Henlius 2696.HK 3Q 2023 Results Investor Presentation

November 2023



Our Mission and Vision

Affordable Innovation
Reliable Quality

Biosimilars

Maximize the commercialization value in China and international markets

Innovative Drugs

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

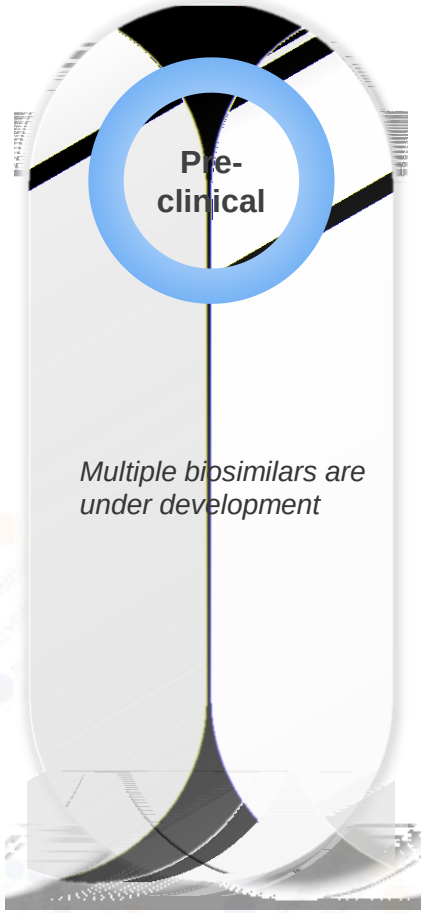
Globalization

Develop towards a biopharma with global presence & scale

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

- 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





Sales Revenue of Marketed Biosimilars (100 million RMB)

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

- 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.)

- 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

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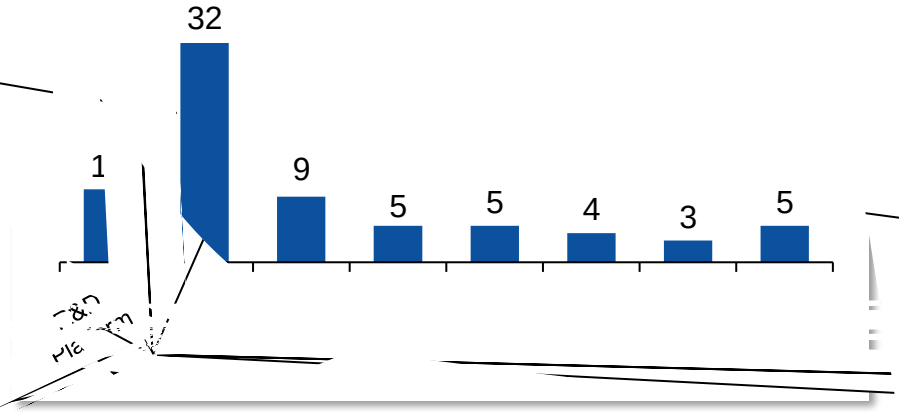
R&D for Innovative Drugs: Beyond Oncology, Expanding into New TAs for Long-term Growth

Pipeline Type & Introduction

Total 63 molecules in pipeline with 45 innovative drugs and 18 biosimilars

Pipeline mainly focuses around oncology while starting to explore new TAs including Autoimmune, Ophthalmology / Metabolism / Rare Disease.

Innovative Pipeline Distribution by Stage (by Molecule)



Modality Distribution (1)

1 Swi... all... Antibody X conjugates, including AEC, AOC & A...

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02 Commercialization

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Excellent Performance of HANQUYOU



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HANSIZHUANG Commercialization Highlights

First-class Commercialization Efficiency

Outstanding Achievements

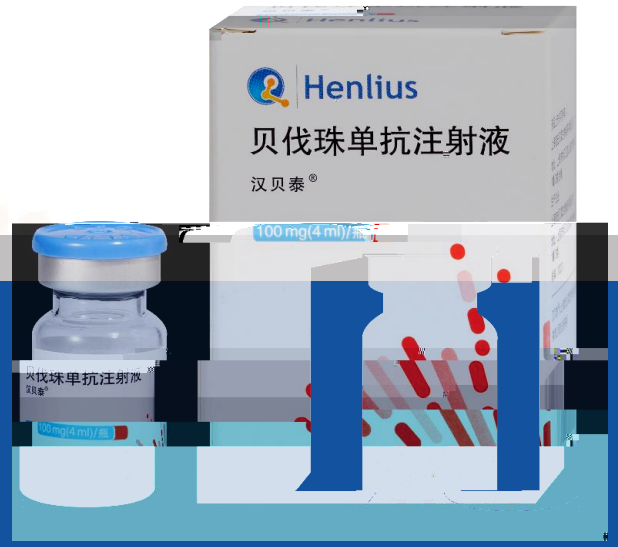
- Sales outperformed most of the competing PD-1/PD-L1 since its launch in 2021
- Expected to be Tier-1 PD-1/PD-L1 products by 2023

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~180K RMB
per month

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HANBEITAI (Bevacizumab): Commercialization Acceleration 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

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

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HANLIKANG (Rituximab): Strengthen the Market Leader Position

- Jiangsu Fosun, a subsidiary of Fosun Pharma, is responsible for HANLIKANG's commercialization in China
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HANDAYUAN (Adalimumab): Entered Autoimmune Disease Area

32M RMB

- 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:

- 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-**

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03 Business Development

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Collaboration Expansion with Existing Partner about HLX10 EU & India

Intas Pharmaceuticals Limited[1]

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

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Collaboration Expansion with Existing Partner about HLX10 EU & India

Upfronts up to 42 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 42 million will be paid on the effective date of the license agreement, and the second upfront

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04 Research & Development

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Product Pipeline

Pre-clinical	IND	Phase I	Phase II	Phase III	NDA	In-Market

HLX6018
GARP/TGF-β1
Chronic inflammatory diseases

HLX17 (pembrolizumab)

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

- **Focusing on China, the US and Europe, the MRCT[1]**

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Serplulimab: Targeting Differentiated Indications



Gastric Cancer (GC)

Neoadjuvant treatment in combination with Chemotherapy / Adjuvant with Serplulimab only

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**

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

Currently, the median EFS of perioperative SoC Tf1MCI5(oC TC Tf1MCI5(oC TC Tf1MCI5(oC TC Tf1MCI

Limited Stage Small Cell Lung Cancer (LS-SCLC)

Serplulimab combined with Concurrent Chemoradiotherapy (CCRT)

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]

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HLX07: Address Unmet Medical Needs of High EGFR Expression Patients

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 B (2L)

HLX07, 1000 mg

Q2W IV

Primary Endpoints:

ORR and PFS (RECIST v1.1)



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

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4.1 R&D: Pre-clinical Assets

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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
- Potential breakthrough innovative drugs

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

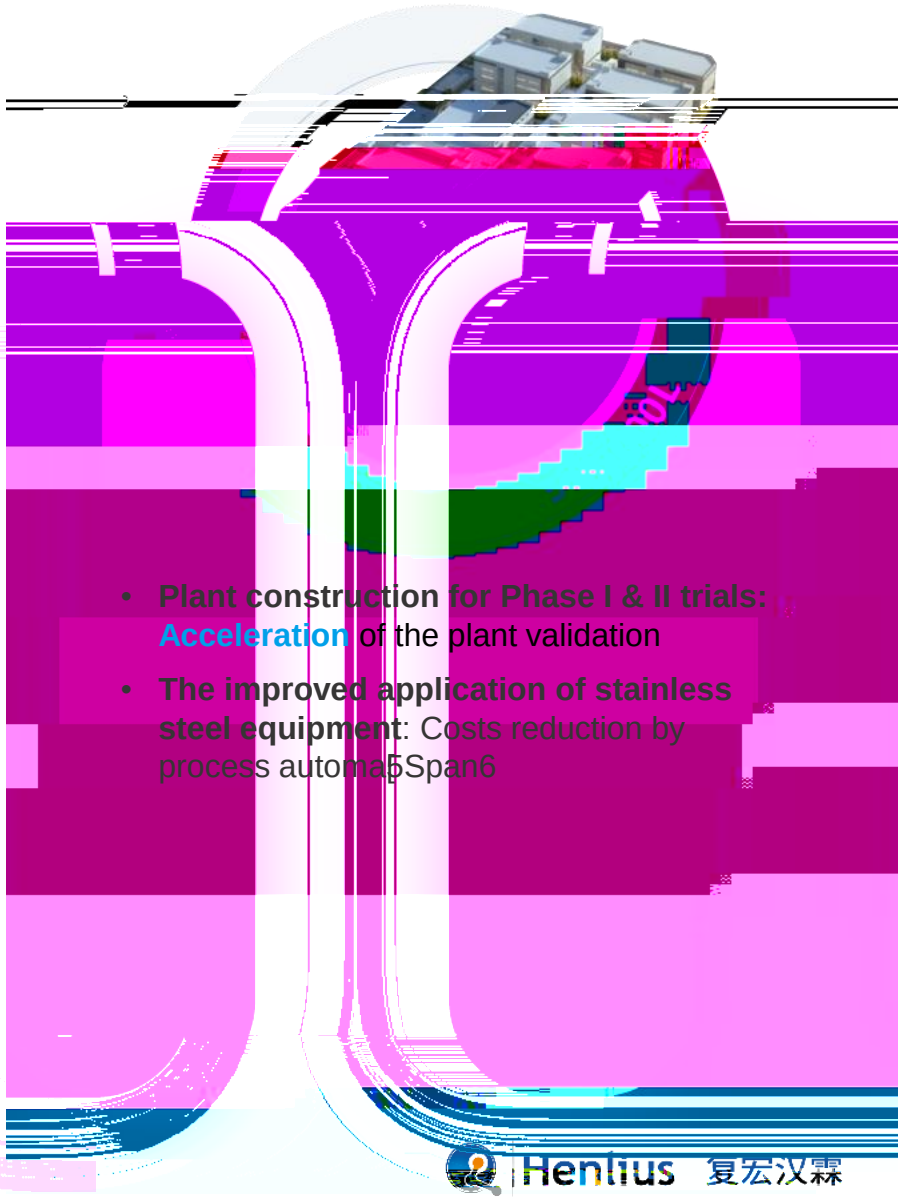
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05 Manufacturing

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International Leading Capabilities on Manufacturing and Quality Management

- **Manufacturing capacity optimization:** The scale of commercial GMP batches has **reached a new high**
- **Henlius 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**



- **Plant construction for Phase I & II trials: Acceleration** of the plant validation
- **The improved application of stainless steel equipment**: Costs reduction by process automa5Span6

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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 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

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06

3Q 2023 Financial Review

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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%

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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

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