Henlius (2696.HK)
2024 Interim Results
Investor Presentation

August 2024

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PATIENT CENTRICITY

01

2024 1H Business Highlights & Company Strategy

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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

R&D

- 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-β1 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 “Quality Benchmark” in 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%

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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

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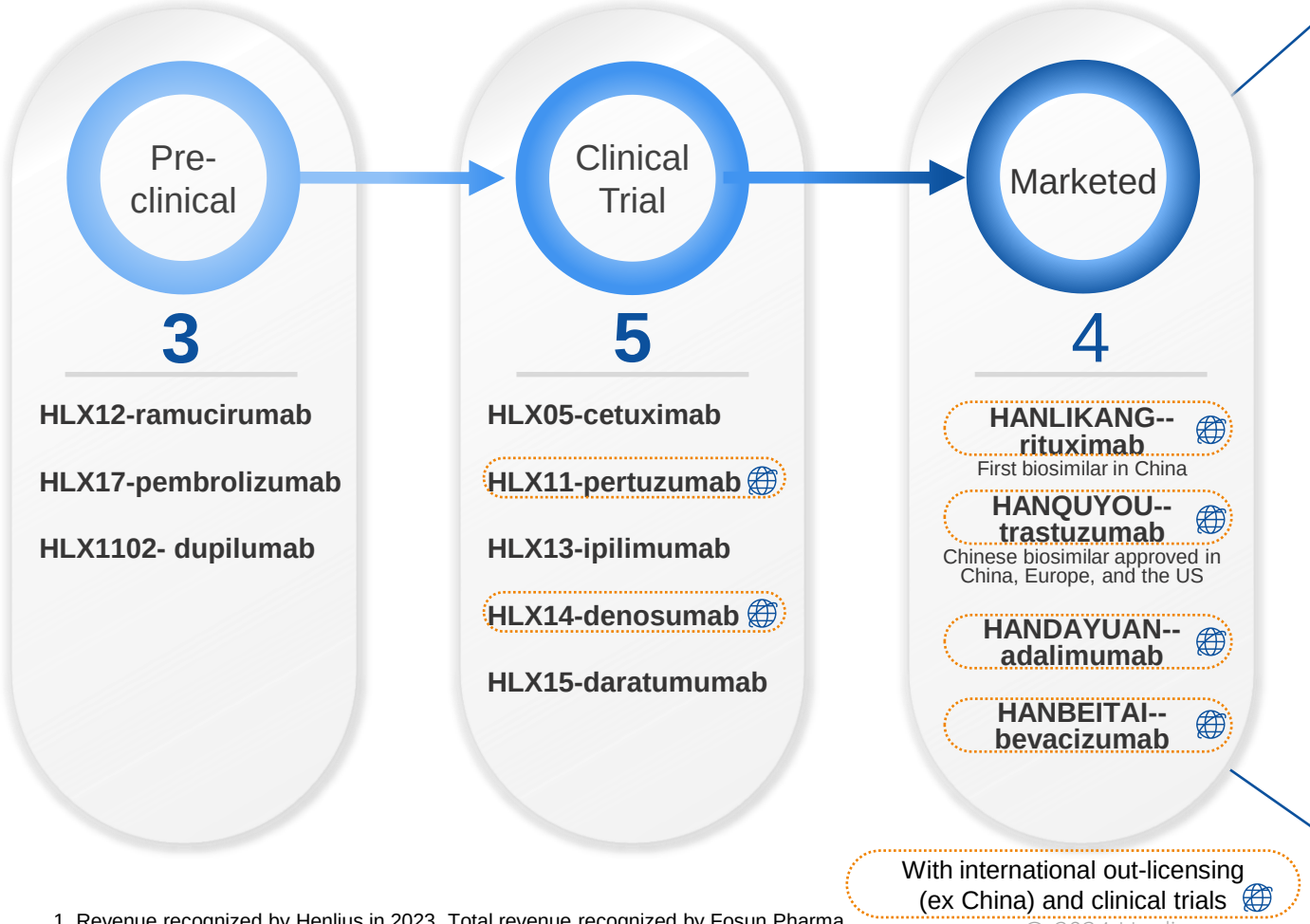
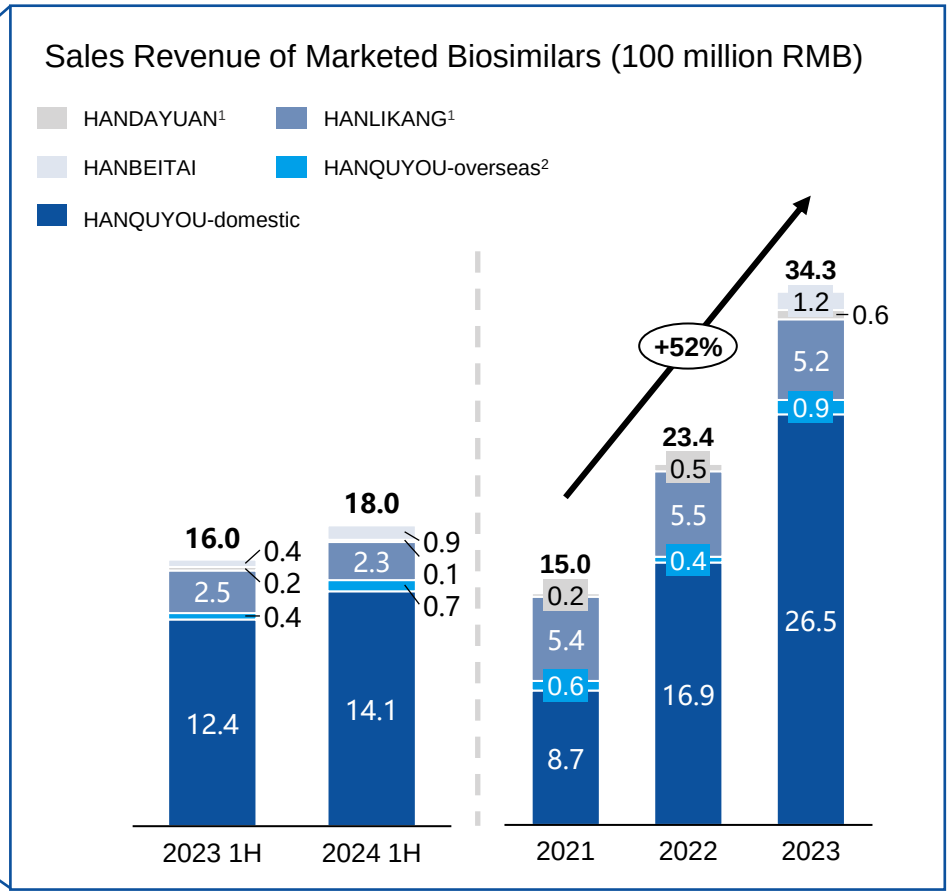
The Sales Growth of Marketed Biosimilars Accelerated; Multiple Pipeline Products Planned for Global Presence

- 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

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Serplulimab Entered into a New High-growth Stage of Commercialization with Differentiated Advantage

678M RMB

- 20241H sales revenue reached 678M RMB
- In March 2023, serplulimab achieved over RMB 100M monthly sales in China for the first time, representing its commercialization stepping up into new stage
- By the end of 2024 1H, serplulimab has completed tendering platform listing for all 31 provinces in China, and established a commercial team of ~630 people with strong professional communication skills and sales experience in oncology

Clinical Advantages

Serplulimab recommended by 9 *Diagnosis and Treatment Guidelines of CSCO in 2023*

- Including *2023 CSCO Diagnosis and Treatment Guidelines* for SCLC, NSCLC, EC, CRC and Clinical Application Guideline for immune checkpoint Inhibitor etc.

Publication

- In 2024, ASTRUM-004 published online in *Cancer Cell* as its cover feature
- In 2024, results of exploratory biomarker analysis of pivotal clinical trial ASTRUM-005 of serplulimab initially released at AACR
- In 2024, advances in immunotherapy for mCRC: serplulimab combo published in *MED*

Differentiated Indications

ES-SCLC (marketed):

ASTRUM-005 mOS: 15.8 vs 11.1 months

GC (Phase 3):

Expected to be the world leading and the only perioperative immune drug in China for GC

LS-SCLC (Phase 3):

Expected to be the world's first PD-1 for the treatment of LS-SCLC

mCRC (Phase 2/3):

Phase 2 clinical data of 1L mCRC has been presented in ASCO with the mPFS of 16.8 months; expected to become the first approved PD-(L)1 for 1L mCRC

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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 / Ophthalmology / Metabolic / Rare Disease…

71% | **29%**

Oncology

Solid Tumor

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

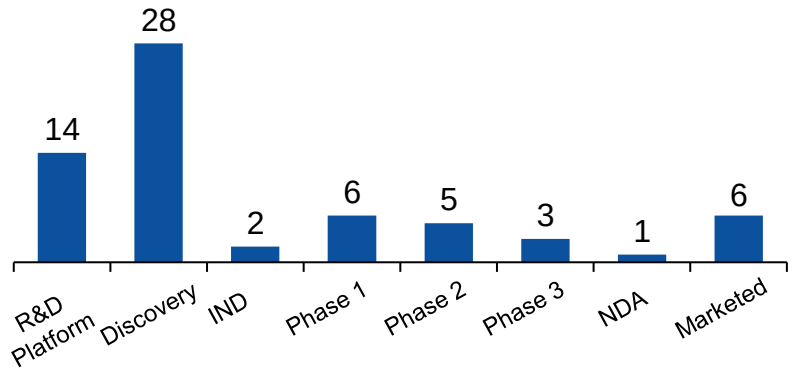
Hematology

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

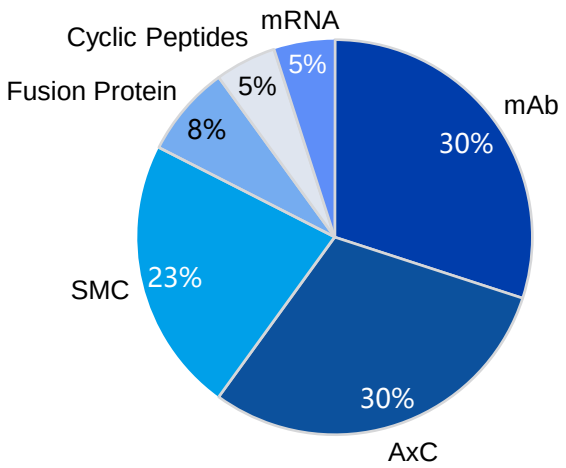
Non-oncology

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

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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

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) has successfully been approved for market launch in Peru, accelerating its benefits to emerging market countries.

HLX11-Pertuzumab biosimilar

- **MRCT has enrolled 908 patients globally, expected to be the first approved pertuzumab biosimilar in the US and Europe**
- **As the 2023 sales of the originator drug was over US$3.95B[2], HLX11 will have a promising global market prospect by licensing collaboration with Organon**

HLX14- Denosumab biosimilar

- **MRCT has enrolled 514 patients globally, and HLX14 filed BLA in the EU in 2024 based on MRCT Phase 3 result**
- **As the originator drug achieved over US$6.16B[2] sales in 2023, HLX14 will have a promising global market prospect by licensing collaboration with Organon**

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

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02

Commercialization

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HANQUYOU (Trastuzumab): Sales Growth 15.4% YoY

1.47B RMB*

Revenue in 1H2024

Zercepac® in Europe

HERCESSI™ in the USA

International quality

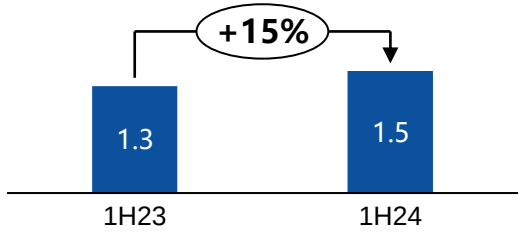
- First approved trastuzumab biosimilar in China
- First “Chinese nationality” mAb biosimilar approved in Europe
- Approved in US and Canada, and becomes the “Chinese nationality” biosimilar approved in all three regions of China, Europe, and the US
- Launched in 40+ countries and regions

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

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

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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 have enhanced the market's 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

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

678M RMB

Revenue in 1H2024

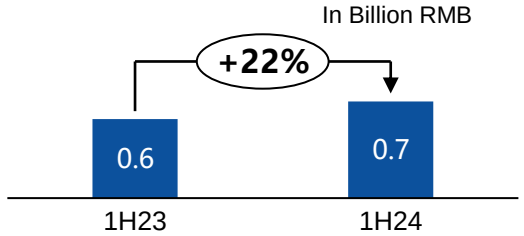
Widespread recognition

- 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 patients' economic burdens, to improve adherence so as to optimize treatment outcomes
- Covered by Huiminbao (Regional Commercial Health Insurance) in 80 provinces/cities incl. Shanghai, Fujian, Shaanxi, Chongqing, Nanjing, Suzhou, Chengdu, Jinan, Xiamen etc. and greatly improve local residents' access 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 to maximize patients' accessibility
- 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

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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 physicians' recognition of HANSIZHUANG's efficacy • Establish marketing synergy in NSCLC & SCLC
ESCC indication approved in 23Q3	• Conduct commercialization for the new indication by leveraging HANSIZHUANG's efficacy for 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

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HANBEITAI (Bevacizumab): Commercialization Acceleration

87M RMB

Revenue in 1H 2024

market access and

- Covered by NRDL in 31 provinces, and completed tendering and procurement platform listing in 29 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

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 tumor types in a combo therapy

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

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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

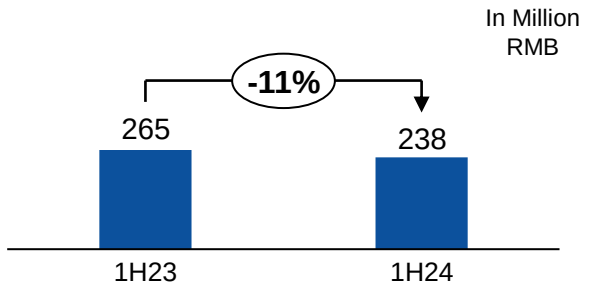
- Approved in February 2019 as the first approved biosimilar in China, the first approved rituximab biosimilar in China
- New indication approved in February 2022: the first rituximab approved for Rheumatoid Arthritis indication in China

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 Pharma, is responsible for HANLIKANG's 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

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HANDAYUAN (Adalimumab): Entered Autoimmune Disease Area

14M RMB

Revenue recognized by Henlius in 1H 2024

Improve patients' availability and accessibility

- Henlius' first 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, Crohn's disease and pediatric Crohn's disease have been approved by NMPA

Work with partners to penetrate the market

- Jiangsu Wanbang 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.
- Out-licensed the commercialization rights of HANDAYUAN to Getz Pharma in 11 countries, including Pakistan, the Philippines and Kenya, and accelerate global footprint

Target: TNF-α

Indications:

- Rheumatoid arthritis
- Ankylosing spondylitis
- Plaque psoriasis
- Uveitis
- Polyarticular juvenile idiopathic arthritis
- Pediatric plaque psoriasis
- Crohn's disease
- Pediatric Crohn's disease

Drug Specifications:

40mg/0.8ml/bottle

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03

Business Development

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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

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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	Neratinib (HANNAIJIA)	Lasofoxifene (HLX78)
1L	Pertuzumab (HLX11)	
2L/2L+		Lasofoxifene (HLX78) • ESR1^{mut} BC (2L+) • HR+/HER2- (2L+) BC

Lasofoxifene (small molecule SERM*):

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

In-licensing deal snapshot:

- Henlius and Sermonix expanded the partnership of Lasofoxifene. Henlius obtained the additional exclusive rights of Lasofoxifene in Asia including Japan, and will co-develop Lasofoxifene with Sermonix to expedite the development progress in Japan.
- Henlius and Convalife established partnership on neratinib (汉奈佳). Henlius obtained the exclusive commercial rights of the product in China, and the conditional license rights in ex-China for regions.

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

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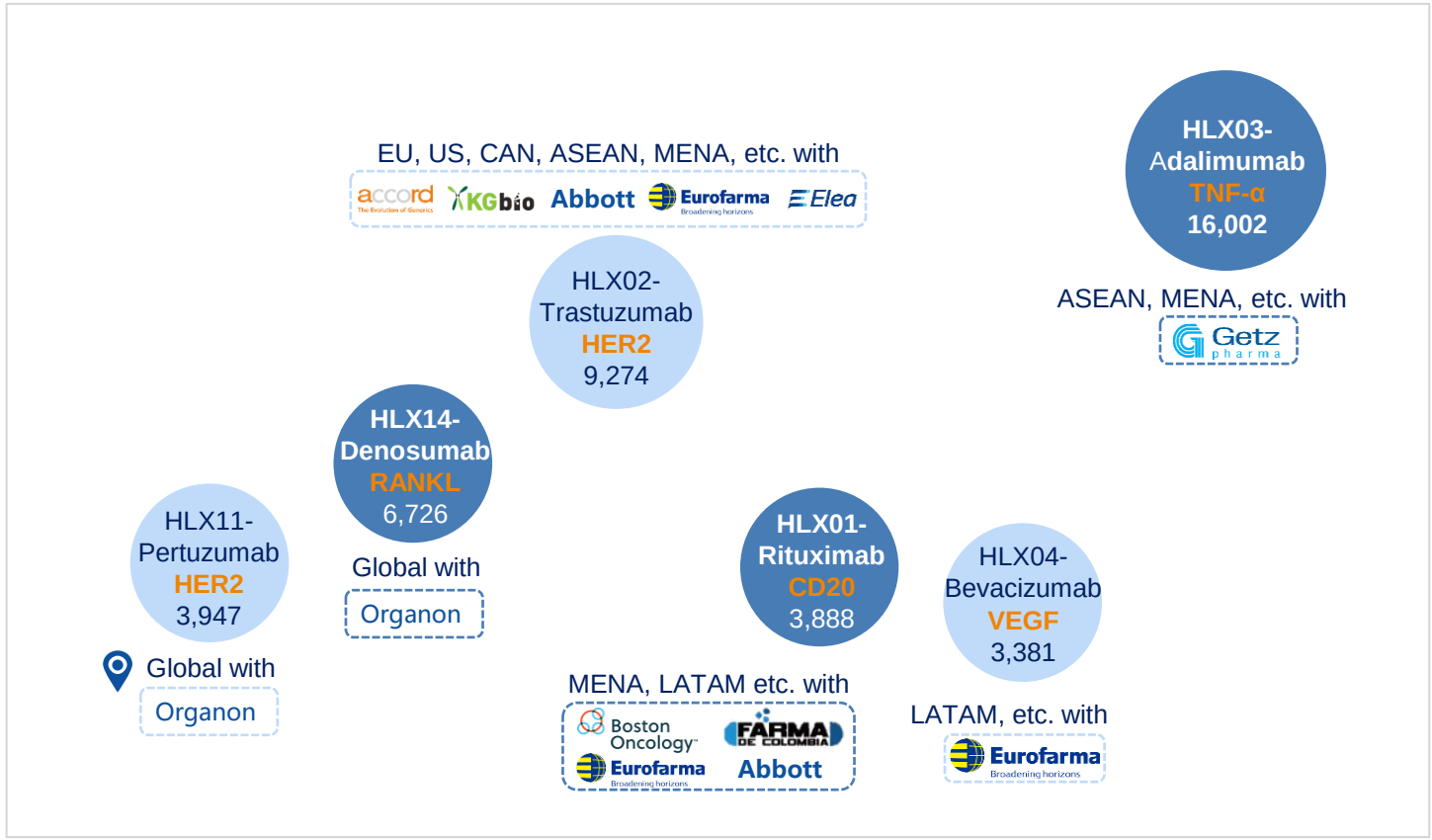
Out-licensing Focus: Henlius' International Quality Biosimilars Scale up across the Globe

Market Size of Originators and Marketed Biosimilars

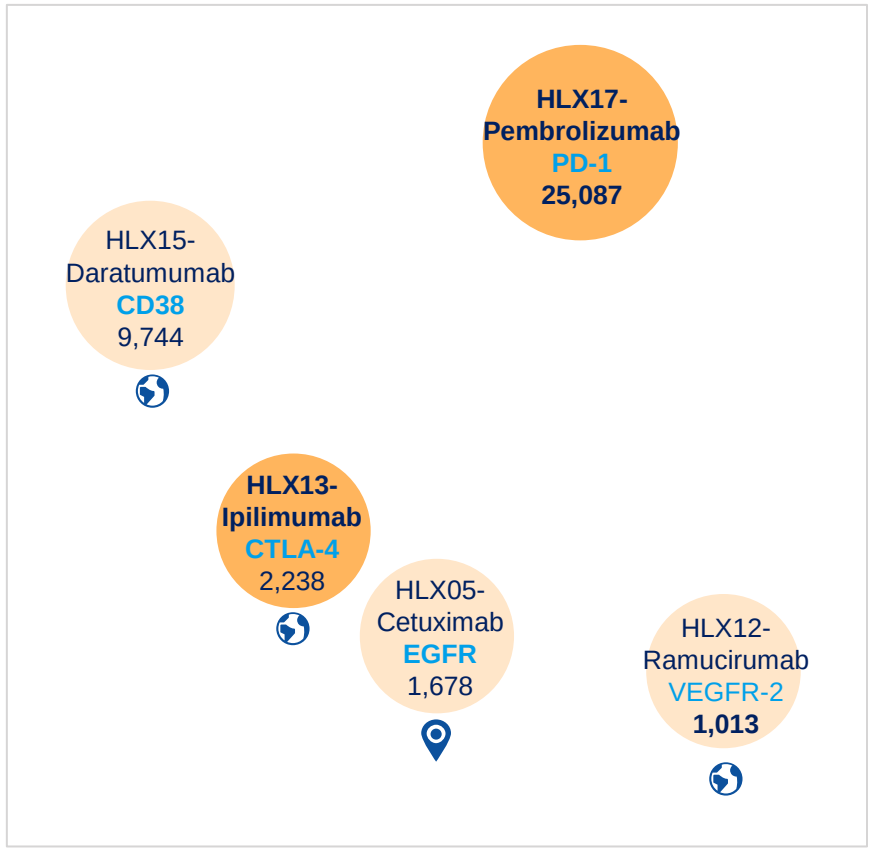
Biosimilars with existing out-licensing partners

Global sales in 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

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04

Research & Development

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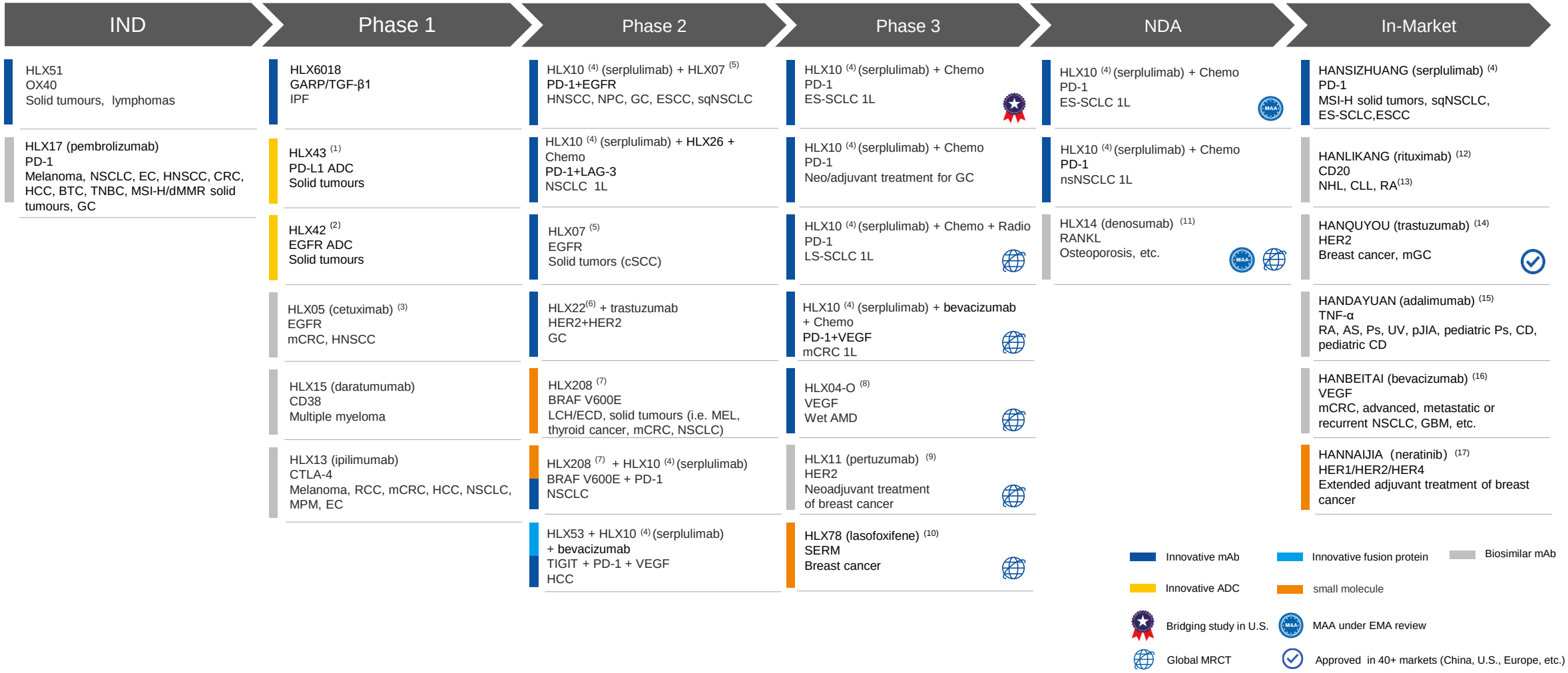
Product Portfolio and Pipeline



(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.

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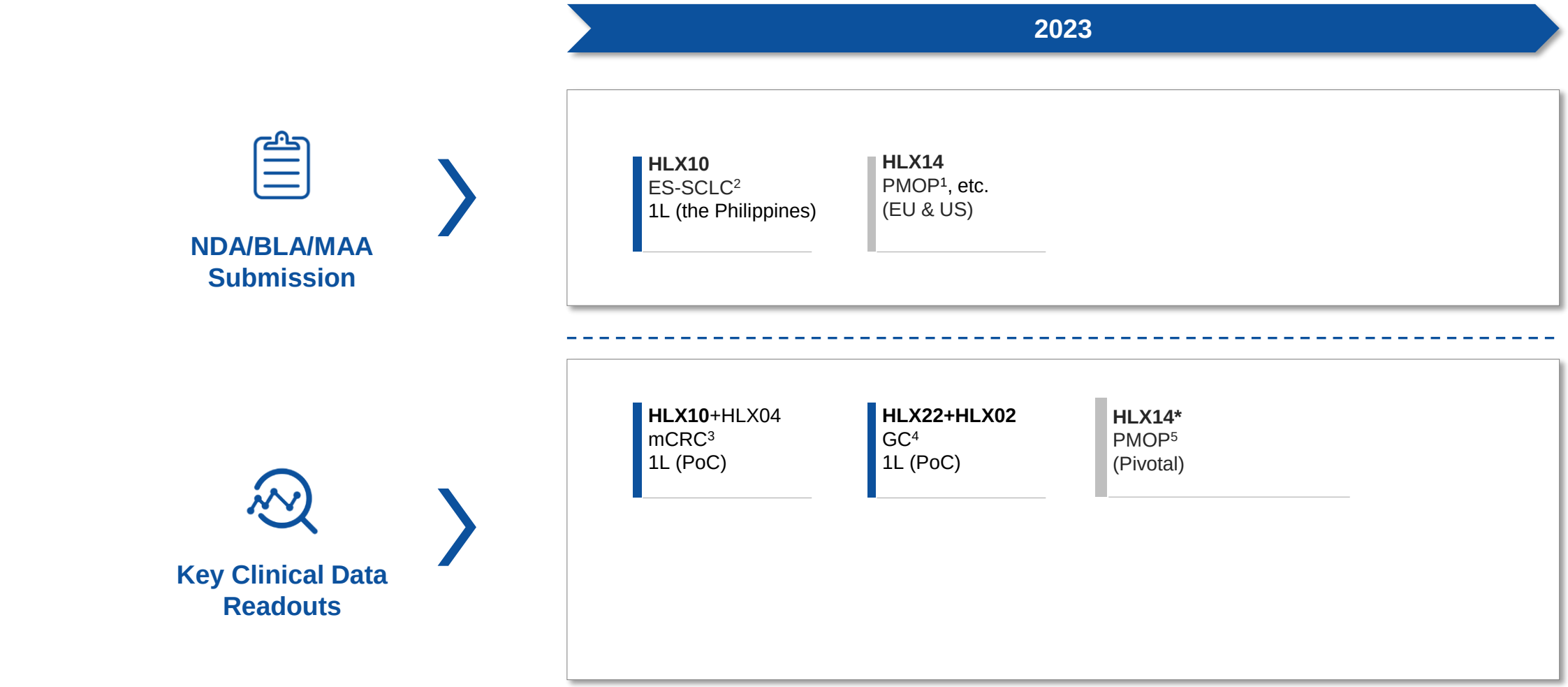
Clinical Pipeline Milestones: 2024 1H Review



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.

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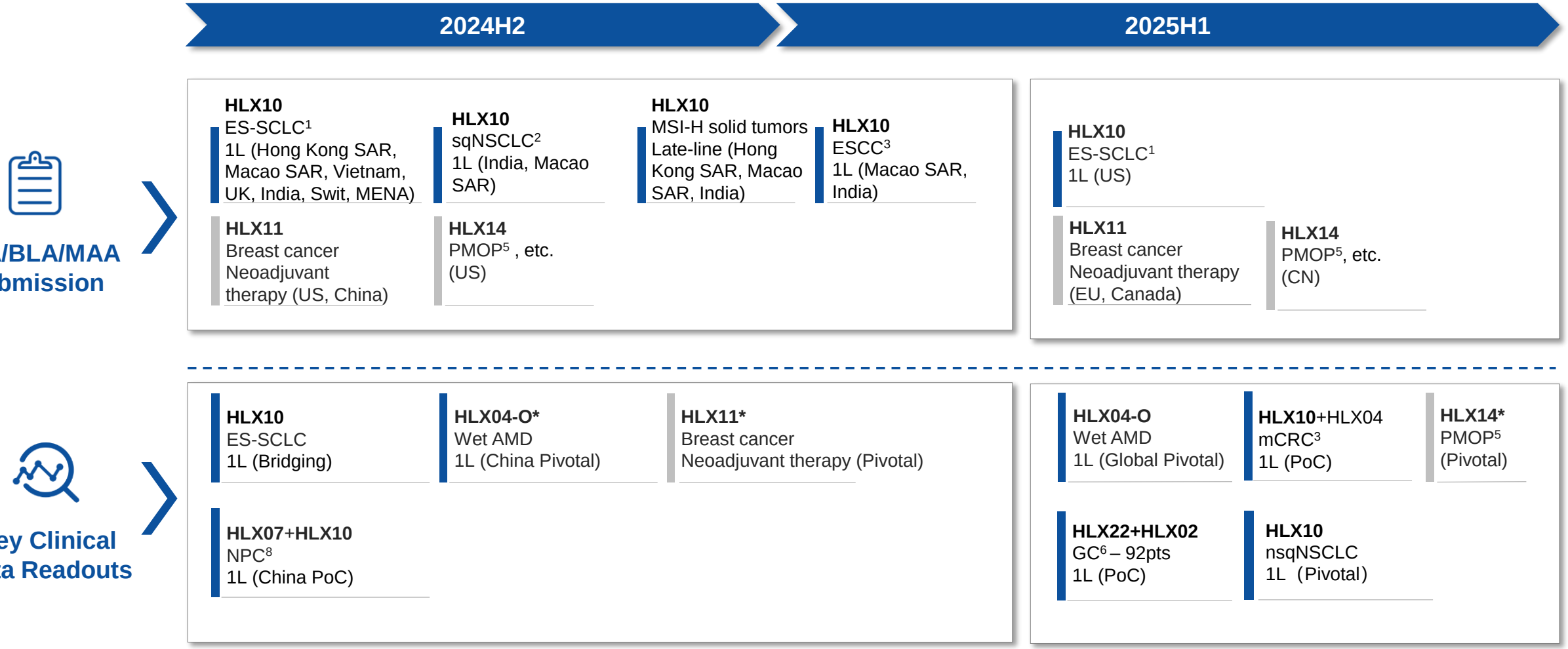
Clinical Pipeline Milestones: Expected in 2024 2H& 2025 1H



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

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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.*

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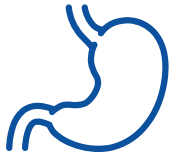
Serplulimab: Targeting Differentiated Indications



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 and China's only perioperative I/O 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. Serplulimab can potentially become the world's first PD-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
2. Strong, Vivian E et al. "Differences in gastric cancer survival between the U.S. and China." Journal of surgical oncology vol. 112,1 (2015): 31-7. doi:10.1002/jso.23940
3. 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

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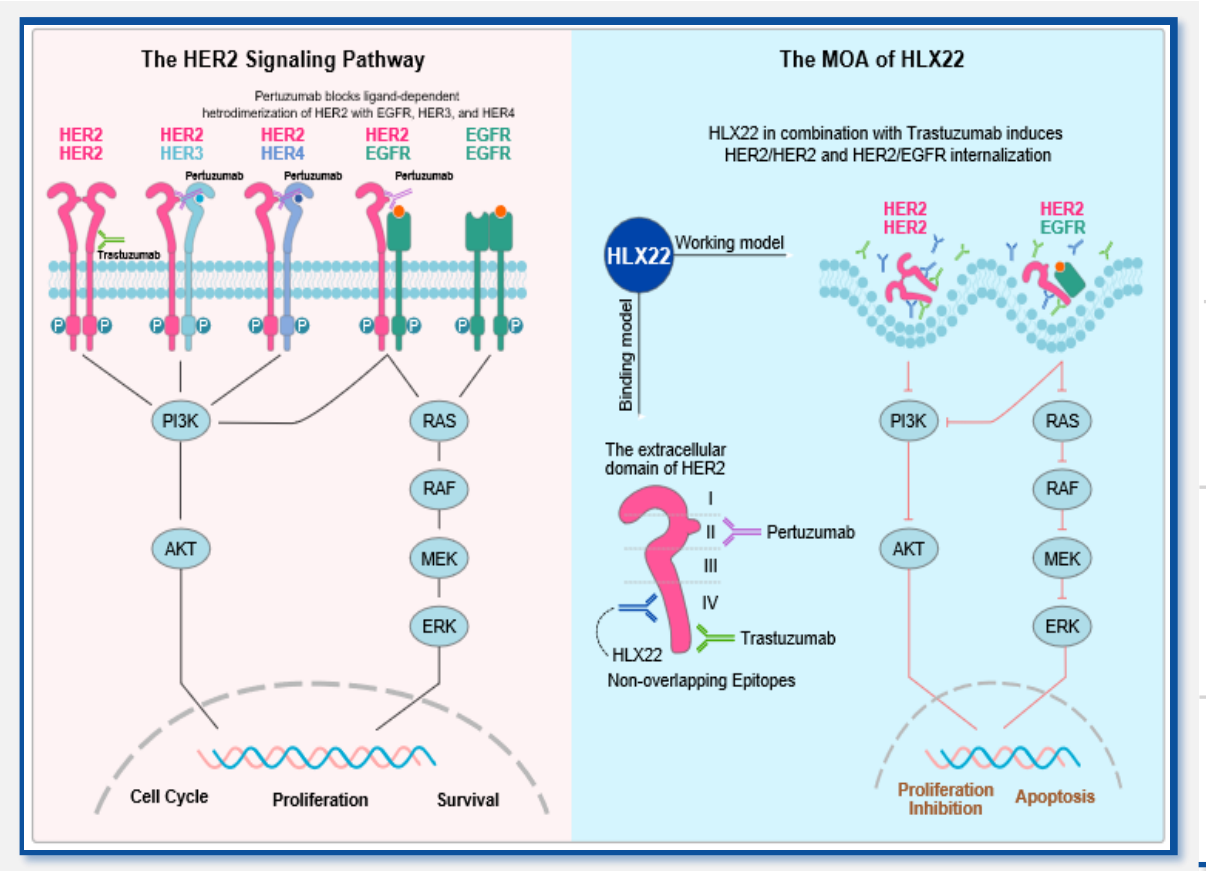
HLX22: Potential to Change the SOC of 1L GC

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

Clinical Data of HLX22-GC-201

Data cut-off date: 2024/03/25 ; median follow-up duration: 22.1 months

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

Product	Clinical Trial	Regimen	Sample Size	mPFS (months)	mOS (months)	mDOR (months)
HLX22	**HLX22-GC-201** (Ph 2)	A：HLX22 (25 mg/kg)+trastuzumab+chemo (XELOX) B：HLX22 (15 mg/kg)+trastuzumab+chemo (XELOX) C：Trastuzumab+chemo (XELOX)	ITT population 18 vs 17 vs 18	13.7 vs NR vs 8.2 A vs C：HR=0.4，p=0.0505 B vs C：HR=0.1，p=0.0002	24.4 vs NR vs NR A vs C：HR=0.7，p=0.4971 B vs C：HR=0.5，p=0.2141	11.8 vs NR vs 6.8 A vs C：HR=0.5，p=0.1655 B vs C：HR=0.1，p=0.0001
Pembrolizumab	**KEYNOTE-811**[1] (Ph 3) **EMA**: approved for PD-L1+ subgroup； **FDA:** expediated approved for PD-L1+ subgroup	A：Pembrolizumab+trastuzumab+chemo (CF/XELOX) B：Trastuzumab+chemo (CF/XELOX)	ITT population 350 vs 348	***IA2***：10.0 vs 8.1 HR=0.72，p=0.0002	***IA3***：20.0 vs 16.8 HR=0.84，p NA	***IA2***：11.2 vs 9.0 HR NA，p NA
			PD-L1+ subgroup 298 vs 296	***IA2***：10.8 vs 7.2 HR=0.70，p NA	***IA3***：20.0 vs 15.7 HR=0.81，p NA	***IA2***：11.3 vs 9.5 HR NA，p NA
			PD-L1- subgroup 52 vs 52	***IA2***：9.5 vs 9.6 HR=1.17，p NA	***IA2***：16.1 vs 22.3 HR=1.61，p NA ***IA3***：NA	***IA2***：8.9 vs 9.0 HR NA，p NA
Trastuzumab	**ToGA**[2, 3] (Ph 3)	A：Trastuzumab+chemo (CF/CX) B：chemo (CF/CX)	Adjusted ITT population 294 vs 290	6.7 vs 5.5 HR=0.71，p = 0.0002	13.8 vs 11.1 HR=0.74，p=0.0046	6.9 vs 4.8 HR=0.54，p <0.0001
			China subgroup 36 vs 48	6.8 vs 5.5 HR=0.69，p NA	12.6 vs 9.7 HR=0.72，p <0.05	5.8 vs 4.5 HR=0.56，p NA
Pertuzumab	**JACOB**[4] (Ph 3 **failed**)	A：Pertuzumab+trastuzumab+chemo (CF/CX) B：Trastuzumab+chemo (CF/CX)	ITT population 388 vs 392	8.5 vs 7.0 HR=0.73，p = 0.0001	17.5 vs 14.2 HR=0.84，p=0.057 (**failed**)	10.2 vs 8.4 HR NA，p NA

CF, cisplatin and fluorouracil; CX, cisplatin and capecitabine; DOR, duration of response; G/GEJ, gastric/gastroesophageal junction; HR, hazard ratio; IA, interim analysis; ITT, intention-to-treat; m, median; NA, not available; NR, not reached; OS, overall survival; Pembro, pembrolizumab; PFS, progression-free survival; Tras, trastuzumab; XELOX, capecitabine and oxaliplatin. 1. Janjigian YY, et al. Lancet 2023; 402 (10418): 2197-2208. 2. Bang Y-J, et al. Lancet 2010; 376 (9742): 687-97. 3. Shen L, et al. Zhonghua Zhong Liu Za Zhi 2013; 35 (4): 295-300. 4. Tabernero J, et al. Lancet Oncol 2018: 19 (10): 1372-1384.

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4.1 Pre-clinical Assets

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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-231 model, weekly administration of HLX43 for three times induced significant tumor regression, superior over anti-PD-L1-GGFG-Dxd and anti-PD-L1-vc-MMAE at equivalent doses

II. In NSCLC PDX model, weekly administration of HLX43 at 8mg/kg for three times induced significant tumor regression, and the treatment group still had durable response in lesions after stopping dosing

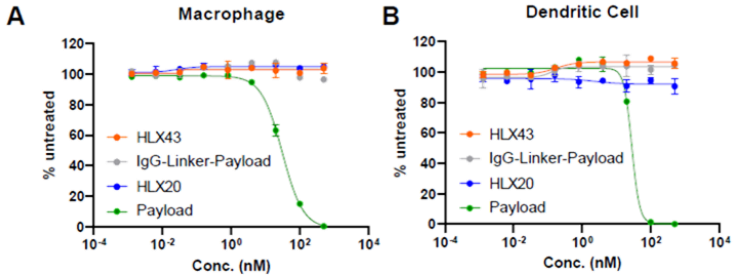
III. HLX43 also induced significant tumor regression in HCC PDX model with (IHC1+) or without (IHC-) PD-L1 expression, meanwhile showed strong synergy with anti-VEGF antibody

- Toxicity studies in mice and cynomolgus monkeys also demonstrated that HLX43 was well tolerated

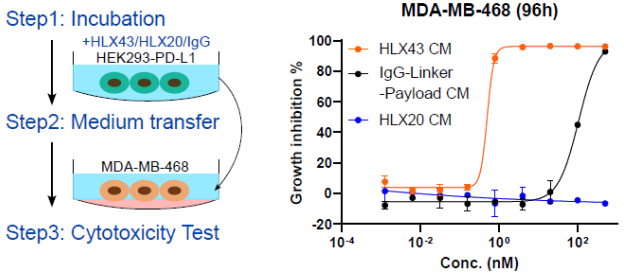
Regulatory and Clinical Trial Progress

- IND of HLX43 for the treatment of advance/metastatic solid tumors has been successively approved by China NMPA and the US FDA during Oct. to Nov., 2023
- On Nov. 24, 2023, the phase 1 clinical trial of HLX43 for the treatment of advance/metastatic solid tumors has completed the first patient dosing in China
- The phase 1 dose escalation study is in process; the indications to be developed include but not limited to lung cancer, esophagus cancer, liver cancer, etc. (NCT06115642)

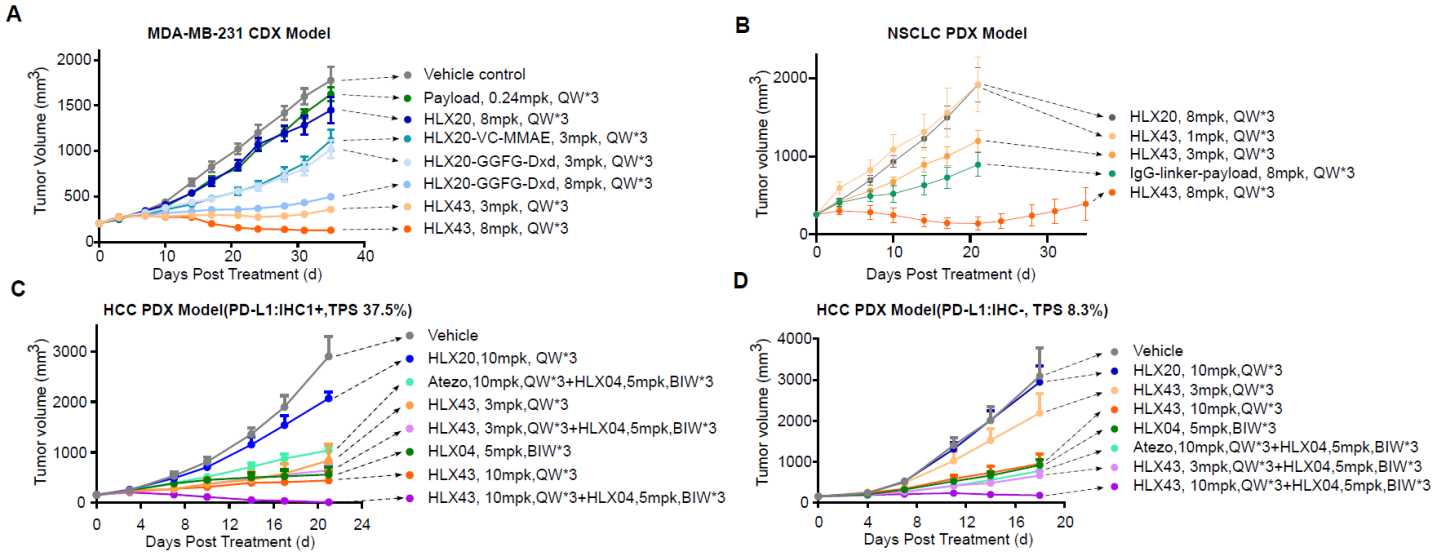
HLX43 Shows No Immunotoxicity Towards PD-L1+ Human APCs



HLX43 Exhibits Excellent Bystander Effect



HLX43 Exhibits Excellent Anti-tumor Efficacy *In vivo*



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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-MMAE treated group

III. In LU3075 PDX model which poorly responded to Osimertinib monotherapy, HLX42 eradicated all lesions

IV. In a NSCLC PDX model harboring EGFR exon19 deletion/T790M/C797S mutations, which exhibited complete tolerance to Osimertinib, a single dose treatment resulted in significantly complete response

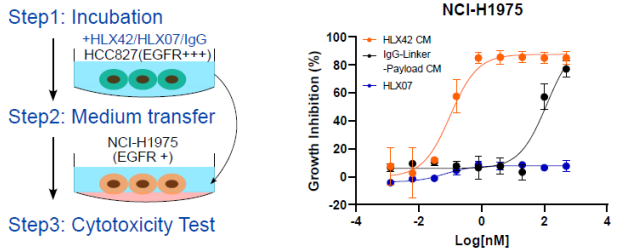
V. HLX42 also showed strong efficacy in HT29 CRC CDX model and Cetuximab and/or anti-PD-1 resistant microsatellite stable (MSS) mCRC PDX model

- In toxicology studies conducted in rats and non-human primates, HLX42 had favorable safety profile

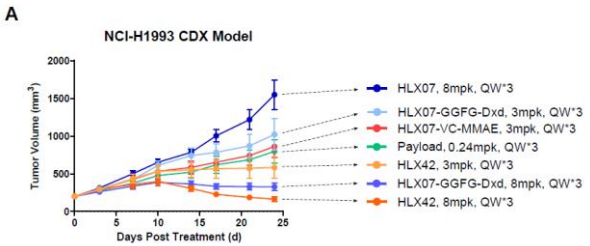
Regulatory and Clinical Trial Progress

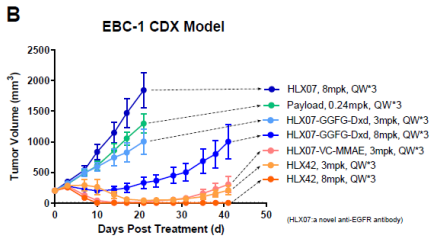
- In December 2023, the US FDA granted Fast Track Designation (FTD) to HLX42 for the treatment of patients with advanced or metastatic EGFR-mutated non-small cell lung cancer whose diseases have progressed on a 3rd-generation EGFR tyrosine kinase inhibitor treatment
- IND of HLX42 for the treatment of advance/metastatic solid tumors has been approved by China NMPA and the US FDA successively during Oct. to Nov., 2023
- In March 2024, the phase 1 clinical trial of HLX42 for the treatment of advance/metastatic solid tumors has completed the first patient dosing in China (NCT06210815)

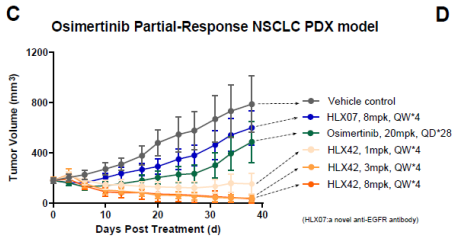
HLX42 Exhibits Excellent Bystander Effect

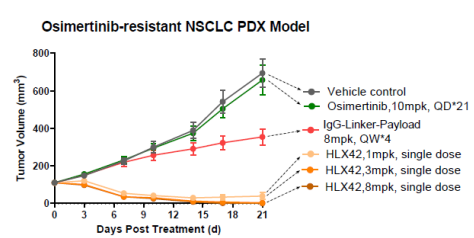


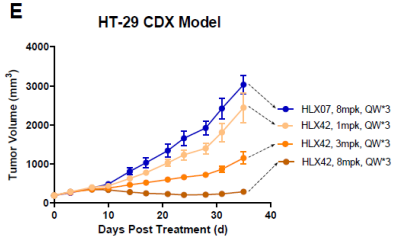
HLX42 Exhibits Excellent Anti-tumor Efficacy *In vivo*

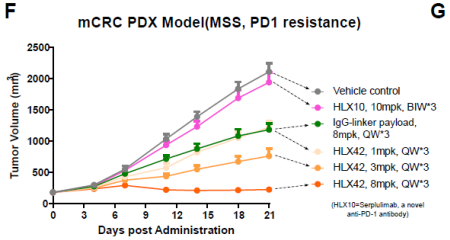


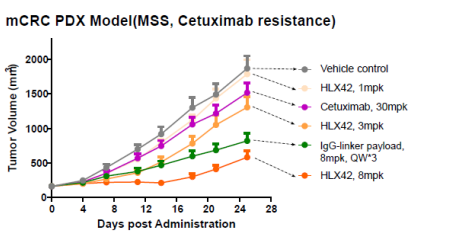












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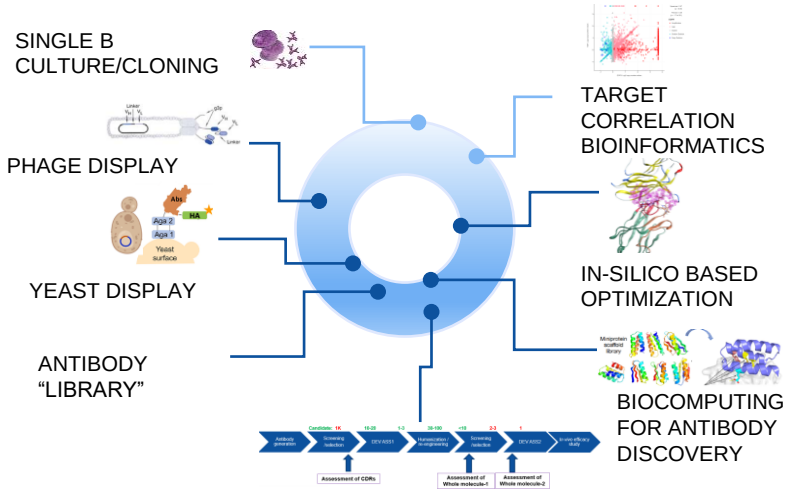
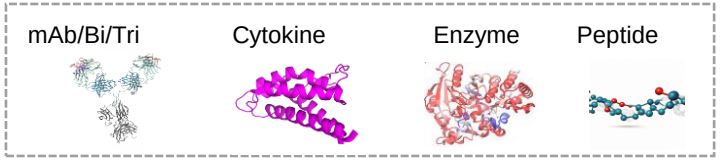
Three Major Preclinical Platforms Drive Full-Speed Development of Representative Molecules

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





HLX6018 (mAb)
GARP/TGF-β1
Idiopathic pulmonary fibrosis

- IND approved in China in Mar. 2024. Phase 1 FPI finished in Apr. 2024.

HLX30 (BsAb)
EGFR x c-Met
Solid tumors

- Balancing cell killing and safety
- EGFR-mutated NSCLC

Hanjugator™: Modular ADC toolbox and development platform

Develop differentiated, clinically valuable ADC products

Establish antibody and linker-payload toolbox with independent intellectual property

1 Improve safety and therapeutic window
Develop tumor microenvironment Conditionally Released Payload-Linker (CRPL) platform

2 Improve ADC selectivity
Develop tumor targeting payload, and tumor microenvironment Conditionally Activated Antibody (CAAb) platform

汉联 *Hanjugator™*
Modular ADC and custom design

3 Expand indication application for ADC
Develop new toxic and non-toxic payload

4 Increase ADC potency
Develop MP-ADC, HC-ADC

HLX41 (ADC)
LIV1 ADC
Solid tumors

HLX48 (ADC)
EGFR x c-MET ADC
Solid tumors

HLX80 (ADC)
STEAP1 ADC
Prostate cancer

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

Based on the Deep Data Driven Drug Discovery (5D) platform, integrate medical informatic data to discover new targets, mechanisms and drugs for metabolism, inflammation, and Immune Intervention

+

Driven by the Biocomputing Accelerated Molecule Design (BAMD) platform, design new drug molecules such as peptides, nucleic acids, and optimize antibodies, small molecule drugs, ADC payload-linkers, etc.

Develop innovative drugs for complex diseases through network biology and polypharmacology

HLX92 (SMC)
Polypharmacology
Primary sclerosing cholangitis, Primary biliary cholangitis

- First-in-class small molecule-drug conjugates (SMDC) with polypharmacological function
- Address unmet clinical needs in PSC and PBC

HLX99 (SMC)
Polypharmacology
Amyotrophic lateral sclerosis

- First-in-class SMDC with polypharmacological function
- Target unmet clinical needs in ALS

AI4T: AI for therapeutics; MP-ADC: Multiple-Payloads ADC; HC-ADCL: High-Capacity ADC

Innovative mAb
Innovative small molecule
Innovative BsAb
Innovative ADC

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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-β1 complex.
Patent filed.

Mechanism

HLX6018 is a monoclonal antibody targeting GARP and TGF-β1 complex. GARP can bind to un-activated TGF-β, thus playing an important role in the activation of TGF-β signaling. TGF-β family is important for the development of fibrosis.

Competitive advantage

HLX6018 is a monoclonal antibody targeting GARP/TGFβ1, 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.

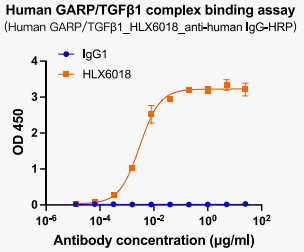
Project progress

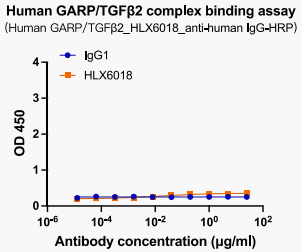
IND approved in China in Mar. 2024.
Phase 1 FPI finished in Apr. 2024 (IPF).

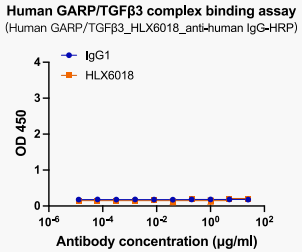
Key data

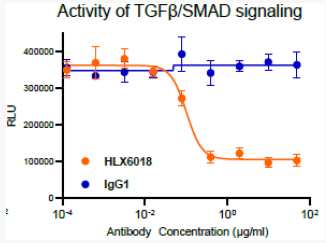
Pharmacology

1. HLX6018 specifically binds to GARP/TGFβ1(no effects on TGFβ2,3) and inhibits integrin mediated release.

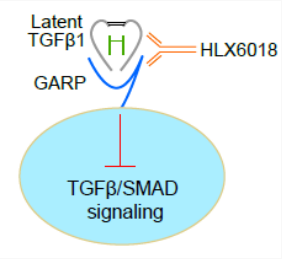




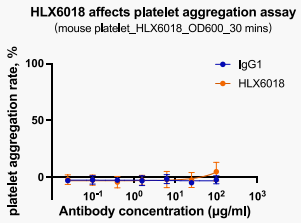


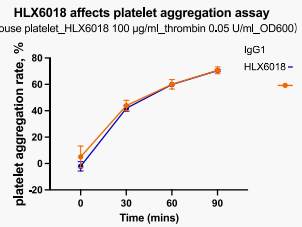


2. HLX6018 inhibits the release of TGFβ1 by targeting GARP/ latent TGFβ1 complex

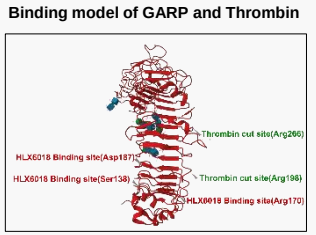


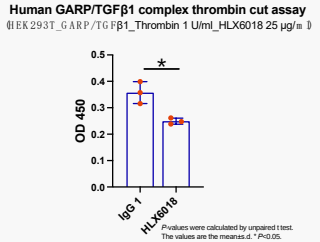
3. HLX6018 has no effects on platelets activation and also doesn't inhibit thrombin mediated activation

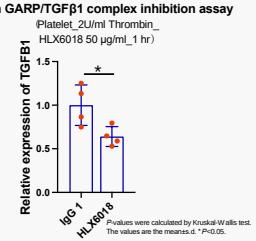




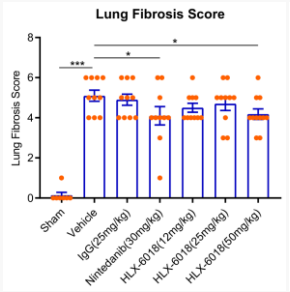
4. HLX6018 inhibits TGFβ1 release from platelets by inhibiting thrombin-mediated GARP cleavage

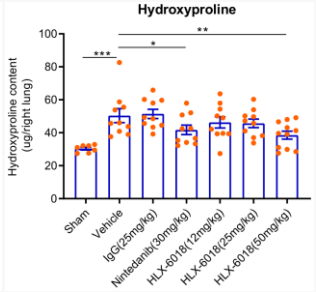




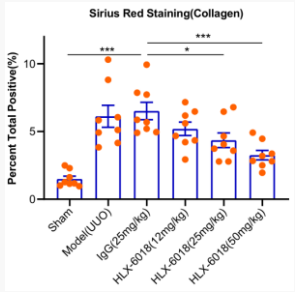


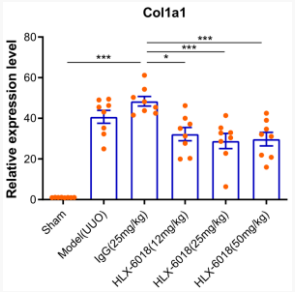
5. HLX6018 inhibits bleomycin-induced pulmonary fibrosis in mice



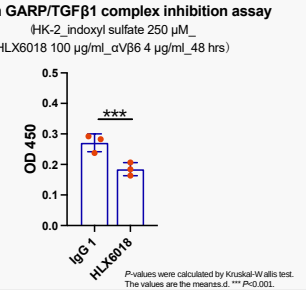


6. HLX6018 inhibits ureteral ligation-induced renal fibrosis in mice





7. HLX6018 inhibits the release of TGFβ1 from renal epithelium



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05 Manufacturing

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International Leading Capabilities on Manufacturing and Quality Management

- **Manufacturing capacity optimization:** Commercial GMP production batches will soon **exceed 1,000 batches** (YS+SJ1) **Production success rate exceeds 98%**
- **"Henlius Quality" with international standard:** obtained GMP certification from **China, the EU and PIC/S members (Indonesia, Brazil)**
- **Won the title of "Quality Benchmark" in Shanghai**

Continuous Improvement

- **Global GMP standards:** Passed **Pre-License Inspections (PLI) by FDA**
- Apply for **segmented production of** biological products
- **Improving the laboratory infrastructure:** **Strengthen** downstream and formulation process optimization and scale-up capabilities

Aligned Quality & Efficiency

- **Plant construction for Phase 1 & 2 trials:** Main structure of manufacturing building #3 was completed. New high speed PFS line has been installed and valid
- **HLX10 (HANSIZHUANG) second-generation process technology transfer successfully completed**

Intelligent Drug Manufacturing

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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

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06

2024H1 Financial Review

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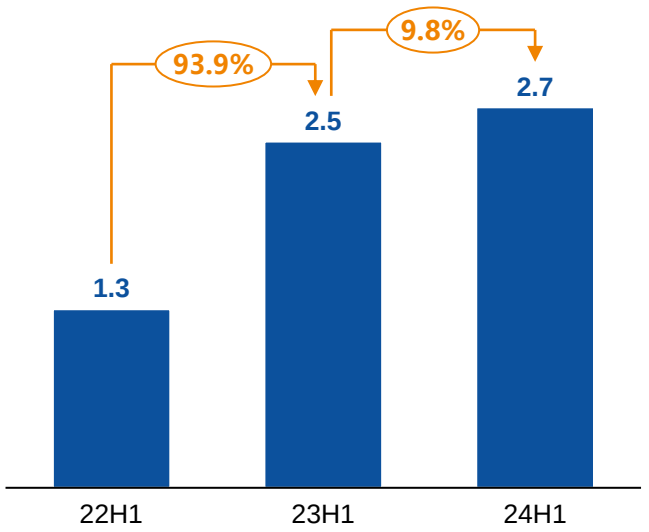
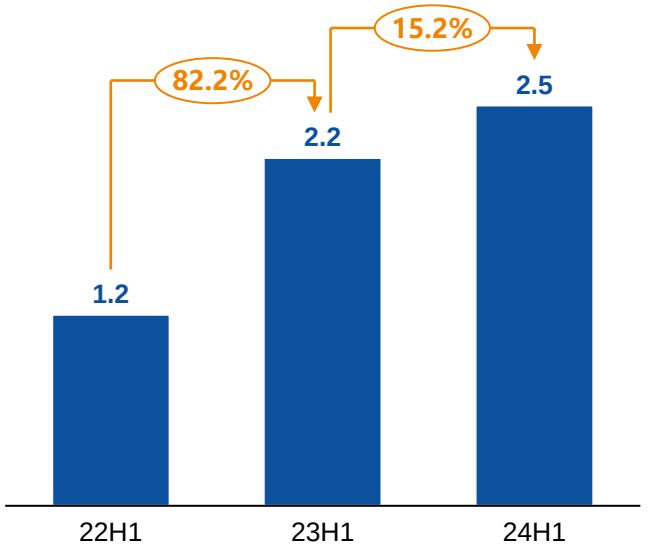
2024 Half Year Revenue of RMB 2.75 Billion with 9.8% YoY

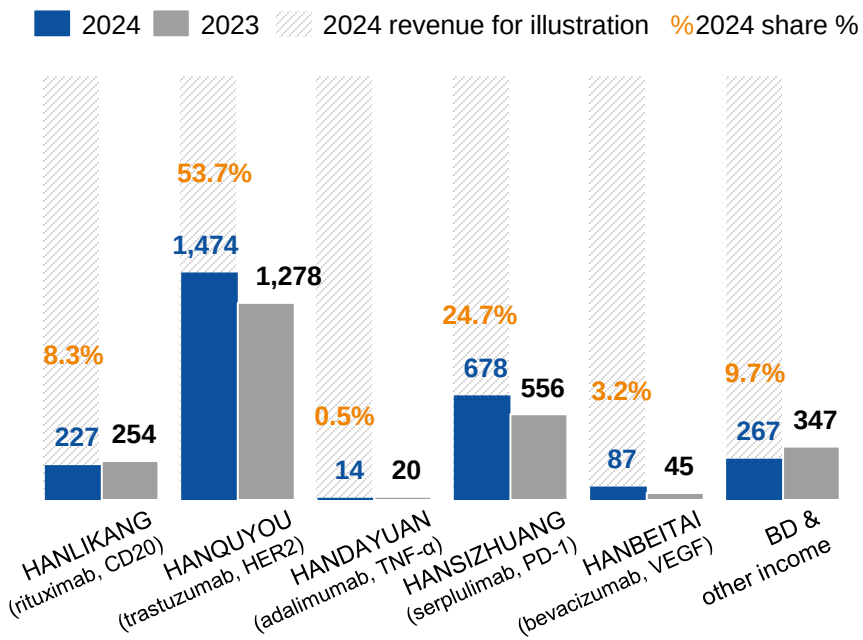
Revenue (in Billion RMB)



Product Sales (in Billion RMB)



2024 Revenue Breakdown (in Million RMB)



Revenue Growth

- Revenue of RMB 2.75B in 2024, 9.8% YoY growth
- Revenue growth mainly driven by: outperformed sales ramp-up of HANQUYOU and HANSIZHUANG
- Gross profit of RMB 1.99B in 2024, 11.9% YoY growth

Product Sales

- Product sales of RMB 2.48B in 2024, 15.2% YoY growth
- Product sales growth mainly from: HANQUYOU sales continue to grow year-on-year, Zercepac® sales in Europe grow significantly; HANSIZHUANG sales grow rapidly

Revenue Breakdown

- HANQUYOU: RMB 1.47B sales* in 2024, 15.4% YoY growth
- HANSIZHUANG: RMB 678M sales in 2024, 21.9% YoY growth
- HANLIKANG: RMB 227M sales in 2024, -10.6% YoY
- HANDAYUAN: RMB 14M sales in 2024, -32.0% YoY
- HANBEITAI: RMB 87M sales in 2024，92.7% YoY growth
- BD and other income: RMB 267M in 2024, -23.1% YoY

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

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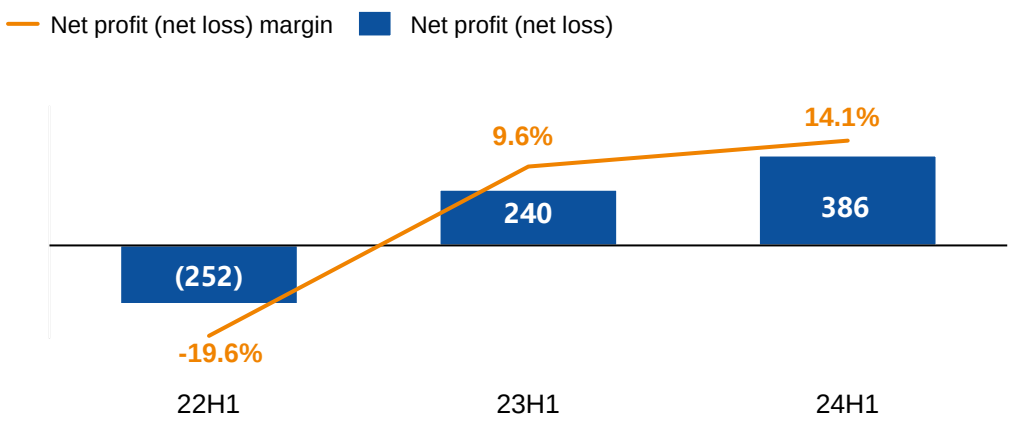
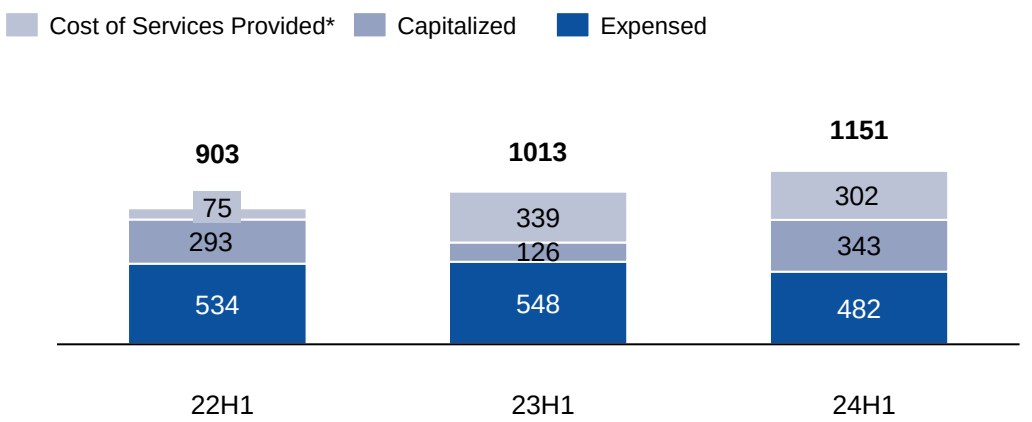
Achieved Profitability in 2024H1 with RMB ~251M Operating CF

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

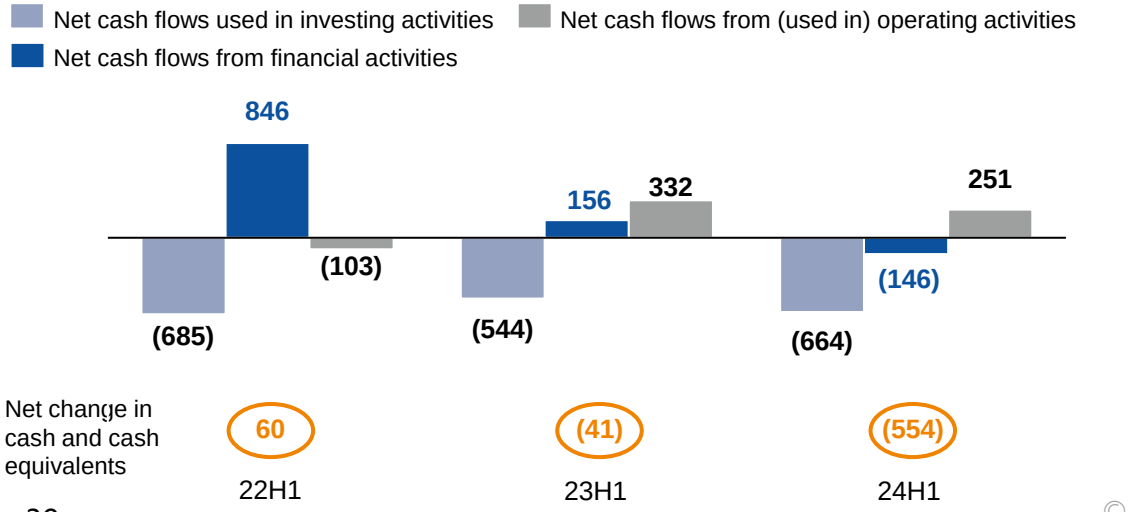


R&D related investment (in Million RMB)

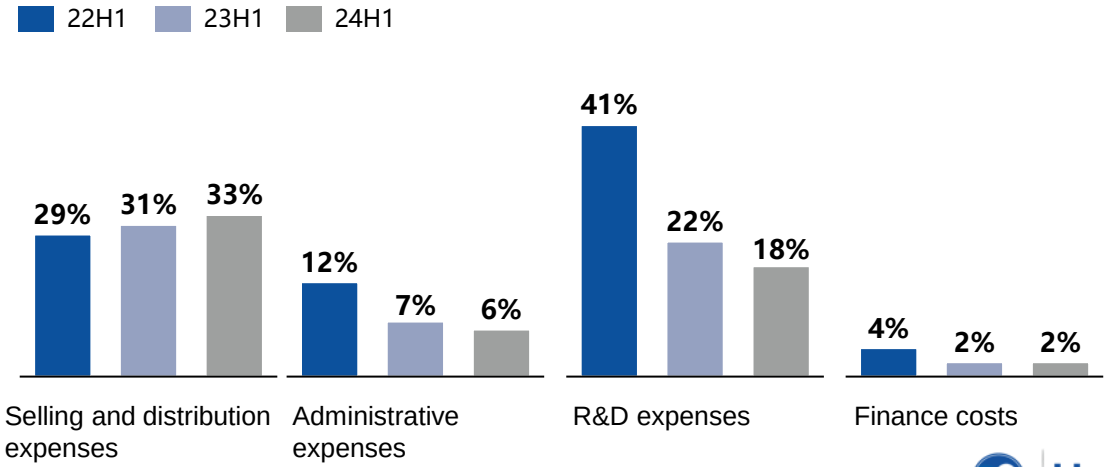


* R&D spending related to out-licensing products accounted into cost of services provided according to accounting practices

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



Expense to revenue ratios : effective controls on expenses



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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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