

Henlius (2696.HK) 2023 Annual Results Investor Presentation

March 2024





01

2023 Business Highlights & Company Strategy

Revenue Tops 5.39B RMB with Net Profit of 546M RMB



BD



Pipeline



Commercial Capacity



Operating Cash Flow



5.39_B RMB

50+

48_{KL}

1.05B RMB

Commercialization

- Achieved sustainable and profitable growth from strong sales team & effective sales management
- Over RMB 100M average monthly sales in China from HLX10 (Serplulimab, PD-1) since March 2023; approval of new indication ESCC
- HLX02 (trastuzumab) average monthly sales in China exceeding RMB 200M since Q2 2023 with a lower expense ratio

BD

- HLX10 out-licensed to Intas in Europe 50+ countries and India, with upfront payment up to EUR 42M1, a total payment up to EUR 185M
- HLX10 out-licensed to Kalbe in the MENA, with upfront payment of USD 7M and a total amount up to USD 665M2
- In-licensed exclusive rights of Lasofoxifene (SERM) in China from Sermonix for HR+/HER2breast cancer

R&D

- The clinical data of HLX10 for 1L sqNSCLC phase III (ASTRUM-004) was presented in WCLC
- HLX10 + chemo combo approved for 1L ESCC in China
- HLX42 (EGFR ADC) for TKI failed NSCLC was granted **FDA Fast Track Destination** (FTD) and entered into phase I
- HLX43 (PD-L1 ADC), a potential first-in-class product, entered into phase I

Manufacturing

- Xuhui Site and Songijang 1st Plant have passed EU GMP inspection of production areas for HLX10
- · Xuhui Site passed Indonesia's BPOM (PIC/S member country) inspection of HLX10 production lines
- · Xuhui Site passed Brazil's ANVISA (PIC/S) GMP compliance inspection for HLX01 and HLX02

Financial

- Total revenue reached RMB 5.39B in 2023, 67.8% YoY growth
- Total product sales reached RMB 4.55B, 70.2% YoY growth
- Net operating cash inflow of **RMB 1.05B**
- Net profit reached RMB 546M, and net profit rate was 10.1%





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



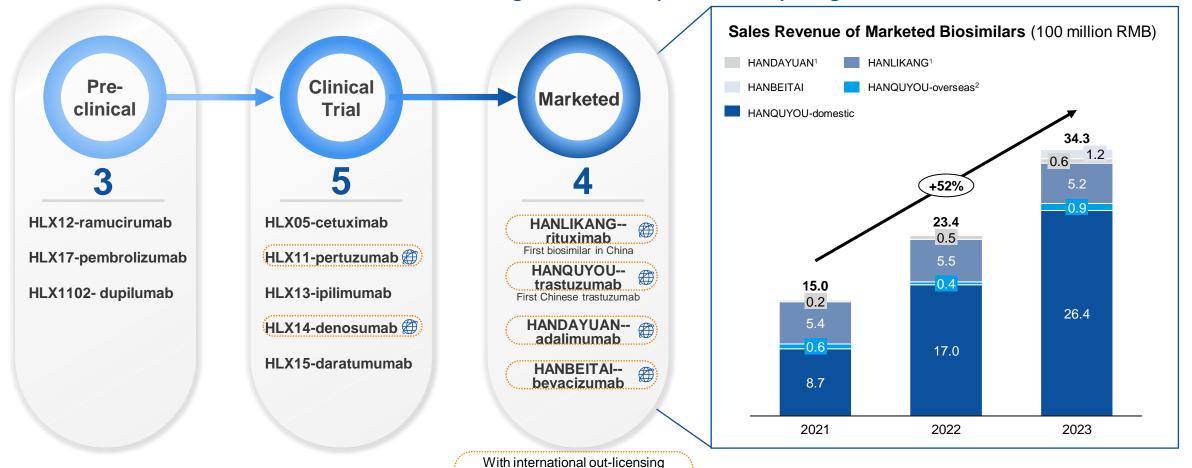
Globalization

Develop towards a biopharma with global presence & scale



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

- 2023 sales revenue of biosimilars reached 3.43 billion RMB, 47% YoY growth
- The biosimilar pipeline covered globally popular targets such as HER2, RANKL, CTLA-4, and conducted MRCT for global market expansion
- HANQUYOU BLA was under FDA review while working with business partners to expand global markets



(ex China) and clinical trials

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



1.12B RMB

- 2023 sales revenue reached 1.12B 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 2023, Serplulimab has completed tendering platform listing for all 31 provinces in China, and established a commercial team of ~580 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.

ASTRUM-004

- In 2023 WCLC, oral presentation of the final analysis results of total population for the first time
- In 2023 ESMO Asia, the data from the Asian subgroup were showcased in a poster session
- In 2024, published online in Cancer Cell as its cover feature



Differentiated Indications

ES-SCLC (marketed):

ASTRUM-005 mOS: 15.8 vs 11.1 months

GC (Phase III):

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

LS-SCLC (Phase III):

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

mCRC (Phase II/III):

Phase II clinical data of 1L mCRC has been presented in ASCO GI with the mPFS of 17.2 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 59 molecules and 18 R&D platforms with 48 innovative drugs and 11 biosimilars
- ✓ Pipeline focuses around oncology while starting to explore new TAs including Autoimmune / Ophthalmology / Metabolic / Rare Disease...

69%

31%

Oncology

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



Solid Tumor

Hematology

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

Non-oncology



Autoimmune

• SLE PBC/PSC

• RA

• IBD

Metabolic

• DKD

NAFLD/NASH

Ophthalmology • Wet AMD

Cardiova scular

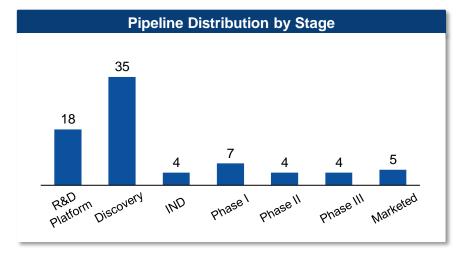
 Heart Failure • HLP

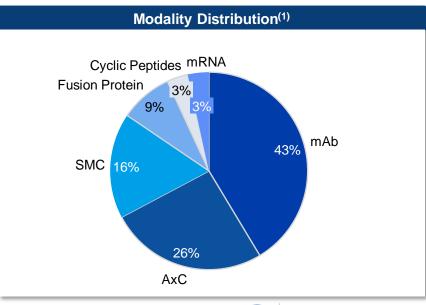
ALS/PD

Rare **Diseases**

CNS

- LCH/ECD
- IPF
- ALS







Globalization Has Entered into Substantial Development Stage

(Marketed) HLX10-Serplulimab



 Serplulimab has been approved for 1L ES-SCLC by Indonesia's food and drug administration (BPOM), 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\$28B¹ in 2030



Serplulimab bridging study in the US is in progress

PD-(L)1 market in the US Expected to reach US\$48.4B¹ in 2030



Explore potential market with unmet medical needs

PD-(L)1 market in Japan Expected to exceed US\$8.4B¹ in 2030

(Marketed) HLX02-Trastuzumab biosimilar

HANQUYOU has marketed in 40+ countries and regions, including the EU,
 Australia, Argentina, Saudi Arabia, Singapore etc., and is expected to be approved
 in the US in 2024. The 2023 ex-China sales of HANQUYOU (revenue reported by
 Henlius) has reached RMB 93M

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\$3.95B², HLX11 will have a promising global market prospect by licensing collaboration with ORGANON

HLX14- Denosumab biosimilar

- MRCT has enrolled 514 patients globally, and HLX14 is expected to file BLA in the US in 2024
- As the originator drug achieved over US\$6.16B² sales in 2023, HLX14 will have a promising global market prospect by licensing collaboration with ORGANON



02

Commercialization



HANQUYOU (Trastuzumab): Sales Growth 58% YoY







International quality

- First approved trastuzumab biosimilar in China
- First "Chinese nationality" mAb biosimilar approved in Europe
- · BLA under FDA review; expected to be the first "Chinese nationality" biosimilar approved in all three regions of China, Europe, and the US
- Launched in 40+ countries and regions

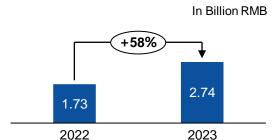


Multiple specifications

- 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



- 150mg specification: completed NRDL and tendering platform listing for all provinces in China
- 60mg specification: completed NRDL listing for all provinces and tendering platform listing in 30 provinces by the end of February 2024
- 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)





Excellent Performance of HANQUYOU

Higher sales per capita than domestic peers

Sales Per Capita¹ (2023)

>5M RMB

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

- In 2023, the competition has become complicated when other local trastuzumab products had been marketed
- 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



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



1.12B RMB

Revenue in 2023



Widespread recognition

- MAA for 1L ES-SCLC indication is under EMA review
- Recommended in 2023 CSCO treatment guidelines for SCLC, NSCLC, EC etc.
- 1L ESCC indication was approved in China in September 2023



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 75 provinces/cities incl. Shanghai, Fujian, Shaanxi, Chongging, 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
- Working with business partners to create more commercial value and expand overseas market



Acceleration on market access and penetration

- Completed tendering and procurement platform listing in all provinces in China
- ~580 people commercial team with strong sales experience in oncology and territories allocated
- Established efficient distribution network, strengthening the coverage of DTP pharmacies and infusion centers to maximize patients' accessibility





Target: PD-1

Indications:

- MSI-H solid tumor
- sqNSCLC
- ES-SCLC
- ESCC

Drug Specifications:

100mg/10ml/bottle

Zerpidio® in Indonesia



HANSIZHUANG Commercialization Highlights

First-class Commercialization Efficiency



1.12B RMB 2023

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 in 2023

Sales Per Capita¹



Industry Leading

Higher than all PD-1/PD-L1 products marketed in China during the same time period²

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

- 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



HANBEITAI (Bevacizumab): Commercialization Acceleration in 2023



119M RMB

Revenue in 2023





Acceleration on market access and penetration

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



Exploration for new medication methods

- The only bevacizumab biosimilars with phase III 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



100mg/4ml/bottle



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HANLIKANG (Rituximab): Strengthen the Market Leader Position



541M RMB

Revenue recognized by Henlius and licensing income in 2023 Total revenue recognized by Fosun Pharma



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



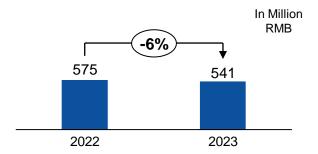
Solid market leader position

- Market leader for rituximab in China with speedy share growth since launch
- Gained the largest market share for consecutive quarters, 49% in Q3 2023*



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



HANDAYUAN (Adalimumab): Entered Autoimmune Disease Area



59M RMB

Revenue recognized by Henlius in 2023
Total revenue recognized by Fosun Pharma



Improve patients' availability and accessibility

- Henlius' first autoimmune disease product
- Covered by NRDL and completed tendering and procurement platform listing in 29 provinces
- The first phase III clinical study of adalimumab biosimilar for psoriasis patients in China
- Established the Da En Home and Zi Mian Home, the first full cycle patient care platforms for autoimmune diseases in China
- Launched ASSC Ankylosing Spondylitis Standardized Diagnosis and Treatment Project together with NCRC-DID



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





ઉ Target: TNF-α

Indications:

- Rheumatoid arthritis
- Ankylosing spondylitis
- Psoriasis
- Uveitis

Drug Specifications:

40mg/0.8ml/bottle



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03

Business Development



2023 Major Business Development Projects







PT Kalbe Genexine Biologics



Accord Healthcare Limited Subsidiary of Intas Pharmaceuticals Limited



Boston Oncology, LLC



Sermonix Pharmaceuticals

(Contract signing date: 2023/08/25)

Upfront payment US\$7M

Up to US\$665M in Total*

HANSIZHUANG (Serplulimab)

Covering 12 countries in the Middle East and North Africa (Contract signing date: 2023/10/27)

Upfront payment up to €42M

Up to €185M in Total

HANSIZHUANG (Serplulimab)

Covering 50+ countries in **Europe and India**

(Contract signing date: 2023/04/04)

First time into the Saudi market

HANLIKANG (Rituximab)

Entered into NUPCO procurement marketplace in Saudi Arabia

(Contract signing date: 2024/01/11)

Milestone payment up to US\$58M

Lasofoxifene

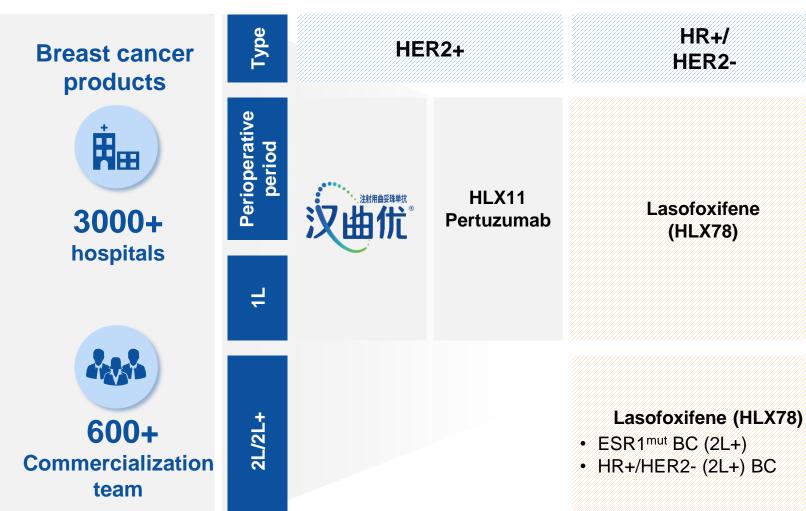
For breast cancer treatment

Exclusive rights in China

Expand HR+ breast cancer portfolio



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



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 II 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 obtained exclusive rights to Lasofoxifene for breast cancer treatment in China. Sermonix will receive up to US\$58M milestone payment in addition to upfront payment and royalties
- Henlius will join in Sermonix's MRCT phase III for at least two indications in China, leveraging Henlius' advantages in clinical operations
- With Henlius' efficient clinical execution and patient enrollment speed, clinical trial of Lasofoxifene is expected to be accelerated in China



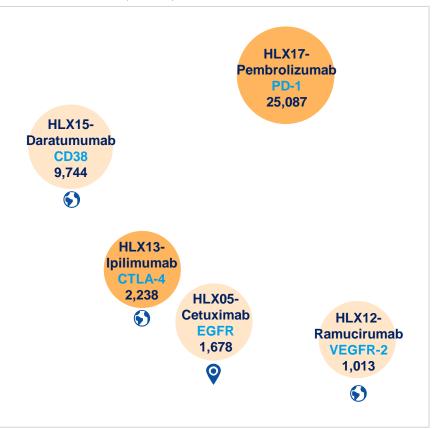
Out-licensing Focus: Henlius' International Quality Biosimilars Scale up across the Globe

Market Size of Originators and Marketed Biosimilars

Biosimilars with existing out-licensing partners Global sales in 2023 (M USD) HLX03-EU, US, CAN, ASEAN, MENA, etc. with **Adalimumab** accord KGbio Abbott Eurofarma Elea 16,002 **HLX02-**ASEAN, MENA, etc. with Trastuzumab Getz HER2 9,274 **HLX14-**Denosumab 6,726 **HLX11-**HLX01-**Pertuzumab** Rituximab HLX04-Global with HER2 Bevacizumab 3,947 Organon 3,888 **VEGF** 3,381 Global with MENA, LATAM etc. with **Organon** LATAM. etc. with Boston Oncology" **Eurofarma Eurofarma Abbott**

Biosimilars to be out-licensed ex-China

Global sales in 2023 (M USD)









04

Research & Development



Product Pipeline

IND	Phase I	Phase II	Phase III		NDA	Marketed
HLX51 OX40 Solid tumors, lymphoma	HLX10 ⁽¹⁾ (serplulimab)+HLX60 ⁽²⁾ PD-1+GARP Solid tumors	HLX10 ⁽¹⁾ (serplulimab)+HANBEITAI PD-1+VEGF mCRC 1L	HLX10 ⁽¹⁾ (serplulimab)+chemo PD-1 ES-SCLC 1L	PD-	(10 ⁽¹⁾ (serplulimab)+chemo 1 SCLC 1L	HANSIZHUANG (serplulimab) ⁽¹⁾ PD-1 MSI-H solid tumors, sqNSCLC, ES- SCLC, ESCC
HLX6018 GARP/TGF-β1 IPF	HLX60 ⁽²⁾ GARP Solid tumors, lymphoma	HLX10 ⁽¹⁾ (serplulimab)+HLX07 PD-1+EGFR HNSCC, NPC, GC, ESCC, sqNSCLC	HLX10 ⁽¹⁾ (serplulimab) +chemo PD-1 Neo/adjuvant treatment for GC	PD-	(10 ⁽¹⁾ (serplulimab)+HANBEITAI 1+VEGF ISCLC 1L	HANLIKANG (rituximab) ⁽¹⁴⁾ CD20 NHL, CLL, RA ⁽¹⁵⁾
HLX17 (pembrolizumab) PD-1 MEL, NSCLC, EC, HNSCC, CRC, HCC, TNBC	HLX53 TIGIT Solid tumors, lymphoma	HLX10 ⁽¹⁾ (serplulimab)+HLX26+chemo PD-1+LAG-3 NSCLC 1L	HLX10 ⁽¹⁾ (serplulimab) +chemo +radio PD-1 LS-SCLC 1L	HEF	(02 (trastuzumab) ⁽¹²⁾ R2 ast cancer, mGC	HANQUYOU (trastuzumab) ⁽¹²⁾ HER2 Breast cancer, mGC
HLX99 Polypharmacology ALS	HLX42 ⁽⁴⁾ EGFR ADC Solid tumors	HLX07 ⁽⁶⁾ EGFR Solid tumors (cSCC)	HLX04-O ⁽⁸⁾ VEGF WetAMD	TNF	NDAYUAN (adalimumab) ⁽¹³⁾ F-α A, pediatric plaque psoriasis, etc.	HANDAYUAN (adalimumab) ⁽¹³⁾ TNF-α RA, AS, psoriasis, uveitis
	HLX43 ⁽³⁾ PD-L1 ADC Solid tumors	HLX22+HANQUYOU HER2+HER2 GC	HLX11 (pertuzumab) ⁽⁹⁾ HER2 Neoadjuvant treatment of breast cand	cer		HANBEITAI (bevacizumab) ⁽¹⁶⁾ VEGF mCRC, advanced, metastatic or recurrent NSCLC, GBM, etc.
	HLX05 (cetuximab) ⁽⁵⁾ EGFR mCRC, HNSCC	HLX208 ⁽⁷⁾ BRAF V600E LCH/ECD, solid tumors (i.e. MEL, TC, mCRC, NSCLC)	HLX14 (denosumab) ⁽¹⁰⁾ RANKL Osteoporosis			
	HLX15 (daratumumab) CD38 Multiple myeloma	HLX208 ⁽⁷⁾ +HLX10 ⁽¹⁾ (serplulimab) BRAF V600E+PD-1 NSCLC	HLX78 (Lasofoxifene) ⁽¹¹⁾ SERM Breast cancer		Innovative mAb	Innovative fusion protein mAb biosimilar
	HLX13 (ipilimumab) CTLA-4 MEL, RCC, CRC, HCC, NSCLC, MPM, EC				Innovative ADC Bridging study in the US	Innovative small molecule BLA under FDA review MAA application in the EU The first Chinese mAb approved both in

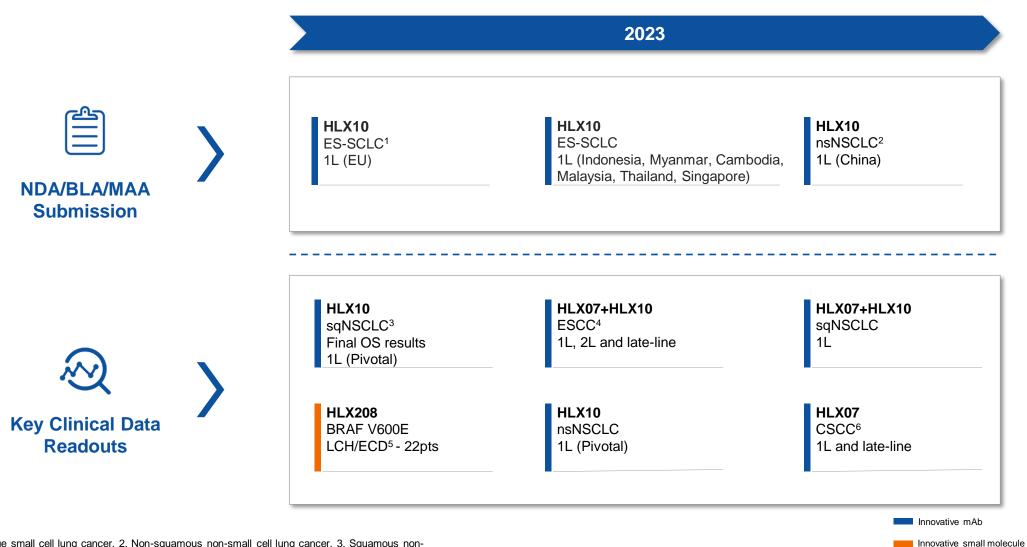
⁽¹⁾ Approved in China and Indonesia, business partners: KGbio/Fosun Pharma/Intas. (2) IND approvals obtained in Australia. (3) IND approvals obtained in China/the US. (4) IND approvals obtained in China/the US, and received fast track designation by FDA. (5) Business partner: Shanghai Jingze. (6) IND approvals obtained in China/the US. (7) Exclusive right in China. (8) IND approvals obtained in China/the EU. Business partner: Organon. (10) IND approvals obtained in China/the EU/Australia. Business partner: Organon. (11) Exclusive rights in China, MRCT phase III global enrolment is in process. (12) Approved in 40+ countries, including China, the UK, Germany, France and Australia, trade name registered in Europe: Zercepac®, trade name registered in Australia: Tuzucip® and Trastucip®. Business partners: Fosun Pharma/FARMA DE COLOMBIA/Eurofarma/Abbott. (15) The first rituximab approved for the indication in China. (16) Business partner: Eurofarma.

DE COLOMBIA/Eurofarma/Abbott. (15) The first rituximab approved for the indication in China. (16) Business partner: Eurofarma.

② 2024 Henlius.

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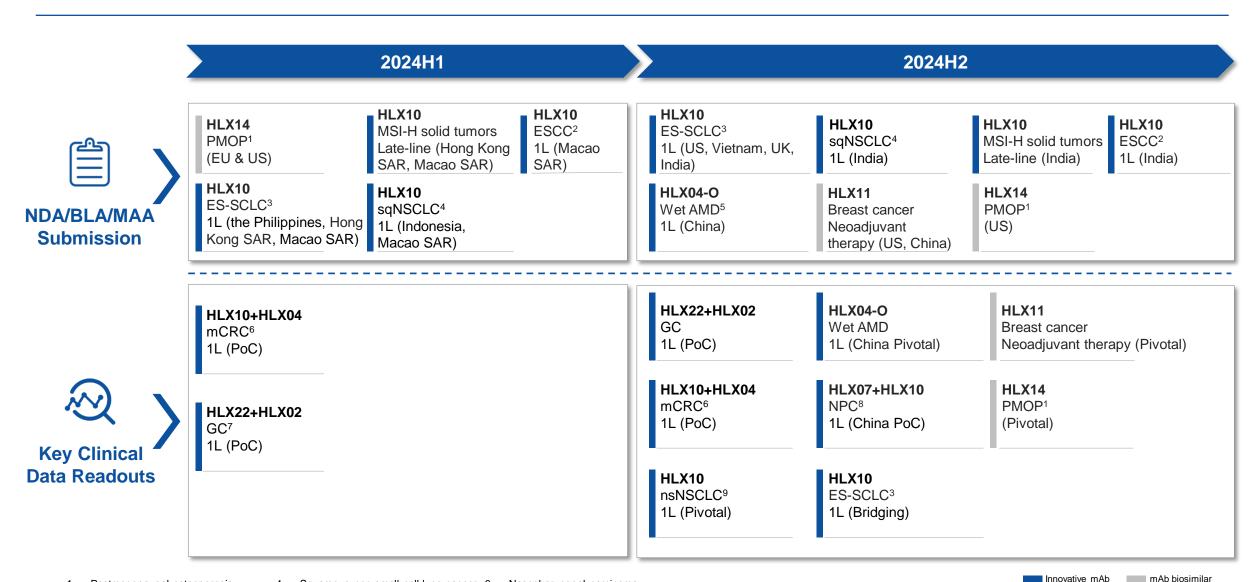
Clinical Pipeline Milestones: 2023 Full-Year Review



^{1.} Extensive stage small cell lung cancer. 2. Non-squamous non-small cell lung cancer. 3. Squamous non-small cell lung cancer. 4. Esophageal squamous cell carcinoma 5. Langerhans cell histiocytosis (LCH) and Erdheim-Chester disease (ECD). 6. Cutaneous squamous cell carcinoma



Clinical Pipeline Milestones: Expected in 2024



Postmenopausal osteoporosis

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.





Esophageal squamous cell carcinoma 5. Age-related macular degeneration

Extensive stage small cell lung cancer

Squamous non-small cell lung cancer 8.

Metastatic colorectal cancer

Gastric cancer

Nasopharyngeal carcinoma

Non-squamous non-small cell lung cancer © 2024 Henlius

- The latest clinical data of the phase II/III 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 GI
- The results of this study demonstrated that serplulimab plus bevacizumab and XELOX was safe and markedly improved PFS and other efficacy endpoints compared to placebo plus bevacizumab and XELOX in patients with mCRC. The probability of grade ≥3 treatment-related adverse events (AEs) of the two treatment groups were similar, with the most common AEs are reduced neutrophil count and reduced platelet count
- Serplulimab plus bevacizumab and XELOX warrants further large-scale investigation and could be a new1L treatment option for mCRC patients including MSS mCRC patients

Product	Clinical Trial	Regimen	Sample Size	mPFS (months)	mOS (months)	mDOR (months)
Serplulimab+ HLX10-015-CR SOC (Ph II)	HLX10-015-CRC301	A: Serplulimab+Bevacizumab+chemo	ITT population 55 vs 57	17.2 vs 10.7 (extended 6.5 months) HR=0.60, p=0.114	NR vs NR HR=0.77, p=0.409	<u>15.9</u> vs 12.6 HR=0.27, p=0.007
	(Ph II)	(XELOX) B: Bevacizumab+chemo (XELOX)	MSS subgroup 40 vs 50	17.2 vs 10.1 (extended 7.1 months) HR=0.58, p=0.110	NR vs NR HR=0.67, p=0.293	15.9 vs 8.3 HR=0.36, p=0.023
Atezolizumab	AtezoTRIBE¹ (Ph II)	A: Atezolizumab+Bevacizumab+chemo (FOLFOXIRI) B: Bevacizumab+chemo (FOLFOXIRI)	ITT population 145 vs 73	13.1 vs 11.5 HR=0.71,p=0.015	33 vs 27.2 HR=0.81,p=0.136	NA
+ SOC			pMMR subgroup 134 vs 67	13.0 vs 11.5 HR=0.79,p=0.073	30.8 vs 26.9 HR=0.83,p=0.172	NA
Nivolumab+ SOC	CheckMate 9X8 ² (Ph II)	A: Nivolumab+Bevacizumab+chemo (mFOLFOX6) B: Bevacizumab+chemo (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)	Bevacizumab+chemo (IFL*) for mCRC³ (Ph III)	A: Bevacizumab+chemo (IFL*) B: chemo (IFL*)	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

^{*} IFL, irinotecan, bolus fluorouracil, and leucovorin.



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

Serplulimab: Targeting Differentiated Indications



Gastric Cancer (GC)

Neoadjuvant treatment in combination with Chemotherapy / Adjuvant with Serplulimab only

Phase III clinical data readout: H1 2025

- 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
- 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
- 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



Serplulimab combined with Concurrent Chemoradiotherapy (CCRT)

Phase III clinical data readout: H2 2026

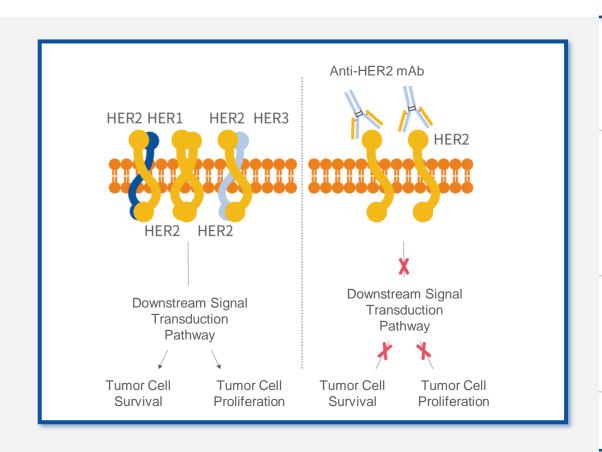
- Globally, the incidence for lung cancer ranks #2 and the mortality ranks #1. In China, both incidence and mortality of lung cancers ranks #1. Among 820,000 new cases of lung cancers in China every year, 15% is SCLC. Among SCLC patents, about 30%-40% are LS-SCLC³
- Phase III MRCT had 238 patients enrolled as of Dec. 2023, from mainland China, Hong Kong SAR, Australia, the US, etc.; by Oct. 2023, the first patient has been dosed in the EU
- 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
- 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 months¹
- Phase II 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 II clinical data of HLX22-GC-201 has been presented in 2024 ASCO GI

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





- The clinical data of Phase II 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 ASCO 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 anemia
- 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 II)	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	·	NR vs NR vs NR A vs C: HR=0.4, p=0.1621 B vs C: HR=0.3, p=0.0894	12.4 vs NR vs 6.8 A vs C: HR=0.6, p=0.2848 B vs C: HR=0.1, p=0.0006
	KEYNOTE-811 ¹ (Ph		ITT population 350 vs 348	<i>IA2:</i> 10.0 vs 8.1 HR=0.72, p=0.0002	<i>IA3:</i> 20.0 vs 16.8 HR=0.84, pNA	<i>IA2∶</i> 11.2 vs 9.0 HR NA,p NA
Pembrolizumab	EMA: approved for PD-L1+ subgroup;	A: Pembrolizumab+Trastuzumab+chemo (CF/XELOX)	PD-L1+ subgroup 298 vs 296	<i>IA2:</i> 10.8 vs 7.2 HR=0.70, p NA	<i>IA3:</i> 20.0 vs 15.7 HR=0.81, p NA	<i>IA2∶</i> 11.3 vs 9.5 HR NA, p NA
FDA: expediated approved for PD-L1+ subgroup	B: Trastuzumab+chemo (CF/XELOX)	PD-L1- subgroup 52 vs 52	<i>IA2:</i> 9.5 vs 9.6 HR=1.17,p NA	<i>IA2 :</i> 16.1 vs 22.3 HR=1.61,p NA <i>IA3 :</i> NA	IA2 : 8.9 vs 9.0 HR NA, ρNA	
Trastuzumab	ToGA ^{2, 3} (Ph III)	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 III <mark>failed</mark>)	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 (<mark>failed</mark>)	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.



4.1

Pre-clinical Assets



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

ESMO 2023 FPN: 693P

HLX43 shows no immunotoxicity towards PD-L1 positive human APCs

HLX34 exhibits excellent anti-tumor efficacy in vivo

Title

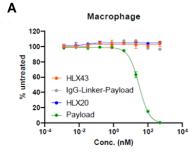
 Preclinical activity of HLX43, a PD-L1-targeting ADC, in multiple PD-1/PD-L1 refractory/resistant models

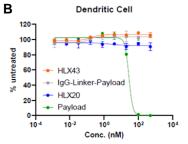
Results

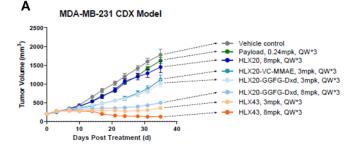
- HLX43 shows no immunotoxicity towards PD-L1 positive human APCs
- In in vivo efficacy studies, HLX43 induced tumor regression in in multiple PD-L1positive CDX & PDX models, and was well tolerated, with no major changes in body weight of administered mice compared to control animals, across all dosing groups
- I. As in the MDA-MB-231 model, weekly administration of HLX43 at 8 mg/kg for three weeks induced significant tumor regression, while no body weight loss was observed
- II. In all tested models (weak PD-L1 expression and high heterogeneity, as well as PD-1/PD-L1 nonresponsive models), HLX43 always **showed superior anticancer efficacy** over the anti-PD-L1 Ab-GGFG-Dxd at equivalent doses.
- Preliminary toxicity assessments in rats and cynomolgus monkeys also demonstrated that HLX43 was safe

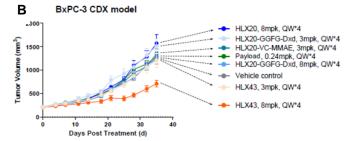
Regulatory and Clinical Trial Progress

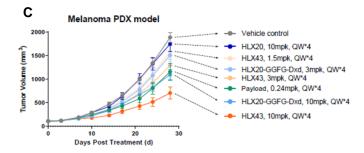
- IND of HLX43 for the treatment of advance/metastatic solid tumors has been successively approved by China NMPA and the US FDA during Oct. to Nov., 2023
- On Nov. 24, 2023, the phase I clinical trial of HLX43 for the treatment of advance/metastatic solid tumors has completed the first patient dosing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













HLX42 (EGFR ADC) Presented Excellent Preclinical Data in ESMO and Was Granted Fast Track Designation by FDA

ESMO 2023 FPN: 683P

Title

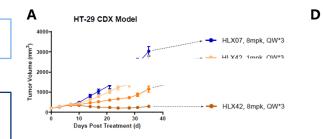
Preclinical evaluation of HLX42, a novel EGFR-targeting ADC, for Cetuximab or TKI resistant cancer

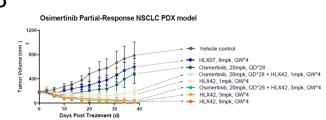
In vivo efficacy results

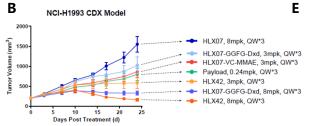
- In in vivo studies, HLX42 showed potent tumor suppression in several CDX and PDX models that were cetuximab or TKIs resistant
- As in the HT-29 model, weekly administration of HLX42 at 8 mg/kg for 3 weeks resulted in 90.2% TGI. HLX42 showed better in vivo efficacy and elicited more durable antitumor responses in a head-to-head comparison with conventional ADC technologies VC-MMAE
- II. In the 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
- III. In the EBC-1 model, weekly administration of HLX42 at 8 mg/kg for 3 weeks eradicated all lesions; all mice remained tumor free three weeks after the last dose, while tumor began to regrow in the anti-EGFR Ab-VC-MMAE treated group
- IV. HLX42, combined with a 3rd generation TKI, showed strong synergy in the LU3075 lung cancer PDX model while the model poorly responded to Osimertinib monotherapy
- V. In another lung cancer PDX model harboring EGFR exon19 deletion/T790M/C797S mutations, which exhibited complete resistance to Osimertinib, a single dose of HLX42 1mg/kg treatment resulted in significantly complete response compared with the control group
- In our pilot toxicity studies conducted in rats and cynomolgus monkeys, HLX42 demonstrated good safety profiles in both species

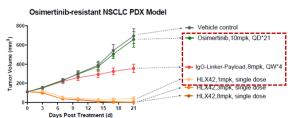
Regulatory and Clinical Trial Progress

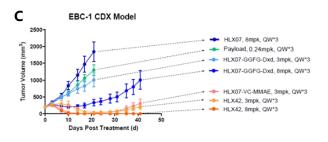
- On Dec. 27, 2023, the US FDA granted Fast Track Designation (FTD) to HLX42 for the treatment of patients with advanced or metastatic EGFR-mutated non-small cell lung cancer whose diseases have progressed on a 3rd-generation EGFR tyrosine kinase inhibitor treatment
- IND of HLX42 for the treatment of advance/metastatic solid tumors has been approved by China NMPA and the US FDA successively during Oct. to Nov., 2023
- On Mar. 14, 2023, the phase I clinical trial of HLX42 for the treatment of advance/metastatic solid tumors has completed the first patient dosing in China









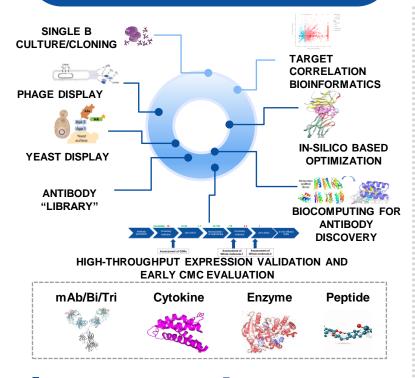




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Three Major Preclinical Platforms Drive Full-Speed Development of **Representative Molecules**

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



HLX6018 (mAb) GARP/TGF-B1 Idiopathic pulmonary fibrosis

· IND accepted in China in Dec. 2023 for indications of IPF

HLX30 (bisAB) EGFR x c-Met

Solid tumors

- · Balancing cell killing and
- 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

Improve safety and Improve ADC therapeutic window selectivity Develop tumor Develop tumor targeting

microenvironment Conditionally Released Payload-Linker (CRPL)

platform

Increase ADC

HLX41 (ADC)

LIV1 ADC

Solid tumors

汉联 Haniugator™ Modular ADC and

custom design

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potency Develop MP-ADC, HC-ADC

Expand indication application for ADC

payload, and tumor

Conditionally Activated

microenvironment

Antibody (CAAb)

platform

Develop new toxic and non-toxic payload

HLX80 (ADC)

HLX48 (ADC) EGFR x c-MET ADC STEAP1 ADC Solid tumors 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 payloadlinkers. etc.



Develop innovative drugs for complex diseases through network biology and polypharmacology

HLX92 (SMC)

Polypharmacology Primary sclerosing cholangitis, Primary biliary

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

Polypharmacology Amyotrophic lateral sclerosis

HLX99 (SMC)

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

Innovative mAb Innovative small molecule







HLX99: "First-In-Class" anti-ALS/PD Drug Candidate

Indication

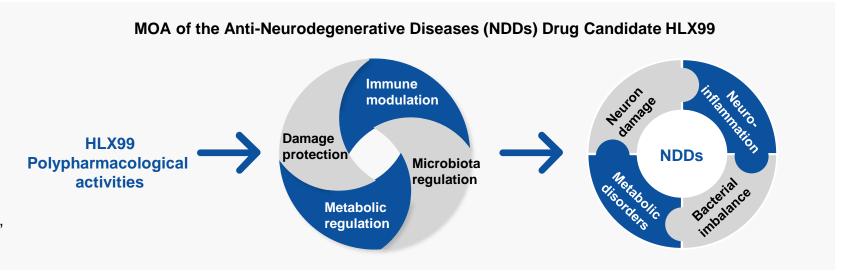
Amyotrophic Lateral Sclerosis (ALS); Parkinson's disease (PD)

Entity

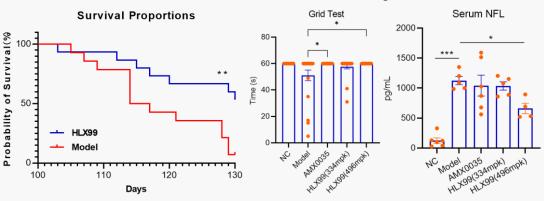
Patent filed. IND to be approved in China in 2024 H1

MOA

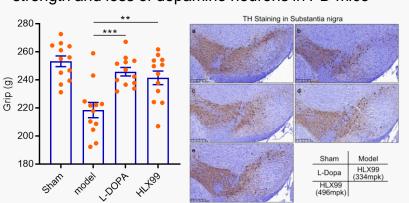
Polypharmacology, the molecule has a variety of biological activities including but not limited to modulation of neurotransmitters, inhibition of oxidative stress, regulation of body metabolism, modulation of immune disorders, and modulation of gut microbiota



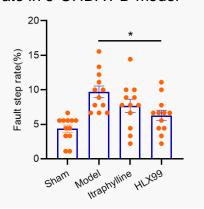
1. HLX99 prolongs the survival of ALS transgenic mice, improves the behavior of this model mice and decreases the neuronal damage marker NFL in blood



2. HLX99 ameliorates MPTP-induced decrease in grip strength and loss of dopamine neurons in PD mice



3. HLX99 improves fault step rate in 6-OHDA PD model





05

Manufacturing



International Leading Capabilities on Manufacturing and Quality Management



- Manufacturing capacity optimization:
 The scale of commercial GMP batches has reached a new high
- "Henlius Quality" with international standard: obtained GMP certification from China, the EU and PIC/S members (Indonesia, Brazil)
- Global expansion: Products available in Europe, Australia, South America and Southeast Asia

Continuous Improvement



- Increasing supply of HANQUYOU
 (Trastuzumab): Over 100 batches in total,
 manufacturing successful rate > 98%
- Global GMP standards: completed Pre-License Inspections (PLI) by FDA
- Improving the laboratory infrastructure: Strengthen downstream and formulation process optimization and scale-up capabilities

Aligned Quality & Efficiency



- Plant construction for Phase I & II trials: two main manufacturing buildings were completed and accepted; the engineering batch for the 2nd generation process of HANSIZHUANG has completed; PFS production line has been validated, ADC manufacturing workshop has put into use
- The improved application of stainless steel equipment: Costs reduction by process automation



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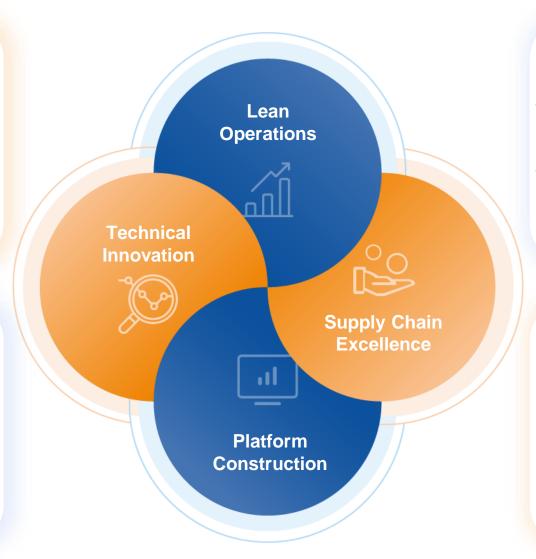
Operation Excellence and Continuous Innovation

Technical Innovation

- Reached key milestone of using domestic production consumables and completed commercial scale process validation
- Achieved the automatic control of cell culture in bioreactor by Raman Spectroscopy

Platform Construction

- Adopted SCADA system for realtime production monitoring to achieve lean digital production
- Applied the satellite tank scaledown models: mature in applications such as material screening, process change evaluation, tech transfer etc.



Lean Operations

- 30+ on-going lean operations projects with ~10M RMB expected annualized returns
- The batch output using the 2nd
 generation process increased 28%
 compared with 2022 for HANQUYOU
 (trastuzumab), the first approved Chinese
 mAb biosimilar by both China and the EU

Supply Chain Excellence

- The direct material cost was 10% lower than that in 2022
- Completed the sustainability process design for supply chain and implemented risk-warning mechanism



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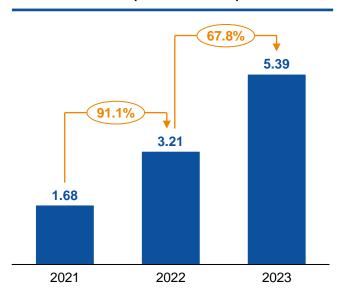
06

2023 Financial Review



2023 Full Year Revenue of RMB 5.39 Billion with 67.8% YoY

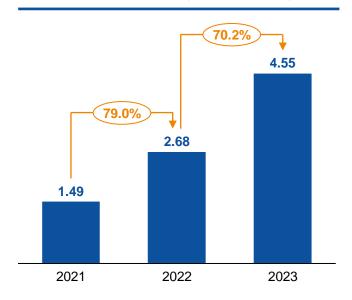
Revenue (in Billion RMB)



Revenue Growth

- Revenue of RMB 5.39B in 2023, 67.8% YoY growth
- Revenue growth mainly driven by: outperformed sales ramp-up of HANQUYOU and HANSIZHUANG
- Gross profit of RMB 3.92B in 2023, 65.3% YoY growth

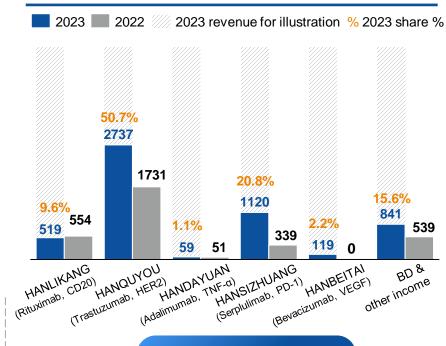
Product Sales (in Billion RMB)



Product Sales

- Product sales of RMB 4.55B in 2023, 70.2% YoY growth
- Product sales growth mainly from: HANQUYOU sales volume open-up with additional capacity released after Songjiang 1st Plant being approved; HANSIZHUANG ES-SCLC 1L treatment was approved

2023 Revenue Breakdown (in Million RMB)



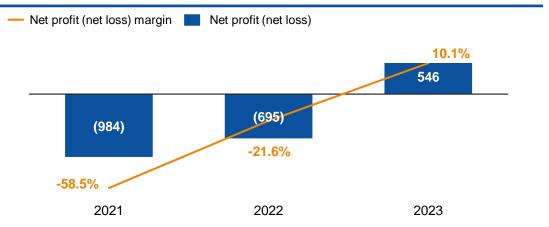
Revenue Breakdown

- HANQUYOU: RMB 2.74B sales* in 2023, 58.1% YoY growth
- HANSIZHUANG: RMB 1.12B sales in 2023, 230.2% YoY growth
- HANLIKANG: RMB 519M sales in 2023, -6.4% YoY
- HANDAYUAN: RMB 59M sales in 2023, 14.5% YoY growth
- HANBEITAI: RMB 119M sales in 2023
- BD and other income: RMB 841M in 2023, 56.0% YoY growth

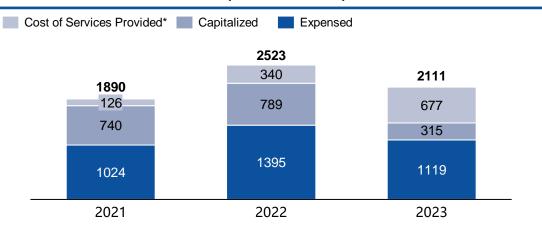


Achieved Profitability in 2023 with RMB ~1.05B Operating CF

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



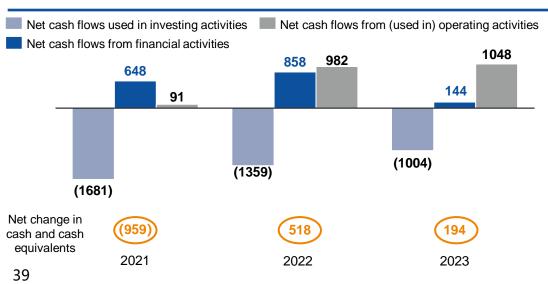
R&D related investment (in Million RMB)

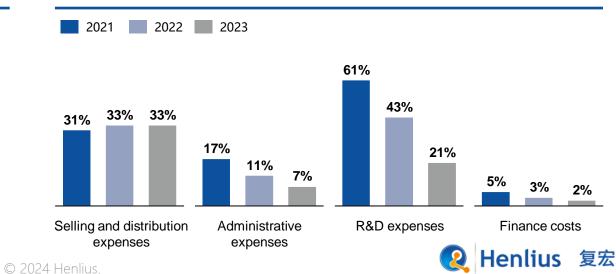


^{*} R&D spending related to out-licensing products accounted into cost of services provided according to accounting practices

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

Expense to revenue ratios : effective controls on expenses





Financial Highlights

Financial Data (selected)	2023		202	YoY Growth	
Unit	In Million RMB	% of revenue	In Million RMB	% of revenue	%
Revenue	5,394.9	100.0%	3,214.7	100.0%	67.8%
Product sales	4,553.5	84.4%	2,675.4	83.2%	70.2%
BD and other revenue	841.4	15.6%	539.4	16.8%	56.0%
Cost of sales	(1,476.1)	(27.4%)	(844.6)	(26.3%)	74.8%
Selling and distribution expenses	(1,754.2)	(32.5%)	(1,049.3)	(32.6%)	67.2%
Administrative expenses	(383.8)	(7.1%)	(354.0)	(11.0%)	8.4%
R&D expenses	(1,118.7)	(20.7%)	(1,394.5)	(43.4%)	(19.8%)
Financial costs	(110.5)	(2.0%)	(105.7)	(3.3%)	4.6%
Net profit (net loss)	546.0	10.1%	(695.3)	(21.6%)	/
Cash and bank balances	987.7	18.3%	680.5	21.2%	45.1%
Net cash flows from operating activities	1,047.9	19.4%	981.6	30.5%	6.8%

07

2024 Performance Outlook

Our Goals for 2024

- Revenue: maintain rapid growth in overall revenue by continuously promoting clinical advantage of HANSIZHUANG and HANQUYOU
- **Profitability**: improve P&L level, and consolidate profitability from internal operation
- Cashflow: positive OCF generated for three consecutive years; further strengthen organic growth in 2024 and build strong and health cash flows
- **R&D**: advance late-stage pipeline faster, develop early-stage pipeline with differentiation, and introduce multiple modality assets to enter clinical stage
- Overseas Markets: accelerate HANQUYOU approval in the US and NDA submissions in multiple overseas countries; advance HANSIZHUANG to be marketed in Europe
- Resource Allocation: optimize resource allocation, and improve return on investment of R&D, manufacturing and commercialization, to assure long-term sustainable growth



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Reliable Quality Affordable Innovation

