Henlius（2696.HK）3Q 2023 Results Investor Presentation

November 2023

01 3Q 2023 Business Highlights & Company Strategy

3Q23: Revenue Tops 1.4B RMB with Net Profit of 168M RMB

Revenue	BD	Pipeline	Commercial Capacity	Operating Cash Flow
1.4B RMB	3	60+	48KL	240M RMB

Commercialization

- Achieved sustainable and profitable growth from strong sales team & effective sales management
- HANSIZHUANG launched in March 2023 and got the record of RMB 100M monthly sales. ESCC has been approved by the NMPA
- HANQUYOU maintains outstanding monthly sales exceeding RMB 200M since Q2 2023 while improving expense ratio. 3Q sales achieved 52% YoY growth

Business Development

- HLX10 (HANSIZHUANG) out-licensed to Intas in 50+ countries in EU and India with total upfront payment of EUR 42M*and a total amount of EUR 185M, with double-digit royalties
- HLX10 (HANSIZHUANG) out-licensed to Kalbe in the Middle East and North Africa, with upfront payment of USD 7M and a total amount of USD 665M
- Co-develop the innovative technology platform for the potential first-in-class new drugs with HanchorBio

R&D

- The study results of ASTRUM-004, a pivotal Ph III MRCT of HANSIZHUANG for sqNSCLC, were released at the 2023 WCLC
- The NDA for HANSIZHUANG in combination with drugs containing 5-FU & platinum for ESCC has been approved by the NMPA
- 2 ADC products HLX42 (EGFR ADC) and HLX43 (PD-L1 ADC) were published as posters at the 2023 ESMO

Manufacturing

- Xuhui Facility passed the GMP inspection of HLX10 from PIC/S member - Indonesia BPOM
- Xuhui Facility passed the GMP inspection of HLX01 and HLX02 from PIC/S member - Brazil ANVISA
- High utilization of 48kL total capacity, completing over 700 commercial batches

Financial

- Total revenue reached RMB 1.4B in 3Q 2023, 69% YoY growth; total product sales reached RMB 1.2B in 3Q, 56% YoY growth
- Total revenue reached RMB 3.9B YTD 3Q23, 84% YoY growth; total product sales reached RMB 3.4B YTD 3Q23, 72% YoY growth
- Net operating cash inflow of RMB 240M in 3Q 2023; net profit reached RMB 168M and net profit excl. extraordinary items reached RMB 146M in 3Q

* The first upfront payment of €26 million will be paid on the effective date of the license agreement, and the second upfront payment of €16 million will be paid upon the European Medicines Agency issuing a positive opinion (day 210 of the centralized procedure) for the licensed product to be used as a first-line treatment of extensive-stage small cell lung cancer (ES-SCLC)

Our Mission and Vision

Affordable Innovation
Reliable Quality

Biosimilars

Maximize the commercialization value in China and international markets

Innovative Drugs

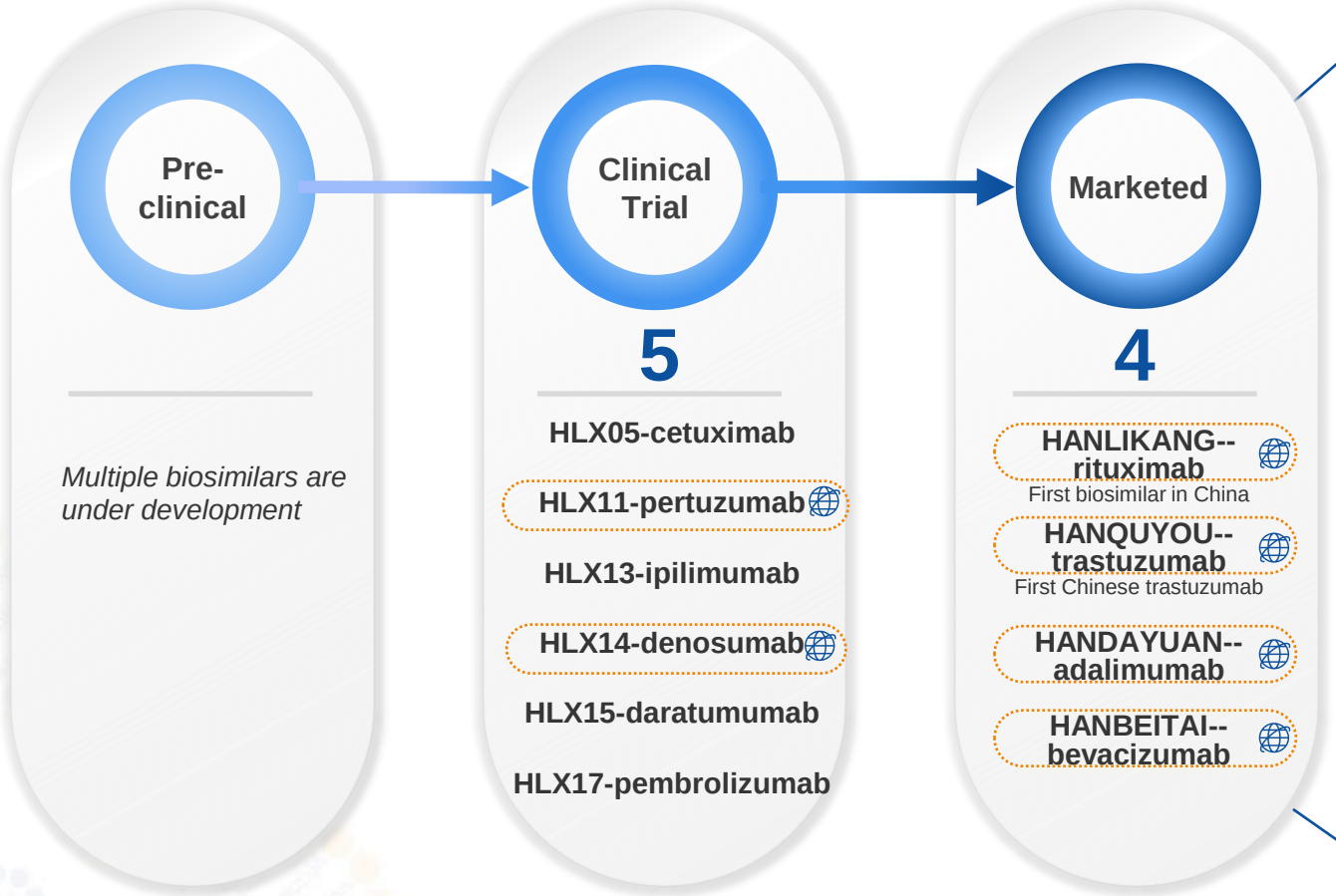
Explore new mechanisms, new technology platforms and expand the therapeutic area coverage

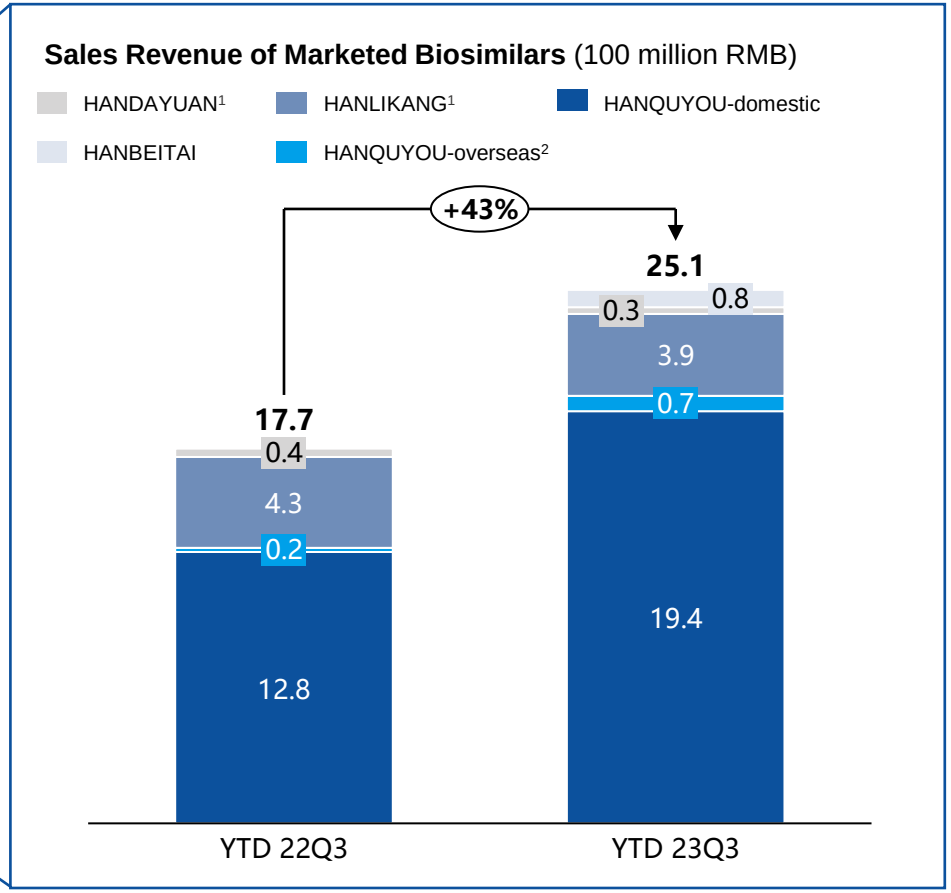
Globalization

Develop towards a biopharma with global presence & scale

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

- By 3Q 2023 sales revenue of biosimilars reached ~2.5 billion RMB, 43% YoY growth, exceeding the sales revenue of biosimilars in the full year of 2022
- The biosimilar pipeline covered globally popular targets such as HER2, RANKL, CTLA-4, and conduct MRCT for global market expansion
- HANQUYOU BLA was under FDA review while working with business partners to expand global markets





With international out-licensing (ex China) and clinical trials

1. above are revenue reported by Henlius
2. Including sales of HANQUYOU substance and Zercepac®

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HANSIZHUANG Entered into a New High-growth Stage of Commercialization with Differentiated Advantages

865M RMB

- In March 2023, HANSIZHUANG achieved over **RMB 100M monthly sales** in China for the first time, representing its commercialization stepping up into new stage
- By June 2023, HANSIZHUANG has completed tendering platform listing for **30 provinces** in China, covering about **1,500 hospitals** (focus on departments related to lung cancer, gastrointestinal cancer and etc.)

Differentiated Antibody

- HANSIZHUANG (serplulimab) has shown a stronger affinity and slower dissociation rate[1] with PD-1, compared with peers
- HANSIZHUANG (serplulimab) activates T cells with higher strength and longer duration through a unique molecular mechanism[1]

Clinical Advantages

HANSIZHUANG recommended by *9 CSCO Guidelines for Diagnosis and Treatment*

- Including *2023 CSCO Diagnosis and Treatment Guidelines* for SCLC, NSCLC, EC, CRC and *Clinical Application Guideline* for immune checkpoint Inhibitor etc., and brought more survival benefits to cancer patients

Differentiated Indications

ES-SCLC (Marketed):

mOS: 15.8 months, the globally first approved PD-1 for ES-SCLC

ESCC（New Indication）:

mOS: 18.6 months, HR 59%

(PD-L1 CPS≥10)

GC (Phase III):

Expected to be the world's first 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

1. Issafras H, Fan S, Tseng C-L, Cheng Y, Lin P, Xiao L, et al. (2021) Structural basis of HLX10 PD-1 receptor recognition, a promising anti-PD-1 antibody clinical candidate for cancer immunotherapy. PLoS ONE 16(12): e0257972.

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

Product Type & Introduction

- ✓ Total 63 molecules in pipeline with 49 innovative drugs and 14 biosimilars
- ✓ Pipeline focuses around oncology while starting to explore new TAs including Autoimmune / Ophthalmology / Metabolic / Rare Disease…

75% | **25%**

Oncology

Solid Tumor

- Breast Cancer
- Lung Cancer
- MSI-H
- Gastric Cancer
- CRC
- ESSS
- HNSCC
- NPS
- NSCC
- HCC
- …

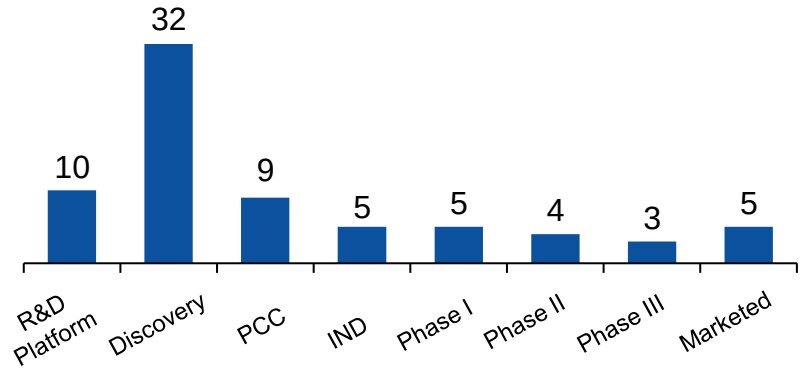
Hematology

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

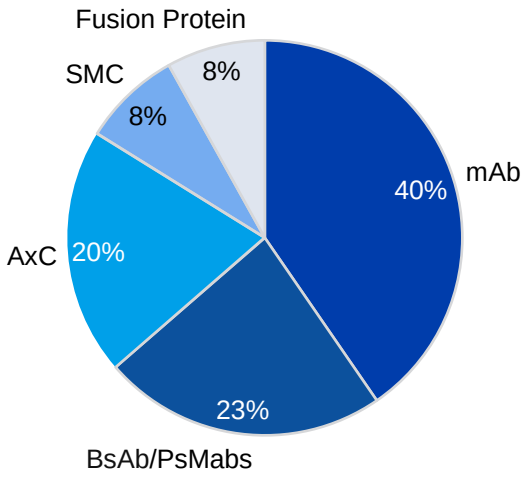
Non-oncology

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

Innovative Pipeline Distribution by Stage (by Molecule)



Modality Distribution (1)



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

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02 Commercialization

HANQUYOU (Trastuzumab): 3Q23 Sales Growth 52% YoY

738M RMB*

3Q 2023 Revenue

2.01B RMB*

YTD 3Q 2023 Revenue

Zercepac® in Europe

Tuzucip® and Trastucip® in Australia

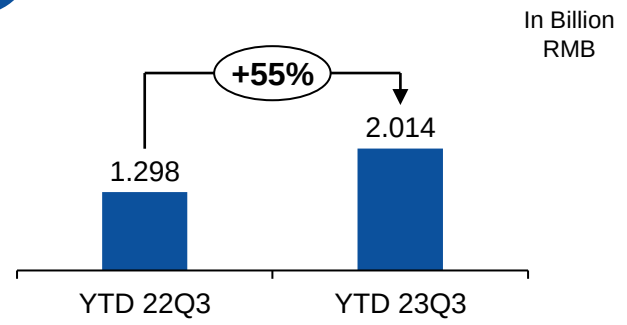
International quality

- 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 China, Europe, and the US
- Launched in 41 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; access to more than 87% of Top 1,000 hospitals
- 60mg specification: completed NRDL for all provinces and tendering platform listing in 29 provinces; access to more than 60% of Top 1,000 hospitals
- 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/vial (China, Europe, Australia)

60mg/vial (China, Europe)

420mg/vial (Europe)

* Sum of sales revenue of HANQUYOU, drug substance of trastuzumab and Zercepac®

Excellent Performance of HANQUYOU

Higher sales per capita than domestic peers

Sales Per Capita* (YTD 3Q 2023)

>400K RMB per month

The only trastuzumab with two specifications

- 2 specifications were customized to address HER2-positive 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 advantage to build competition advantage

- As more local trastuzumab products launched in 2023, the competition situation is increasingly complicated. HANQUYOU made strategy and comprehensive preparations in advance, kept strengthening international quality and two specifications advantage to increase market awareness and acceptance.

Develop Broad market

- Trastuzumab is widely used across China, hospitals in small towns and rural area have been growing fast and gaining share
- HANQUYOU has expanded coverage, deepened promotion activities to develop the broad market in small towns and rural area

* Sales per capita =Product sales / # of salesforce / 9 months

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

309M RMB

3Q 2023 Revenue

865M RMB

YTD 3Q 2023 Revenue

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 newly approved in China

Efforts to product accessibility

- Launched patient assistance programs to optimize treatment outcomes, with reduced economic burden and improved medication adherence for patients
- Has been covered in Huiminbao (Regional Commercial Health Insurance) of 44 regions incl. Shanghai, Fujian, Chengdu, Shaanxi、Chongqing、Nanjing、Suzhou、Jinan、Xiamen

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 30 provinces, access to over 50 hospitals of 365 major hospitals
- ~580 people specialized commercial team with strong sales experience in oncology
- Built efficient distribution network, strengthening the coverage of DTP pharmacies and infusion centers

Target: PD-1

Indications:

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

Drug Specifications:

100mg/10ml/vial

HANSIZHUANG Commercialization Highlights

First-class Commercialization Efficiency

865M RMB
YTD 3Q 2023

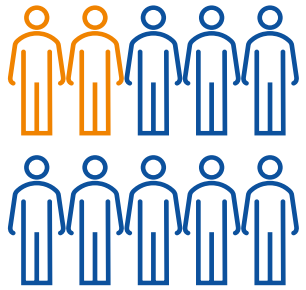
Outstanding Achievements

- Sales outperformed most of the competing PD-1/PD-L1 since its launch in 2021
- Expected to be Tier-1 PD-1/PD-L1 products by 2023

>100M RMB
Monthly average
Since March 2023
Excellent Sales

YTD 3Q 2023
Sales Per Capita[1]
~180K RMB
per month
Industry Leading in China

High Market Share Driven by Differentiation Strategy



Differentiation Strategy Focus on SCLC

(15-20% of total lung cancer patients)

ESCC Approved in China

- Carry out promotion activities on the indication, leverage HANSIZHUANG's outstanding efficacy in IO treated ESCC patients to deliver concept of precise treatment, bringing precise benefit to increase market share.

Effective actions to challenges

- Take effective actions to challenges from newly launched competitors in SCLC area, precisely interpretate clinical trial data, broadly deliver product advantage, keep strengthening leading position in SLCL

1. Sales per capita =Product sales / # of salesforce / 9 months

HANBEITAI (Bevacizumab): Commercialization Acceleration in 2023

36M RMB

3Q 2023 Revenue

81M RMB

YTD 3Q 2023 Revenue

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
- Combine with HANSIZHUANG (anti-PD-1 mAb), treating on 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/vial

HANLIKANG (Rituximab): Strengthen the Market Leader Position

131M RMB

3Q 2023 revenue recognized by Henlius

385M RMB

YTD 3Q 2023 revenue recognized by Henlius

Acceleration on market access and penetration

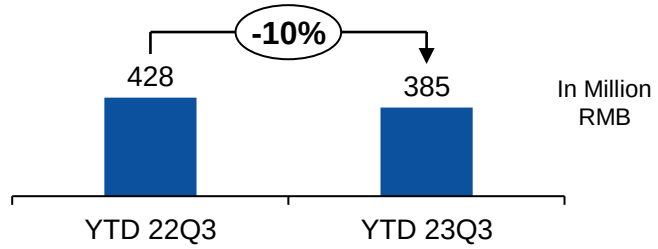
- Approved in February 2019 as the first approved biosimilar in China, the first approved rituximab biosimilar in China
- New indication approved in March 2022: the first rituximab approved for Rheumatoid Arthritis indication in China

Solid market leader position

- Market leader for rituximab in China with speedy share growth since launch
- Gained the largest market share for consecutive quarters , 47% in 2Q 2023*

Commercialization Progress

- Jiangsu Fosun, a subsidiary of Fosun Pharma, is responsible for HANLIKANG's commercialization in China
- Listed on the procurement platform in most provinces by the end of September 2023, and covered by NRDL in all provinces
- Completed in-hospital sales in 241 hospitals of the Top 300 hospitals in China by the end of September 2023



Target: CD20

Indications:

- Non-Hodgkin lymphoma
- Chronic lymphocytic leukemia
- Rheumatoid Arthritis (RA)

Drug Specifications:

100mg/10ml/vial

500mg/50ml/vial

* Source: Henlius internal analysis

HANDAYUAN (Adalimumab): Entered Autoimmune Disease Area

11M RMB

3Q 2023 revenue recognized by Henlius

32M RMB

YTD 3Q 2023 revenue recognized by Henlius

Improve patients' availability and accessibility

- Henlius' first autoimmune disease product
- Covered by NRDL in 31 provinces, and completed tendering and procurement platform listing in 31 provinces
- The first phase III clinical study of adalimumab biosimilar for psoriasis patients in China
- ~79,000 patients benefited since launch
- Contributed to standardize the diagnosis and treatment on ankylosing spondylitis in China through:
  - Established the *Da En Home*, a full cycle patient care platform
  - Launched *ASSC Ankylosing Spondylitis Standardized Diagnosis and Treatment Project*

Work with partners to penetrate the market

- Jiangsu Wanbang is responsible for China-region sales of HANDAYUAN. It has a sizable rheumatic immunity business unit and experienced salesforces in RA as well as a mixed line sales team
- Out-licensed the commercialization rights of HANDAYUAN to Getz Pharma in February 2022 in 11 countries, including Pakistan, the Philippines and Kenya

Target: TNF-α

Indications:

- Rheumatoid arthritis
- Ankylosing spondylitis
- Psoriasis
- Uveitis

Drug Specifications:

40mg/0.8ml/vial

03 Business Development

Collaboration Expansion with Existing Partner about HLX10 EU & India

Intas Pharmaceuticals Limited[1]

Oncology Leader

30% volume share of major chemotherapy molecules in key geographies

Pharmaceutical Major

US$2.5Bn global sales FY2022

Global Presence

Sales derived from **85+** countries with 60% from EU regions and the US

Generic Expert

#1 Generic Company in the UK[2]

1. Accord is a fully owned subsidiary of Intas
2. Source: Intas homepage

Collaboration Expansion with Existing Partner about HLX10 EU & India

Upfronts up to €42 million*

Deal size €185 million

HANSIZHUANG (serplulimab)

Covering EU & India 50+ countries

- Since 2018, Intas/Accord started cooperation with Henlius on the registration, technology transfer and commercial launch of HLX02 in more than 70 countries and regions, including the EU (2018), the United States & Canada (2021).
- Through this cooperation, Henlius has a royalty up to 27% , with the right to supply at premium pricing, contributing to a long-term stable growth of cashflow.
- The deal of HLX10 EU could also strengthen the HLX02 EU deal，to further maximize the commercial benefits of the company and strengthen the overseas promotion of the brand.
- The leading position of Intas/Accord in the European market can further promote oversea marketing of HLX10 product.

* The first upfront payment of €26 million will be paid on the effective date of the license agreement, and the second upfront payment of €16 million will be paid upon the European Medicines Agency issuing a positive opinion (day 210 of the centralized procedure) for the licensed product to be used as a first-line treatment of extensive-stage small cell lung cancer (ES-SCLC)

04 Research & Development

Product Pipeline

Pre-clinical

- HLX61
  Undisclosed (tumor immunity)
  Solid tumors
- HLX6018
  GARP/TGF-β1
  Chronic inflammatory diseases
- HLX41
  LIV1 ADC
  Solid tumors
- HLX44
  Nectin4 ADC
  Solid tumors
- HLX80
  STEAP1 ADC
  Prostate cancer
- HLX309
  Nectin4 x 4-1BB
  Solid tumors
- HLX314
  HER2xSialidase
  Solid tumors
- HLX92
  Polypharmacology
  PSC, PBC
- HLX94
  Polypharmacology
  ALS, PD

IND

- HLX51
  OX40
  Solid tumors, lymphoma
- HLX13 (ipilimumab)
  CTLA-4
  Solid tumors
- HLX42
  EGFR ADC
  Solid tumors
- HLX43
  PD-L1 ADC
  Solid tumors
- HLX17 (pembrolizumab)
  PD-1
  Solid tumors

Phase I

- HLX10(1) (serplulimab)+HLX60(2)
  PD-1+GARP
  Solid tumors
- HLX60
  GARP
  Solid tumors, lymphoma
- HLX301(3)
  PD-L1 x TIGIT
  Solid tumors, lymphoma
- HLX53
  TIGIT
  Solid tumors, lymphoma
- HLX05 (cetuximab) (4)
  EGFR
  mCRC, HNSCC
- HLX15 (daratumumab)
  CD38
  Multiple myeloma

Phase II

- HLX10(1) (serplulimab)+HANBEITAI
  PD-1+VEGF
  mCRC 1L
- HLX10(1) (serplulimab)+HLX07
  PD-1+EGFR
  HNSCC, NPC, GC, ESCC, sq-NSCLC
- HLX10(1) (serplulimab)+HLX26+chemo
  PD-1+LAG-3
  NSCLC 1L
- HLX10(1) (serplulimab)+HLX26
  PD-1+LAG-3
  mCRC 3L+
- HLX07(5)
  EGFR
  Solid tumors (cSCC)
- HLX22+HANQUYOU
  HER2+HER2
  GC
- HLX208(6)
  BRAF V600E
  LCH/ECD, solid tumors (i.e. MEL, thyroid cancer, mCRC, NSCLC)
- HLX208(6)+HLX10(1) (serplulimab)
  BRAF V600E+PD-1
  NSCLC

Phase III

- HLX10(1) (serplulimab)+chemo
  PD-1
  ES-SCLC 1L
- HLX10(1) (serplulimab)+chemo
  PD-1
  Neo/adjuvant treatment for GC
- HLX10(1) (serplulimab)+chemo+radio
  PD-1
  LS-SCLC 1L
- HLX10(1) (serplulimab)+HANBEITAI
  PD-1+VEGF
  nsNSCLC 1L
- HLX04-O(7)
  VEGF
  Wet AMD
- HLX11 (pertuzumab) (8)
  HER2
  Neoadjuvant treatment of breast cancer
- HLX14 (denosumab) (9)
  RANKL
  Osteoporosis

NDA

- HLX10(1) (serplulimab)+chemo
  PD-1
  ES-SCLC 1L
- HLX02 (trastuzumab) (10)
  HER2
  Breast cancer, mGC

In-Market

- HANSIZHUANG (serplulimab) (1)
  PD-1
  MSI-H solid tumors, sqNSCLC, ES-SCLC, ESCC
- HANLIKANG (rituximab) (11)
  CD20
  NHL, CLL, RA (12)
- HANQUYOU (trastuzumab) (10)
  HER2
  Breast cancer, mGC
- HANDAYUAN (adalimumab) (13)
  TNF-α
  RA, AS, psoriasis, uveitis
- HANBEITAI (bevacizumab) (14)
  VEGF
  mCRC, advanced, metastatic or recurrent NSCLC, GBM, etc.

Innovative mAb | Innovative BsAb | Innovative fusion protein
mAb biosimilar | Innovative ADC | Innovative small molecule
Bridging study in U.S. | BLA under FDA review | MAA application in Europe
MRCT | The first Chinese mAb approved both in Mainland China and the EU

(1) IND approvals obtained in China/the U.S./EUUS countries/Australia, etc. Approved by the NMPA in March 2022. Business partners: KGbio/Fosun Pharma/Intas. (2) IND approvals obtained in Australia. (3) IND approvals obtained in China/Australia. (4) Business partner: Shanghai Jingze. (5) IND approvals obtained in China/the U.S.. (6) Commercialization rights obtained for Mainland China, Hong Kong, Macao and Taiwan. (7) IND approvals obtained in China/Australia/the US/Singapore/EU countries, etc. Business partner: Essex. (8) IND approvals obtained in China/EU. Business partner: Organon. (9) IND approvals obtained in China/EU/Australia. Business partner: Organon. (10) 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: Accord/ Cipla/ Jacobson/ Elea/ Eurofarma/ Abbott/KGbio. (11) The first biosimilar approved in China. Business partners: Fosun Pharma/Farma de Colombia/Eurofarma/Abbott. (12) The first rituximab approved for the indication in China. (13) Business partners: Wanbang/Getz Pharma. (14) Business partner: Eurofarma.

Clinical Pipeline Milestones: YTD 3Q 2023 Review

YTD 3Q 2023

NDA/BLA/MAA Submission

HLX10
ES-SCLC[1]
1L (EU)

HLX10
ES-SCLC
1L (Indonesia, Myanmar, Cambodia)

Key Clinical Data Readouts

HLX10
sqNSCLC[2]
Final OS results
1L (Pivotal)

HLX07+HLX10
ESCC[3]
1L, 2L and late-line (PoC)

HLX208
BRAF V600E
LCH/ECD[4] - 22pts

Innovative mAb

Innovative small molecule

1. Extensive stage small cell lung cancer
2. Squamous non-small cell lung cancer
3. Esophageal squamous cell carcinoma
4. Langerhans cell histiocytosis (LCH) and Erdheim-Chester disease (ECD)

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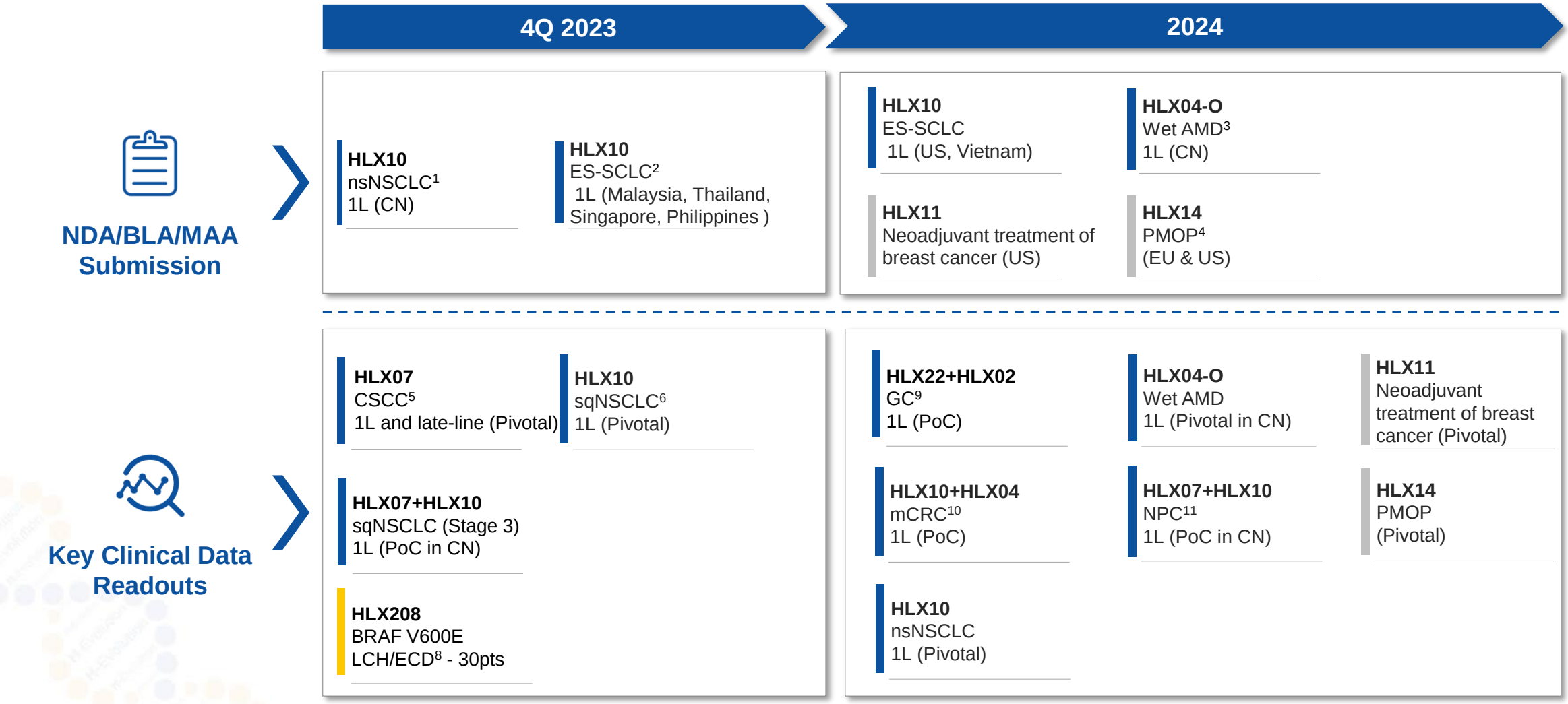
Clinical Pipeline Milestones: 2023-2024 (expected)



1. Non-squamous non-small cell lung cancer
2. Extensive stage small cell lung cancer
3. Age-related macular degeneration
4. Postmenopausal osteoporosis
5. Cutaneous squamous cell carcinoma
6. Squamous non-small cell lung cancer
7. Hepatocellular carcinoma
8. Langerhans cell histiocytosis (LCH) and Erdheim-Chester disease (ECD)
9. Gastric cancer
10. Metastatic colorectal cancer
11. Nasopharyngeal carcinoma

Innovative mAb | Innovative small molecule | mAb biosimilar

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HLX11 and HLX14: Multi-Regional Phase III Clinical Trials Ongoing

HLX11 – Pertuzumab Biosimilar

- Focusing on China, the US and Europe, the MRCT[1] plans to enrol 900 patients globally, expected to be the first globally approved pertuzumab biosimilar
- As the sales of the originator drug was over US$4.4B[2] in 2022, HLX11 would have a considerable sales potential if globally approved as the first biosimilar

	NDA/BLA/MAA Submission[3]	NDA/BLA/MAA Approval[3]
US	2H 2024	2H 2025
EU	1H 2025	1H 2026
China	1H 2025	2H 2026

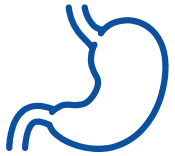
HLX14 – Denosumab Biosimilar

- As the first China-made denosumab biosimilar aiming to be approved globally, the MRCT[1] which focuses on the US and Europe has enrolled 514 patients
- As the originator drug achieved over US$3.6B[2] sales in 2022, HLX14 will have a promising global market prospect by licensing collaboration with global MNCs

	NDA/BLA/MAA Submission[3]	NDA/BLA/MAA Approval[3]
US	2H 2024	2H 2025
EU	2H 2024	2H 2025
China	1H 2025	2H 2026

1. MRCT = Multi-Regional Clinical Trial
2. Date sources: Financial reports of the companies of the originator drugs
3. Expected timeline. The Company cannot guarantee the successful development and commercialization of HLX11 and HLX14. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

Serplulimab: Targeting Differentiated Indications



Gastric Cancer (GC)

Neoadjuvant treatment in combination with Chemotherapy / Adjuvant with Serplulimab only

Phase III clinical data readout: Q2 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 **first perioperative I/O treatment in China for GC**
2. Around 2/3 of 300,000 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 III clinical data readout: Q1 2025

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 820K new cases of lung cancers in China every year, 15% is SCLC. Among SCLC patents, about 30%-40% are LS-SCLC[3]
2. Phase III MRCT has begun. 226 patients have enrolled by end of September 2023, including sites of China Mainland, Hong Kong, USA, Australia, etc. First patient has been dosed in EU in October 2023.
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 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.

HLX07: Address Unmet Medical Needs of High EGFR Expression Patients

ESCC Study Design (Phase II)

Inclusion Criteria:

- Age 18-75 years; ECOG PS 0 or 1
- ESCC or esophageal adenosquamous carcinoma
- Group A: no prior systemic antitumor therapy;
- Group B: failed first-line immuno-chemotherapy combination; ≥ 2 lines of other systemic antitumor therapy
- No prior therapy with systemic anti-EGFR antibody

Group A (1L)
HLX07, 1000 mg; Serplulimab, 200 mg; Chemotherapy
Q2W IV

Group B (≥2L)
HLX07, 1000 mg
Q2W IV

Primary Endpoints:
ORR and PFS (RECIST v1.1)

ESCC Efficacy Summary

Tumor Response[a] in Efficacy Evaluable Patients

	Group A (n=29)	Group B (n=13)
ORR, % (95% CI)	55.2 (35.7-73.6)	23.1 (5.0-53.8)
DCR, % (95% CI)	72.4 (52.8-87.3)	38.5 (13.9-68.4)

VS

SOC Efficacy Summary

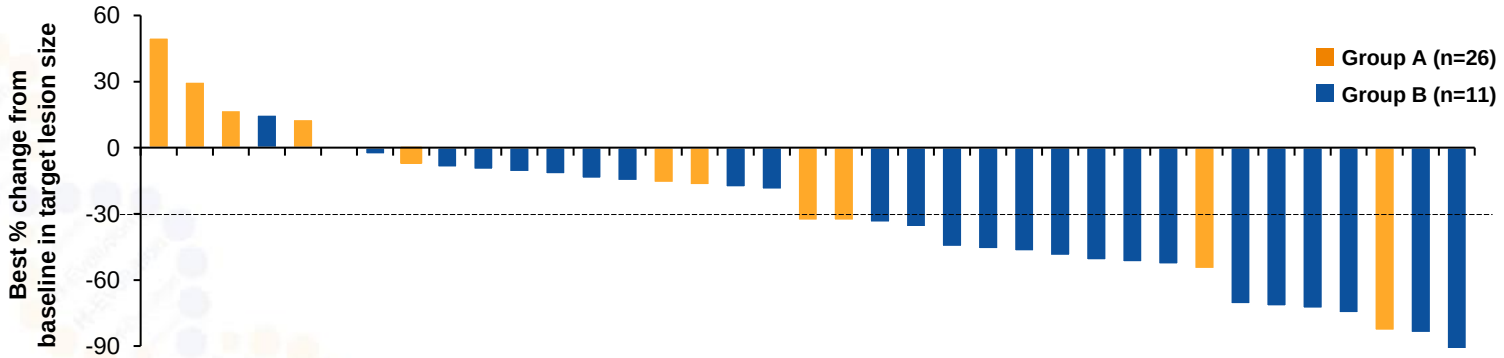
ESCC ≥2L ORR[b]:

- ICIs: 16.7%-20.2%
- CT: 21.5%

ESCC 1L ORR[c]:

- ICIs+CT: 45.0%-72.1%

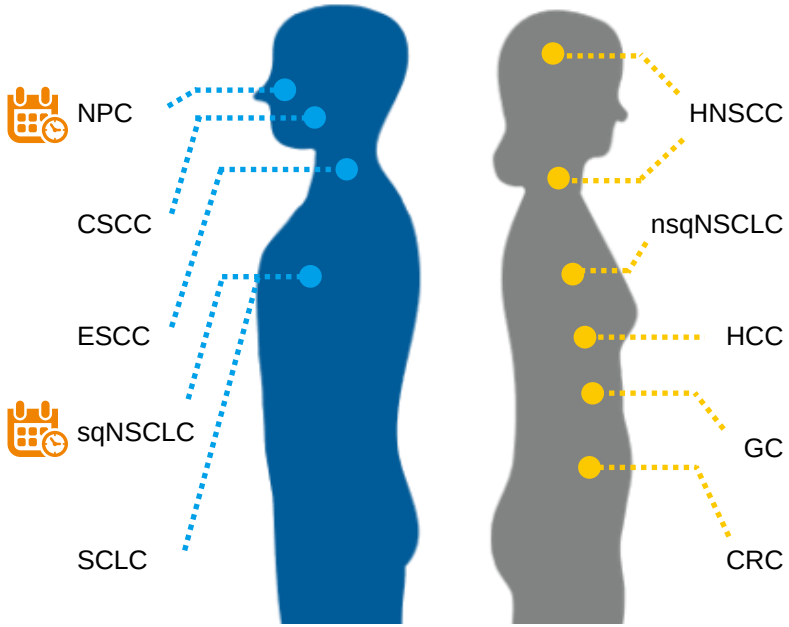
Best percentage change from baseline in target lesion size assessed by investigators



2023 American Society of Clinical Oncology (ASCO) Annual Meeting, June 2 – June 6, 2023ASCO; Data cutoff: February 4, 2023

HLX07 Indication Profile (Phase II)

10 indications have been planned:

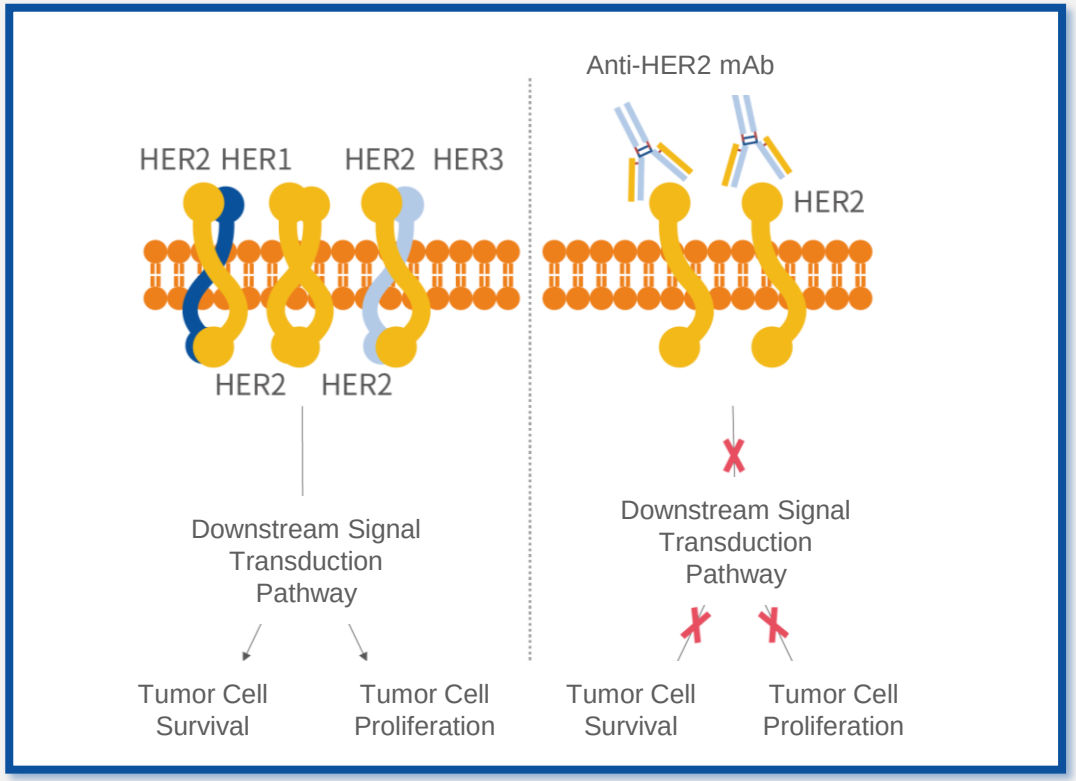


Readout date (expected): 2024 Q1

a: Unconfirmed tumor response assessed by investigators per RECIST v1.1 median follow-up duration was 2.9 months in group A and 4.0 months in group B median PFS was not reached in group A; it was 1.5 months in group B; **b**: KEYNOTE-181, ATTRACTION-3, ESCORT, ESWN 01; **c**: KEYNOTE-590, CheckMate-648, ESCORT

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 months[1]
- Phase II study data shows HLX 22 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 similar trials of competing products

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
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

4.1 R&D: Pre-clinical Assets

Antibody Drug Conjugate (ADC) R&D Platform: Hanjugator™

1. Develop differentiated ADC products: establish a new payload-linker and conjugate technology platform with proprietary IP rights
2. Increase the efficacy of ADCs: develop Multiple-Payloads ADC (MP-ADC)
3. Improve safety and therapeutic window of ADCs: build Tumor microenvironment (TME) Conditionally Released Payload-Linker (CPRL) platform
4. Enhance the selectivity of ADCs: build Tumor microenvironment (TME) Conditionally Activated Antibody (CAAb) platform
5. Expand the application scenarios of ADCs: discover new toxin and non-toxin payloads

Innovative Antibody Drug Conjugate (ADC): HLX42 and HLX43

- **The IND applications of HLX42 EGFR ADC and HLX43 PD-L1 ADC have been approved by the NMPA, and the phase 1 clinical trials will be initiated.**
  - **The results of the preclinical studies of these two ADC candidates were published as poster presentations at the 2023 ESMO Congress.**
  - **HLX42 and HLX43 are comprised with antibodies connected to novel topoisomerase-I inhibitor payloads, with a drug to antibody ratio of 8.**
- **Animal studies showed that HLX42 and HLX43 have excellent anti-tumor effects on tumor models resistant to EGFR targeted therapy or PD-1/PD-L1 inhibitors respectively.**

MADRID 2023 ESMO congress

HLX42 EGFR ADC

683P

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

Y. Shan[1], R. Liu[1], G. Song[1], H. Song[1], J. Jiang[1], C. Jia[1], X. Huang[1], X. Yuan[1], W-J. Yang[1], X. Wang[2], Q. Wang[2], C. Hu[2], C. Zhao[2], Q. Wang[2], J. Zhu[2]

[1] Shanghai Innovation Center, Shanghai Henlius Biotech, Inc., Shanghai, China[2] Global Product Development, Shanghai Henlius Biotech, Inc., Shanghai, China

Background

EGFR is highly expressed in various tumour types and is a driving force in tumourigenesis and progression. Although anti-EGFR and EGFR TKIs have demonstrated success in cancer treatment, a considerable medical need remains for patients who do not respond to or experience relapse following standard care. EGFR ADCs in clinical evaluation displayed preliminary efficacy, but conventional EGFR ADCs could pose considerable toxicity risks due to the universal expression of EGFR in normal epithelial tissues.

Methods

HLX42, a next-generation EGFR ADC, is comprised of a highly specific humanized IgG1 anti-EGFR connected to a novel topoisomerase-I inhibitor payload, whose cleavage and release are tumour microenvironment dependent and do not necessitate internalisation of ADC. This distinct mechanism of payload release grants HLX42 a superior therapeutic index compared to its predecessors. HLX42 was examined in antigen binding, internalisation, and plasma stability assays; efficacy analyses were also performed in multiple CDX and PDX models.

Results

In vitro evaluations verified that HLX42 possessed a similar binding affinity and internalisation rate as its parental antibody. Additionally, the ADC remained stable in rat and cynomolgus monkey plasma. HLX42 exhibited robust tumour suppression in several CDX and PDX models that were resistant to anti-EGFR or TKIs. In comparison to conventional ADC technologies such as vc-MMAE and GGFG-Dxd, HLX42 displayed superior efficacy and elicited more durable antitumour responses. In the NCI-H1993 model, weekly administration of HLX42 at 8 mg/kg for three times resulted in a 91.5% TGI compared to 79.8% TGI induced by anti-EGFR-GGFG-Dxd. Furthermore, the combination of HLX42 and osimertinib exhibited strong synergy in the LU3075 PDX model which poorly responded to osimertinib alone. In our pilot toxicity studies, HLX42 was well tolerated in rats and non-human primates (severely toxic dose in 10% of animals = 50 mpk in rats; highest non-severely toxic dose = 20 mpk in non-human primates).

Conclusions

Taken together, these preclinical data strongly suggest that HLX42 is a potential best-in-class EGFR-targeting ADC which is worth further clinical investigations.

MADRID 2023 ESMO congress

HLX43 PD-L1 ADC

693P

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

Y. Shan[1], R. Liu[1], G. Song[1], H. Song[1], J. Jiang[1], C. Jia[1], Y. Chen[1], X. Yuan[1], Z. Hou[1], X. Wang[2], X. Hou[2], Y. Shen[2], C. Hu[2], H. Wei[2], Q. Wang[2], J. Zhu[2]

[1] Shanghai Innovation Center, Shanghai Henlius Biotech, Inc., Shanghai, China[2] Global Product Development, Shanghai Henlius Biotech, Inc., Shanghai, China

Background

PD-1/PD-L1 monoclonal antibodies have revolutionised the landscape of cancer treatment. Nonetheless, some PD-L1+ patients do not respond to or become resistant to such therapy. The elevated expression of PD-L1 in tumours makes it an attractive target for ADC development, which could potentially alter the treatment for PD-1/PD-L1 inhibitor refractory/resistant (R/R) cancers.

Methods

HLX43 is a novel PD-L1-targeting ADC consisting of an engineered anti-PD-L1 humanised IgG1 antibody linked to a camptothecin-based toxin, with a drug to antibody ratio of 8. Our innovative linker-payload is activated preferentially in the tumour microenvironment, enabling its tumour-specific release of the toxin without needing internalisation of the ADC. Toxin release in PD-L1+ cancer cells is efficient and tumour-specific, minimizing damage to normal cells and reducing systemic toxicity from non-specific toxin release in periphery. HLX43 was examined in antigen binding, internalisation, and plasma stability assays; efficacy studies were performed in multiple CDX and PDX models.

Results

HLX43 has been shown to have similar affinity and internalisation rates as the parental antibody. It was stable in the plasma of rats and cynomolgus monkeys. In *in vivo* efficacy studies, HLX43 induced tumour regression in multiple PD-L+ CDX and PDX models, and was well tolerated across all dosing groups. Weekly administration of HLX43 8 mg/kg for three times significantly reduced tumours in the MDA-MB-231 model without causing weight loss. HLX43 exhibited superior anticancer efficacy compared to anti-PD-L1-GGFG-Dxd at equal doses in all models tested, including those with low PD-L1 levels, high heterogeneity, and non-responsiveness to PD-1/PD-L1 inhibitors. Preliminary toxicity assessments demonstrated good tolerability of HLX43 in rats and cynomolgus monkeys, with the maximum tolerated dose being 60 mg/kg in rats and 10 mg/kg in non-human primates. GLP toxicology studies will explore a higher dose at 20 mg/kg.

Conclusions

HLX43 showed promising efficacy and tolerability in preclinical assessments. It may offer a novel treatment for PD-1/PD-L1 inhibitor R/R cancers like NSCLC, HNSCC, ESCC, MEL, and OVC.

Henlius 复宏汉霖

5D Platform Targeting Oncology, Metabolism, Immunity and Neurology

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

HLX307 (rPro)

- **First-in-class recombinant protein products**
- Unique MOA, simultaneously lower blood glucose and improve kidney damage repair
- Good efficacy in **DKD**[4] models
- Large patient population with huge unmet needs

HLX30 (bisAb)

- **First-in-class bi-specific antibody**
- Differentiated molecule design with better tumor selectivity
- Address unmet clinical needs in the field of **advanced or metastatic tumors with EGFR mutations**
- Potential breakthrough innovative drugs

HLX92 (SMC)

- **First-in-class small molecule drug conjugates**
- Polypharmacology with a unique MOA
- Address unmet needs in the fields of **PSC**[1] and **PBC**[2]
- Potential breakthrough innovative drugs

HLX94 (SMC)

- **First-in-class small molecule drug conjugates**
- Polypharmacology with a unique MOA
- Address unmet needs in the fields of **ALS**[3] and **Parkinson's Disease**
- Potential breakthrough innovative drugs

1. PSC = primary sclerosing cholangitis
2. PBC = primary biliary cholangitis
3. ALS = amyotrophic lateral sclerosis
4. DKD = diabetic kidney disease

05 Manufacturing

International Leading Capabilities on Manufacturing and Quality Management

- **Manufacturing capacity optimization:** The scale of commercial GMP batches has **reached a new high**
- **Implement "Henlius Quality" with international standards:** as of Oct 2023, GMP certified by **NMPA, EMA and PIC/S members (Indonesia and 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:** has undergone the **Pre-License Inspection (PLI) of FDA**
- **Improving the laboratory infrastructure: Strengthen** downstream and formulation process optimization and scale-up capabilities

Scientific Optimization

- **Plant construction for Phase I & II trials: Acceleration** of the plant validation
- **The improved application of stainless steel equipment**: Costs reduction by process automation

Intelligent Drug Manufacturing

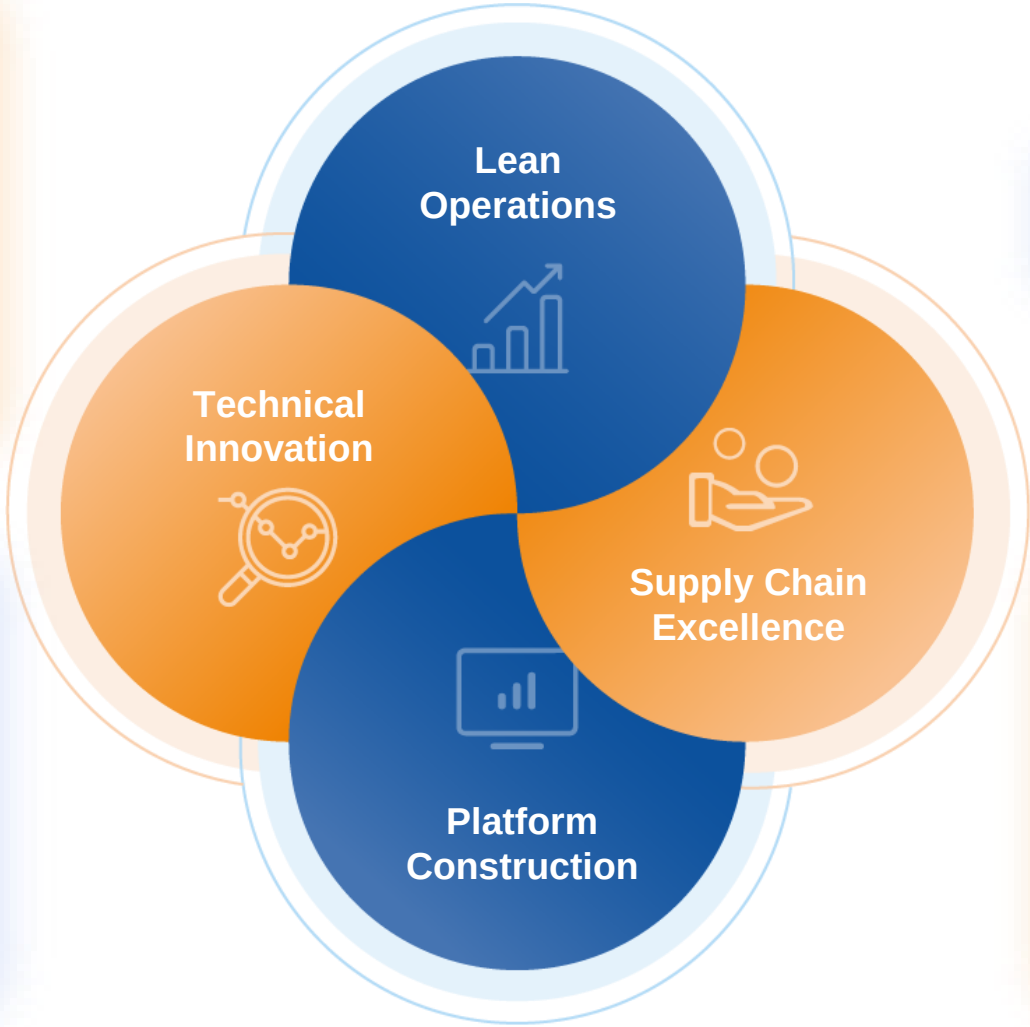
Operation Excellence and Continuous Innovation

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 real-time production monitoring to achieve lean digital production**
- Optimized the satellite tank and scale-down models



Lean Operations

- **34 on-going lean operations projects** with ~10M RMB expected annualized returns
- **The batch output increased 10% compared with 2022** for serplulimab

Supply Chain Excellence

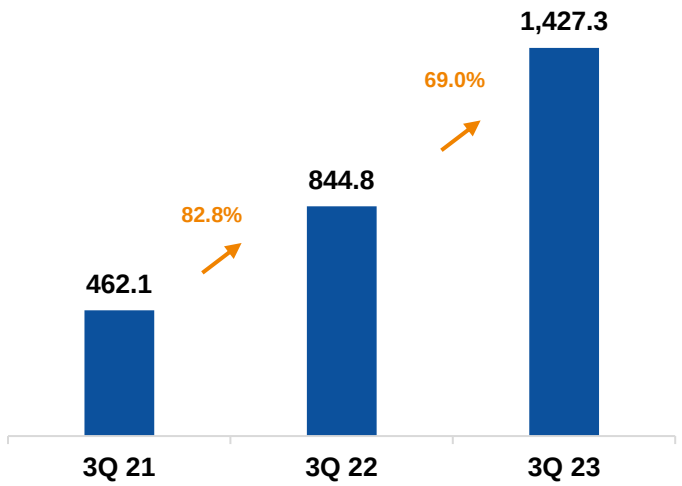
- The direct material cost was **11.4% lower than that in 2022**
- Completed the sustainability process design for supply chain and implemented risk-warning mechanism

06

3Q 2023 Financial Review

3Q 2023 Revenue of RMB 1.43 Billion with 69.0% YoY

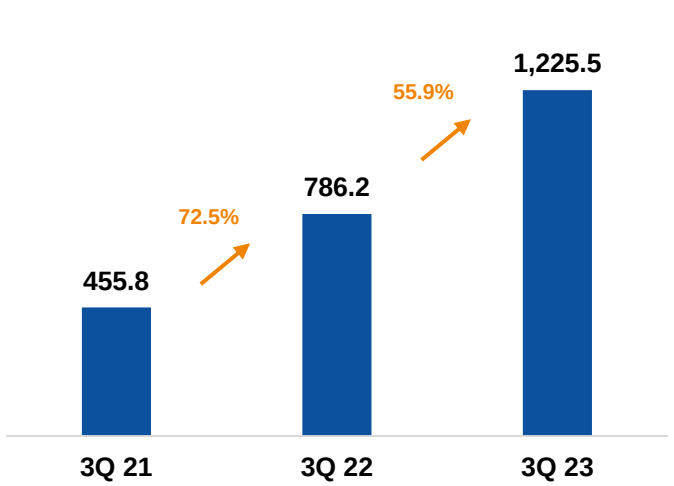
Revenue (in Million RMB)



Revenue Growth

- Revenue of RMB 1.43B in 3Q 2023, 69.0% YoY growth. Revenue of RMB 3.93B in YTD 3Q 2023, 84.0% YoY growth
- Revenue growth mainly driven by: outperformed sales ramp-up of HANQUYOU and HANSIZHUANG

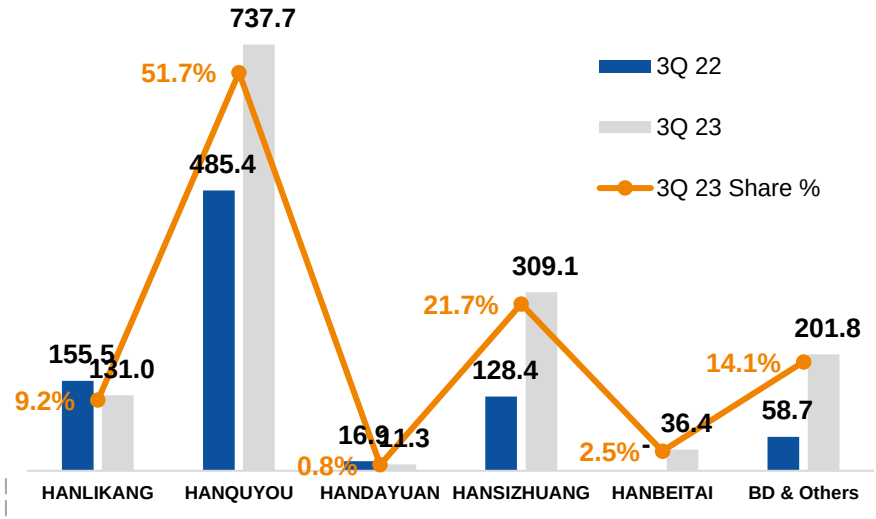
Product Sales (in Million RMB)



Product Sales

- Product sales of RMB 1.23B in 3Q 2023, 55.9% YoY growth. Product sales of RMB 3.38B in YTD 3Q 2023, 71.7% 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

3Q 2023 Revenue Breakdown (in Million RMB)



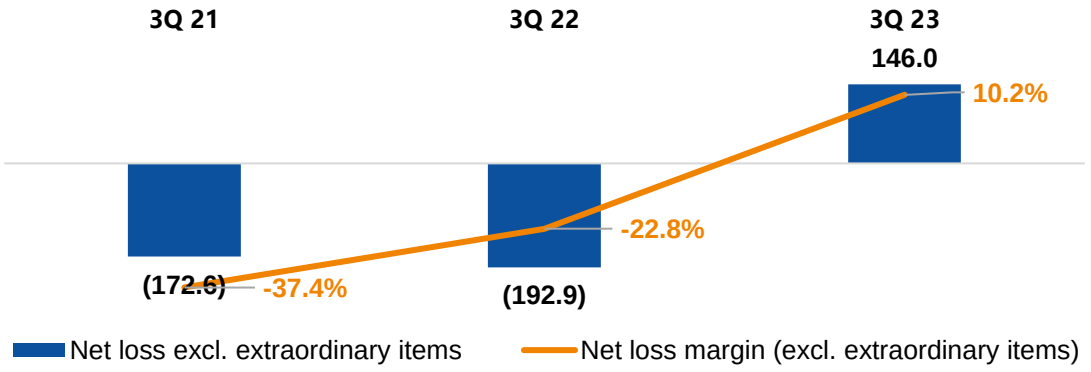
Revenue Breakdown

- HANQUYOU*: RMB 738M sales in 3Q23, 52.0% YoY growth; RMB 2.01B sales in YTD 3Q23, 55.2% YoY growth
- HANSIZHUANG: RMB 309M sales in 3Q23, 140.7% YoY growth; RMB 865M sales in YTD 3Q23, 321.4% YoY growth
- HANLIKANG: RMB 131M sales in 3Q23, -15.7% YoY growth; RMB 385M sales in YTD 3Q23, -9.9% YoY
- HANDAYUAN: RMB 11M sales in 3Q23, -33.2% YoY growth; RMB 32M sales in YTD 3Q23, -12.6% YoY growth
- HANBEITAI: RMB 36M sales in 3Q23; RMB 81M sales in YTD 3Q23
- BD and other income: RMB 202M in 3Q23, 244.1% YoY growth; RMB 549M in YTD 3Q23, 230.1% YoY growth

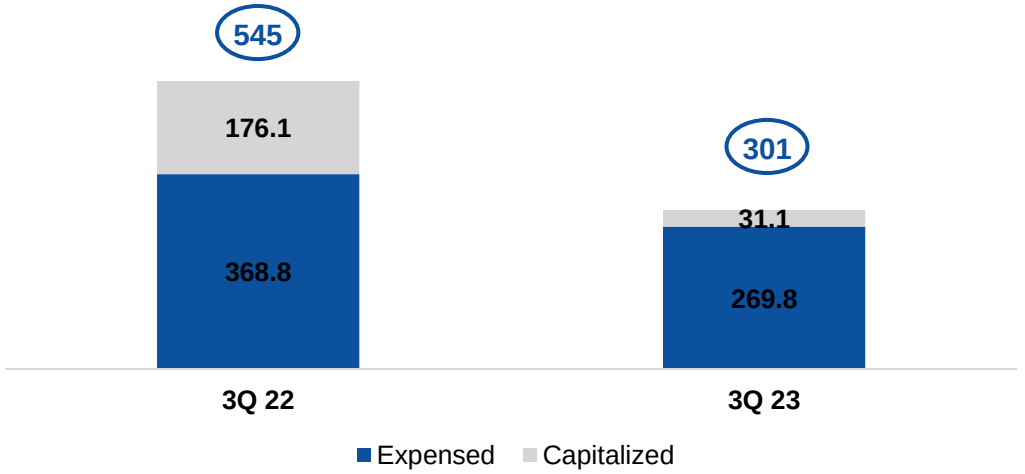
* Sum of sales revenue of HANQUYOU, drug substance of trastuzumab and Zercepac®

Achieved Profitability in 3Q 2023 with RMB ~240M Operating CF

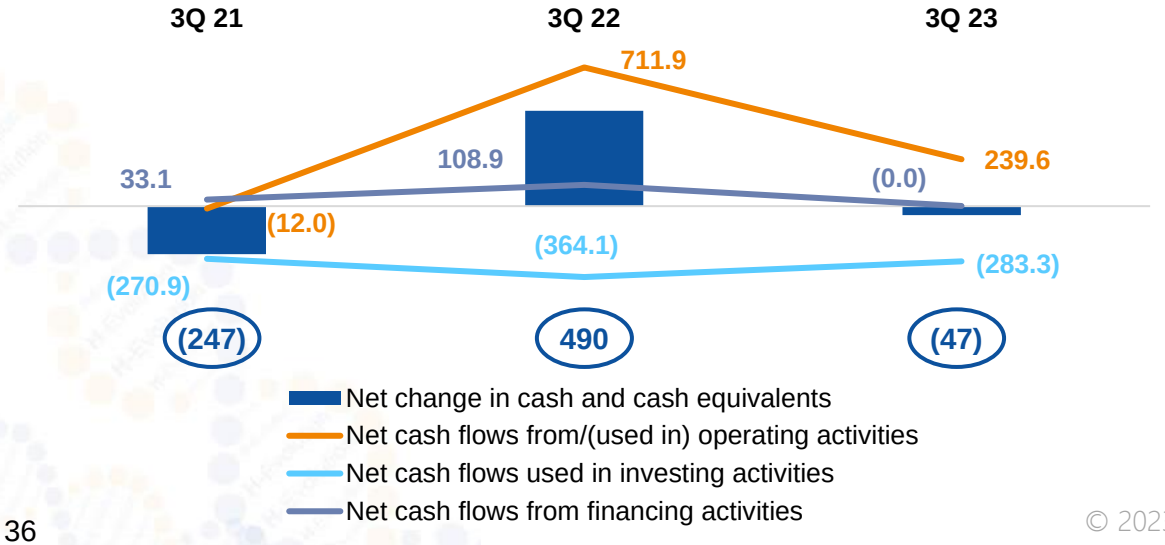
Net profit (net loss) excl. extraordinary items (in Million RMB)



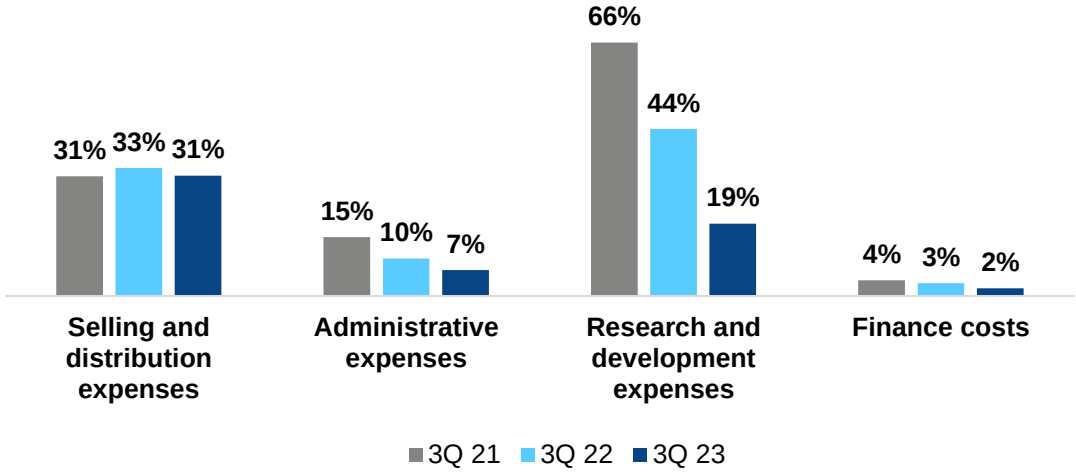
R&D investment (in Million RMB)



Net change in cash and cash equivalents: positive OCF with RMB 240M (in Million RMB)



Expense to revenue ratios steadily decreased



Financial Highlights

Financial Data (selected)	3Q 23		3Q 22		YoY Growth	YTD 3Q 23	
Unit	In Million RMB	% of revenue	In Million RMB	% of revenue	%	In Million RMB	% of revenue
Revenue	1,427.34	100.00%	844.83	100.00%	68.95%	3,927.81	100.00%
Product sales	1,225.50	85.86%	786.17	93.06%	55.88%	3,378.41	86.01%
BD and other revenue	201.83	14.14%	58.66	6.94%	244.09%	549.40	13.99%
Cost of sales	406.88	28.51%	209.07	24.75%	94.62%	1,128.52	28.73%
Selling and distribution expenses	449.26	31.48%	282.39	33.43%	59.09%	1,232.21	31.37%
Administrative expenses	96.46	6.76%	82.34	9.75%	17.16%	260.17	6.62%
R&D expenses	269.77	18.90%	368.79	43.65%	-26.85%	817.60	20.82%
Financial costs	28.46	1.99%	27.80	3.29%	2.40%	82.55	2.10%
Net profit (net loss) excl. extraordinary item	145.96	10.23%	(192.89)	-22.83%	/	375.58	9.56%
Net profit (net loss)	167.82	11.76%	(90.40)	-10.70%	/	407.80	10.38%
Cash and bank balances	586.12	41.06%	704.79	83.42%	-16.84%	586.12	14.92%
Net cash flows from operating activities	239.62	16.79%	711.95	84.27%	-66.34%	572.08	14.56%

07

2023 Performance Outlook

Our Goals for 2023

- **Revenue**: rapid growth driven by promoting clinical advantage of HANSIZHUANG and HANQUYOU
- **Profitability**: improve P&L level, and improve profits from internal operation
- **Cashflow:** positive OCF generated for the past two years; strengthen organic growth in 2023 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 countries; advance HANSIZHUANG MAA filing in Europe
- **Resource Allocation**: optimize resource allocation, and improve return on investment of R&D, manufacturing and commercialization, to assure long-term sustainable growth

声 明
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Reliable Quality
Affordable Innovation