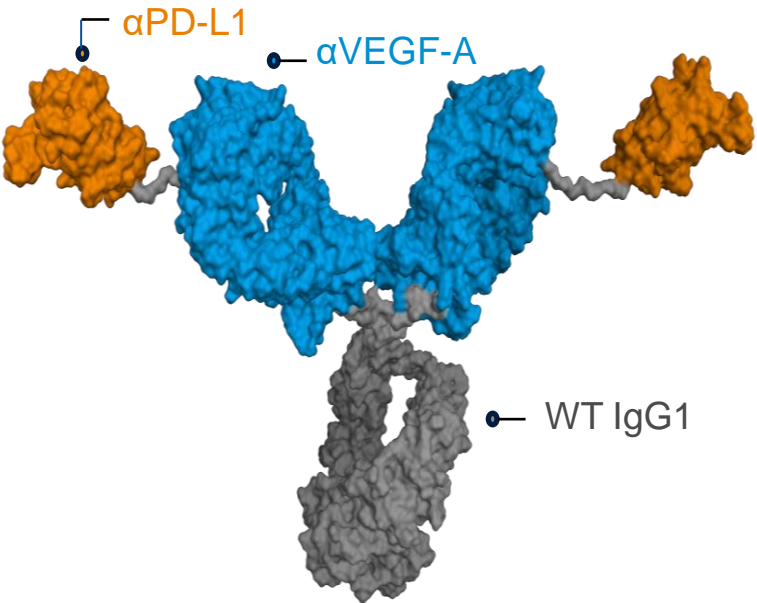
Significantly more efficacious than competitor compounds in the ZR-75-1 model



Reduced hematotoxicity across multiple efficacy models

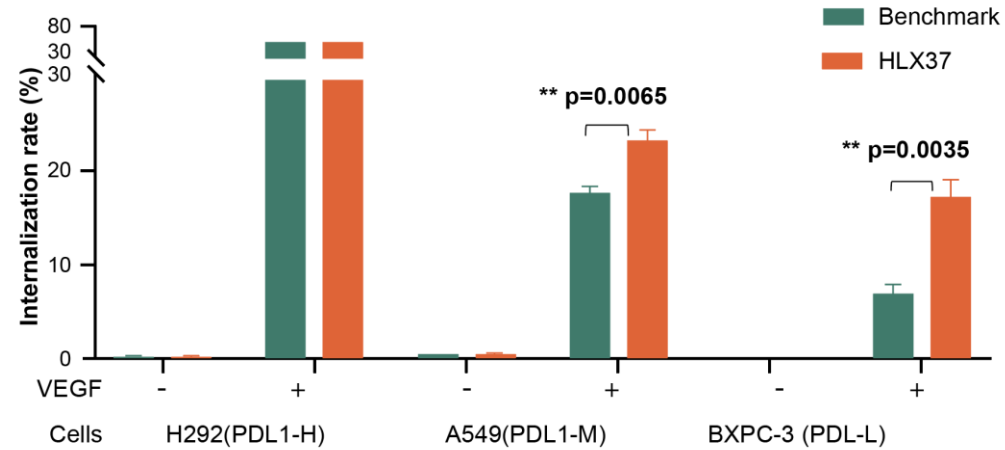
Treatment	Model 1: ZR-75-1				Model 2: PDX				Model 3: T47D			
	Dose (mpk)	TGI (%)	↓WBC# (%)	↓Lym# (%)	Dose (mpk)	TGI (%)	↓WBC# (%)	↓Lym# (%)	Dose (mpk)	TGI (%)	↓WBC# (%)	↓Lym# (%)
Benchmark	0.1	72	19	3	0.3	19	29	47	0.3	50	28	43
	0.3	91	31	24	1	58	54	64				
HLX97	0.1	109	15	3	0.3	61	0.4	10	0.3	67	7	13
	0.3	111	23	15	1	72	32	51				

# HLX37: PD-L1xVEGF bsAb, a next-generation I/O product after Serplulimab (PD-1)

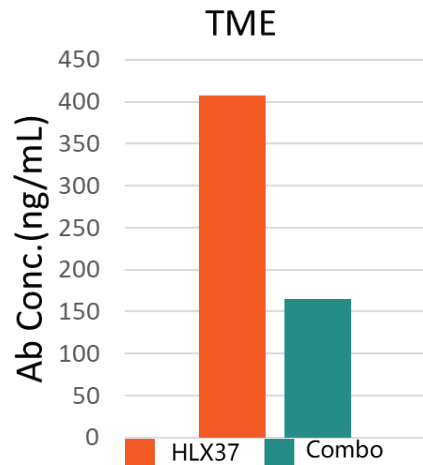


- High PD-L1 affinity, enhanced tumor microenvironment enrichment
- Good drug developability

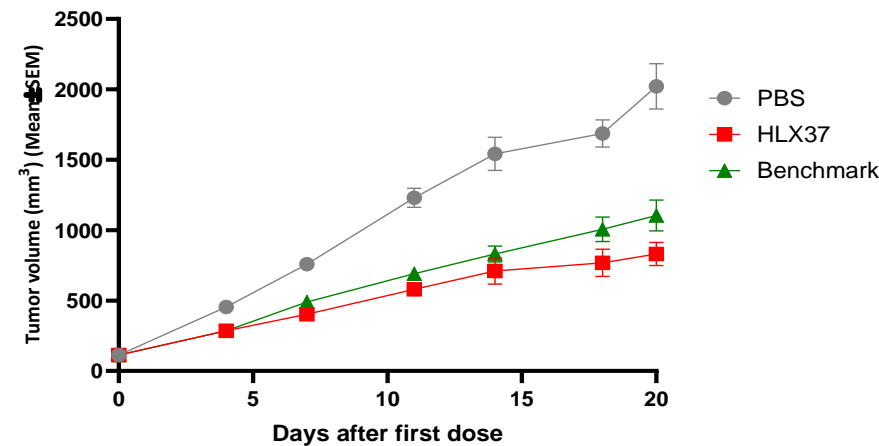
## More efficient induction of PDL1 internalization enhances T cell activation



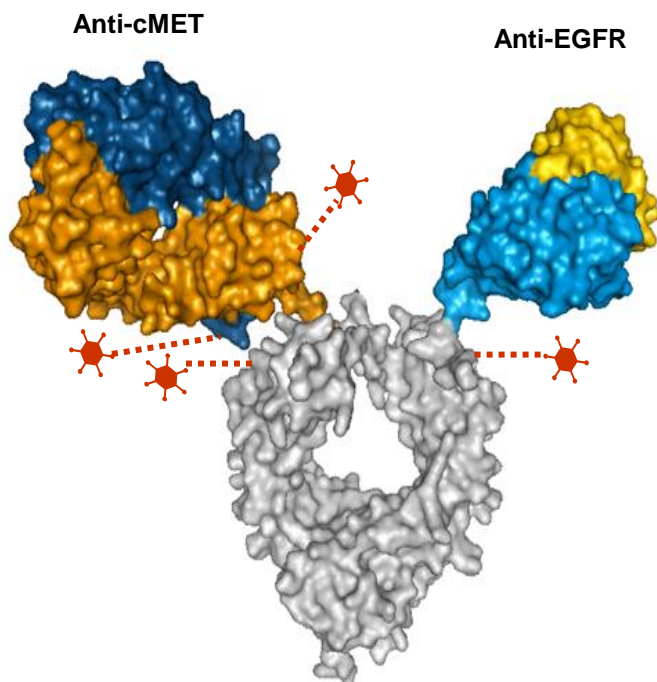
## Higher enrichment rate in TME compared to combo



## Better efficacy compared to competitor in A549 model

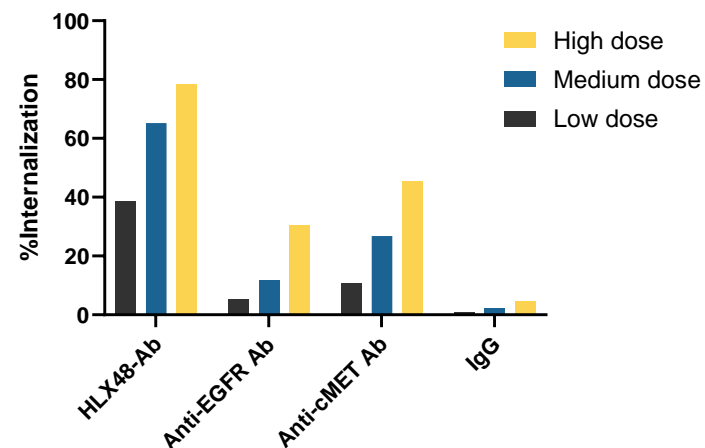


# HLX48: A Potential "Best-In-Class" Anti-EGFRXcMET ADC for NSCLC and CRC

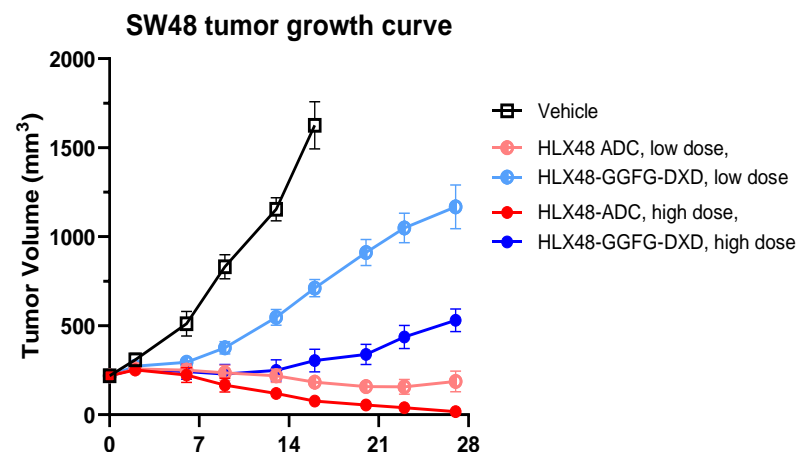


- A higher affinity for cMET and a lower affinity for EGFR is selected to mitigate toxicity
- Improved therapeutic window to maximize antibody function
- A stronger bystander effect, addressing the issue of tumor heterogeneity

## Bispecific Ab with higher internalization efficiency

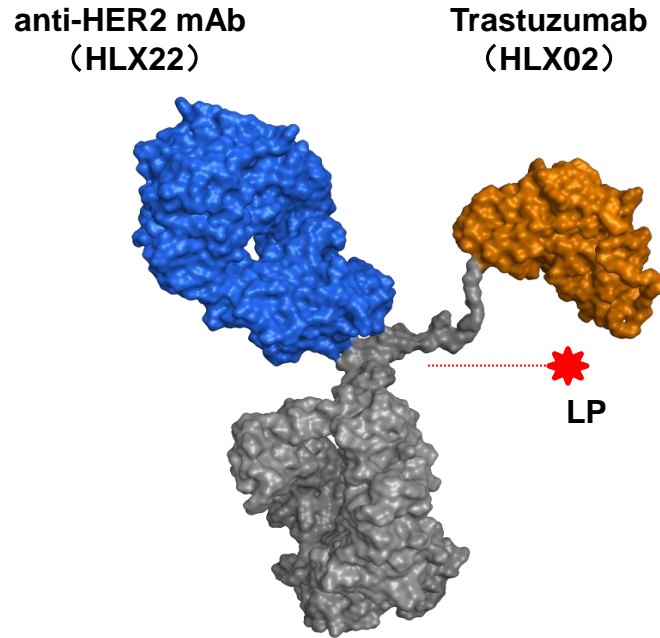


## HLX48 ADC is significantly more efficacious than HLX48-GGFG-DXD





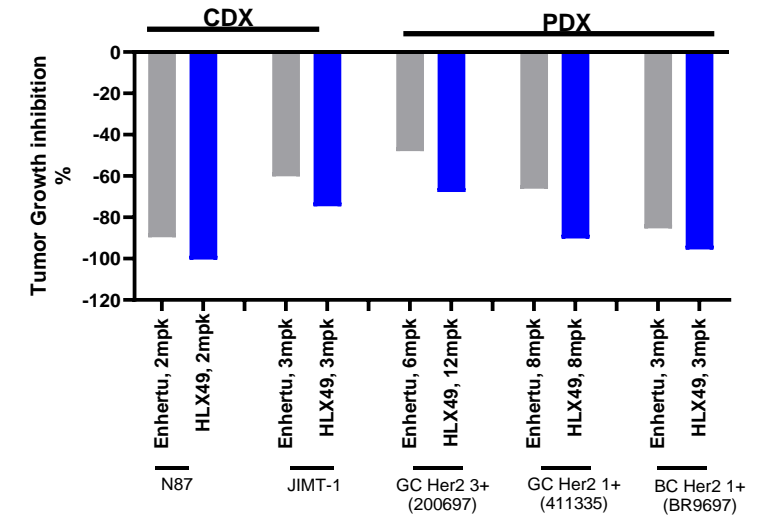
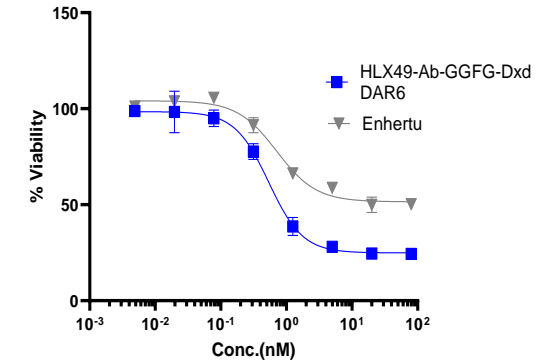
# HLX49: A Potential “Best-In-Class” Anti-HER2 biparatopic ADC



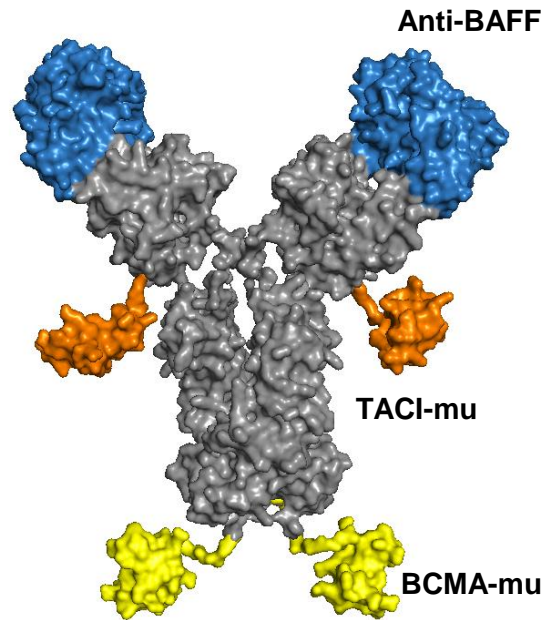
- Enhanced endocytosis of HER2/HER2 and HER2/EGFR by the biparatopic Ab of HLX22
- Better tolerability, improved therapeutic window to maximize antibody function

HLX49 (DAR 6) is significantly more efficacious than HER2 ADC (DAR 8)

For the following CDX and PDX models, HLX49 (DAR 6) is more efficacious than HER2 ADC (DAR 8) *in vivo*

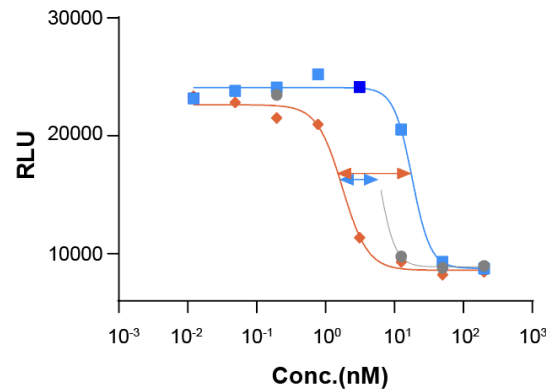


# HLX318: A Potential “Best-In-Class” Anti-BAFFxTACIxBCMA tri-specific



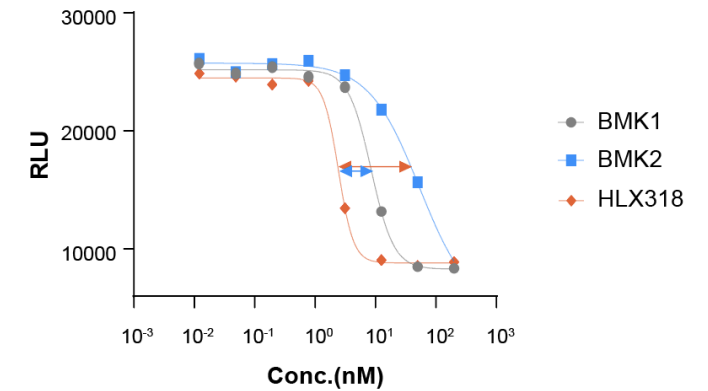
HLX318 is significantly more efficacious than competitor in BAFF-induced activation:  
**5-10X**

**TACI activation blocking**

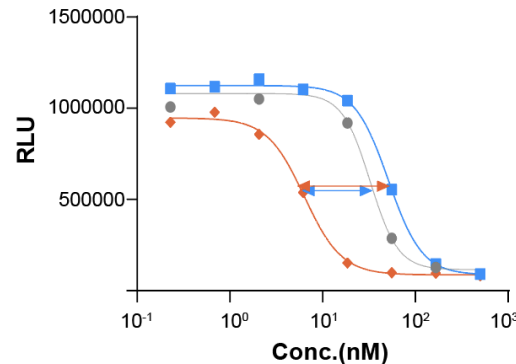


HLX318 is significantly more efficacious than competitor in dual (BAFF/APRIL)-induced activation:  
**5-200X**

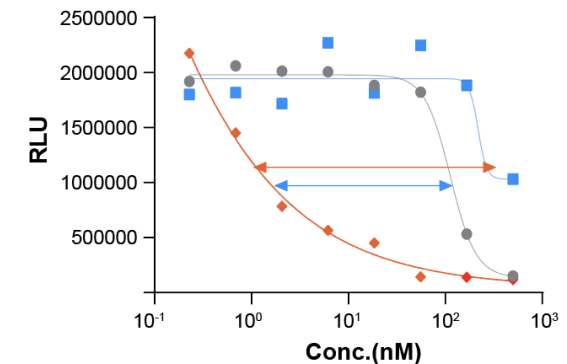
**TACI activation blocking**



**BCMA activation blocking**



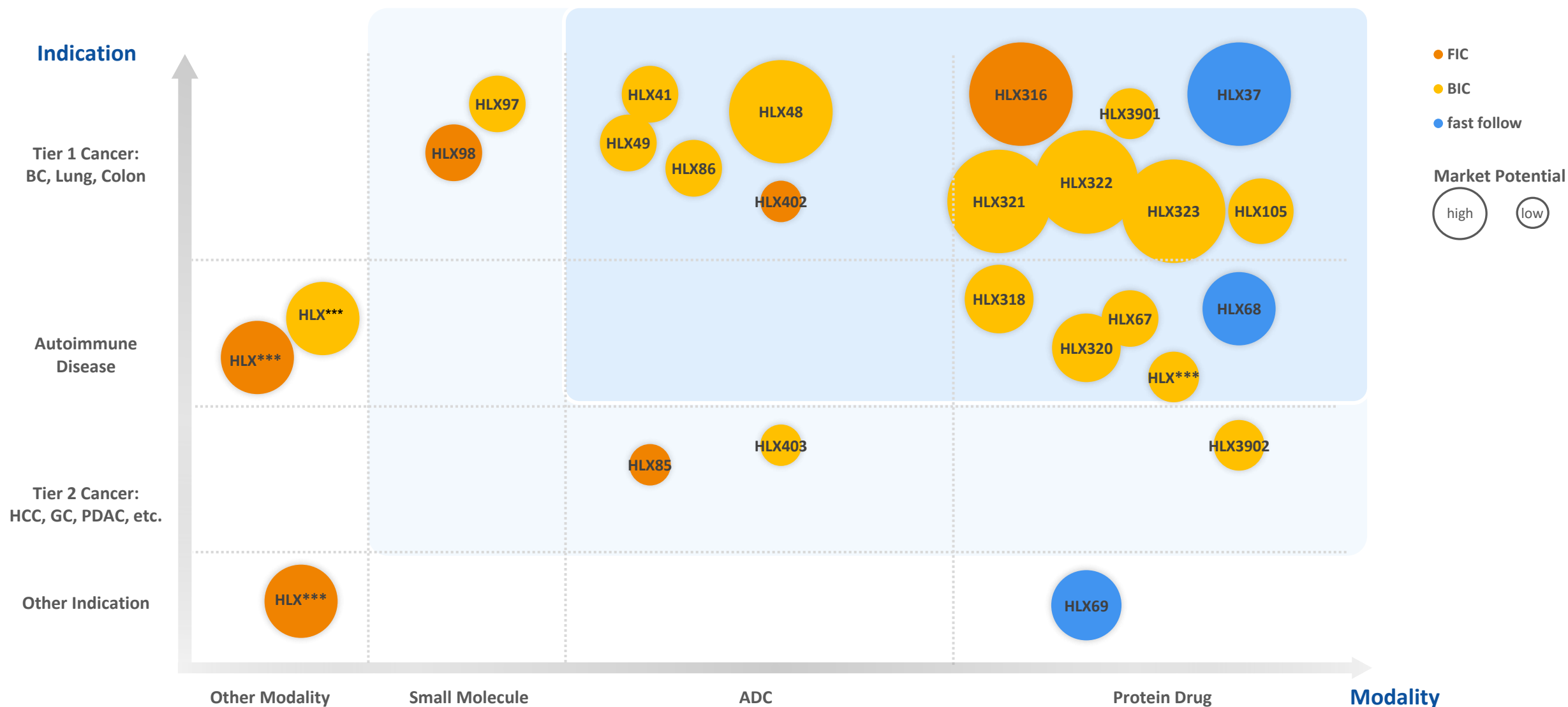
**BCMA activation blocking**



- Enhanced blocking activity of APRIL and BAFF mediated signaling by tri-blocking
- Extended antibody half-life and improved patient compliance
- Broad indications including IgAN, Sjogren's Syndrome, RA, and SLE.

# Preclinical Pipeline Landscape Strategy

Multidimension driven project selection: modality, indication, market size, novelty



# SAB Members (Pre-clinical Assets Focused)

## K. Christopher Garcia

K. Christopher Garcia, Ph.D is a Professor of Molecular and Cellular Physiology, and of Structural Biology at the Stanford University School of Medicine.

Dr. Garcia's interests reside at the cell surface.

Dr. Garcia has founded or co-founded several biotech companies that are attempting to clinically develop technologies from his lab

## Kun-Liang Guan

Kun-Liang Guan, a biochemist and cell biologist, is a chair professor at Westlake University.

He is the most and second most cited investigator in Hippo and mTOR, respectively. Additionally, he is one of the most highly cited researchers in Molecular Biology and Genetics.

## Yang-Xin Fu

Professor Yang-Xin Fu is an endowed Professor at Tsinghua University.

He made great contribution to the cellular and molecular mechanisms for drug and radiation-induced immunity.

## Lixin Zhang

Professor Lixin Zhang is the Director of National Key Laboratory of Bioreactor Engineering at East China University of Science and Technology.

His research focused on taxonomy-guided diversification of marine microbial natural product library Technology; His Avermectin project received The National Award for Excellence in Science and Technologies. In 2024, he was elected as Foreign Member of Academia Europaea.

## Alberto Mantovani

Alberto Mantovani, MD, is Emeritus Professor of Pathology at the Humanitas University in Milan, His attention has been focused on molecular mechanisms of innate immunity and inflammation and on the role in the tumor microenvironment and cancer progression of tumor-associated macrophages (TAM). For his research activity he has received several national and international awards

## Jun Wang


















Dr. Jun Wang is currently an Assistant Professor in the Department of Pathology at NYU Grossman School of Medicine; his work focuses on immune checkpoint biology and the discovery of novel immunomodulatory receptor-ligand pathways. He was the first to identify and analyze new pathways such as FGL1/LAG-3, advancing the translation of immunotherapy.

04

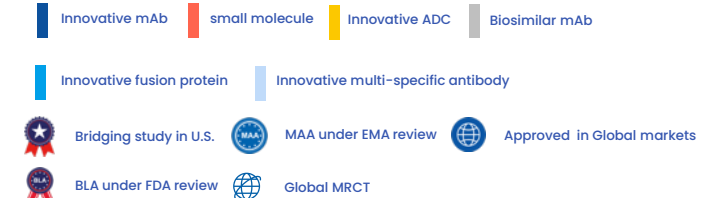
# Clinical Pipelines



# Product Portfolio and Pipeline

Pre-IND / IND	Phase 1	Phase 2	Phase 3	NDA	In-Market
HLX17 (pembrolizumab) PD-1 NSCLC, TNBC, etc.	HLX6018 GARP/TGF-β1 IPF	Serplulimab <sup>(4)</sup> + HLX07 <sup>(7)</sup> PD-1+EGFR sqNSCLC, etc.	Serplulimab <sup>(4)</sup> + Chemo PD-1 ES-SCLC 1L 	HLX04-O <sup>(12)</sup> VEGF Wet AMD	Serplulimab <sup>(4)</sup> PD-1 sqNSCLC, ES-SCLC, ESCC, nsNSCLC 
HLX316 B7H3 x Sialidase Solid tumor	HLX701 <sup>(1)</sup> CD47-SIPRα Blockade Solid tumour	Serplulimab <sup>(4)</sup> + HLX26 + Chemo PD-1+LAG-3 NSCLC 1L	Serplulimab <sup>(4)</sup> + Chemo PD-1 Neo/adjuvant treatment for GC	HLX14 (denosumab) <sup>(15)</sup> RANKL Osteoporosis, etc.   	HLX01 (rituximab) <sup>(17)</sup> CD20 NHL, CLL, RA <sup>(18)</sup> 
HLX105 Fusion protein Solid tumor	HLX42 <sup>(2)</sup> EGFR ADC Solid tumours	HLX07 <sup>(8)</sup> EGFR Solid tumors (cSCC)	Serplulimab <sup>(4)</sup> + Chemo + Radio PD-1 LS-SCLC 1L 	HLX11 (pertuzumab) <sup>(16)</sup> HER2 BC   	HLX02 (trastuzumab) <sup>(19)</sup> HER2 BC, mGC 
HLX318 BAFF x TACI x BCMA Autoimmune disease	HLX43 <sup>(3)</sup> + Serplulimab <sup>(4)</sup> PD-L1 ADC + PD-1 Solid tumours	HLX53 + Serplulimab <sup>(4)</sup> + bevacizumab TIGIT + PD-1 + VEGF HCC	Serplulimab <sup>(4)</sup> + bevacizumab + Chemo PD-1+VEGF mCRC 1L 	HLX03 (adalimumab) <sup>(20)</sup> TNF-α RA, AS, Ps, UV, pJIA, pediatric Ps, CD, pediatric CD	HLX03 (adalimumab) <sup>(20)</sup> TNF-α RA, AS, Ps, UV, pJIA, pediatric Ps, CD, pediatric CD
HLX37 PD-L1 x VEGF BsAb Solid tumors	HLX05 <sup>(5)</sup> (cetuximab) EGFR mCRC, HNSCC	HLX22 <sup>(9)</sup> + T-DXd HER2 HER2-low/HR+ BC	HLX04-O <sup>(12)</sup> VEGF Wet AMD 	HLX04 (bevacizumab) <sup>(21)</sup> VEGF mCRC, NSCLC, GBM, HCC, EOC, FTC or PPC, CC 	HLX04 (bevacizumab) <sup>(21)</sup> VEGF mCRC, NSCLC, GBM, HCC, EOC, FTC or PPC, CC
HLX3901 DLL3 x CD3 x CD28 TsAb SCLC	HLX15 <sup>(6)</sup> (daratumumab) CD38 Multiple myeloma	HLX43 <sup>(3)</sup> PD-L1 ADC Solid tumours (NSCLC, etc.) 	HLX22 <sup>(9)</sup> + trastuzumab + Chemo HER2+HER2 GC 	HLX901 (neratinib) <sup>(22)</sup> HER1/HER2/HER4 Extended adjuvant treatment of BC	HLX901 (neratinib) <sup>(22)</sup> HER1/HER2/HER4 Extended adjuvant treatment of BC
HLX3902 Steap1 x CD3 x CD28 TsAb PCa	HLX13 <sup>(7)</sup> (ipilimumab) CTLA-4 Melanoma, HCC, etc.	HLX208 <sup>(10)</sup> BRAF V600E LCH/ECD, MEL, NSCLC, etc.	HLX87 <sup>(13)</sup> HER2 ADC HER2+ BC		
HLX48 EGFR x cMet BsADC NSCLC, CRC		HLX208 <sup>(10)</sup> + Serplulimab <sup>(4)</sup> BRAF V600E + PD-1 NSCLC	HLX78 (lasofoxifene) <sup>(14)</sup> SERM BC 		
HLX41 LIV-1 ADC BC		HLX79 <sup>(11)</sup> + Rituximab <sup>(16)</sup> Sialidase Fc Fusion Protein + CD20 Active Glomerular Diseases			
HLX97 KAT6A/B ERα+ Breast Cancer					
HLX18 (nivolumab) PD-1 NSCLC, MEL, etc					

(1) Exclusive rights in China (excl. Taiwan), Southeast Asia, and other selected regions; Phase 1b/2a conducting in countries such as China and the U.S. (2) IND approvals obtained in China/the U.S. and granted FDA Fast Track Designation. (3) IND approvals obtained in China/the U.S./Japan/Australia (4) Approved in ~40 countries, including China, the UK, Germany, India, Singapore, trade name: Hetronifly® in Europe. partners: KGBio/Fosun Pharma/Intas. (5) Business partner: Shanghai Jingze. (6) Business partner: Dr. Reddy's, etc. (7) Business partner: Sandoz, etc. (8) IND approvals obtained in China/the U.S. (9) IND approvals obtained in China/the U.S./Japan/the EU. (10) Exclusive license obtained in China. (11) Exclusive license obtained in China. (12) NDA under review in China. IND approvals obtained in Australia/the U.S./Singapore/EU countries, etc. Business partner: Essex. (13) The development and exclusive commercialization rights obtained in China and select ex-China markets. (14) Exclusive license obtained in China. Phase 3 MRCT enrolling globally. IND approval obtained in China. (15) Marketing applications under review in the EU and the U.S. (16) Marketing applications under review in China, the U.S. and the EU. Business partner: Organon. (17) Approved in countries such as China and Peru. The first biosimilar approved in China. Business partners: Fosun Pharma/Eurofarma/Abbott/Boston Oncology. (18) The first rituximab approved for the indication in China. (19) Approved in 50+ countries, including China, U.S., the UK, Germany, France and Australia, trade name in U.S.: HERCESSI™, Trade name in Europe: Zercepac®. Business partners: Accord/ Cipla/ Jacobson/ Elea/ Eurofarma/ Abbott/ KGBio/ Getz. (20) Business partners: Fosun Wanbang/ Getz Pharma. (21) Approved in countries such as China and Bolivia. Business partners: Eurofarma. (22) Exclusive license obtained in China.



# Clinical Pipeline Milestones: 2025 H1 Review & 2025 H2 Outlook

2025H1				2025H2			
<div> NDA/BLA/MAA Submission</div>	<div>HLX10 HANSIZHUANG ES-SCLC<sup>1</sup> 1L (Hong Kong, Mexico, Peru, Colombia)</div>	<div>HLX04-O Wet AMD<sup>4</sup> (CN)</div>		<div>HLX10 HANSIZHUANG ES-SCLC<sup>1</sup> 1L (South Korea, LATAM, Turkey)</div>	<div>HLX10 HANSIZHUANG ESCC<sup>11</sup> 1L (EU)</div>	<div>HLX10 HANSIZHUANG sqNSCLC<sup>5</sup> 1L (EU, the Philippines, Myanmar, Singapore, Malaysia)</div>	<div>HLX10 HANSIZHUANG nsqNSCLC<sup>10</sup> 1L (EU, Indonesia, Cambodia, Thailand)</div>
	<div>HLX04 HANBEITAI mCRC<sup>2</sup>, advanced, metastatic or recurrent NSCLC, GBM, etc. (ex-China)</div>	<div>HLX11 Breast cancer Neoadjuvant therapy (EU, Canada)</div>		<div>HLX04-O Wet AMD<sup>4</sup> 1L (US)</div>	<div>HLX14 PMOP<sup>6</sup>, etc. (UK, CN)</div>	<div>HLX04 HANBEITAI mCRC<sup>2</sup>, advanced, metastatic or recurrent NSCLC, GBM, etc. (US/EU)</div>	
<div> NDA/BLA/MAA Approval</div>	<div>HLX10 HANSIZHUANG ES-SCLC<sup>1</sup> 1L (UK, India, Malaysia, Singapore)</div>	<div>HLX10 HANSIZHUANG sqNSCLC<sup>5</sup> 1L (Indonesia, Thailand)</div>		<div>HLX10 HANSIZHUANG ES-SCLC<sup>1</sup> 1L (Switzerland, Myanmar, the Philippines, Peru)</div>	<div>HLX10 HANSIZHUANG sqNSCLC<sup>5</sup> 1L (Cambodia)</div>	<div>HLX11 Breast cancer Neoadjuvant therapy (US)</div>	<div>HLX14 PMOP<sup>6</sup>, etc. (EMA, US, CAN, UK)</div>
	<div>HLX02 HANQUYOU Breast cancer, mGC (Myanmar, Mexico)</div>	<div>HLX04 HANBEITAI mCRC<sup>2</sup>, advanced, metastatic or recurrent NSCLC, GBM, etc. (Dominican Rep, Mexico)</div>		<div>HLX01 HANLIKANG NHL<sup>7</sup>, CLL<sup>8</sup>, RA<sup>9</sup> etc. (LATAM)</div>	<div>HLX02 HANQUYOU Breast cancer, mGC (SEA, LATAM)</div>	<div>HLX03 HANDAYUAN RA<sup>9</sup>, AS<sup>12</sup>, UC<sup>13</sup>, PSO<sup>14</sup>, etc. (ex-China)</div>	<div>HLX04 HANBEITAI mCRC<sup>2</sup>, advanced, metastatic or recurrent NSCLC, GBM, etc. (LATAM, etc.)</div>
<div> Key Clinical Data Readouts</div>	<div>HLX10 + HLX04 mCRC<sup>2</sup> 1L (PoC)</div>	<div>HLX07+HLX10 sqNSCLC<sup>5</sup> 1L (PoC)</div>	<div>HLX14 PMOP<sup>6</sup> etc. (Pivotal)</div>	<div>HLX10 nsqNSCLC<sup>10</sup> 1L (Pivotal)- IA&amp;FA</div>	<div>HLX43 NSCLC Late-line (PoC)</div>	<div>HLX43 CC Late-line (PoC)</div>	
	<div>HLX22 + HLX02 GC<sup>3</sup> 1L (PoC)</div>	<div>HLX04-O Wet AMD<sup>4</sup> (Pivotal)</div>	<div>HLX43 NSCLC Late Line (PoC)</div>				

Innovative mAb

mAb biosimilar

Innovative ADC

1. Extensive stage small cell lung cancer

2. Metastatic colorectal cancer

3. Gastric cancer

4. Age-related macular degeneration

5. Squamous non-small cell lung cancer

6. Postmenopausal osteoporosis

7. Non-Hodgkin Lymphoma

8. Chronic Lymphocytic Leukemia

9. Rheumatoid arthritis

10. Non-squamous non-small cell lung cancer

11. Esophageal squamous cell carcinoma

12. Ankylosing Spondylitis

13. Ulcerative Colitis

14. Plaque psoriasis

■ Innovative mAb  
■ mAb biosimilar  
■ Innovative ADC

- |   |   |  |
|---|---|--|
| 1. Extensive stage small cell lung cancer | 6. Postmenopausal osteoporosis              | 11. Esophageal squamous cell carcinoma |
| 2. Metastatic colorectal cancer           | 7. Non-Hodgkin Lymphoma                     | 12. Ankylosing Spondylitis             |
| 3. Gastric cancer                         | 8. Chronic Lymphocytic Leukemia             | 13. Ulcerative Colitis                 |
| 4. Age-related macular degeneration       | 9. Rheumatoid arthritis                     | 14. Plaque psoriasis                   |
| 5. Squamous non-small cell lung cancer    | 10. Non-squamous non-small cell lung cancer |  |

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 Pipeline Milestones: Expected in 2026 H1

2026 H1



NDA/BLA/MAA  
Submission

**HLX10  
HANSIZHUANG**  
ES-SCLC<sup>1</sup>  
1L  
(US, Macau)

**HLX10  
HANSIZHUANG**  
GCneo<sup>4</sup>  
(China)

**HLX14**  
PMOP<sup>6</sup>, etc.  
(Japan)



NDA/BLA/MAA  
Approval

**HLX10  
HANSIZHUANG**  
ES-SCLC<sup>1</sup>  
1L (Hong Kong, LATAM)

**HLX10  
HANSIZHUANG**  
ESCC<sup>5</sup>  
1L  
(EU)

**HLX10  
HANSIZHUANG**  
nsqNSCLC<sup>7</sup>  
1L  
(EU, Indonesia, Thailand)

**HLX10  
HANSIZHUANG**  
sqNSCLC<sup>12</sup>  
1L  
(EU)

**HLX01  
HANLIKANG**  
NHL<sup>2</sup>, CLL<sup>3</sup>, RA etc.  
(LATAM)

**HLX02  
HANQUYOU**  
Breast cancer, mGC  
(SEA, LATAM)

**HLX03  
HANDAYUAN**  
RA<sup>8</sup>, AS<sup>9</sup>, UC<sup>10</sup>,  
PSO<sup>11</sup>, etc.  
(Kenya)

**HLX04  
HANBEITAI**  
mCRC<sup>13</sup>, advanced, metastatic or  
recurrent NSCLC, GBM, etc.  
(Colombia, Chile, Nicaragua)

**HLX11**  
Breast cancer  
Neoadjuvant therapy  
(CN, EU, Canada)



Key Clinical  
Data Readouts

**HLX10**  
GCneo<sup>4</sup>  
(Pivotal)

**HLX26+HLX10**  
NSCLC  
1L  
(PoC)

**HLX43**  
Solid Tumor  
Late-line  
(PoCs)

■ Innovative mAb  
■ mAb biosimilar  
■ Innovative ADC

1. Extensive stage small cell lung cancer  
2. Non-Hodgkin Lymphoma  
3. Chronic Lymphocytic Leukemia  
4. Gastric cancer neo-adjuvant therapy  
5. Esophageal squamous cell carcinoma



6. Postmenopausal osteoporosis  
7. Non-squamous non-small cell lung cancer  
8. Rheumatoid arthritis  
9. Ankylosing Spondylitis  
10. Ulcerative Colitis

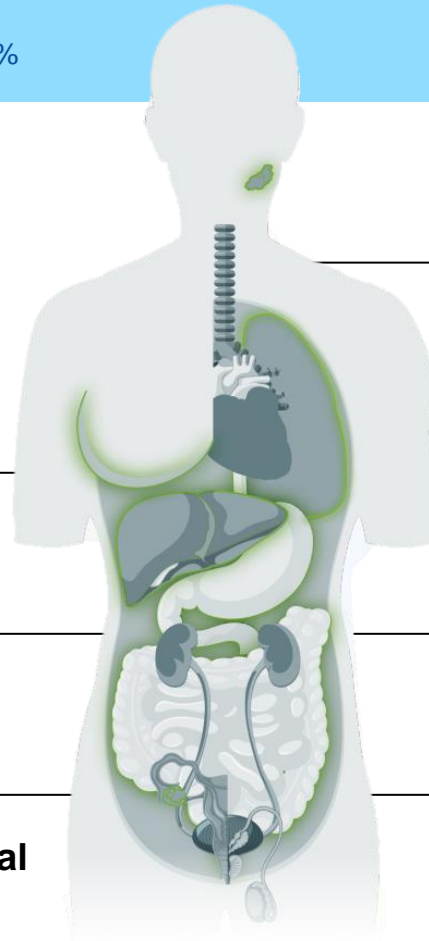
11. Plaque psoriasis  
12. Squamous non-small cell lung cancer  
13. Metastatic colorectal cancer

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.

# HLX43 Phase 2 Clinical Trials Exploration in Various Tumor Type, Enroll >600 Patients

Expression observed in a broad spectrum of solid tumors  
Low expression in normal tissue | Primarily expressed in immune cell

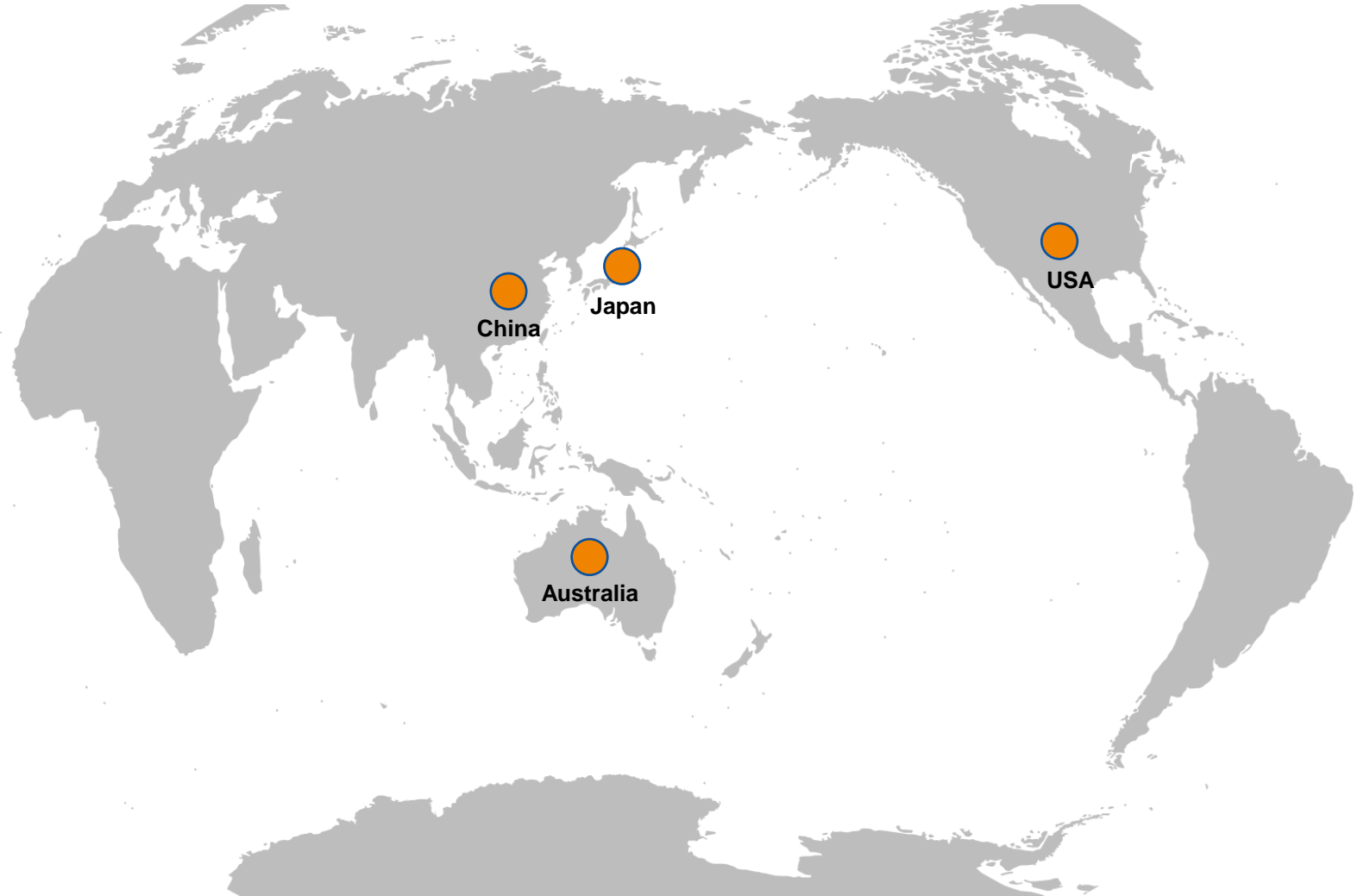
Epidemiology Inc. cases per year in CN/Global	Ongoing clinical trial of <b>HLX43</b>	PDL1 Expression in Solid Tumors		Ongoing clinical trial of <b>HLX43</b>	Epidemiology Inc. cases per year in CN/Global
		TPS >1%   ≥50%	CPS >1%		
1000k/2000k 	HLX43-FIH101 NSCLC LL Ph1b, CN Only	<b>Lung (NSCLC)</b> 71%   37%	<b>Gastric</b> 84%	HLX43-GC201 GC ≥2L Ph2, CN Only	470k/1140k
	HLX43-NSCLC201 NSCLC LL Ph2, Global (CN,US,JP,AU,EU)		<b>Esophageal</b> 86%	HLX43-ESCC201 ESCC LL Ph2, CN Only	320k/600k
	HLX43HLX10-ST201 NSCLC EGFRm 2L Ph2, CN Only		<b>Hepatocellular</b> ~20%	HLX43-HCC201 HCC LL Ph2, CN Only	300k/799k
510k/1900k	HLX43-mCRC201 mCRC ≥2L Ph2, CN Only	<b>Colon</b> 31%   5%	<b>Cervical</b> 60~70%	HLX43-CC201 CC LL Ph2, CN Only	160k/690k
<500/<3k Rare disease 	HLX43-FIH101 TC ≥2L Ph1b/2, Global (CN,US,JP,AU)	<b>Thymic</b> 71%   35%		HLX43-HNSCC201 HNSCC LL Ph2, CN Only	110k/800k
51k/120k	HLX43-NPC201 NPC ≥3L Ph2, CN Only	<b>Nasopharyngeal</b> 52%   26%			



# International In-house Global Team Covering Key Regions

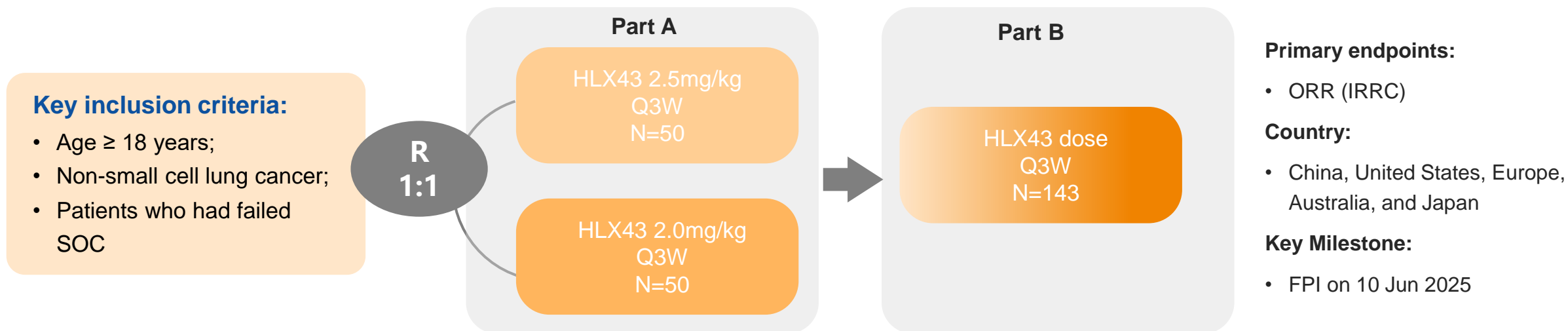
## Global Clinical Study Sites Cooperation Summary

- **20+** Countries
- **1,000+** sites
- **10,000+** patients (1,700+ from ex-China)
- CRO-free for key regions (CN, US, JP, AU) , with an **in-house clinical team** of ~500 professionals



# HLX43-NSCLC201: Non-Small Cell Lung Cancer Later Line Ph 2 Trial

## MRCT led by top global KOLs



### Leading Principal Investigator:

#### Dr. Jie He

- Director of Thoracic Surgery Department, Cancer Hospital Chinese Academy of Medical Sciences
- Academician of the Chinese Academy of Sciences
- President of the Cancer Hospital Chinese Academy of Medical Sciences



### Leading Principal Investigator in US:

#### FRED R. HIRSCH, MD, PHD

- Executive director, Center for Thoracic Oncology Mount Sinai Health System
- Professor of medicine, Icahn School of Medicine Joe Lowe and Louis Price Professor of Medicine



### Leading Principal Investigator:

#### Dr. Jie Wang

- Director of Medical Oncology Department, Cancer Hospital Chinese Academy of Medical Sciences
- Tenured Professor at Peking Union Medical College



### Leading Principal Investigator in Japan:

#### Dr. Hidetoshi Hayashi

- Kindai University, Faculty of Medicine Department of Medical Oncology Professor



# HLX10-005-SCLC301-E: Serplulimab (PD-1) ES-SCLC US Bridging Study



## Dr. David Gandara

- 2009-2011 IASLC Chair
- Professor Emeritus: UC Davis Health System
- Senior Advisor: UC DAVIS Comprehensive Cancer Center
- Professor Gandara has published more than 450 peer-reviewed papers.
- Professor Gandara has received numerous awards and accolades, including the Lifetime Science Award from the International Association for Lung Cancer Research (IASLC), the Team Science Award from the Addario Lung Cancer Foundation, and the Trajectory Achievement Award from the International Society for Liquid Biopsy (ISLB).
- In 2017, Professor Gandara was awarded the Giants of Cancer Care Award for his achievements in the field of lung cancer.

### Key Inclusion Criteria

1. Age > 18 years
  2. Histologically or cytologically diagnosed with ES-SCLC
  3. No prior systemic therapy for ES-SCLC
  4. At least one measurable lesion
  5. An ECOG PS score of 0 or 1
  6. Normal major organ functions
- N=200

R  
1:1

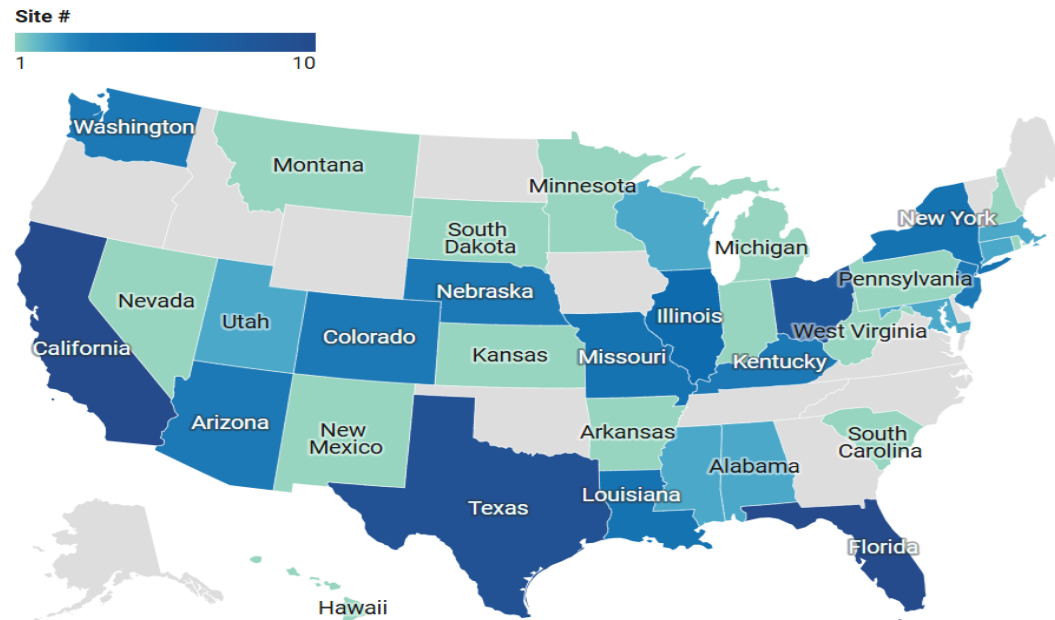
Arm A:  
HLX10 (300mg.D1) + Carboplatin (AUC=5,D1) + Etoposide (100/m2,D1-3)

Arm B:  
Atezolizumab (1200mg.D1) + Carboplatin (AUC =5.D1) + Etoposide (100/m2D1-3)

### Primary Endpoints

- OS
- PFS (IRRC)

### Site Distribution Map



- Launched **100+ sites** in United State and site managed by Henlius US team
- Plan to complete the 200-patient enrollment in September, which is the **largest SCLC study** in the US

# HLX22-GC301: 1L HER2+ GC Ph 3 Study

## MRCT led by top global KOLs



### Dr. Shen Lin

Beijing Cancer Hospital, CSCO GC Chair

Chief Scientist of the National Key Research and Development Program, Beijing Scholar, and Outstanding Contribution Expert of Beijing, the first prize of the Chinese Medical Science and Technology Award



### Dr. Jaffer A. Ajani

M.D Anderson, NCCN GC Chair

Cited in *Good Housekeeping Magazine* as Best Doctors in America for Colorectal Carcinoma, Best Cancer Doctors in the United States, MD Anderson Cancer Center Clinical Oncology Research Excellence Award



### Dr. Ken Kato

NCCH

The Japanese Cancer Society - Chugai Pharmaceutical Advanced Oncology Academic Award

### Key Inclusion Criteria

1. Age  $\geq 18$ Y (JP  $\geq 20$ Y)
2. Treatment naïve, advanced unresectable, HER2+ G/GEJ adenocarcinoma
3. Life expectancy  $\geq 6$  month
4. HER2 and PD-L1 expression status assessed by central lab

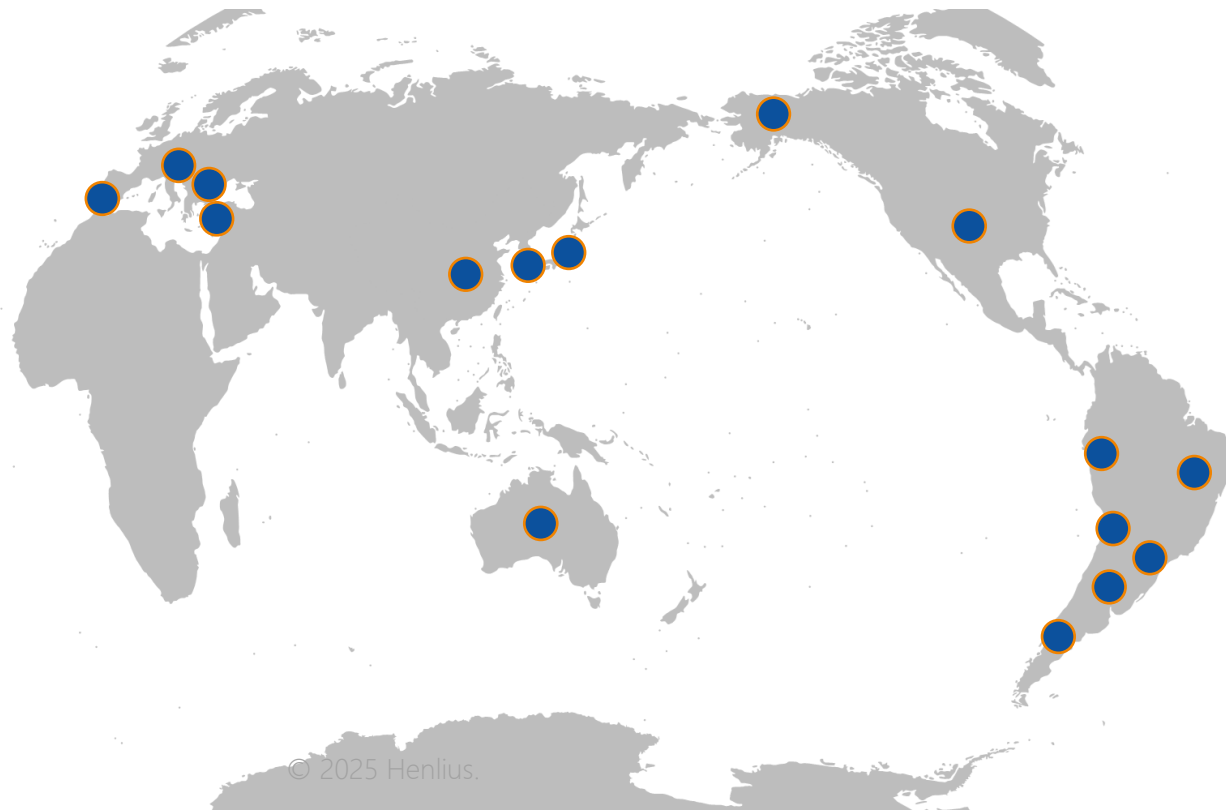
R  
1:1

HLX22 (15mg/kg) + SOC  $\pm$  placebo(Keytruda), Q3W

Placebo (HLX22) + SOC  $\pm$  Keytruda, Q3W

### Primary Endpoints

- PFS (IRRC)
- OS



Key Milestone:  
FPI on 22 Nov 2024

# SAB Members (Research & Development)

## David R. Gandara

David Gandara, Professor of Medicine Emeritus at the University of California, Davis. He is the co-director of the Center for Experimental Therapeutics in Cancer and Senior Advisor to the Director at UC Davis Comprehensive Cancer Center. As an internationally renowned clinical scientist and a leading figure in the field of lung cancer;

Dr. Gandara has been selected for many awards and honors including the lifetime Scientific Award from the International Association for Study of Lung Cancer (IASLC), the Team Science Award from the Addario Lung Cancer Foundation, and the Trajectory Achievement Award from the ISLB.

## Shun Lu

Professor Lu Shun is a lifetime professor at the Shanghai Chest Hospital affiliated with Shanghai Jiao Tong University School of Medicine and the director of the Shanghai Pulmonary Tumor Clinical Medicine Center. As the primary investigator, he has received the First Prize of Shanghai Science and Technology Progress Award and other honors.

## Jianjun Zhang

Dr. Jianjun Zhang is a thoracic oncology expert at MD Anderson Cancer Center, a tenured professor of the Department of Thoracic/Head and Neck Medical Oncology and the Department of Genomic Medicine. He serves as the Director of the Moon Shot GEMINI Data Center, the Director of the Lung Cancer Genomics Program, and the Director of the Lung Cancer Interception Program at MD Anderson Cancer Center. His primary focus is on the clinical and translational research in the treatment and prevention of lung cancer. He has published over 250 articles in renowned medical and scientific journals. He has received numerous awards including the Ruth L. Kirschstein National Research Service Award, the A. Lavoy Moore Endowment Fund Award, etc.

## Yu Xue

Fudan University Huashan Hospital  
Deputy Director of the Department of Rheumatology,  
Chief Physician, Master's Supervisor  
Vice Chairman of the Rheumatology  
Specialty Branch of the Shanghai Medical  
Association Member, Focus on the  
diagnosis and treatment of rheumatic  
immune disorders.

## Jian Zhang

Fudan University Shanghai Cancer Center  
Chief Physician, Department of Medical Oncology Doctoral  
Supervisor  
Medical Director, Department of Phase1 Clinical Trial Ward  
Fudan University Shanghai Cancer Center affiliated  
Fujian Hospital  
Director of Clinical Research Center/  
Executive Deputy Director, Department of Medical Oncology  
Awarded 2023 Top Ten Medical Pioneer Experts,  
2023 "People's Good Doctor" Outstanding  
Contribution Award. First author/corresponding  
author has published multiple high-quality SCI papers.

05

# Commercialization

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



## 1.44B RMB

Global Revenue in 1H2025



### 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, becoming the Chinese biosimilar with the most approved 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 China BC Market

- Commercial team with ~600 professionals, focusing on breast cancer area
- Devoted in benefiting every HER2+ patients, continuously build HER2+ ecosystem by providing medical education, medical big data, HER2 testing and innovative payment



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\***  
**>450K RMB**  
**per month**  
**1H2025**



## The only trastuzumab with two specifications

- 2 specifications were customized to address medical needs of HER2+ BC patients 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

- 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
- The leading brand in Chinese trastuzumab IV market



## Synergy between HANQUYOU and HANNAIJIA

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

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



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



97M RMB

Revenue in 1H2025



## Product Synergy

- Leverage HANQUYOU commercial team's market coverage and customer connection to promote HANNAIJIA more efficiently and widely
- Completed NRDL and tendering platform listing for all provinces in China



## Strengthen extended adjuvant concept education

- Promote awareness and adoption of extended adjuvant therapy in early HER2 BC patients, and build HANNAIJIA as the leading brand of neratinib to benefit more Chinese HER2+ patients



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): Full coverage in LC And EC



## 598M RMB

Global Revenue in 1H2025



### Widespread recognition

- First Approved PD-1 mAb for 1L ES-SCLC
- In Feb 2025, approved in EU for treatment for first line extensive SCLC patients, which is the first approved PD-1 monoclonal antibody for ES-SCLC in EU
- Approved in nearly 40 countries and regions



### 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 ~119 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

Zerpido® in SEA  
Hetronifly® in Europe

# HANSIZHUANG: Outstanding Commercialization Efficiency and Differentiated Strategy

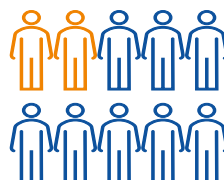


## First-class Commercialization Efficiency

Sales Per Capita\*  
**> 190K RMB**  
**per month**  
1H2025



## Differentiated Strategy To Tackle Challenges And Win Opportunities



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

- Proactively tackle with challenges from competitors in SCLC area, and accurately interpret the research results
- Widely and effectively deliver 21.9% 4-year OS rate data to solidify leadership in SCLC

#### Develop NSCLC Market

- Target brain metastatic patients and deliver the effect advantage for this segment, build differentiated brand advantage, fully develop NSCLC market potential

#### Increase Share in EC

- Promote HANSIZHUANG's efficacy advantage in ESCC treatment compared to other immuno-therapies.
- Grow market share rapidly by delivering the concept of precise treatment for precise benefits

#### Plan for CRC and GC

- Prepare for the upcoming data readout of phase 3 pivotal studies in CRC and GC areas, as well as the possible indication approval in the future

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



## 116M RMB

Revenue in 1H2025



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

- Approved in several Latin American countries
- Grant Eurofarma exclusive rights on HANBEITAI in Latin American countries, including Mexico, Argentina and Chile etc, and Eurofarma obtains a semi-exclusive right to HANBEITAI in Brazil



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
- Hepatocellular Carcinoma
- 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



**274M RMB**

Revenue recognized by Henlius  
and licensing income in 1H2025



**First Biosimilar in China**

- Approved in February 2019, as the first approved biosimilar as well as 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, 42% in Q1 2025<sup>1</sup>
- Fosun Yaohong<sup>2</sup>, a subsidiary of Fosun Pharma, is responsible for HANLIKANG's commercialization in China



### HANLIKANG

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



**27M RMB**

Revenue recognized by Henlius  
and licensing income in 1H2025



**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.



### 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.

06

# Manufacturing



# International Leading Capabilities on Manufacturing and Quality Management



Xuhui Site

24,000L

- **Supply Covered Globally:** Commercial GMP production exceeds **1,150 batches (YS + SJ1)**, with a success rate over 98 %
- **“Henlius Quality”** with international standard: products supply covering **China, the EU, Brazil, Indonesia, and Singapore**, etc.
- 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**
- **Certificated by ISO 14001 Environment Management System and ISO 45001 Occupational Health & Safety Management System**
- **Accelerate new products to the market:** Completed GMP inspections for **HLX11 and HLX14** before commercialized in China, the EU and US

Global  
Standard



Songjiang  
2<sup>nd</sup> Plant

36,000L

- **Phase 1 of the plant will be completed soon:** capacity covering **drug substance, liquid filling, pre-filled syringes, and ADC conjugation.**
- **Accelerate the manufacturing lines to achieve globalized supply**  
Manufacturing lines for HLX14 **complies with EU GMP standards, received positive CHMP recommendation on HLX14**

Intelligent Drug  
Manufacturing

# Operation Excellence and Continuous Innovation

## AI Empowerment

### Multifaceted AI Tool Practice

AI enhances the efficiency, standardization, and comprehensiveness of quality processes

Automated analysis of production process data and AI predictive models

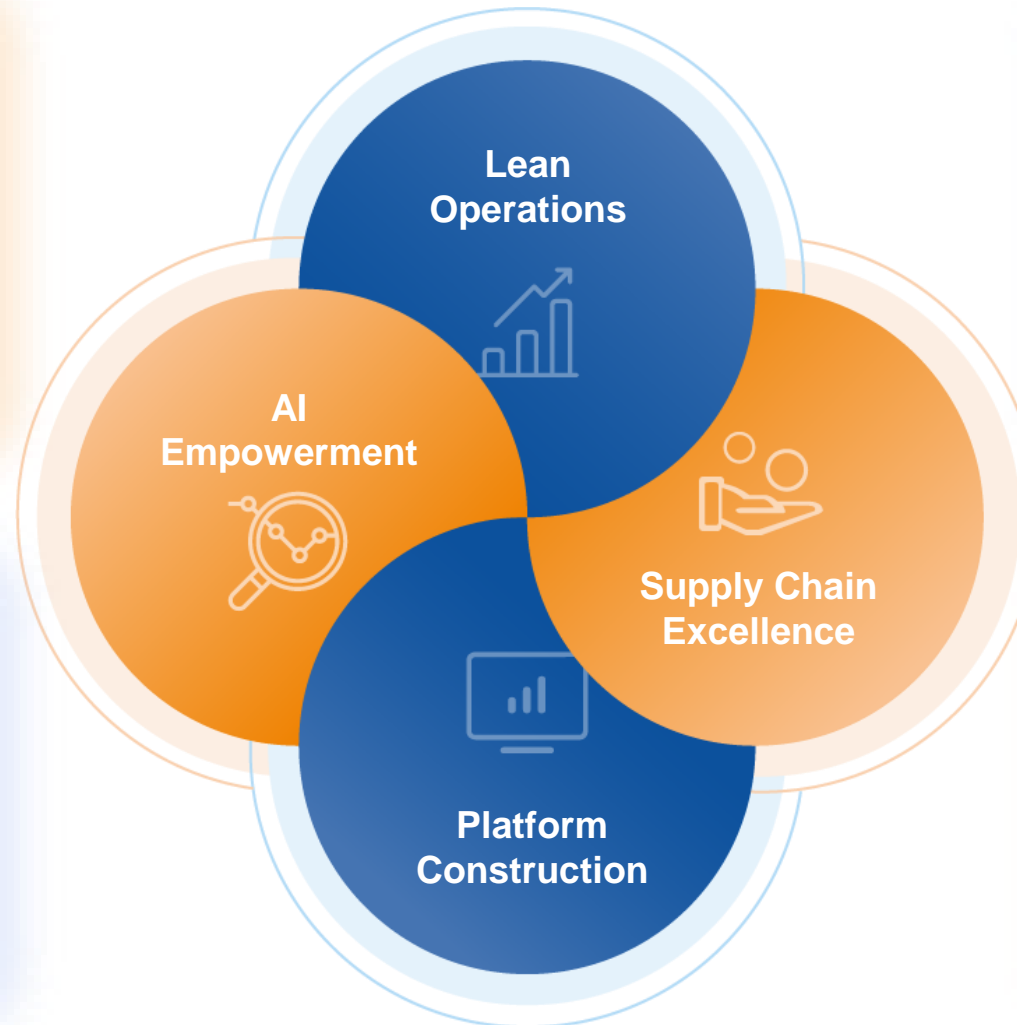
AI energy-saving analysis and intelligent production planning

## Platform Construction

### Large-scale Bio-reactor

Collaborative construction of 15kL stainless steel reactor. Reducing production costs and enhancing market competitiveness

**Actively establishing ADC capacity**



## Lean Operations

### Lean Operations Diagnosis

Identification of 100+ lean improvement points identified Estimated annualized benefits exceed 30 Million

Process of commercial products optimized continuously, HANQUYOU process optimization PPQ batches completed

## Supply Chain Excellence

The direct material cost was **over 10%\* lower than that in 2025.H1**

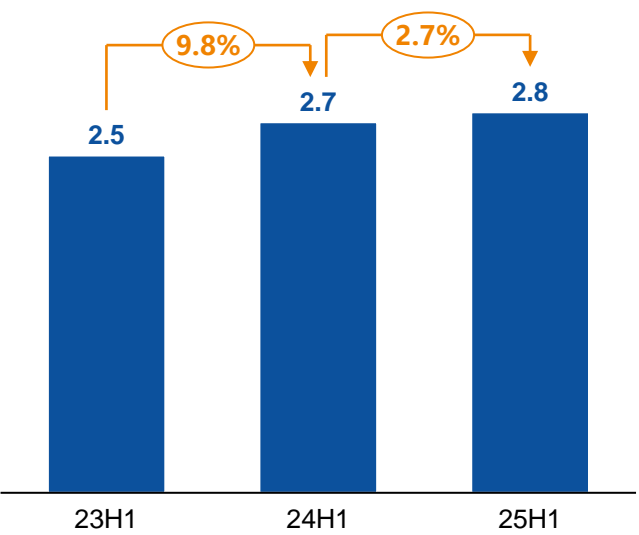
**Commercial Supply Stability**  
**Product Delivery OTIF >99.7%\***

07

## 2025H1 Financial Review

# 2025 1H Revenue of RMB 2.82 Billion, Product Revenue of RMB 2.56 Billion

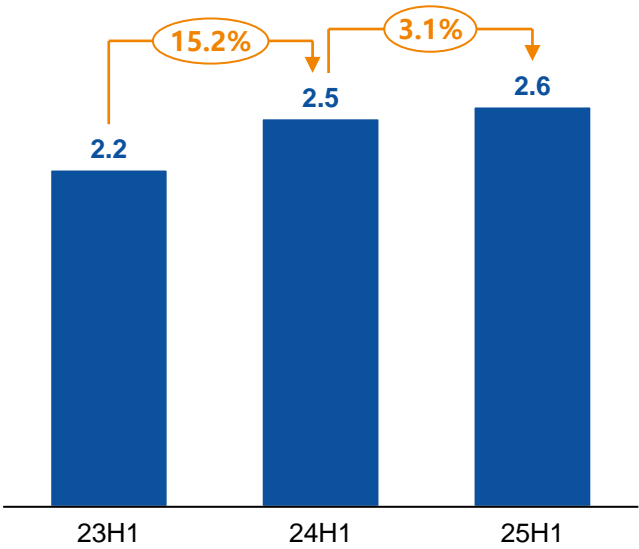
Revenue (in Billion RMB)



### Revenue Growth

- Revenue of RMB 2.82B in 2025, a 2.7% YoY growth
- Revenue growth mainly driven by: sales ramp-up of HANNAIJIA and other products
- Gross profit of RMB 2.20B in 2025, a 10.5% YoY growth

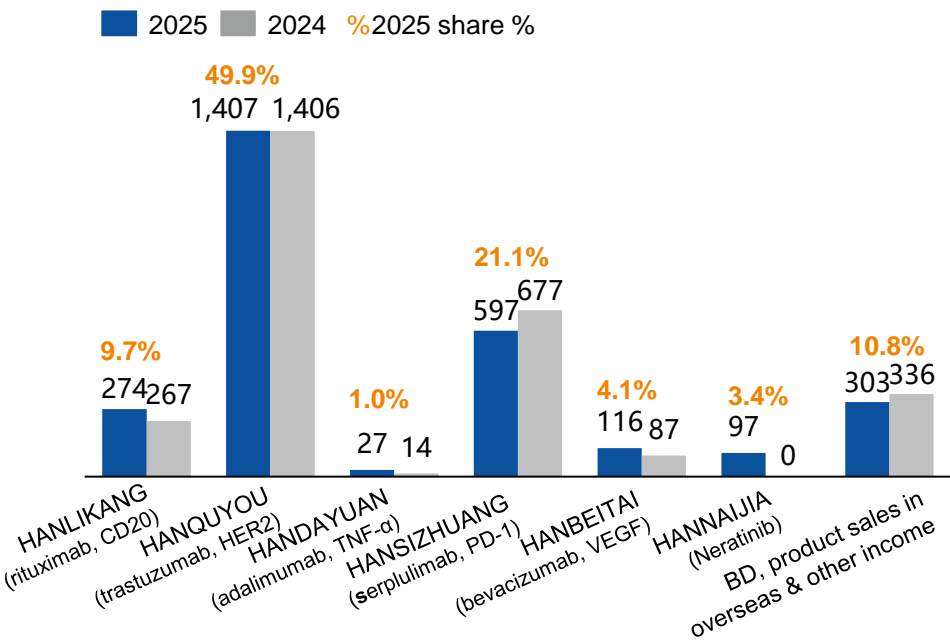
Product Sales (in Billion RMB)



### Product Sales

- Product sales of RMB 2.56B in 2025, 3.1% YoY growth
- Product sales growth mainly from: HANLIKANG, HANBEITAI, and HANNAIJIA sales grow rapidly

2025 Revenue Breakdown (in Million RMB)

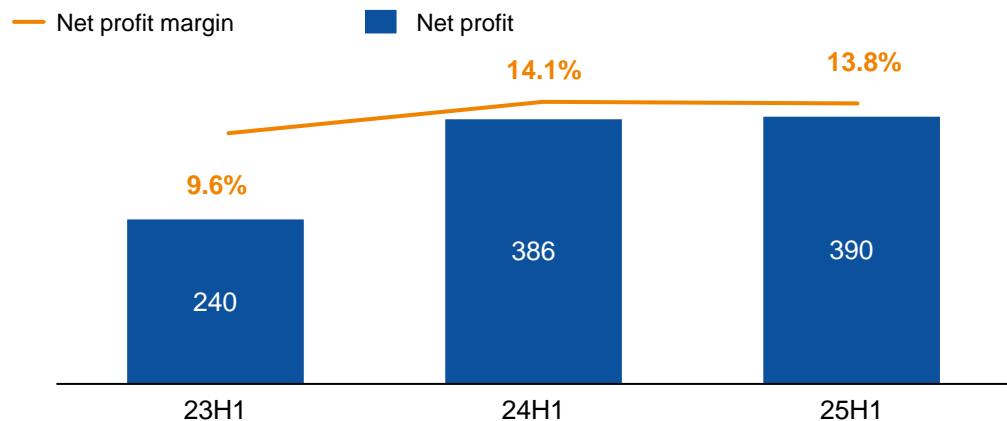


### Revenue Breakdown

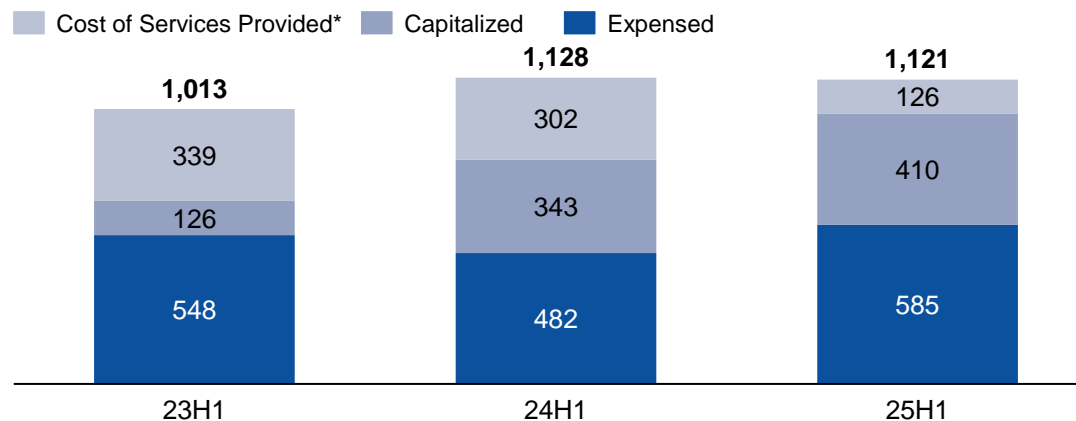
- HANQUYOU: RMB 1.41B sales in 2025, 0.1% YoY growth
- HANSIZHUANG: RMB 594M sales in 2025, -12.3% YoY
- HANLIKANG: RMB 274M sales in 2025, 20.9% YoY growth
- HANDAYUAN: RMB 27M sales in 2025, 101.2% YoY growth
- HANBEITAI: RMB 116M sales in 2025, 34.2% YoY growth
- HANNAIJIA: RMB 97M sales in 2025
- BD, product sales in overseas and other income: RMB 303M in 2025, -11.8% YoY

# Achieved Profitability in 2025H1 with RMB ~771M Operating CF

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

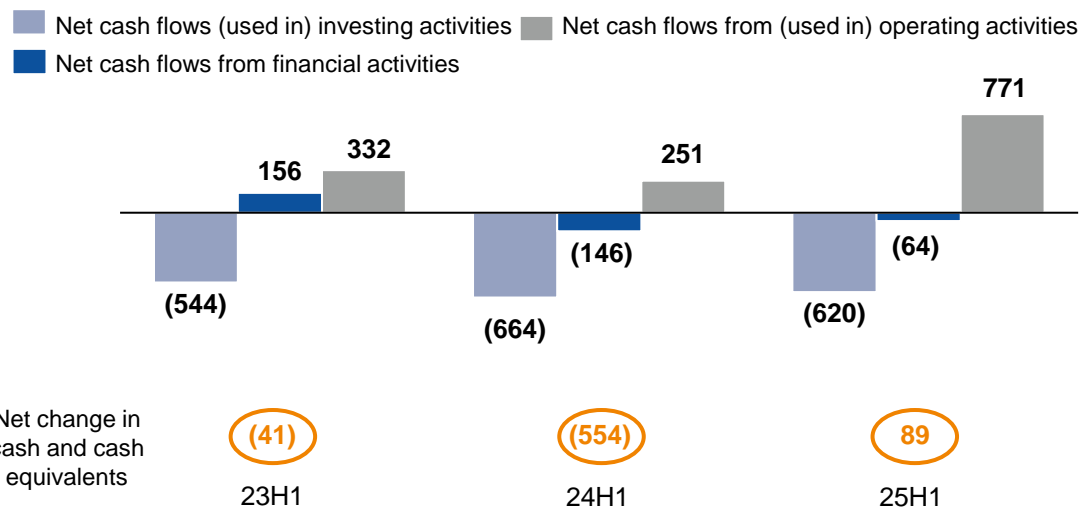


## R&D related investment (in Million RMB)

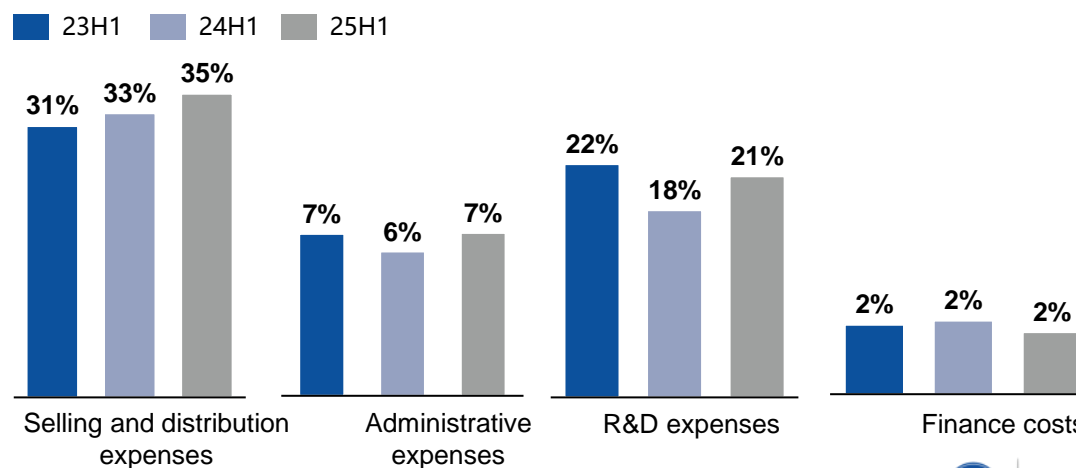


\* R&D spending related to out-licensing products accounted into cost of services provided according to accounting practices

## Positive OCF (in Million RMB)



## Expense to revenue ratios



# Financial Highlights

Financial Data (selected)	25H1		24H1		YoY Growth
Unit	In Million RMB	% of revenue	In Million RMB	% of revenue	%
Revenue	2,819.5	100.0%	2,746.1	100.0%	2.7%
Product sales	2,556.8	90.7%	2,479.4	90.3%	3.1%
BD and other revenue	262.8	9.3%	266.7	9.7%	(1.5%)
Cost of sales	(620.4)	(22.0%)	(755.4)	(27.5%)	(17.9%)
Selling and distribution expenses	(987.8)	(35.0%)	(900.2)	(32.8%)	9.7%
Administrative expenses	(185.4)	(6.6%)	(159.9)	(5.8%)	16.0%
R&D expenses	(585.5)	(20.8%)	(482.5)	(17.6%)	21.3%
Financial costs	(54.3)	(1.9%)	(62.8)	(2.3%)	(13.5%)
Net profit	390.1	13.8%	386.3	14.1%	1.0%
Cash and bank balances	853.5	30.3%	649.4	23.6%	31.4%
Net cash flows from operating activities	770.9	27.3%	251.3	9.1%	206.8%



# 声明

## Disclaimer

- 复宏汉霖、陈述人或提供人对本文件内容（文件内容亦有可能包括前瞻性陈述）均不做出明示或默示的保证、声明或陈述（包括但不限于：本内容针对为任意特定目的而关于内容所具有的及时性、通用性、精确性的声明，或者关于使用本文件内容所获得信息无误可信的声明）。如因有关内容存在错误、遗漏或失准之处而引致的行为或结果，复宏汉霖、陈述人或提供人对此不承担责任。
- 本文件及其中所包含内容的所有权利包括版权均由复宏汉霖独家所有，其中相关的“Henlius”和“复宏汉霖”字样、图案及相关LOGO标识均为复宏汉霖合法所有的字号、商标和标识。未经复宏汉霖书面同意，任何第三方不得以包括转载在内的任何方式加以使用。
- 本文件内容不包含亦不应被视为任何建议（包括但不限于医疗建议、投资建议），您基于本文件中内容做出的任何决策，责任自负。
- Henlius, the representor or the provider does not make express or implied warranties, statements or representations on the content of this document (the content of this document may also include forward-looking statements), including but not limited to the statements about the timeliness, universality and accuracy of the content for any specific purpose or with regard to the correctness of the information obtained by using the content of this document. If any conduct or consequence is caused due to any mistake, omission or incorrectness of relevant content, Henlius, the representor or the provider shall not be liable.
- All rights, including copyrights, of this document and the content contained herein shall be exclusively owned by Henlius, among which the relevant words “Henlius” and “复宏汉霖”, patterns and relevant logos are the names, trademarks and logos legally owned by Henlius. No third party could use them by any means including reproduction without written consent from Henlius.
- The content of this document does not include and shall not be deemed as any advice (including but not limited to medical advice and investment advice). You shall be liable for any decision made by yourself based on the content of this document.



可负担的创新 值得信赖的品质

Reliable Quality  
Affordable Innovation

