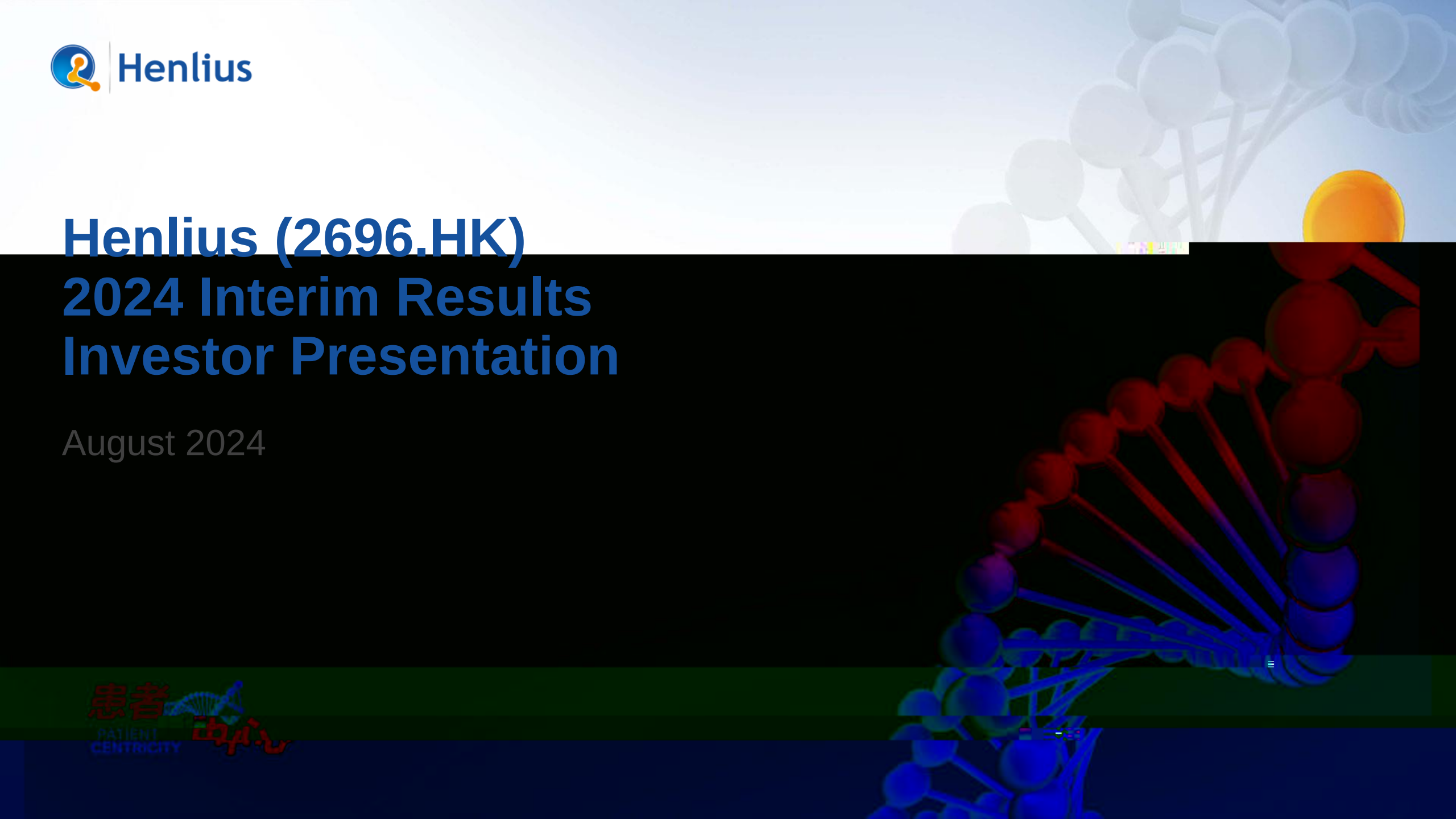
Henlius

Henlius (2696.HK)
2024 Interim Results Investor Presentation

August 2024



01

2024 1H Business Highlights & Company Strategy

Revenue Tops 2.7B RMB with Net Profit of 386M RMB

Revenue	BD	Pipeline	Commercial Capacity	Operating Cash Flow
2.7B RMB	2	50+	48KL	251m RMB

Commercialization

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

HLX10 sales in 2024 1H reached RMB 678M, YoY GR 22%.The sales per capita is higher than all PD-1/PD-L1 products marketed in China during the same time period

HLX02 average monthly sales in China exceeding RMB 200M since Q2 2023 with a lower expense ratio and YoY GR of 15% in 2024 1H

BD

In-licensed exclusive rights of lasofoxifene (SERM) in Asia and co-dev right in Japan from Sermonix for HR+/HER2- breast cancer

In-licensed exclusive rights in China & conditional license in ex-China regions of Neratinib generics from Convalife

Trastuzumab was approved by the US FDA and Health Canada; plots Southeast Asia expansion to enter Philippines; approved in Brazil, a semi-exclusive license area in Latin America

Pipeline

First subject dosed for Phase 1 clinical trial of EGFR ADC candidate HLX42

HLX22, novel anti-HER2 mAb, combo therapy receives Phase 3 MRCT IND approval from U.S. FDA

First subject dosed for Phase 1 clinical trial of novel anti-GARP/TGF- mAb HLX6018

Henlius receives approval in Japan for Phase 3 MRCT of Anti-PD-1 mAb serplulimab combo on first-Line mCRC

Manufacturing

Henlius won the title of

Shanghai

Passed Pre-License Inspections (PLI) by FDA

Manufacturing capacity optimization: Commercial GMP production batches will soon exceed 1,000 batches (YS+SJ1) Production success rate exceeds 98%

HLX10 second-generation process technology transfer completed

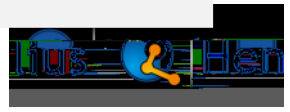
Financial

Total revenue reached RMB 2.7B in 2024 1H, YoY growth 10%

Total product sales reached RMB 2.5B, YoY growth 15%

Net operating cash inflow of RMB 251M

Net profit reached RMB 386M, and net profit rate was 14%



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

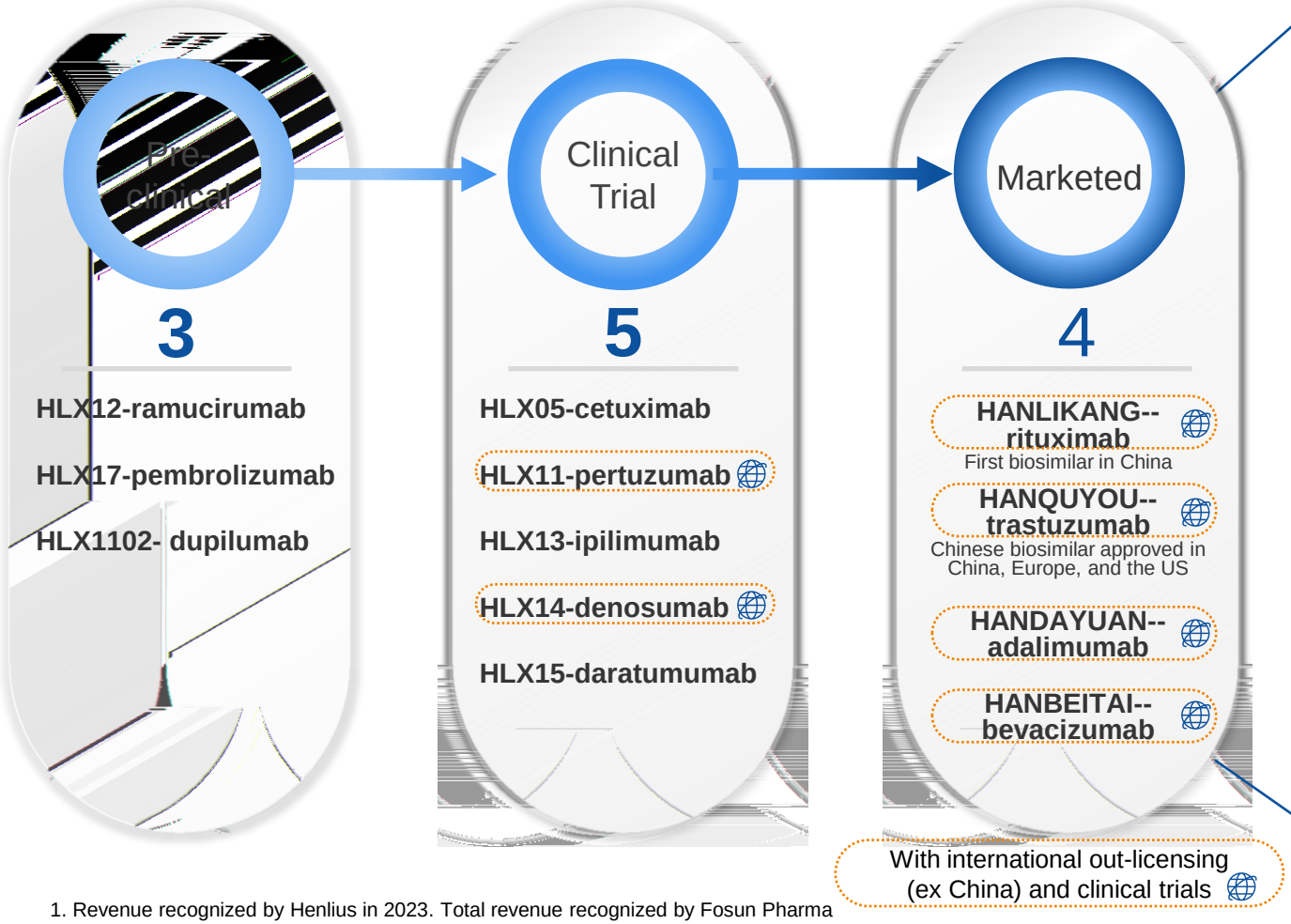
Develop towards a biopharma with global presence & scale

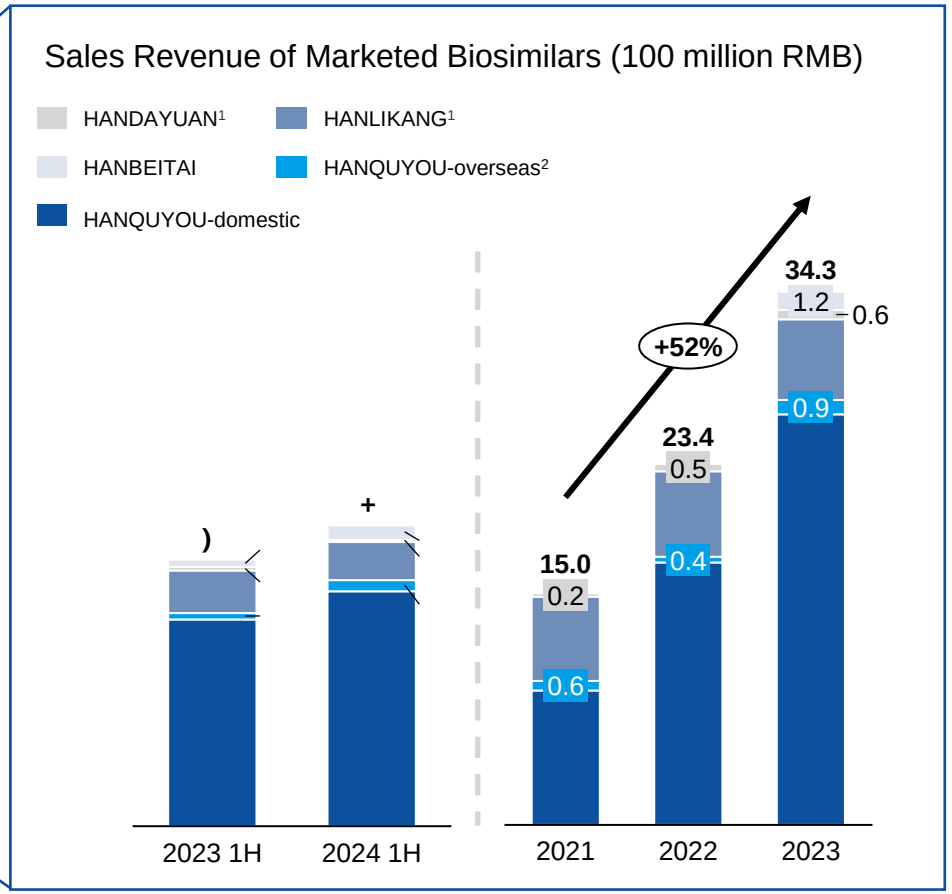
The Sales Growth of Marketed Biosimilars Accelerated; Multiple Pipeline Products Planned for Global Presence

2024 1H sales revenue of biosimilars reached 1.80 billion RMB, 12.8% YoY growth

The biosimilar pipeline covered globally popular targets such as HER2, RANKL, CTLA-4, CD38 and conducted MRCT for global market expansion

HANQUYOU BLA was approved by FDA, being the first product for commercial launch in US





1. Revenue recognized by Henlius in 2023. Total revenue recognized by Fosun Pharma
2. Including Zercepac® and drug substance

R&D for Innovative Drugs: Beyond Oncology, Expanding into New TAs

Product Type & Introduction

- ✓ Henlius pipeline contains 51 molecules and 14 R&D platforms
- ✓ Pipeline focuses around oncology while starting to explore new TAs including Autoimmune /

71% | **29%**

Oncology

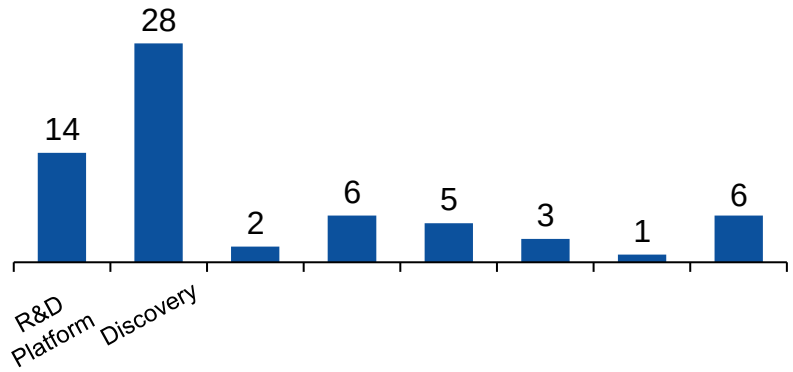
Solid Tumor
- Breast Cancer
- Lung Cancer
- MSI-H Solid Tumor
- Gastric Cancer
- CRC
- ESCC
- HNSCC
- NPS
- NSCC
- HCC

Hematology
- Non-Hodgkin Lymphoma
- Chronic Lymphocytic Leukemia
- Multiple Myeloma

Non-oncology

Autoimmune	IBD SLE PBC/PSC RA
Metabolic	DKD NAFLD/NASH
Ophthalmology	Wet AMD
Cardiovascular	Heart Failure HLP
CNS	ALS/PD
Rare Diseases	LCH/ECD IPF ALS

Pipeline Distribution by Stage



Modality Distribution(1)

(1) SMC: Small molecule conjugates; AXC: Antibody X conjugates, including AEC, AOC & ADC

Globalization Has Entered into Substantial Development Stage

(Marketed) HLX10-serplulimab

Serplulimab has been approved in Indonesia, Thailand, and Cambodia for 1L ES-SCLC, becoming the **first marketed China-made PD-1 mAb in Southeast Asia**

Serplulimab MAA under EMA review

PD-(L)1 market in Europe
Expected to exceed US$28B[1] in 2030

Serplulimab bridging study in the US is in progress

PD-(L)1 market in the US
Expected to reach US$48.4B[1] in 2030

Japan

Explore potential market with unmet medical needs

PD-(L)1 market in Japan
Expected to exceed US$8.4B[1] in 2030

(Marketed) HLX02-trastuzumab biosimilar, HLX01-rituximab biosimilar

HANQUYOU (HLX02) has marketed in 40+ countries and regions, including US, EU, Australia, Argentina, Saudi Arabia, Singapore etc. The 2024 ex-China sales of HANQUYOU (revenue reported by Henlius) has reached RMB 68M

HANLIKANG (HLX01)

HLX11-Pertuzumab biosimilar

MRCT has enrolled 908 patients globally, expected to be the first approved pertuzumab biosimilar in the US and Europe

HLX14- Denosumab biosimilar

MRCT has enrolled 514 patients globally, and HLX14 filed BLA in the EU in 2024 based on MRCT Phase 3 result

1.Data source: IQVIA MIDAS AUDITED VALUE, the European market includes EU and the UK
2.From the annual report of the originator drug owners

02

Commercialization

HANQUYOU (Trastuzumab): Sales Growth 15.4% YoY

1.47B RMB*

Revenue in 1H2024

International quality

First approved trastuzumab biosimilar in China

mAb biosimilar approved in Europe

Approved in US and Canada, and becomes the all three regions of China, Europe, and the US

Launched in 40+ countries and regions

Multiple specifications

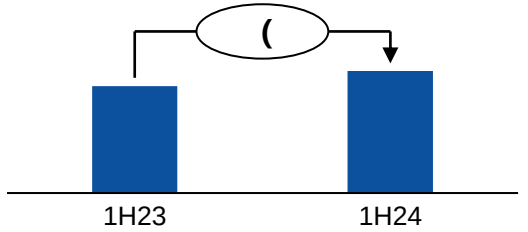
Tailored for HER2-positive breast cancer patients in China with flexible specs to fit with personalized dosage and reduce residual fluid waste

No preservatives, solution preparation upon product usage to improve safety

Improved patient medication safety and good practice for drug administration

Strong growth momentum

In Billion RMB



Both 150mg and 60mg specifications completed NRDL and tendering platform listing for all provinces in China

Commercial team with ~600 professionals, covering 6 major sales regions and ~3,700 hospitals in China

Zercepac® in Europe

HERCESSI™ in the USA

Target: HER2

Indications:

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

Drug Specifications:

- 150mg/bottle (China, overseas)
- 60mg/bottle (China, overseas)
- 420mg/bottle (overseas)

*Sum of sales revenue of HANQUYOU in China and overseas, and drug substance of trastuzumab

Excellent Performance of HANQUYOU

Higher sales per capita than domestic peers

Sales Per Capita[1]
(1H 2024)

>450k RMB per month

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

Strengthen product differentiation for competitive advantages

Competition has become complicated when other local trastuzumab products launched.

With advanced planning and preparation, HANQUYOU

recognition of the product advantages on international quality and two specifications

Bold expansion into broad market

Trastuzumab has wide application and its sales in the broad market (outside the Top1,000 hospitals) have increased rapidly, resulting to fast-growing market share in China

HANQUYOU has expanded the coverage with marketing activities in lower tier areas to capture potential of broad market

Sales per capita = Product sales / # of salesforce

HANSIZHUANG (Serplulimab): First Approved PD-1 mAb for 1L SCLC

678M RMB

Revenue in 1H2024

Widespread recognition

Recommended in 2024 CSCO treatment guidelines for SCLC, NSCLC, EC etc.

First patient dosed for MRCT phase 3 study on first-line mCRC of serplulimab ASTRUM-015

Approved in Thailand and Cambodia in 2024

Efforts to product accessibility

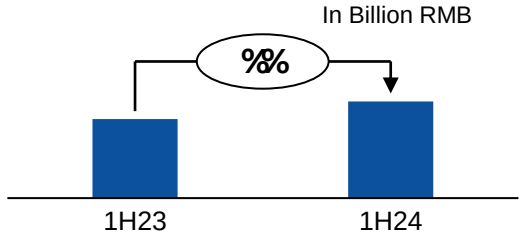
Launched patient assistance programs to reduce

to optimize treatment outcomes

Covered by Huiminbao (Regional Commercial Health Insurance) in 80 provinces/cities incl. Shanghai, Fujian, Shaanxi, Chongqing, Nanjing, Suzhou, Chengdu, Jinan,

of HANSIZHUANG

Differentiated strategies to seize the market

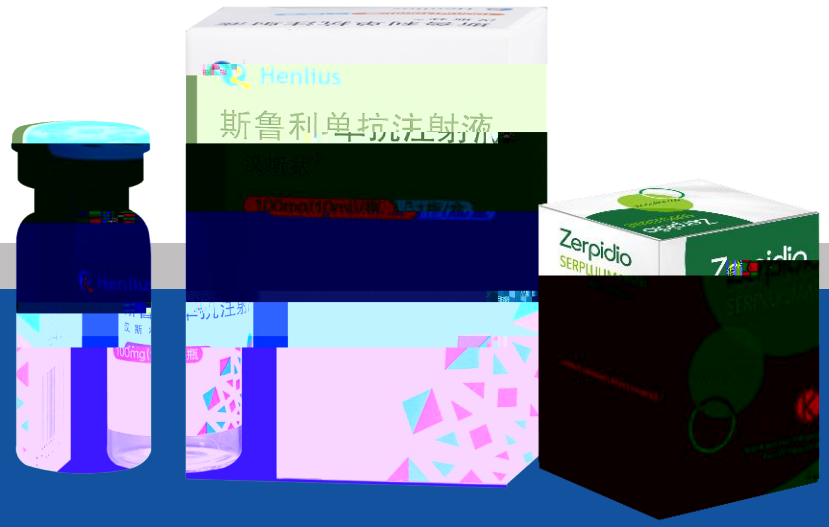


Developed differentiated marketing strategies and focused on SCLC to rapidly increase market share and gain customer trust

~630 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

Working with business partners to create more commercial value and expand overseas market



Zerpidio® in SEA

Target: **PD-1**

Indications:

MSI-H solid tumor
sqNSCLC
ES-SCLC
ESCC

Drug Specifications:

100mg/10ml/bottle

HANSIZHUANG Commercialization Highlights

First-class Commercialization Efficiency

678M RMB
1H 2024

Sales Per Capita[1]
210K RMB per month
1H 2024

Outstanding Achievements

Sales outperformed most of the competing PD-1/PD-L1 in China since its launch in 2021

Became the Tier-1 PD-1 /PD-L1 products in China

Industry Leading

Higher than all PD-1/PD-L1 products marketed in China during the same time period[2]

Differentiation strategy to tackle challenges and win opportunities

Differentiation Strategy Focus on SCLC

(15-20% of total lung cancer patients)

Challenges & opportunities	Actively tackle with challenges from newly launched SCLC products, and accurately interpret the research results Effectively promote messages of product advantages to keeping the leading position
NSCLC survival data read-out	The superior survival data for sqNSCLC, especially the Chinese subgroup read-outs, increased efficacy Establish marketing synergy in NSCLC & SCLC
ESCC indication approved in 23Q3	Conduct commercialization for the new indication ESCC patients with immuno-therapy advantages Deliver the concept of precise treatment for precise benefits to rapidly increase ESCC market share

1. Sales per capita = Product sales / # of salesforce
2. Henlius internal data

HANBEITAI (Bevacizumab): Commercialization Acceleration

87M RMB

Revenue in 1H 2024

The only bevacizumab biosimilars with phase 3

Target: **VEGF**

Indications:

Metastatic colorectal cancer
Advanced, metastatic or recurrent NSCLC
Recurrent glioblastoma
Cervical cancer
Epithelial ovarian, fallopian tube, or primary peritoneal cancer

Drug Specifications:

100mg/4ml/bottle

HANLIKANG (Rituximab): Strengthen the Market Leader Position

238M RMB

Revenue recognized by Henlius and licensing income in 1H 2024

Acceleration on market access and penetration

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

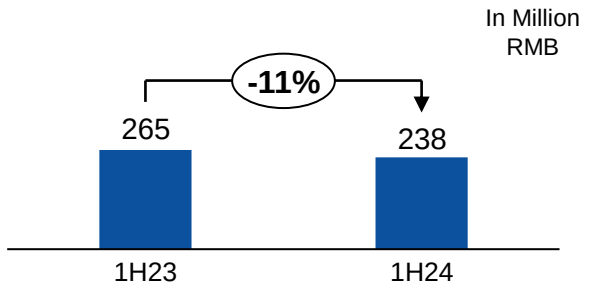
Gained the largest market share for consecutive quarters, 40% in Q1 2024*

Commercialization Progress

Jiangsu Fosun, a subsidiary of Fosun

commercialization in China

Listed on the procurement platforms and covered by NRDL in all provinces in China



Target: **CD20**

Indications:

Non-Hodgkin lymphoma

Chronic lymphocytic leukemia

Rheumatoid Arthritis (RA)

Drug Specifications:

100mg/10ml/bottle

500mg/50ml/bottle

* Source: Henlius internal analysis

HANDAYUAN (Adalimumab): Entered Autoimmune Disease Area

14M RMB

autoimmune disease product

Covered by NRDL and completed tendering and procurement platform listing in all provinces

The first phase 3 clinical study of adalimumab biosimilar for psoriasis patients in China

Four new indications of polyarticular juvenile idiopathic arthritis, pediatric plaque psoriasis,

been approved by NMPA

TNF-

Indications:

- Rheumatoid arthritis
- Ankylosing spondylitis
- Plaque psoriasis
- Uveitis
- Polyarticular juvenile
- idiopathic arthritis
- Pediatric plaque psoriasis

Drug Specifications:

40mg/0.8ml/bottle

03

Business Development

2024 H1 Major Business Development In-licensing Products

Sermonix Pharmaceuticals

Contract signing date: 2024/06/03

Territory Expansion

Lasofoxifene

Exclusive rights in Asia & Co-development in Japan

Expand breast cancer business to Asia

Convalife (Shanghai) Co., Ltd.

Contract signing date: 2024/08/19

In-licensing

Neratinib (HANNAIJIA)

Exclusive commercial rights in China & conditional license in ex-China regions

Enhance Henlius business in breast cancer

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

3000+

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

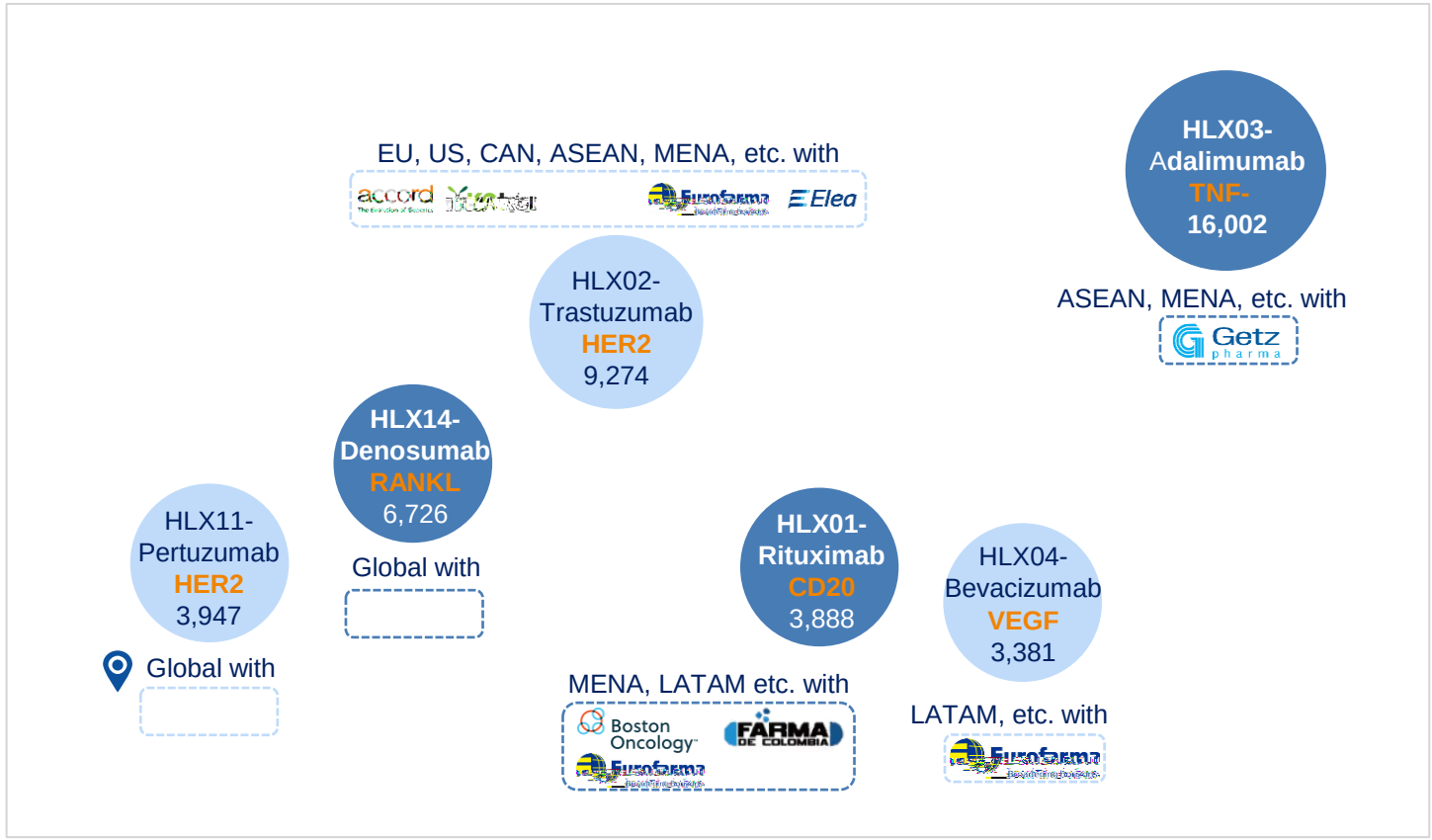
Out-licensing Focus across the Globe

International Quality Biosimilars Scale up

Market Size of Originators and Marketed Biosimilars

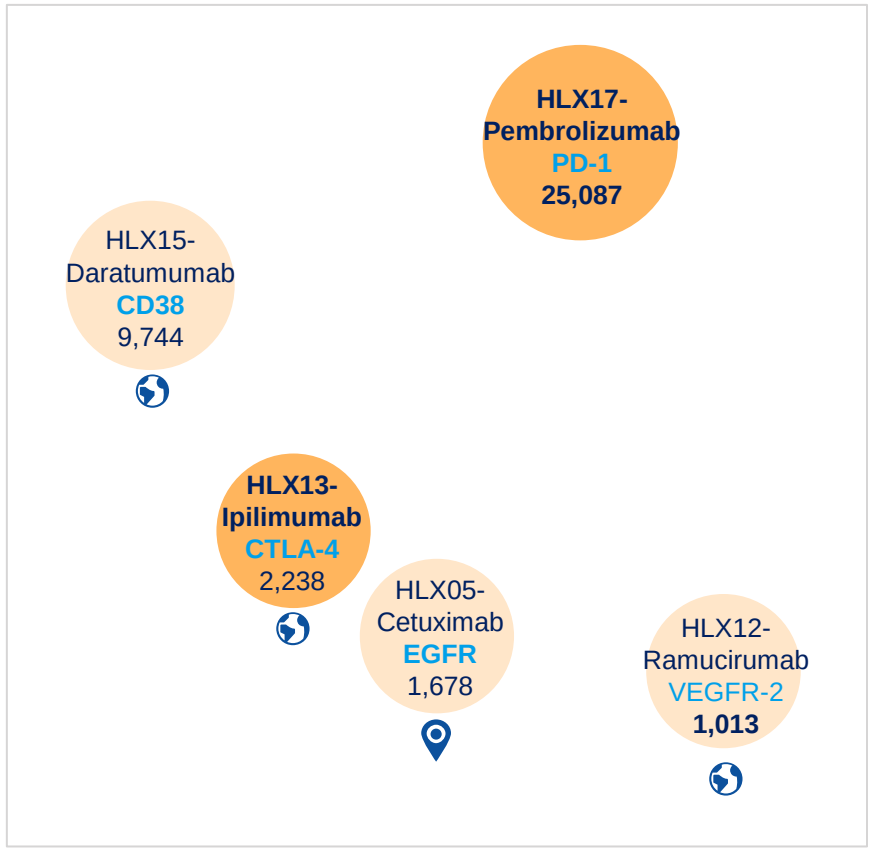
Biosimilars with existing out-licensing partners

Global sales in 2023 (M USD)



Biosimilars to be out-licensed ex-China

Global sales in 2023 (**M USD**)



Potentially first biosimilar in EU and the US

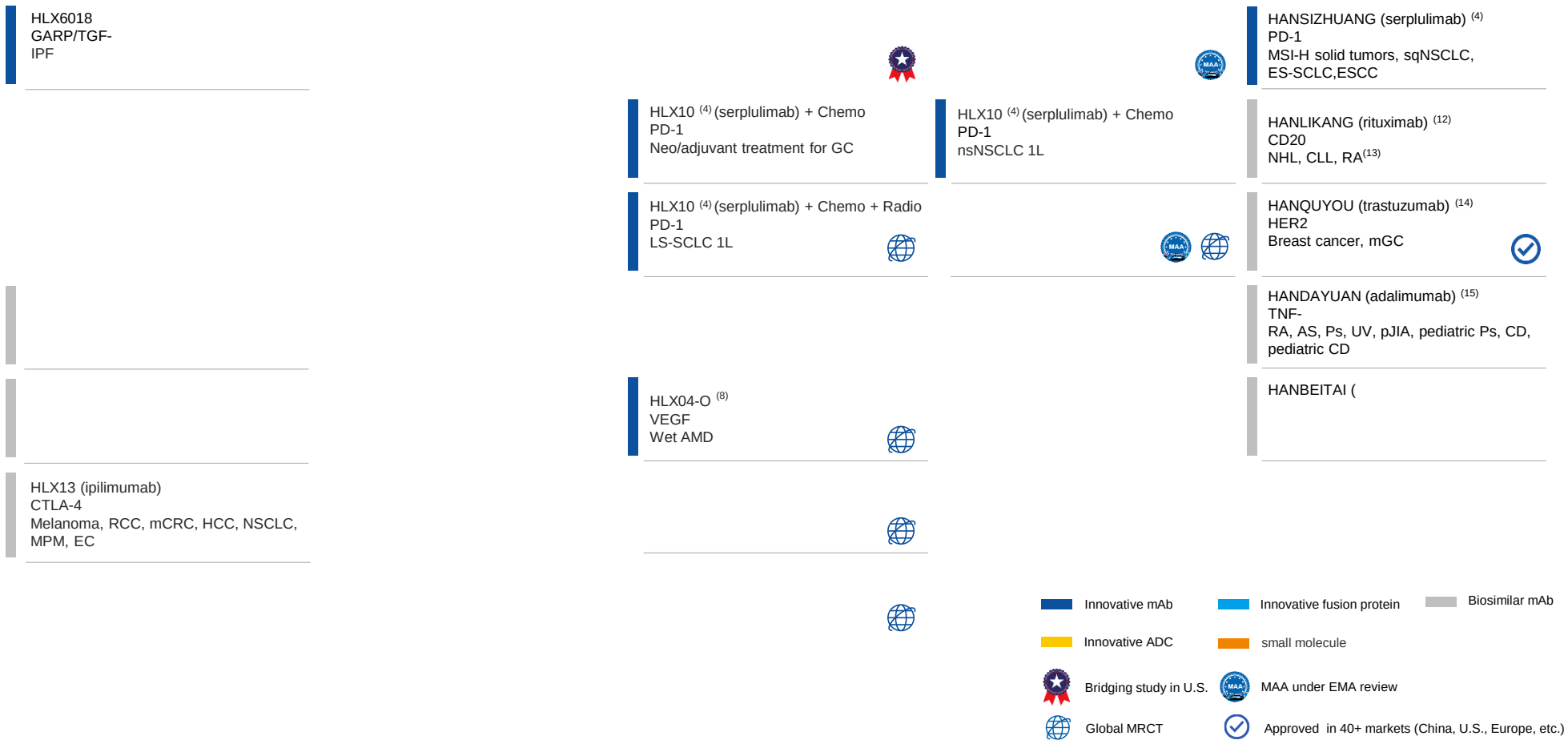
Global potentially first biosimilar

Data Source: Global data

04

Research & Development

Product Portfolio and Pipeline



(1) IND approvals obtained in China/the U.S. (2) IND approvals obtained in China/the U.S. and granted FDA Fast Track Designation. (3) Business partner: Shanghai Jingze. (4) Approved in China and Indonesia. Business partners: KGbio/Fosun Pharma/Intas. (5) IND approvals obtained in China/the U.S. (6) IND approvals obtained in China/the U.S. (7) Exclusive license obtained in China. (8) IND approvals obtained in China/Australia/the U.S./Singapore/EU countries, etc. Business partner: Essex. (9) IND approvals obtained in China/EU. Business partner: Organon. (10) Exclusive license obtained in China. Phase 3 MRCT enrolling globally. IND approval obtained in China. (11) IND approvals obtained in China/EU/Australia. Business partner: Organon. (12) Approved in China and Peru. The first biosimilar approved in China. Business partners: Fosun Pharma/Farma de Colombia/Eurofarma/Abbott/Boston Oncology. (13) The first rituximab approved for the indication in China. (14) Approved in 40+ countries, including China, U.S., the UK, Germany, France and Australia, trade name registered in U.S.: HERCESSI™. trade name registered in Europe: Zercepac®. Business partners: Accord/ Cipla/ Jacobson/ Elea/ Eurofarma/ Abbott/KGbio. (15) Business partners: Wanbang/Getz Pharma. (16) Business partner: Eurofarma. (17) Exclusive license obtained in China.

Clinical Pipeline Milestones: 2024 1H Review

2023

NDA/BLA/MAA Submission

- **HLX10**
  ES-SCLC[2]
  1L (the Philippines)
- **HLX14**
  PMOP[1], etc.
  (EU & US)

Key Clinical Data Readouts

- **HLX10**+HLX04
  mCRC[3]
  1L (PoC)
- **HLX22+HLX02**
  GC[4]
  1L (PoC)
- **HLX14***
  PMOP[5]
  (Pivotal)

Innovative mAb mAb biosimilar

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

* The key clinical data readouts have been obtained followed by BLA submission to Health Authorities, but the detailed study data will not be published in any Public Conference and/or Journal within given certain timeframe.

Clinical Pipeline Milestones: Expected in 2024 2H& 2025 1H

	2024H2	2025H1
NDA/BLA/MAA Submission	**HLX10** ES-SCLC[1] 1L (Hong Kong SAR, Macao SAR, Vietnam, UK, India, Swit, MENA) **HLX10** sqNSCLC[2] 1L (India, Macao SAR) **HLX10** MSI-H solid tumors Late-line (Hong Kong SAR, Macao SAR, India) **HLX10** ESCC[3] 1L (Macao SAR, India) **HLX11** Breast cancer Neoadjuvant therapy (US, China) **HLX14** PMOP[5] , etc. (US)	**HLX10** ES-SCLC[1] 1L (US) **HLX11** Breast cancer Neoadjuvant therapy (EU, Canada) **HLX14** PMOP[5], etc. (CN)
Key Clinical Data Readouts	**HLX10** ES-SCLC 1L (Bridging) **HLX04-O*** Wet AMD 1L (China Pivotal) **HLX11*** Breast cancer Neoadjuvant therapy (Pivotal) **HLX07+HLX10** NPC[8] 1L (China PoC)	**HLX04-O** Wet AMD 1L (Global Pivotal) **HLX10**+HLX04 mCRC[3] 1L (PoC) **HLX14*** PMOP[5] (Pivotal) **HLX22+HLX02** GC[6] 92pts 1L (PoC) **HLX10** nsqNSCLC 1L Pivotal

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.

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

* The key clinical data readouts have been obtained followed by BLA submission to Health Authorities, but the detailed study data will not be published in any Public Conference and/or Journal within given certain timeframe.

Innovative mAb mAb biosimilar

Clinical Data of HLX10-015-CRC301

Data cut-off date: 2023/12/15; median follow-up duration: 24.4 months

The latest clinical data of the phase 2/3 results (HLX10-015-CRC301) of HANSIZHUANG (HLX10, serplulimab)+HANBEITAI (HLX04, bevacizumab)+XELOX for 1L mCRC (metastatic colorectal cancer) treatment was presented in posters at the 2024 ASCO

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

Serplulimab + bevacizumab + XELOX warrants further large-scale investigation and could be a new first-line treatment option for mCRC patients including MSS mCRC patients

Product	Clinical Trial	Regimen	Sample Size	mPFS (months)	mOS (months)	mDOR (months)
Serpulimab +SOC	**HLX10-015-CRC301** (Ph2) **Data cutoff: December 15, 2023, median follow up: 24.4 months**	A: Serplulimab + bev + XELOX B: Bev + XELOX	ITT population 55 vs 57	16.8 vs 10.7, p=0.082 HR=0.58 (95% CI, 0.32-1.08)	NR vs 21.2, p=0.265 HR=0.74 (95% CI, 0.43-1.26)	19.4 vs 11.3, p=0.009 HR=0.31 (95% CI, 0.12-0.78)
			MSS subgroup 40 vs 50	16.8 vs 10.1, p= 0.108 HR=0.60 (95% CI, 0.32-1.12)	NR vs 20.2, p=0.286 HR=0.73 (95% CI, 0.41-1.30)	19.4 vs 8.3, p=0.018 HR=0.40 (95% CI, 0.18-0.88)
Atezolizumab +SOC	**AtezoTRIBE**[1] (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
			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**[2] (Ph2)	A: Nivolumab + bev + mFOLFOX6 B: Bev + mFOLFOX6	ITT population 127 vs 68	11.9 vs 11.9 HR=0.81, p=0.3 (**Negative**)	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[3] (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)[4]	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)[5]	11.1 vs 12.3 HR=1.14 (95% CI, 0.80-1.61)

bev, bevacizumab.

1. J Clin Oncol 41, 2023 (suppl 16; abstr 3500) . 2. Lenz, H-J. et al. J Clin Oncol 40, 4_suppl.008 (2022). 3. Hurwitz, H. et al. N Engl J Med 350, 2335-2342 (2004). *4. BioDrugs (2021) 35:445 458. 5. CSCO 2021 oral.*

Serplulimab: Targeting Differentiated Indications

Gastric Cancer (GC)

Neoadjuvant treatment in combination with Chemotherapy / Adjuvant with serplulimab only

Phase 3 clinical data readout: H2 2025

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

Limited Stage Small Cell Lung Cancer (LS-SCLC)

Serplulimab combined with Concurrent Chemoradiotherapy (CCRT)

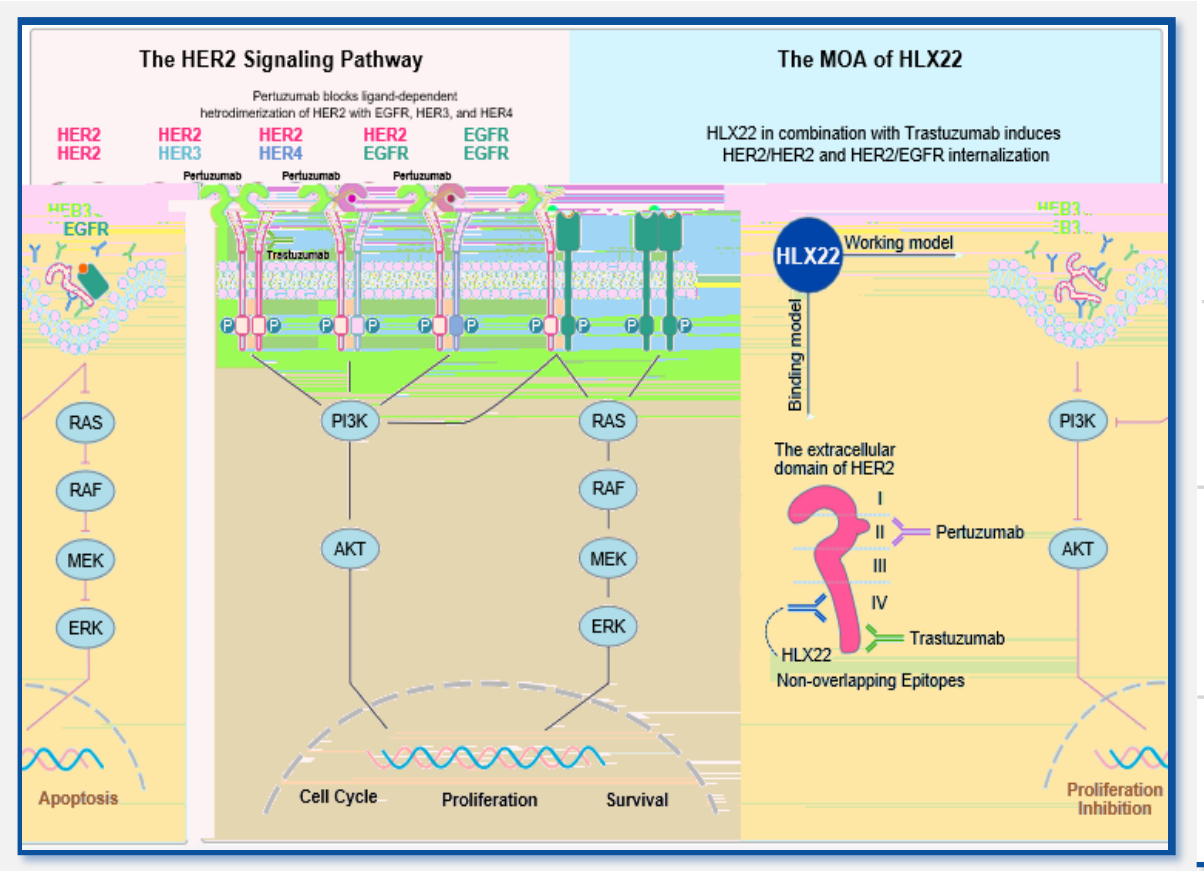
Phase 3 clinical data readout: H2 2026

1. Globally, the incidence for lung cancer ranks #2 and the mortality ranks #1. In China, both incidence and mortality of lung cancers ranks #1. Among 820,000 new cases of lung cancers in China every year, 15% is SCLC. Among SCLC patents, about 30%-40% are LS-SCLC[3]
2. Phase 3 MRCT had 370 patients enrolled as of 23rd August. 2024, from mainland China, Hong Kong SAR, Australia, the US, etc.; by Oct. 2023, the first patient has been dosed in the EU
3. Concurrent chemoradiotherapy (CCRT) is the SoC for LS-SCLC and globally no PD-1/PD-L1 was approved yet for this indication. -1 mAb for LS-SCLC treatment if the trial succeeds

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
vol. 112,1 (2015): 31-7. doi:10.1002/jso.23940
3. Ha IB, Jeong BK, Jeong H, et al. Effect of early chemoradiotherapy in patients with limited stage small cell lung cancer. Radiat Oncol J. 2013 Dec;31(4):185-90

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[1]

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

HLX22 dual targeting of HER2 MOA and its research result have been published in Journal of Translational Medicine

1.Bang, Yung-Jue et al. 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. KEYNOTE-811 trial of dual PD-1 and HER2 blockade in HER2-positive gastric cancer. Nature vol. 600, 7890 (2021): 727-730. doi: 10.1038/s41586-021-04161-3; Zanidatamab (zani), a HER2-targeted bispecific antibody, in combination with chemotherapy (chemo) and tislelizumab (TIS) as first-line (1L) therapy for patients (pts) with advanced HER2-positive gastric/gastroesophageal junction adenocarcinoma (G/GEJC): Preliminary results from a phase 1b/2 study. Keun Wook Lee, Li-Yuan Bai, et al Journal of Clinical Oncology 2022 40: 16_suppl, 4032-4032

Clinical Data of HLX22-GC-201

Product	Clinical Trial	Regimen	Sample Size	mPFS (months)	mOS (months)	mDOR (months)
HLX22	**HLX22-GC-201** (Ph 2)	A HLX22 (25 mg/kg)+trastuzumab+chemo (XELOX) B HLX22 (15 mg/kg)+trastuzumab+chemo (XELOX) C Trastuzumab+chemo				

X22-chemo an]TJETQ E4028.0Tm-GBubgroup5 0 960 540 reW* nBT/F4 9.9899Tf1 0 0 1 213.46 291.89 Tm0 g0 G[-0379]TJETQ EMC /Span <</MCID 31829

4.1 Pre-clinical Assets

HLX43 (PD-L1 ADC) Presented Excellent Preclinical Efficacy Data and Entered into Clinical Phase 1

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

I. In MDA-MB

HLX43 Shows No Immunotoxicity Towards PD-L1+ Human APCs

HLX43 Exhibits Excellent Bystander Effect

HLX42 (EGFR ADC) Presented Excellent Preclinical Efficacy Data, Granted Fast Track Designation by FDA, and Entered into Clinical Phase 1

Preclinical Results

HLX43 exhibits excellent bystander effect

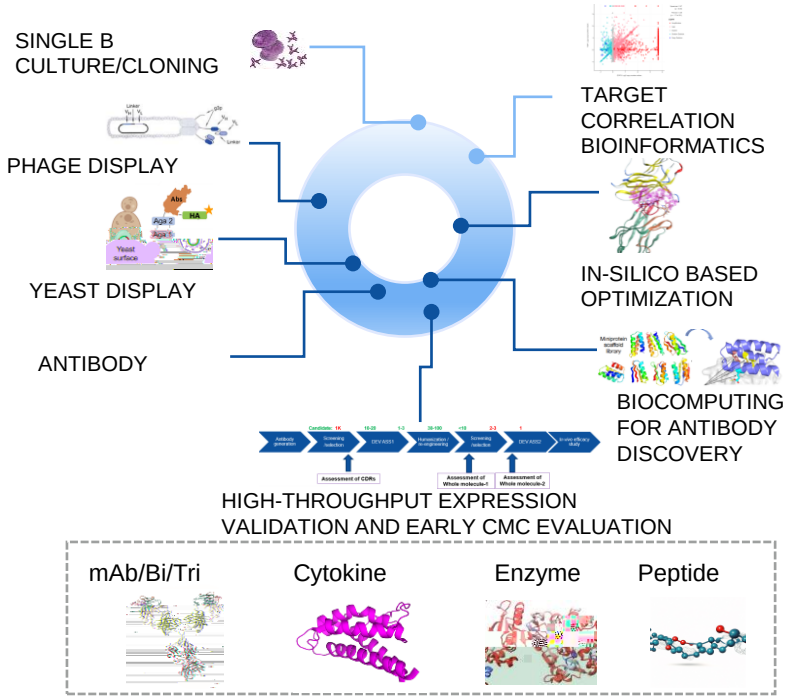
In *in vivo* studies, HLX42 showed potent tumor suppression in several models that were resistant to Cetuximab or EGFR TKIs or anti-PD-1 antibody

I. In NCI-H1993 model, weekly administration of HLX42 at 8 mg/kg for 3 weeks resulted in 91.5% TGI compared to 79.8% TGI when treated with anti-EGFR Ab-GGFG-Dxd

II. In EBC-1 model, weekly administration of HLX42 at 8 mg/kg for 3 weeks eradicated all lesions; all mice remained tumor free 24 days after the last dose, while tumor began to regrow in the anti-EGFR Ab-VC

Three Major Preclinical Platforms Drive Full-Speed Development of Representative Molecules

Protein drug discovery and engineering platform to enable innovative therapeutic R&D



Hanjugator™: Modular ADC toolbox and development platform

Develop differentiated, clinically valuable ADC products

AI4T (AI for Therapeutics) to drive innovative drug discovery for oncology, metabolism, immunology and neurology

HLX6018: First-in-class anti-Pulmonary/Kidney Fibrosis Candidate, Phase 1 ongoing

Project information

Indication

Pulmonary fibrosis: Currently approved drugs are nintedanib and pirfenidone.
Renal fibrosis: Currently there are no approved drugs.

Molecule information

mAb targeting GARP\ TGF- 1 complex.
Patent filed.

Mechanism

HLX6018 is a monoclonal antibody targeting GARP and TGF- 1 complex. GARP can bind to un-activated TGF- thus playing an important role in the activation of TGF- signaling. TGF- family is important for the development of fibrosis.

Competitive advantage

HLX6018 is a monoclonal antibody targeting GARP/TGF 1, a novel target in fibrosis. It has excellent physicochemical properties, low immunogenicity, and exhibits excellent anti-fibrotic activity in multiple mouse models of fibrosis. The unique mechanism of action of HLX6018 puts it in a leading position in the research and development of anti-fibrosis drugs.

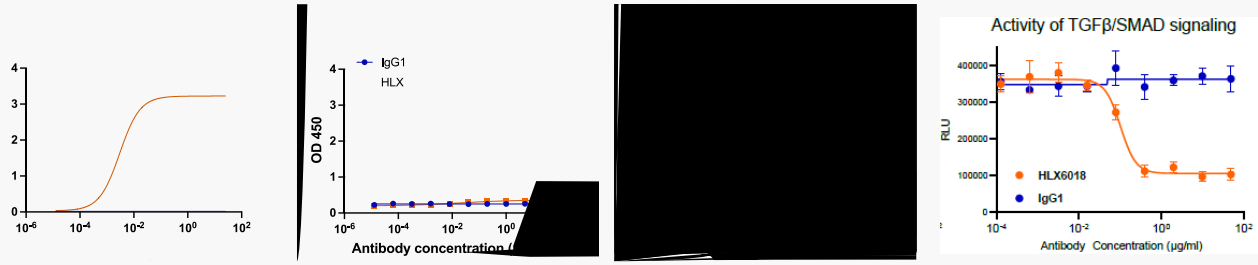
Project progress

IND approved in China in Mar. 2024.
Phase 1 FPI finished in Apr. 2024 (IPF).

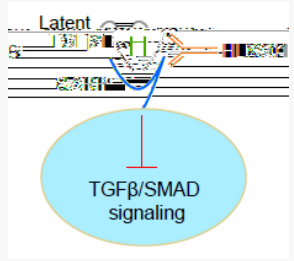
Key data

Pharmacology

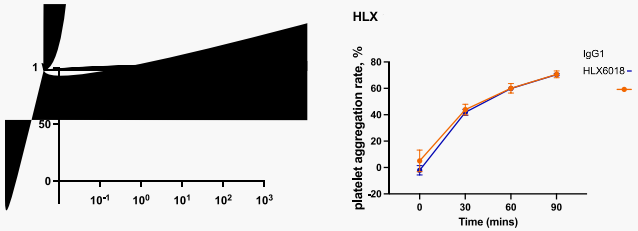
1. HLX6018 specifically binds to GARP/TGF 1(no effects on TGF 2,3) and inhibits integrin mediated release.



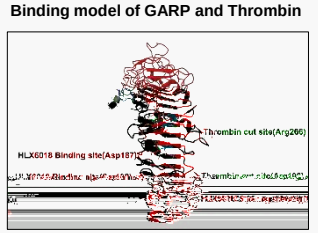
2. HLX6018 inhibits the release of TGF 1 by targeting GARP/ latent TGF 1 complex



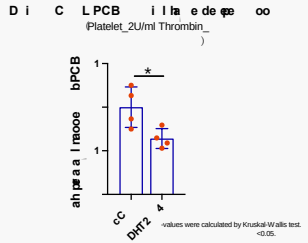
3. HLX6018 has no effects on platelets activation and



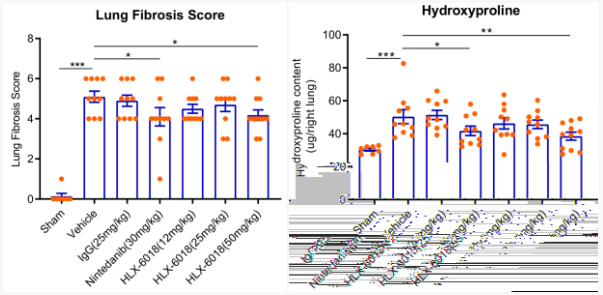
GARP cleavage



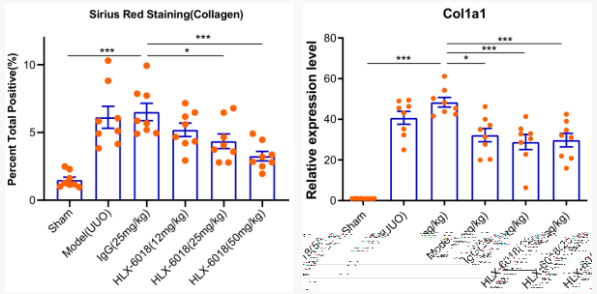
-mediated



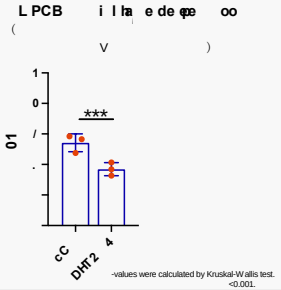
5. HLX6018 inhibits bleomycin-induced pulmonary fibrosis in mice



6. HLX6018 inhibits ureteral ligation-induced renal fibrosis in mice



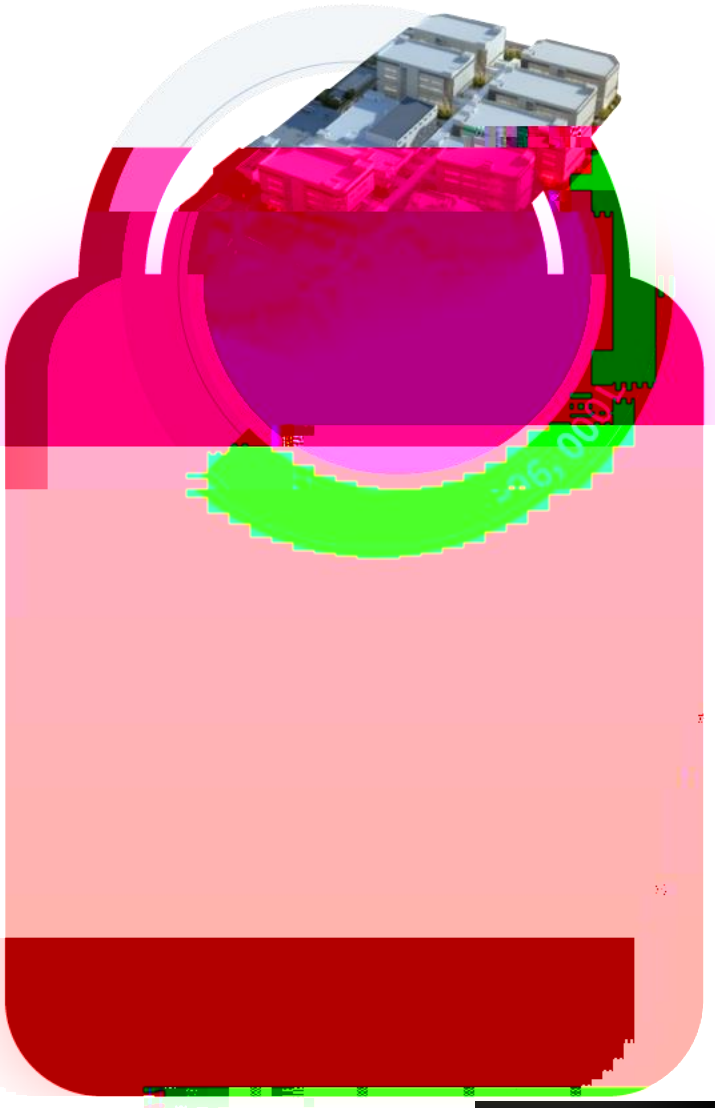
HLX6018 inhibits the release of TGF from renal epithelium



05 Manufacturing

International Leading Capabilities on Manufacturing and Quality Management

Manufacturing capacity optimization:
Commercial GMP production batches will



Operation Excellence and Continuous Innovation

Technical Innovation

Multiple Regression Analysis Model for Prediction

The objects for multiple regression analysis have been locked, and data collection is complete

Successfully completed connection testing between Raman spectroscopy and the stainless steel system

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

Breakthrough of employee capabilities from specialization to versatility

Lean Operations

30+ on-going lean operations projects with ~10M 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 9%* lower than that in 2023**

Optimization of international logistics transportation loading has resulted in an **average reduction of logistics costs by over 30%***

* Internal data of the company

06

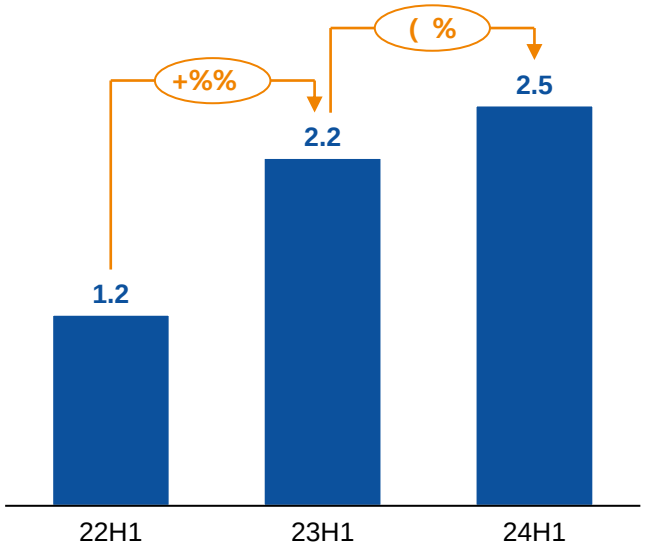
2024H1 Financial Review

2024 Half Year Revenue of RMB 2.75 Billion with 9.8% YoY

Revenue (in Billion RMB)

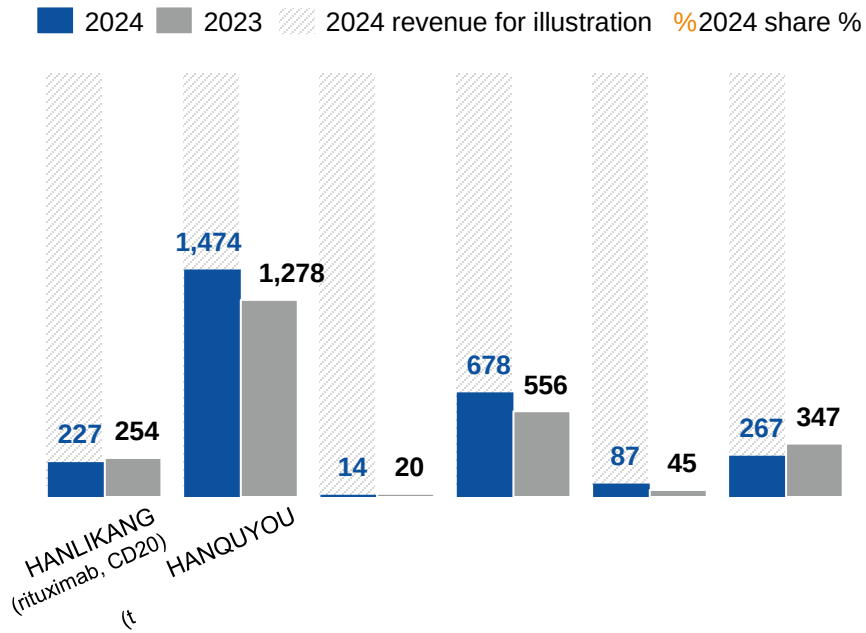
Revenue Growth

Product Sales (in Billion RMB)



Product Sales

2024 Revenue Breakdown (in Million RMB)

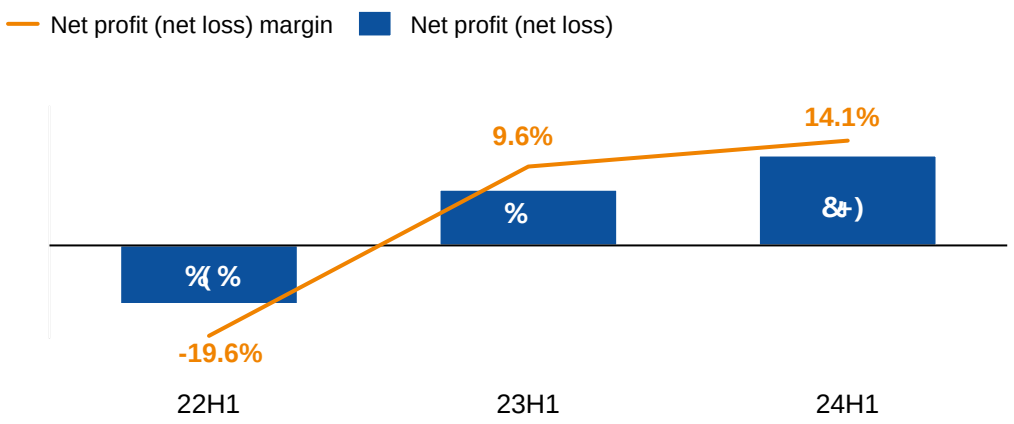


Revenue Breakdown

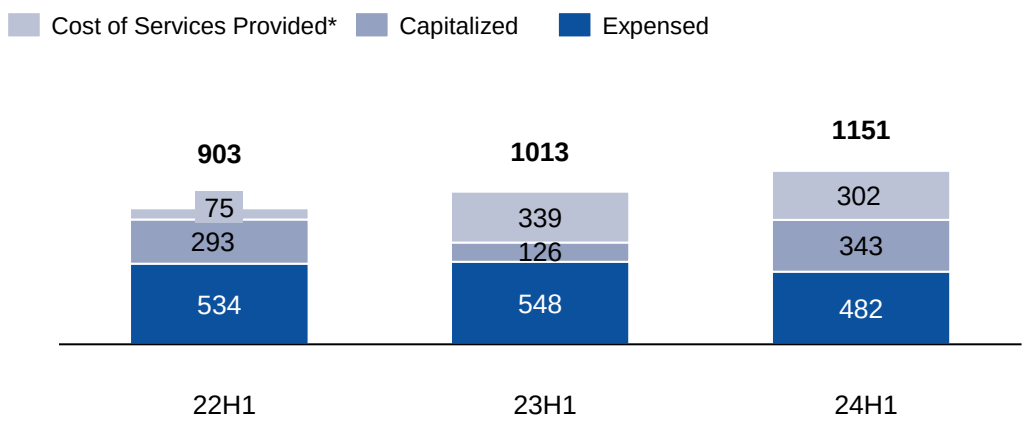
*Sum of sales revenue of HANQUYOU in China and overseas, and drug substance of trastuzumab

Achieved Profitability in 2024H1 with RMB ~251M Operating CF

Net profit (net loss): turned into profitability (in Million RMB)

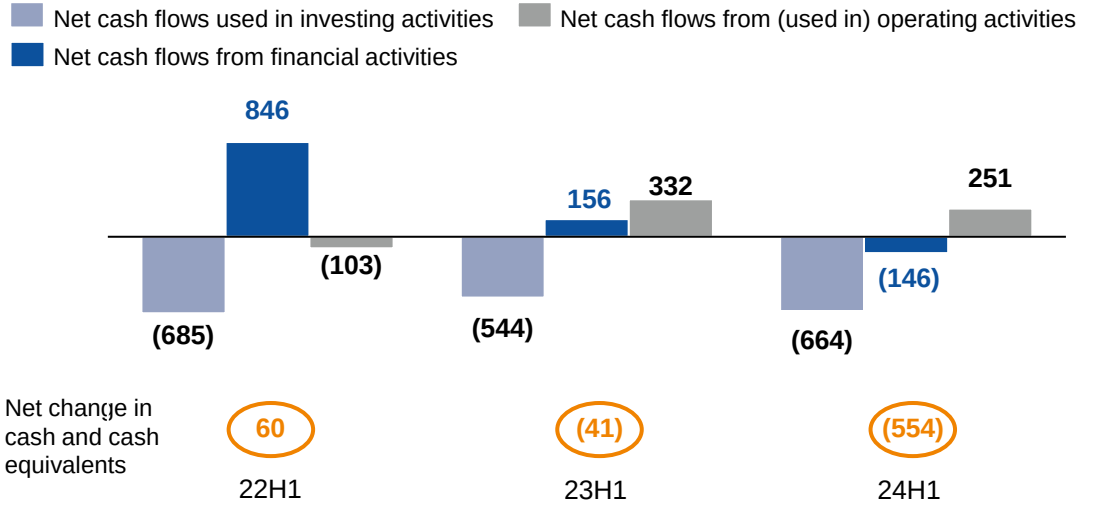


R&D related investment (in Million RMB)

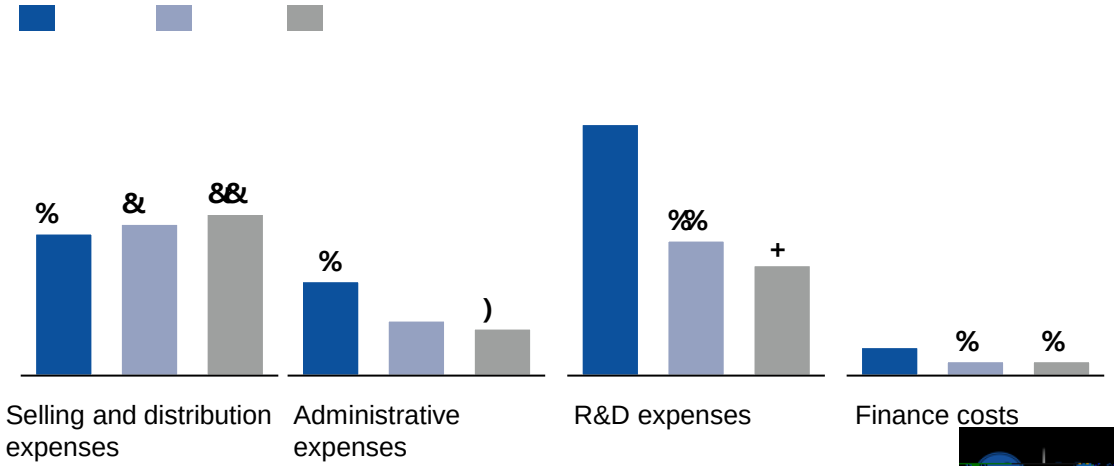


* R&D spending related to out-licensing products accounted into cost of services provided according to accounting practices

Net change in cash & cash equivalents: positive OCF (in Million RMB)



Expense to revenue ratios : effective controls on expenses



Financial Highlights

Financial Data (selected)	24H1		23H1		YoY Growth
Unit	In Million RMB	% of revenue	In Million RMB	% of revenue	%
Revenue	2,746.1	100.0%	2,500.5	100.0%	9.8%
Product sales	2,479.4	90.3%	2,152.9	86.1%	15.2%
BD and other revenue	266.7	9.7%	347.6	13.9%	(23.3%)
Cost of sales	(755.4)	(27.5%)	（721.6）	(28.9%)	4.7%
Selling and distribution expenses	(900.2)	(32.8%)	（783.0）	(31.3%)	15.0%
Administrative expenses	(159.9)	(5.8%)	（163.7）	(6.5%)	(2.3%)
R&D expenses	(482.5)	(17.6%)	（547.8）	(21.9%)	(11.9%)
Financial costs	(62.8)	(2.3%)	（54.1）	(2.2%)	16.1%
Net profit (net loss)	386.3	14.1%	240.0	9.6%	61.0%
Cash and bank balances	649.4	23.6%	759.2	30.4%	(14.5%)
Net cash flows from operating activities	251.3	9.1%	332.5	13.3%	(24.4%)

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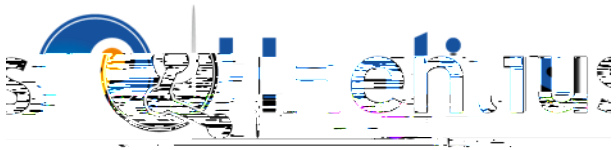

Reliable Quality

Affordable Innovation