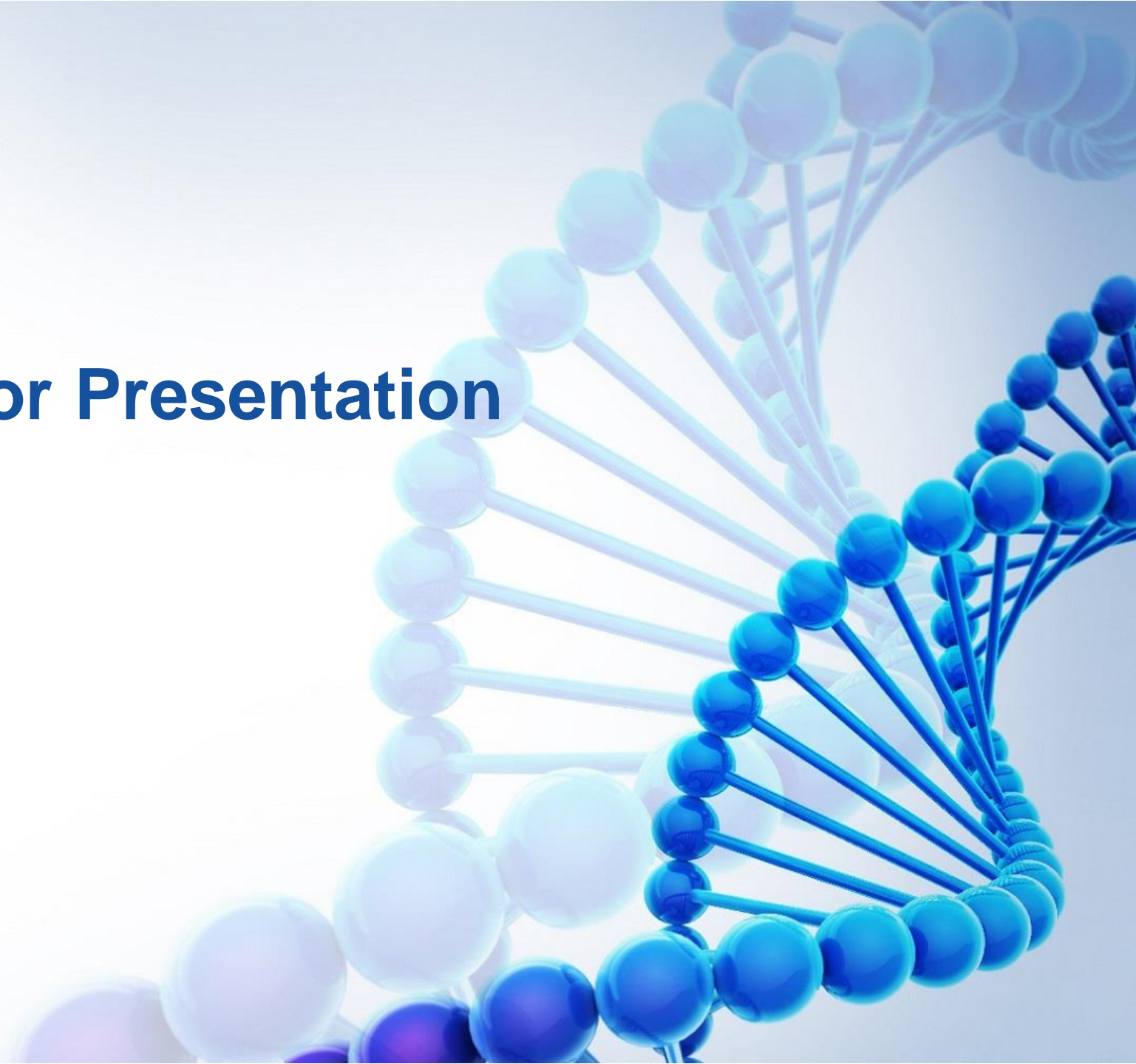


Henlius (2696.HK) 1H22 Results Investor Presentation

August 2022





CONTENTS

1

1H22 Business Highlights

2

Core Business Updates

- 2.1 Commercial Operation
- 2.2 Innovative Biologics R&D Milestones (Clinical Phase)
- 2.3 Early-stage R&D Strategies (Pre-clinical Phase)
- 2.4 Biosimilar Milestones
- 2.5 Manufacturing Capacity Breakthroughs

3

Financial Review & Outlook

1






1H22 Business Highlights

1H22: The Pivotal 6 Months of Henlius' Evolution from Biotech to Biopharma

- ✓ Sustained operations during Covid outbreaks and lockdowns
- ✓ Doubled production capacity, breaking through the bottleneck
- ✓ Received NMPA approval for the first innovative biological drug, *Serplulimab*
- ✓ Accelerated product sales growth (HANQUYOU & HANSIZHUANG)
- ✓ New license-out milestones (Organon)
- ✓ Innovative R&D transformation starts to bloom

1H22 Key Milestones

**Our Mission:
Affordable Innovation, Reliable Quality**

	Products Launched Domestically	5
	Products Launched Internationally	1
	NDA's Under NMPA Review*	3
	Phase 3 Trials*	8
	Total Commercial Production Capacity	48,000L

- IND of HLX53 (anti-TIGIT Fc fusion protein) approved by NMPA
- Reached license agreement with Palleon for bifunctional sialidases
- Reached license agreement with Organon, with payments up to US\$541M on two mAbs products
- HLX35 (anti-EGFR×4-1BB BsAb) first patient dosing in a phase 1 clinical trial in China completed
- 2022.06** ● HANSIZHUANG's 1L ES-SCLC clinical data presented at 2022 ASCO
- 2022.05** ● Songjiang First Plant with a 24,000L capacity began commercial operation for HANQUYOU
- HANSIZHUANG granted orphan-drug designation for SCLC by FDA
- 2022.04** ● NDA for HANSIZHUANG for Extensive Stage Small Cell Lung Cancer (ES-SCLC) accepted by NMPA
- 2022.03** ● HANSIZHUANG (serplulimab) for MSI-H solid tumour indication treatment launched
- 2022.02** ● HANLIKANG (rituximab) for Rheumatoid Arthritis (RA) indication approved in China

* Note: as of the latest practicable date

5 Products Launched: Revenue Tops 1.29 Billion RMB



First Chinese biosimilar

HANLIKANG (rituximab)

Approved in 2019.02

China's first self-developed mAbs approved in China and EU

HANQUYOU (trastuzumab)

Zercepac® in Europe

Tuzucip® & Trastucip® in Australia

Approved in 2020.08

Approved in 2020.07

Approved in 2022.07

First Chinese adalimumab manufactured in China and EU GMP-certificated production facilities

HANDAYUAN (adalimumab)

Approved in 2020.12

The only bevacizumab biosimilar with Phase 3 clinical data for mCRC in China

HANBEITAI (bevacizumab)

Approved in 2021.11

Our first self-developed innovative mAb drug

HANSIZHUANG (serplulimab)

Approved in 2022.03



13+11

Candidates/Combo Therapies under Clinical Studies



20+

Clinical Studies



3

NDA's under NMPA review

Note: All data as of the Latest Practicable Date

High-performing Leadership Team with A Global Vision



Wenjie Zhang

Chairman

Executive Director and CEO

- Joined Henlius in Mar 2019
- Nearly 30 years of operational experience in the pharmaceutical industry
- Former business head, business vice president and general manager at Bayer China, Roche China and Amgen China
- MBA from Yale University and bachelor degree of microbiology from Shandong University



Jason Zhu
President



Wei Huang
Chief Operation Officer
SVP



James Guo
SVP



Jifeng Zhang
Chief Technology Officer
SVP



Jean-Michel Gries
President of Hengenix
Biotech



Kurt Yu
Chief Commercial Officer
VP



Gino Li
Chief Financial Officer
VP



Jessie Li
Chief Human Resource Officer
VP



Ping Cao
VP of Business
Development



Wallis Zeng
VP of Oncology
Business Unit



Jinzhi Liu
VP of Legal and
Compliance



Ming Yang
GM of Immune-Oncology
Business Unit



Yongqiang Shan
GM of Shanghai
Innovation Centre



Arthur Sheng
GM of Global Strategy &
PMO



Jim Hua
GM of Finance &
Procurement



Jasmin Wang
Deputy GM of Quality



Nancy Wang
Board Secretary

Enhance R&D and Commercialisation Capabilities, Evolving to Biopharma

While maximising the commercial value of biosimilars, we rely on our own R&D expertise, complemented by external collaborations and license-in, to accelerate our innovation.



Synergise **China and US** R&D centres, strengthen **translational medicine capability**, advance **differentiated innovation**, to address unmet medical needs

R&D



Assure **Henlius quality**, further improve **manufacturing capacity**, optimise **manufacturing technology**, in order to create competitive **economies of scale**

Manufacturing

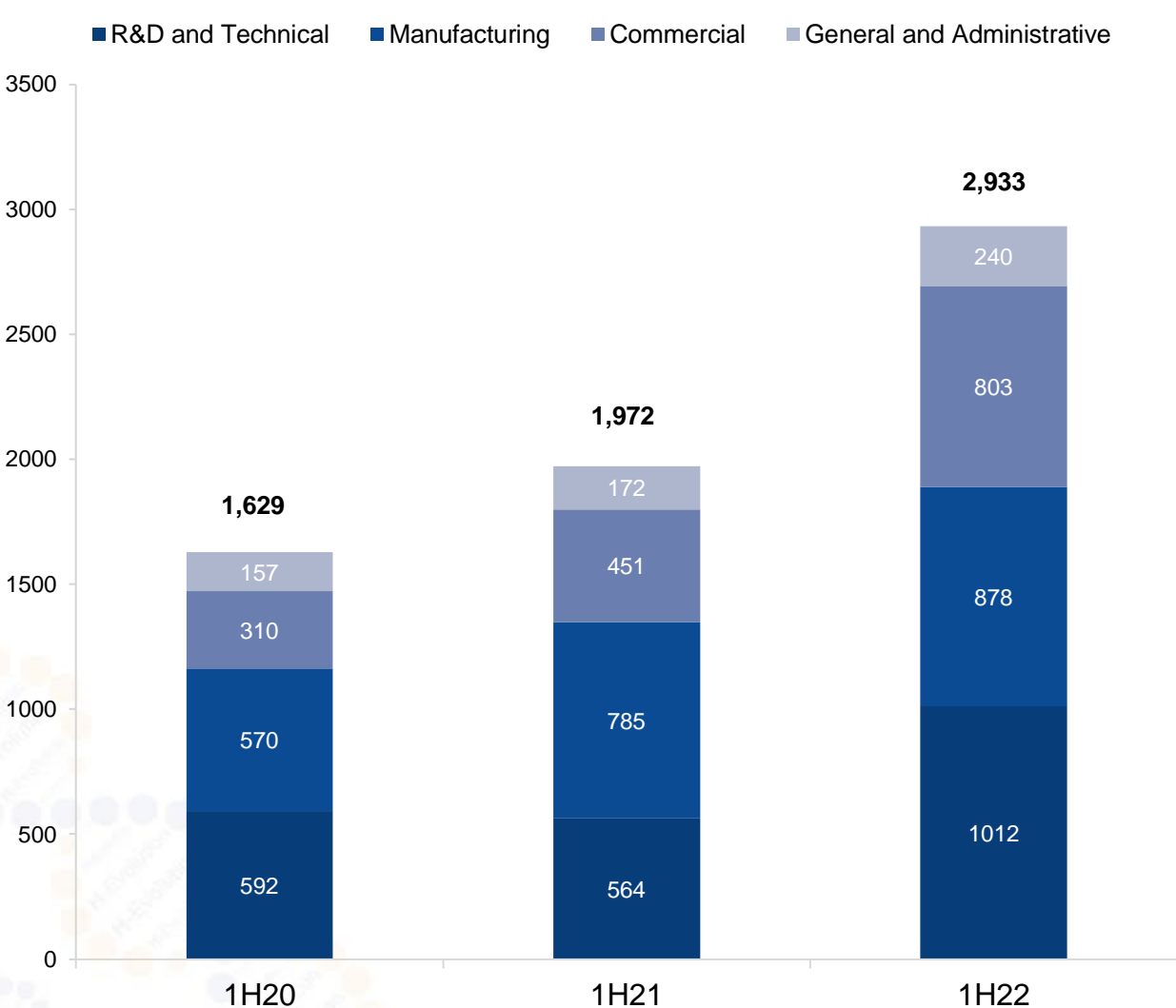


Aim to establish a first-class **commercial team** able to deliver **strong performance** through innovative marketing, access, channel and sales strategies

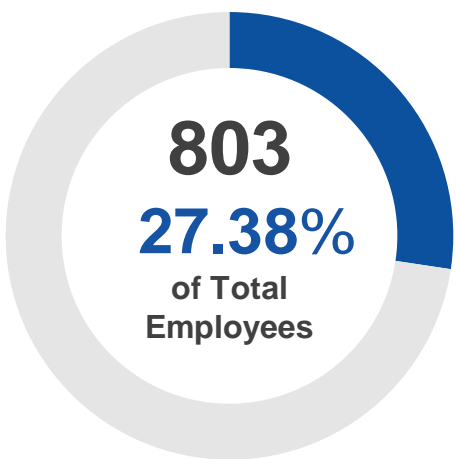
Commercialisation

Company Scale: Rapid Team Expansion

Company Size and Composition*



R&D and Technical	1012
Manufacturing	878
Commercial	803
General & Administrative	240



Commercial Team



R&D and Technical Team

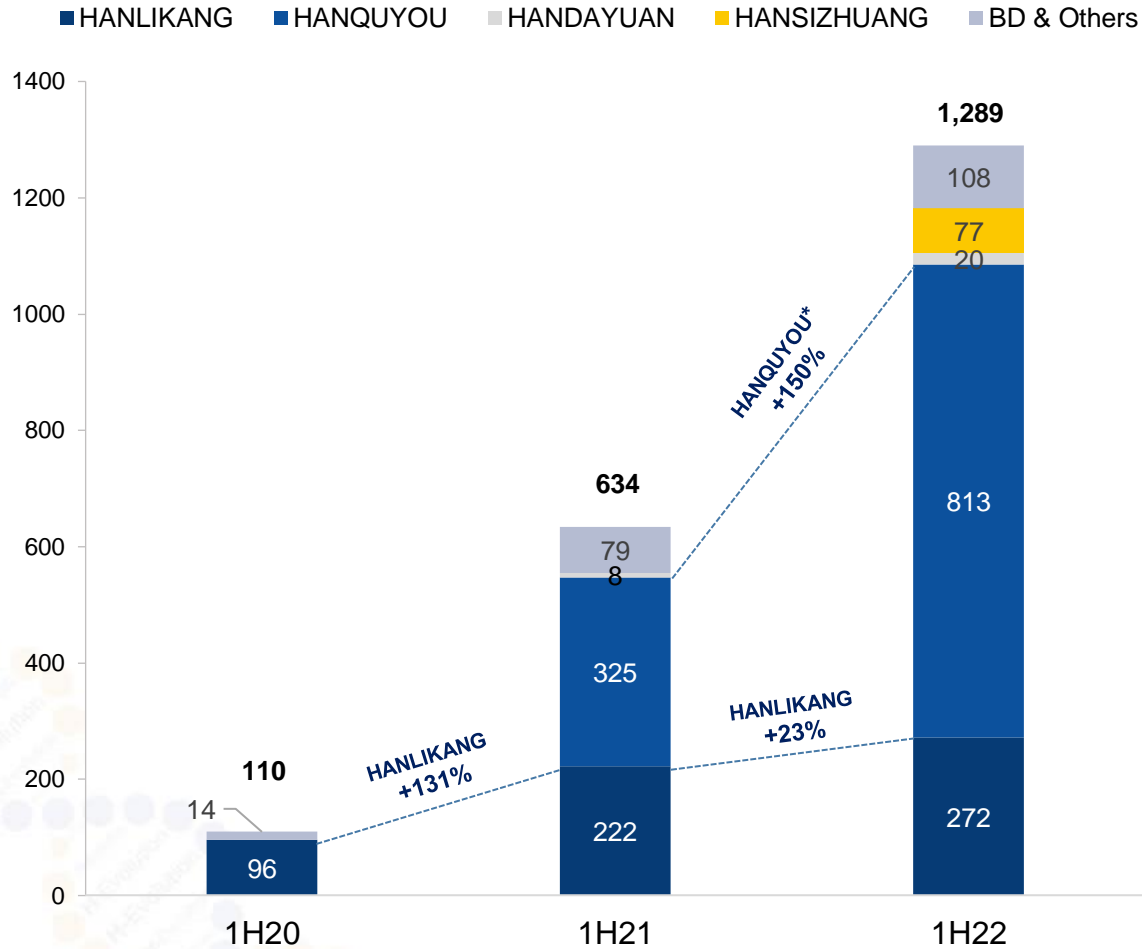
Note: as of June 30, 2022
1H20 and 1H21 R&D Team only includes R&D and clinical teams;
1H22 R&D Team includes R&D, clinical and technical teams

2.1

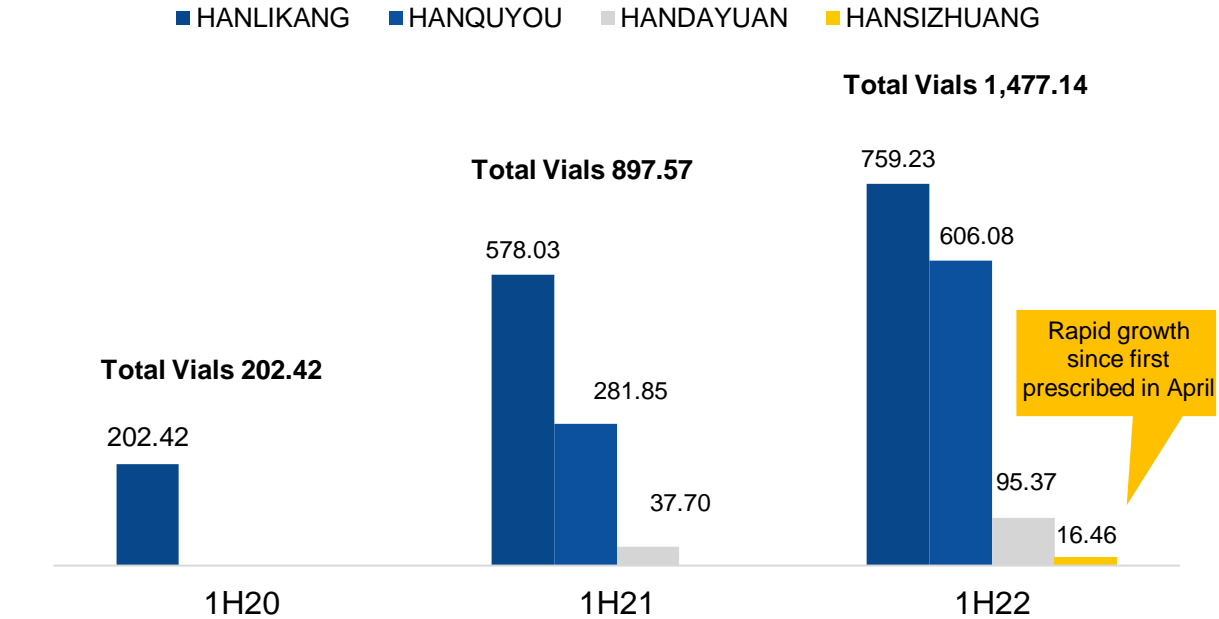
Commercial Operation

1H22 Sales: Growth Driven by Core Products

Revenue by Product (in million RMB)



Ex-Factory Volume * (Unit: 1,000 Vials)



* Note: Internal data. HANQUYOU volumes are converted into 150 mg/vial

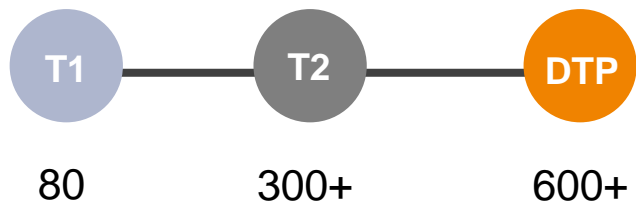
- Rapid revenue growth:** achieved revenue of RMB 1.29 billion in 1H22, up 103% YoY, mainly due to the sales volume growth of HANLIKANG and HANQUYOU*. HANQUYOU* recorded revenue of RMB 813 million in 1H22, up RMB 488 million or 150% YoY. HANLIKANG realized 272 million revenue. HANSIZHUANG reached revenue of RMB 77 million within 3 months of launching.
- Revenue increase driven by core product sales:** the ex-factory volume reached 1.48 million vials, which is 1.6 times of that in 1H21. HANQUYOU ex-factory volume was 0.61 million vials, up 115% over 1H21. HANLIKANG achieved 0.76 million vials ex-factory volume, while HANSIZHUANG achieved 16,500 vials, which resulted in a tremendous increase in sales since its launch.

• Note: Sales of HANQUYOU included the sales of HANQUYOU, Zercepac® and the drug substance trastuzumab
 • HANQUYOU ex-factory volume included overseas sales volume

HANQUYOU (trastuzumab): Rapid Increase in Production Volume

Optimised distribution network

- Optimised distributor & DTP pharmacy channels
- Simplified distribution process, improved efficiency to drive sales growth



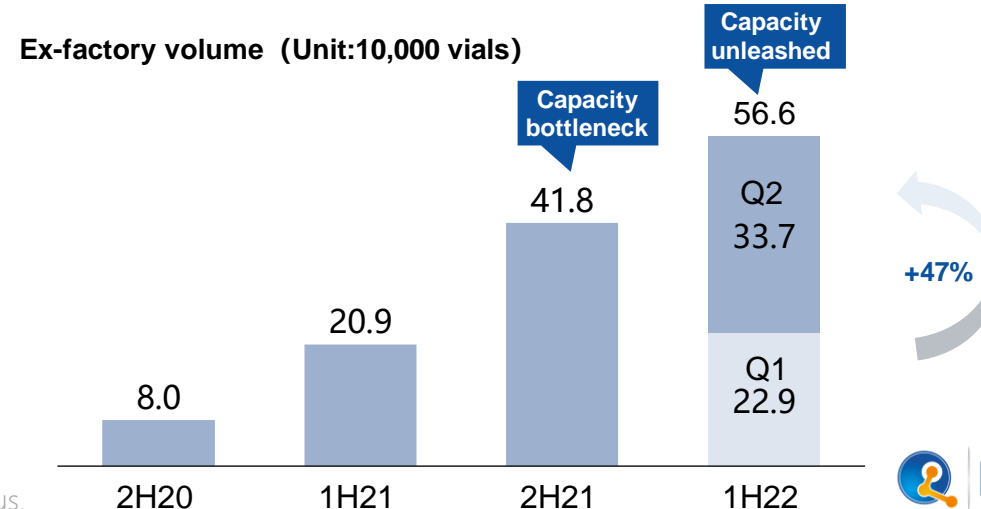
Strengthened business division

- Commercial team: **518** as of Jun 30, 2022.
- Comprehensive coverage of nearly **3,500 hospitals** in 7 major sales regions across China, reaching **20,000+ breast cancer oncologists and gastroenterologists**
- Benefited **over 70,000 HER2+ patients** since product launch in China. Compared to other trastuzumab biosimilars which will be commercialised soon, the target doctor group has more hands-on experience with HANQUYOU

Better market access

- **150mg**: Entered national reimbursement drug list and completed tenders on procurement platforms in all provinces and municipalities. Gained access to 714 hospitals out of Top 1,000 hospitals, of which 71% have included the product in their official procurement list.
- **60mg**: Since being commercialised in April, has entered the national reimbursement drug list and completed tenders on procurement platforms in 26 provinces and municipalities by June. Gained access to 149 hospitals out of Top 1,000, of which 64% have included the product in their official procurement list.

Ramping up production



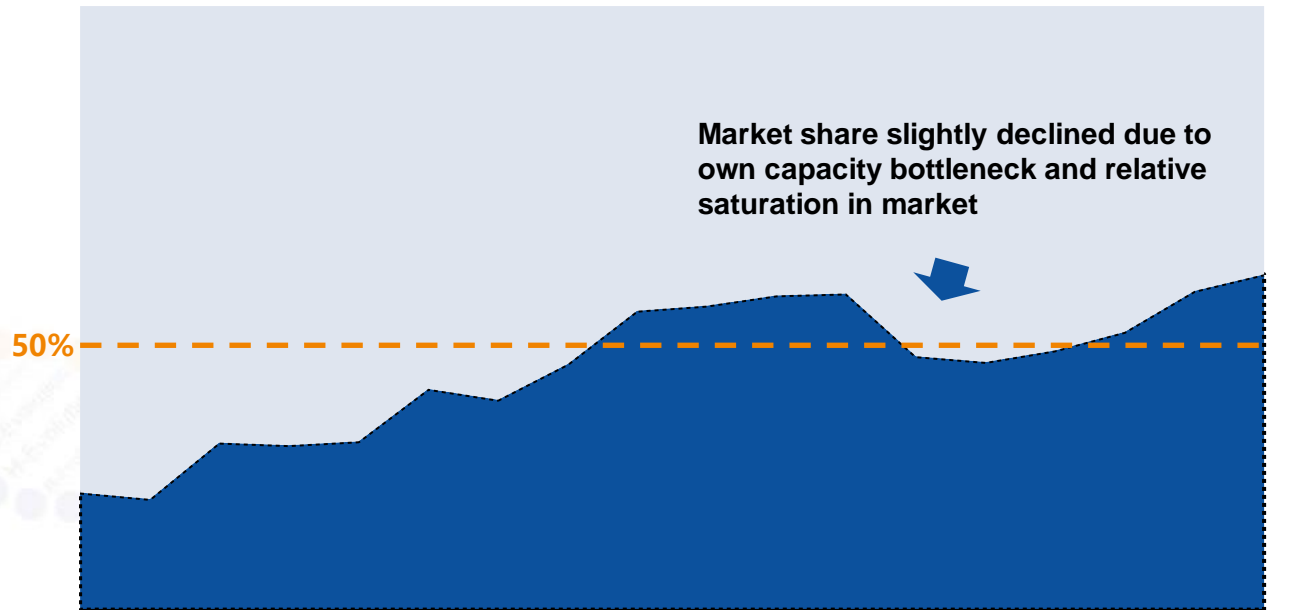
HANQUYOU (trastuzumab): Outstanding Sales Performance



Sales performance

Total estimated accessed market rate reached 70%* as of Jun 30, 2022, market share in accessed market reached 50%

Market Share



Efficient sales investment

Enhanced efficiency to achieve sustainable development and returns

>3.16M
RMB

Sales per capita

Benchmark against domestic counterparts (~1.5M-2M) *

<39%

Sales Expenses as share of Revenue

Benchmark against domestic counterparts (~60%-80%) *

01/21 02/21 03/21 04/21 05/21 06/21 07/21 08/21 09/21 10/21 11/21 12/21 01/22 02/22 03/22 04/22 05/22 06/22

Data source: 1. internal sales data; 2. IQVIA CHPA;
3. Accessed market rate=accessed market potential / total market potential
4. Annual report of domestic innovative biopharma

HANQUYOU: 60mg Specification Launched, Advanced Leading Position in the Trastuzumab Market



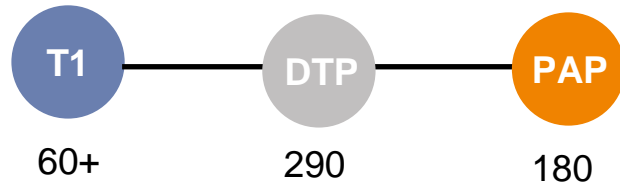
Establishing new standard among peers

- 01 Adjustable Dosage**
Suitable for Asian Female Patients
- 02 Dual Drug Specifications**
Standardising Drug Adoption
- 03 Superior Formulation**
No preservatives, fewer side effects

HANSIZHUANG (serplulimab): Successful Launch in March

DTP channel optimisation

- Pursued synergistic effect with HANQUYOU, established efficient distribution network
- Maximised access by leveraging DTP pharmacies and infusion centres



Refined management

- Establish a field team of **200+** who have extraordinary communications skills and experience in the oncology drugs market
- Created a team culture of professionalism, efficiency and compliance

Access and market penetration

Accelerated bidding

Complied with national drug code system regulation, completed tenders on procurement platforms in 18 provinces

Focus on core hospitals

Introduced to 21% of the Top 110 hospitals

Henlius Speed: outstanding sales performance



HANSIZHUANG (serplulimab): Under China NDA Review for sqNSCLC and SCLC Indications



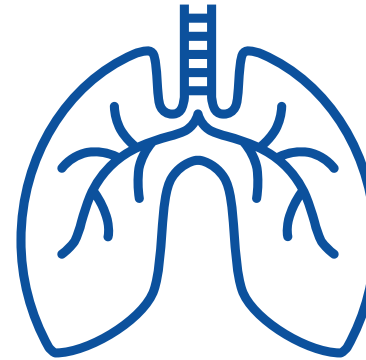
Market prospects

- 800k+ new lung cancer patients every year (170k+ in sqNSCLC, 120k + in SCLC)
- HANSIZHUANG would potentially be the world's first PD-1 inhibitor for the first-line treatment of SCLC indication



Clinical efficacy profile

- Significantly extended the mOS of patients with sqNSCLC
- Superior mOS among all anti-PD-1 mAb for first-line treatment of SCLC
- Lowest HR value among all registered treatments for SCLC, with better efficacy among Asian demographics



Exploring lung cancer treatment potential

sqNSCLC expected to be approved in 2H22

ES-SCLC expected to be approved in 1H23

HANLIKANG (rituximab) :Market Leader amid Competition and COVID-19 Pandemic



Market Access

100mg:

Listed on the procurement platform in **30 provinces and municipalities** except Yun Nan by the end of June; Covered by medical insurance schemes in **30 provinces and municipalities** except Tibet

500mg:

Listed on the procurement platform in **26 provinces and municipalities** by end of June; Covered by medical insurance schemes in **14 provinces and municipalities**

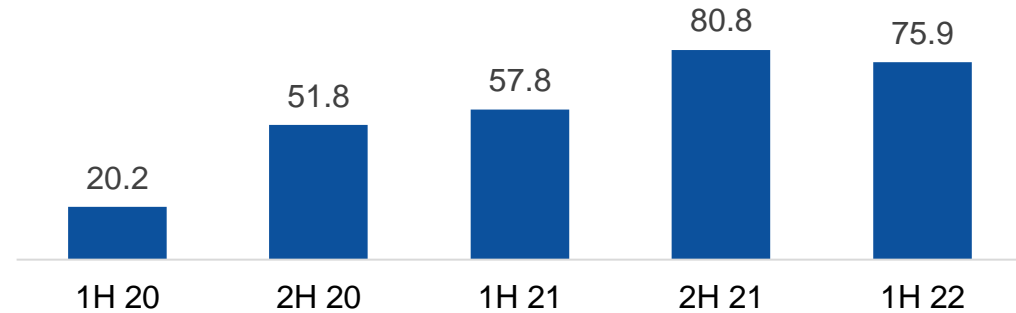
Hospital listing:

74% of Top300 hospitals have introduced the product

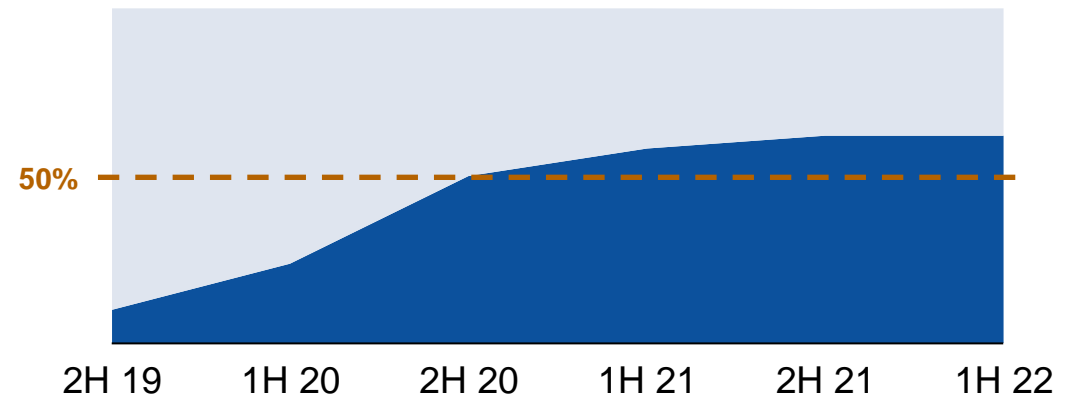


Sales Performance*

Ex-factory Sales* (Unit:10,000 vials)



Market Share



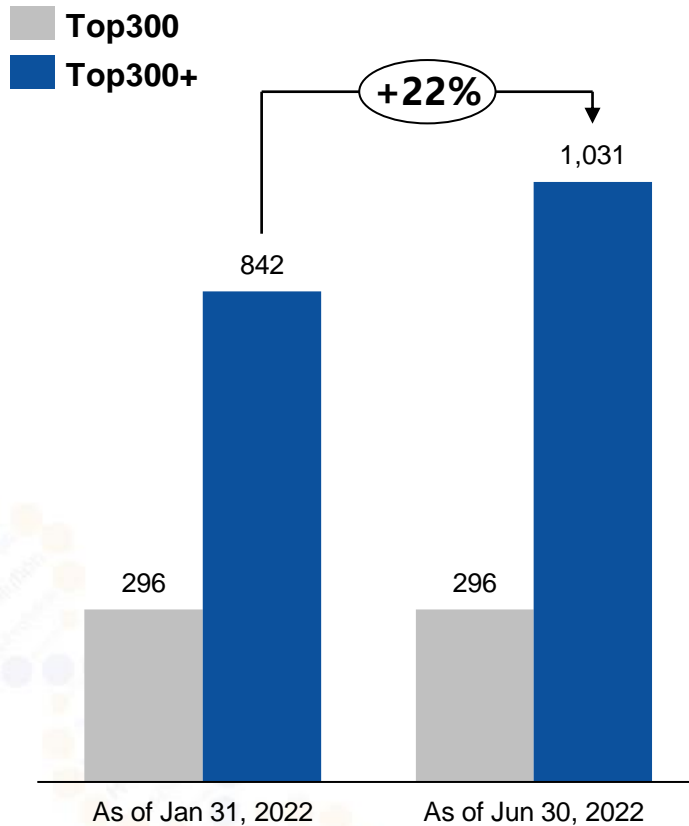
* Fosun Pharma is responsible for the commercialisation of HANLIKANG

* ex-factory sales volume based on 100mg for calculation

HANLIKANG: Rapidly Claiming Market Share in RA Treatment

Consolidated leadership in core market and expanded further

By June, the number of Top 300+ hospitals with HANLIKANG prescriptions has climbed 22% since the beginning of the year



Hospital no. by Tiers

Approved for RA Indication, proactively preparing NRDL negotiations



Expanding application scenarios

The originator drug has not approved for RA indication treatment by NMPA

Low dosing frequency, sustained efficacy

Combined treatment in full course with HANDAYUAN

2.2




Innovative Biological Drugs R&D Milestones (Clinical Phase)

Product Pipeline - Innovative Biological Drugs

	Products	Targets	Indications	Pre-clinical	IND	Phase 1	Phase 2	Phase 3	NDA	Launch	Business Partners	
Launched	HANSIZHUANG (serplulimab) ⁽¹⁾	PD-1	MSI-H solid tumours									
Under Clinical Studies	HLX10 (serplulimab injection) ⁽²⁾	+chemo	PD-1	squamous non-small cell lung cancer 1L								
			PD-1	extensive-stage small cell lung cancer 1L								
	HLX10 (serplulimab injection) ⁽²⁾	+chemo	PD-1	metastatic esophageal squamous-cell carcinoma 1L								★ Met Primary Endpoint OS & PFS
				neo-/adjuvant treatment of gastric cancer								
		+chemo +radio	PD-1	limited-stage small cell lung cancer 1L								
				non-squamous non-small cell lung cancer 1L								
		+HANBEITAI	PD-1+VEGF	hepatocellular carcinoma 1L								
				metastatic colorectal cancer 1L								
				squamous cell carcinoma of head&neck 2L								
		+HLX07	PD-1+EGFR	squamous non-small cell lung cancer 1L								
	solid tumours, lymphomas											
	HLX04-O ⁽³⁾	VEGF	wet age-related macular degeneration									
	HLX22 +HANQUYOU	HER2+HER2	gastric cancer									
	HLX07 ⁽⁴⁾	EGFR	solid tumours (non-small cell lung cancer, esophageal carcinoma, etc.)									
	HLX208 ⁽⁵⁾	BRAF V600E	Metastatic colorectal cancer, non-small cell lung cancer, LCH and ECD									
	HLX26	LAG-3	solid tumours, lymphomas									
HLX35 ⁽⁶⁾	EGFR x 4-1BB	solid tumours										
HLX301 ⁽⁷⁾	PD-L1 x TIGIT	solid tumours										
HLX23 ⁽⁸⁾	CD73	solid tumours										
HLX53	TIGIT	solid tumours, lymphomas										

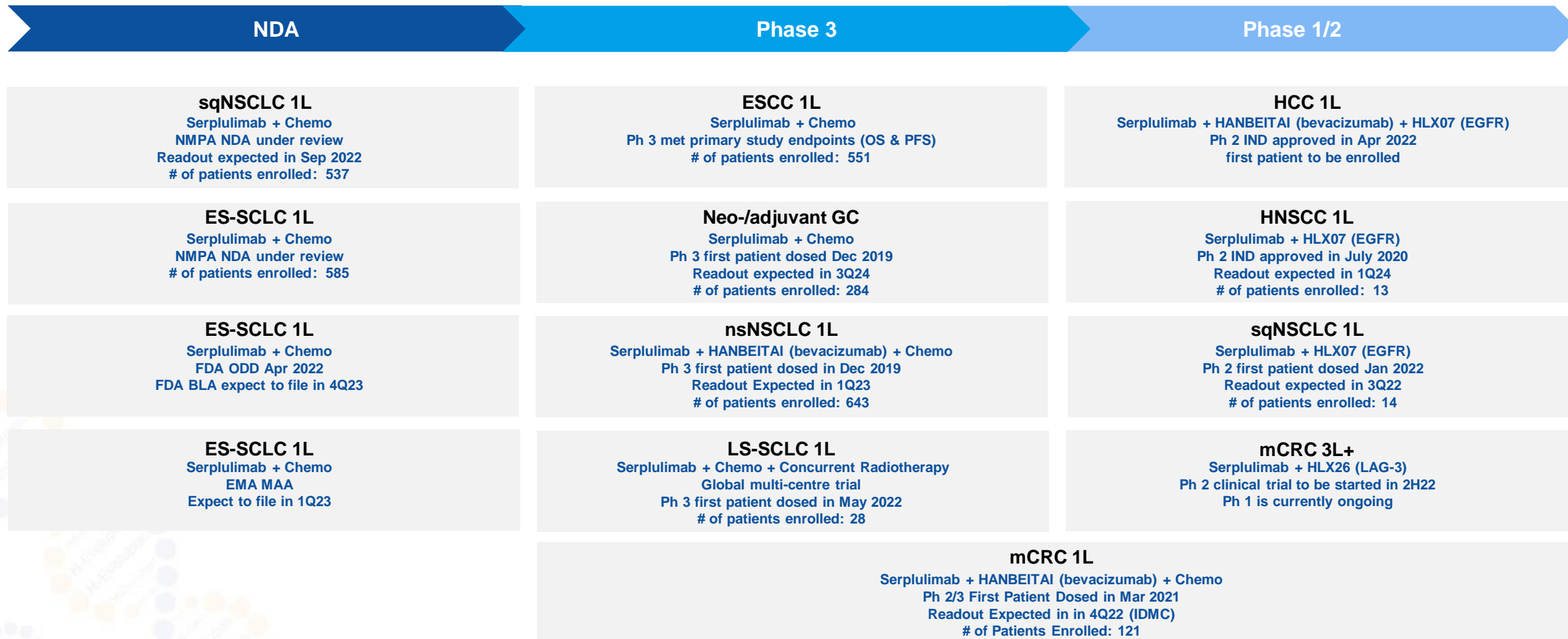
(1) Indication of MSI-H solid tumours approved in March 2022.
 (2) Clinical approvals obtained in China/the US/EU countries, etc.
 (3) Clinical approvals obtained in China/Australia/the US/Singapore/EU countries, etc.
 (4) Clinical approvals obtained in China/the US
 (5) Commercialisation rights obtained in China including Chinese mainland, Hong Kong, Macao and Taiwan regions
 (6) Global commercialisation rights excluding Chinese mainland, Hong Kong, Macao and Taiwan region granted to Binacea
 (7) Clinical Trial Notification has been acknowledged by the Therapeutic Goods Administration in China and Australia
 (8) Clinical approvals obtained in the US

Pipeline Catalysts in 2H22 and 2023

	2H2022	1H2023	2H2023
 <p>NDA/BLA/MAA Submission</p>	HLX10 – Esophageal squamous cell carcinoma (ESCC) 1L (CN)	HLX10 – Extensive Stage Small Cell Lung Cancer (ES-SCLC) 1L (EU)	<p>HLX10 – Non-squamous Non-Small Cell Lung Cancer (nsNSCLC) 1L (CN)</p> <p>HLX10 – Extensive Stage Small Cell Lung Cancer (ES-SCLC) 1L (US)</p>
	 <p>Key Study Clinical Data Readouts</p>	<p>HLX07 – Cutaneous squamous cell carcinoma (CSCC)</p> <p>HLX10 – squamous Non-Small Cell Lung Cancer (sqNSCLC) 1L (Pivotal)</p> <p>HLX10 – metastatic Colorectal Cancer (mCRC) 1L (PoC)</p> <p>HLX22 – Gastric Cancer (GC) 1L (PoC)</p> <p>HLX04-O – wet age-related Macular Degeneration (wAMD) (PoC)</p>	<p>HLX10 – Non-squamous Non-Small Cell Lung Cancer (nsNSCLC) 1L (Pivotal)</p> <p>HLX208 – metastatic Colorectal Cancer (mCRC) (PoC)</p>
 <p>New Phase 3</p>		HLX10 – metastatic Colorectal Cancer (mCRC) 1L	<p>HLX22 – Gastric & Gastroesophageal junction cancer (GC&GEJ) 1L</p> <p>HLX301 – Non-Small Cell Lung Cancer (NSCLC) 1L</p>

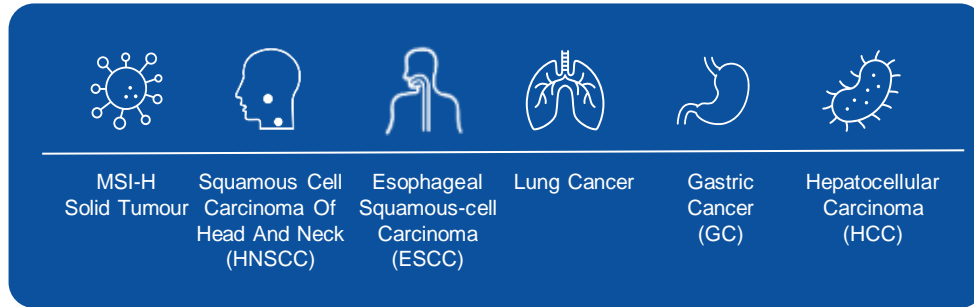
Serplulimab: Clinical Trials on Major Oncology Indications

Serplulimab approved for 10+ clinical trial projects in China, the US, the EU, etc.



Serplulimab Global Layout: Clear Registration Plan on BLA in the US and MAA in the EU

Visionary Global Layout

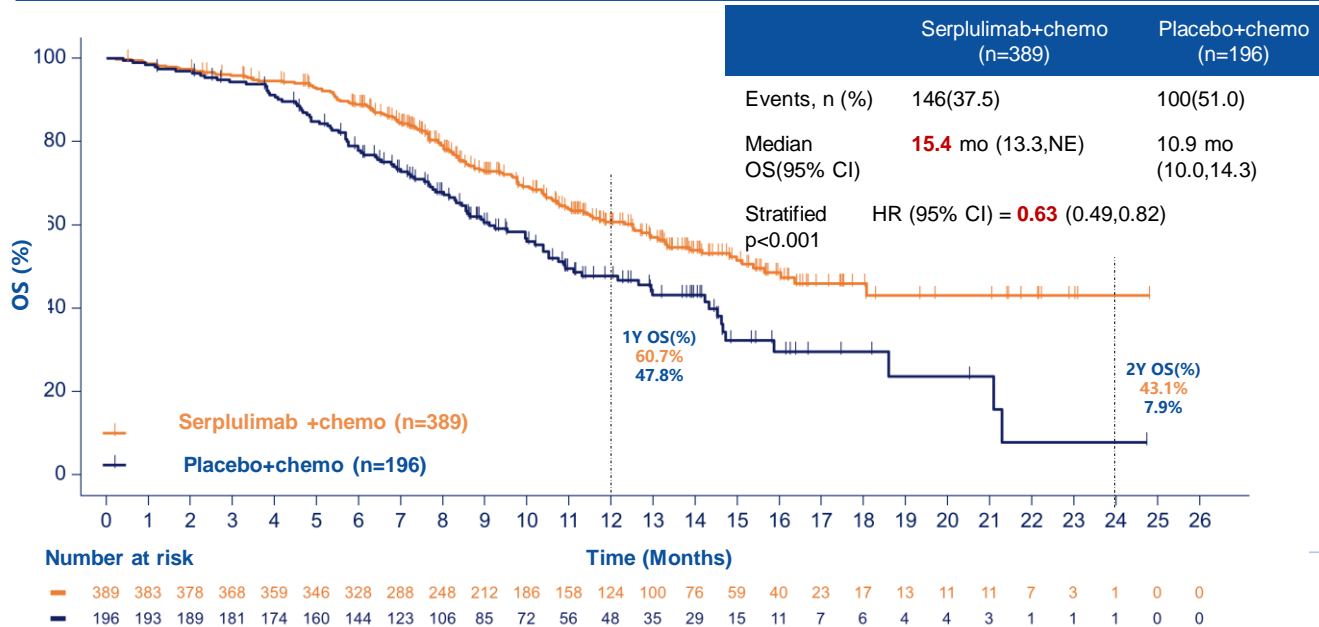


- Actively filling the gap in **1L SCLC** in the **next 5 years**.
- Based on the positive feedback received from FDA on March 2, 2022 regarding our ES-SCLC submission, and the results of the **FDA Type C Meeting** held on July 12, 2022, Henlius is planning to recruit 100 pairs of patients in the US for the bridging study. Expect to **submit BLA to FDA by the end of 2023**.
- After receiving positive feedback from the EMA Scientific Advice Working Party on Serplulimab ES-SCLC indication treatment on May 19, 2022, we expect to **submit MAA to EMA in 1Q23**.
- Reached a license-out agreement with KG Bio to develop, manufacture and commercialise Serplulimab in 10 Southeast Asian countries.



Serplulimab: Presented Orally at ASCO, Shows Extraordinary Clinical Data for 1L ES-SCLC

ASCO data cut-off: 2021-10-22



2022 ASCO ANNUAL MEETING

ASTRUM-005

Serplulimab, A Novel Anti-PD-1 Antibody, Plus Chemotherapy versus Chemotherapy as First-Line Treatment for Extensive-Stage Small-Cell Lung Cancer: An International Randomized Phase 3 Study

Ying Cheng, MD

Jilin Cancer Hospital, Changchun, China

Ying Cheng¹, Liang Han², Lin Wu³, Jun Chen⁴, Hongmei Sun⁵, Guilan Wen⁶, Yinghua Ji⁷, Mikhail Dvorkin⁸, Jianhua Shi⁹, Zhijie Pan¹⁰, Jinsheng Shi¹¹, Xicheng Wang¹², Yuansong Bai¹³, Tamar Melkadze¹⁴, Yueyin Pan¹⁵, Xuhong Min¹⁶, Maksym Viguro¹⁷, Wenying Kang¹⁸, Qingyu Wang¹⁸, Jun Zhu¹⁸, ASTRUM-005 Investigators;

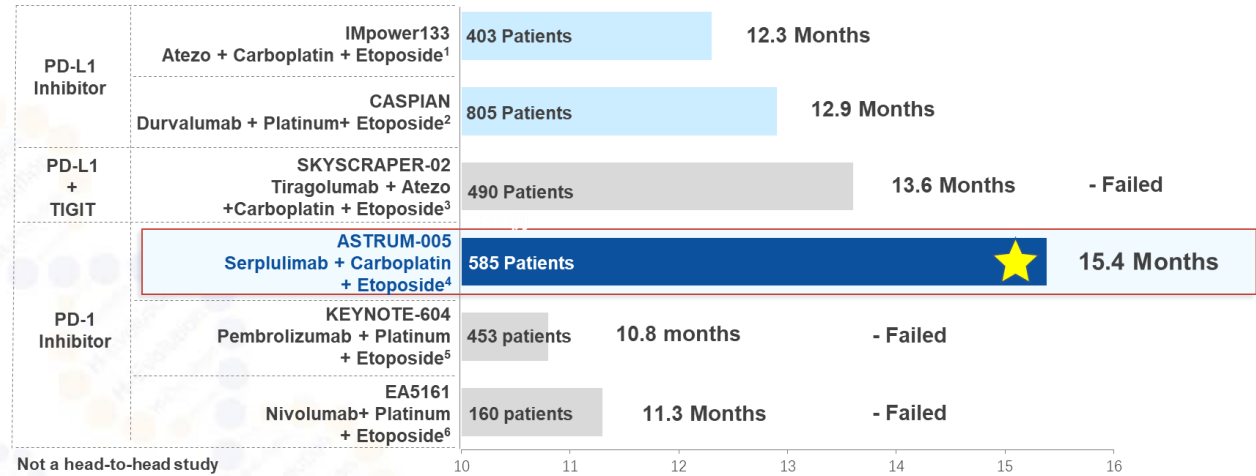
¹Jilin Cancer Hospital, Changchun, China; ²Xuzhou Central Hospital, Xuzhou, China; ³Hunan Cancer Hospital, Changsha, China; ⁴Tianjin Medical University General Hospital, Tianjin, China; ⁵Jiamusi Cancer Hospital, Jiamusi, China; ⁶The First Affiliated Hospital of Nanchang University, Nanchang, China; ⁷The First Affiliated Hospital of Xinxiang Medical University, Xinxiang, China; ⁸Budgetary Healthcare Institution of Omsk Region "Clinical Oncology Dispensary", Omsk, Russia; ⁹Linyi Cancer Hospital, Linyi, China; ¹⁰The First Affiliated Hospital of Zhejiang University School of Medicine, Hangzhou, China; ¹¹Cangzhou People's Hospital, Cangzhou, China; ¹²The First Affiliated Hospital of Guangdong Pharmaceutical University, Guangzhou, China; ¹³China-Japan Union Hospital of Jilin University, Changchun, China; ¹⁴Acad.Fridon Todua Medical Center, Research Institute of Clinical Medicine, Tbilisi, Georgia; ¹⁵Anhui Provincial Hospital, Hefei, China; ¹⁶Anhui Chest Hospital, Hefei, China; ¹⁷Medical Center "Mriya Med-Service", Kryvyi Rih, Ukraine; ¹⁸Shanghai Henlius Biotech, Inc., Shanghai, China

2022 ASCO ANNUAL MEETING #ASCO22

PRESENTED BY Ying Cheng, MD

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ASCO AMERICAN SOCIETY OF CLINICAL ONCOLOGY KNOWLEDGE CONQUERS CANCER



- Serplulimab combo with chemotherapy showed **consistent benefits** in OS, PFS, ORR and DOR. Long-term efficacy benefits were also observed;
 - mOS: 15.4 vs 10.9 months, HR=0.63, p <0.001**
 - mPFS: 5.7 vs 4.3 months, HR=0.48**
- Serplulimab plus chemotherapy showed a manageable safety profile; no new safety signals were observed during the study
- The **Orphan-Drug Designation (ODD)** of serplulimab in SCLC has been granted by FDA.

1. Horn L, et al. N Engl J Med. 2018 Dec 6;379(23):2220-2229. 2. Paz-Ares L, et al. 2020 ASCO Abstract 9002. 3. Charles M, Rudin 2022 ASCO 4. Ying Cheng. 2022 ASCO. 5. Rudin CM, et al. J Clin Oncol. 2020 Jul 20;38(21):2369-2379. 6. Leal TA, et al. 2020 ASCO Abstract 9000.



Serplulimab: Better mOS and HR Results

data cut-off: 2021-10-22

Phase 3 Trial Name	IMpower133		CASPIAN		KEYNOTE 604		ASTRUM-005	
Company	Roche		AstraZeneca		Merck & Co		Henlius	
Investigational drug	Atezolizumab		Durvalumab		Pembrolizumab		Serplulimab	
Study design	Randomized Double Blind 2-arm Co-Primary Points: OS and PFS		Open Label 3-arm Single End Point: OS		Randomized Double Blind 2-arm Co-Primary Points: OS and PFS		Randomized Double Blind 2-arm Single End Point: OS	
Regimen	Atezolizumab +Carboplatin +Etoposide	Placebo +Carboplatin +Etoposide	Durvalumab+ Platinum +Etoposide	Platinum +Etoposide	Pembrolizumab+Platinum +Etoposide	Placebo+ Platinum +Etoposide	Serplulimab+ Carboplatin +Etoposide	Placebo +Carboplatin +Etoposide
Number of enrolled patients	201	202	268	269	228	225	389	196
ecog 0/1(%)	35/65		36.9/63.1		26/74		18.3/81.7	
mOS (months)	12.3 vs 10.3 HR =0.76 (0.60–0.95) P=0.0154		12.9 vs 10.5 HR=0.75(0.62-0.91) P=0.0032		10.8 vs 9.7 HR=0.80(0.64-0.98) P=0.0164		15.4 vs 10.9 HR=0.63 (0.49-0.82) P<0.001	
Median follow-up (months)	13.9		14.2		21.6		12.3	
2 Year OS rate	<25%		22.9%		/		43.1%	
mPFS (months)	5.2 vs 4.3 HR=0.77(0.62~0.96) P=0.017		5.1 vs 5.4 HR=0.78 (0.65~0.94)		4.5 vs 4.3 HR=0.75(0.61~0.91) P=0.0023		5.7 vs 4.3 HR=0.48 (0.38-0.59) P < 0.001	
ORR	60.2% vs 64.4%		67% vs 58%		71% vs 62%		80.2% vs 70.4%	
DOR (months)	4.2 vs 3.9		5.1 vs 5.1		4.2vs 3.7		5.6 vs 3.2	

Advancement of Clinical Pipeline (Ph 2/Ph 3)

HLX07

(EGFR)

- A recombinant **humanised** anti-EGFR monoclonal antibody, with a **LONGER half-life** compared with Cetuximab
- Showed higher safety and antitumour activity in phase 2 clinical trial. The ORR confirmed by IRRC and INV was 38.5%, better than the historical data of 23% (Pembrolizumab)

HLX208

(BRAF
V600E)

- Has strong oral bioavailability and safety profile. Expected to be the world's **first BRAF inhibitor** approved in adult LCH indication treatment
- Now in phase 2. Expected to be the **first BRAF inhibitor** to be combined with immunotherapy in China

HLX22

(HER2)

- Targeting distinct epitopes within **domain IV** of Her2. PDx data demonstrates the combo of HLX22 and Trastuzumab (also target epitope domain IV) excels the combo of Trastuzumab and Pertuzumab in GC
- Shows big potential for upgrading SoC of 1L metastatic GC/GJC treatment, with a predicted ORR of 85+%, based on current phase 2 data (unblind in Oct.)

HLX04-O

(VEGF)

- Showed significant BCVA improvement in phase 1/2 trial and high success rate in phase 3 trial
- Expected to become the **first batch** of domestic ophthalmic mAb to go overseas, through two head-to-head controlled phase 3 trials with LUCENTIS conducted in China and worldwide

HLX22: Great Efficacy in Ph 2 Clinical Trial

A candidate of 1L HER2+ gastric cancer treatment with great potential

1. HLX22 emerges as a strong candidate with an expected ORR of 85% in HER2+ locally advanced/metastatic GC, based on the efficacy data from a double-blind, randomized, multi-centre Ph 2 study. The subsequent study will continue exploring the synergistic efficacy of HLX22 and Serplulimab
2. A global pivotal study for HLX22 in treatment of HER2+ GC 1L is planned in 2023
3. Enhertu has yet to initiate Ph 2/3 study in 1L GC. It was approved by FDA for the treatment of patients with HER2+ locally advanced or metastatic GC who have received a prior anti-HER2-based regimen(DESTINY-Gastric01) with ORR at 51% vs. 14% (Enhertu 125pts vs. Chemo 62pts)

Clinical Trial	Regimen	Sample Size	Primary Endpoint	ORR
HLX22	HLX22-GC-201 Ph 2 HLX22(25mg/kg)+Trastuzumab+XELOX vs HLX22(15mg/kg)+Trastuzumab+XELOX vs Trastuzumab+XELOX	54+128	PFS/ORR	INV : • HLX22 15mg cORR 100%(2/2) • Blind data cORR 77.3% (17/22) Predicted unblind ORR of HLX22 cohorts reaches 85+%
Pembrolizumab	KN811 Ph 3 Pembrolizumab + Trastuzumab + CF/XELOX vs Trastuzumab + CF/XELOX	732 (1:1) Efficacy based on first 264 pts	PFS/OS	IRRC cORR: 74.4% vs 51.7% (N= 133 vs 131) P = 0.00006
ZW25	NCT04276439 Ph 2 Tislelizumab+ZW25+Chemo	33	ORR	INV: cORR 75.8%
SOC	ToGA Ph 3 Trastuzumab+CF/CX vs CF/CX	584 (1:1)	OS	47.3% vs 34.5% P = 0.0017

HLX07 (EGFR Inhibitor): Ongoing Clinical Trials

Indications	Strategic Significance	Stage
<ul style="list-style-type: none"> HLX07-FIH Solid tumour (ST) HLX07-002 Solid tumour (ST) 	<ul style="list-style-type: none"> Phase 1 dose escalation, 19 patients enrolled, no DLTs, ORR 5.3%, mPFS 1.87m. HLX07-002 56 patients enrolled, no DLTs, ORR 16.1%. 	<ul style="list-style-type: none"> Ph 1 Ph 1b/2
<ul style="list-style-type: none"> Head and neck squamous-cell cancer (HNSCC) combined with serplulimab 1L 2L 	<ul style="list-style-type: none"> 13 patients enrolled, IRRC-ORR 38.5%, INV-ORR 38.5%, INV-mPFS 5.45 mo, INV-6-mo PFS rate 34.6%. 	Ph 2
<ul style="list-style-type: none"> Squamous non-small-cell lung cancer (sqNSCLC) combined with serplulimab+ CT 1L 	<ul style="list-style-type: none"> 14 patients enrolled, no DLTs. 	Ph 2
<ul style="list-style-type: none"> Cutaneous squamous cell carcinoma (CSCC) mono 1L 2L 3L 	<ul style="list-style-type: none"> Expected to be approved for rare diseases and become the first anti-EGFR monoclonal antibody for the treatment of CSCC in China. 	Ph 2
<ul style="list-style-type: none"> Nonsquamous non-small-cell lung cancer (nsqNSCLC) combined with CT 2L, mono 3L 	<ul style="list-style-type: none"> In the first tier for the indication of lung adenocarcinoma (EGFR H score\geq200). 	Ph 2
<ul style="list-style-type: none"> Gastric cancer (GC) combined with serplulimab + CT 1L, mono 3L 	<ul style="list-style-type: none"> Expected to be the first anti-EGFR monoclonal antibody for the treatment of HER2-negative gastric cancer. 	Ph 2
<ul style="list-style-type: none"> Esophageal squamous cell carcinoma (ESCC) combined with serplulimab + CT 1L, mono 3L Small-cell lung cancer (SCLC) combined with serplulimab + CT 1L Metastatic colorectal cancer (mCRC) combined with serplulimab + CT 1L, mono 3L Hepatocellular carcinoma (HCC) combined with serplulimab + HLX04 (VEGF) 1L; combined with CT 2L, mono 3L 	<ul style="list-style-type: none"> Potentially fill the unmet clinical needs of cetuximab treatment and explore the application of combined with immunotherapy. A variety of animal models have shown the synergistic antitumour effect in EGFR inhibitor combined with PD-1 inhibitor. Worth further exploring the efficacy in tumours with high expression of EGFR and potential indications for phase 3 clinical studies. 	Ph 2

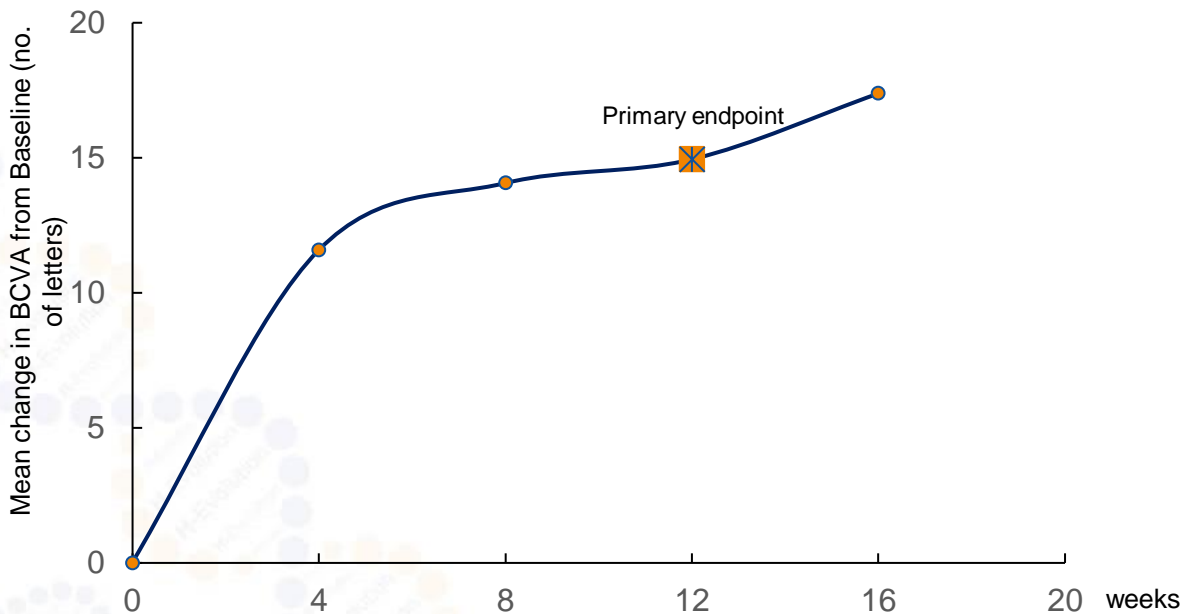
HLX208 (BRAF V600E Inhibitor): Ongoing Clinical Trials

Indications	Strategic Significance	Stage
<ul style="list-style-type: none"> • Solid tumour - NeuPharma 	<ul style="list-style-type: none"> • Phase 1 dose escalation with primary efficacy achieved • 26 subjects evaluable, 20 cases achieved SD, DCR 77%, 13 (50%) cases see SOD decrease 	Ph 1
<ul style="list-style-type: none"> • Non-Small Cell Lung Cancer (NSCLC) 	<ul style="list-style-type: none"> • Fast to Market Scheme • Expected to be the second approved domestic BRAF inhibitor in lung cancer treatment 	Ph 2
<ul style="list-style-type: none"> • Langerhans cell histiocytosis (LCH) and Erdheim-Chester Disease (ECD) 	<ul style="list-style-type: none"> • Fast to Market Scheme • Expected to be the only approved BRAF product (LCH&ECD) in the medium and long term • Efficacy was evaluated as CMR and PMR in two patients (based on PERCIST) 	Ph 2
<ul style="list-style-type: none"> • Metastatic colorectal cancer (mCRC, Mono and Combo) 	<ul style="list-style-type: none"> • Quickly start the first-line Phase 3 clinical trial after getting the efficacy data of HLX208 • One of the strongest players in terms of development speed 	Ph 2
<ul style="list-style-type: none"> • Anaplastic Thyroid Cancer (ATC) 	<ul style="list-style-type: none"> • Expected to be the only approved BRAF inhibitor in the medium and long term (ATC) 	Ph 1b/2
<ul style="list-style-type: none"> • Melanoma (Mel) • Brain tumour (BT) • Other solid tumour 	<ul style="list-style-type: none"> • Explore the other potential indications 	Ph 2

HLX04-O: Ph 1/2 Showed Safety and Preliminary Efficacy

Clinical Trials	Ph 1	Ph 2	Ph 3
HLX04-O-wAMD-CN01	Ph 1/2, n=20, HLX04-O, primary endpoint: Mean change of BCVA at 12W.		
HLX04-O-wAMD-CN	Ph 3, n=388, HLX04-O/Lucentis, primary endpoint: Mean change of BCVA at 48W.		
HLX04-O-wAMD-Global	Ph 3, n=388 HLX04-O/Lucentis, primary endpoint: Mean change of BCVA at 36W.		

The mean changes from baseline in BCVA of HLX04-O
(HLX04-O-wAMD-CN01 cutoff date: July 7, 2022)



HLX04-O-wAMD-CN01: The results indicated the safety and preliminary efficacy of HLX04-O among patients with wet Age-related Macular Degeneration (wAMD).

The mean improvements of BCVA was 6.6 and 10.7 respectively in the two pivotal Phase 3 trials of Lucentis.

	Baseline	4W	8W	12W	16W
Pts Num.	20	19	17	18	13
Mean Change from Baseline	0.00	11.58	14.06	14.94	17.38
SD	/	13.56	13.14	11.49	14.99

Highlights of Early-Stage Clinical Assets (Ph 1/2)

HLX23 (CD73)

- With differentiated mechanism, no hook effect compared to previous CD73 inhibitors
- More significantly and persistently inhibit CD73 activity and induce CD73 internalisation

HLX53 (TIGIT)

- Strong immune regulating effects in TME
- HLX53 combo with Serplulimab was observed significantly superior to Tiragolumab combo with Atezolizumab

HLX26 (LAG-3)

- Significant synergy in virous xenograft models (mCRC, NSCLC) in combination with anti-PD-1 antibody
- Good tolerability and safety profile

HLX60 (GARP)

- **Potentially a first-in-class innovative drug**
- **The first IND in China and the third globally**
- Single agent or combo with ICI showed good efficacy in different tumour model

HLX35 (EGFRx 4-1BB)

- **Potentially a first-in-class innovative drug** and the first IND globally
- Potent efficacy by simultaneously blocking EGFR signaling and activating T effector cells and NK cells, and is effective for EGFR antibody insensitive tumours

HLX301 (PD-L1 x TIGIT)

- Differentiated molecule design from other competitors
- Significantly superior to Tiragolumab combo with Atezolizumab in different animal models in cancer research

2.3

Early Stage R&D Strategies (Pre-clinical Phase)

R&D Goal: Antibody-centric approach with further innovation to be the backbone of innovative drug ecosystem

10
Years

2010-2020

Leader in biosimilars

Start with Biosimilars, entered innovative drugs:

- HLX01/ 02/ 03/ 04¹ and other biosimilars as an initial focus
- Innovative drugs (e.g. HLX10 (PD-1)) entered late clinical stage.

- **Antibody production with internationally recognised quality and reasonable cost**

Accomplished ✓

5
Years

2020-2025

Benchmark in innovative biologics

Focus on major cancer types, expand non-oncology, evolve new modalities:

- Capitalise fully on marketed and existing late-stage clinical assets (PD-1, HER2).
- Address unmet clinical needs with innovative antibody design with AXC, small antibodies and bispecific antibodies
- Develop new drug modalities such as nucleic acid and iPS cell therapy.

- **R&D system for innovative antibody drugs such as small antibodies and transmembrane antibodies**
- **AXC innovative technology platform**
- **New drug modalities, e.g. nucleic acid, iPS cell**
- **Rely on in-house R&D, complemented by external in-licensing and co-de**

Accelerating innovation

5
Years

2025-2030

Backbone of innovative drug ecosystem

Further Innovation with data-driven pharmaceuticals and diagnostics:

- **Medical data + Bioinformatics:** First-in-indication, or best-in-indication targets
- **Molecular engineering + Bio-computation:** Dynamic molecule design and combo development.
- **Precise diagnostics + Optimised therapy:** Highly precise and personalised medication solutions.

- **Discovery and validation of innovative targets**
- **Diversified platforms for drug development:** antibody, peptide, nucleic acid, cell, XXC, etc.
- **Pan-ecosystem collaboration:** universities, hospitals, research institutes, biopharma/biotechs, etc.
- **A powerful translational science platform**

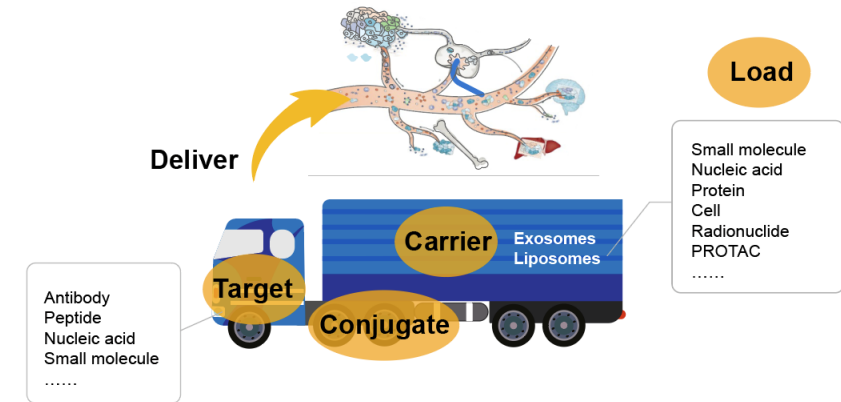
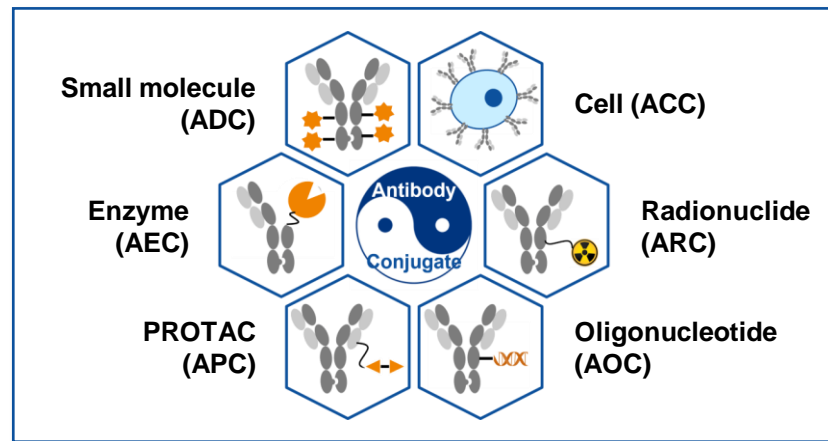
Key
Features

Core
Ability

R&D Strategy: Build up AXC Platform, Empower Further Innovation

Within 1 Year

1-3 Years



- Antibody-centric, Evolved Modality (AXC: Antibody X-molecule conjugate)
- **Expected IND:** 4-5 ADC and AXC products, including 2 potential first-in-class ADC products, which are expected to be submitted for an IND in June 2023
- Completed ADC pilot production workshop construction, will adopt Payload (with intellectual property rights) to develop ADC products
- **IND enabling stage:** 4 potential first-in-concept products will start IND enabling, as well as 6 potential differentiated innovative Best-in-class products
- Several products for non-oncology indications entered preclinical development stage

- Expand R&D of XXC products, focusing on developing targeted delivery and blood-brain barrier drugs coupled with exosomes;
- Further develop CAMD (Computation Accelerated Molecule Design) platform to improve molecular design and R&D capabilities
- Focus on nucleic acid drug design and development, iPS cell induction and differentiation technology
- Conduct translational medicine research, improve R&D efficiency through in-depth exploration of biological networks and biomarker discovery
- Accelerate the integration and differentiated innovation of China and US R&D centres, push forward talent recruitment schemes, and strengthen methods to introduce outside intelligence

Pre-Clinical Pipeline: Aim to Solve Unmet Medical Needs

HLX51 (mAb)

- Induces **OX40** clustering through tetravalent binding and exerts immune activation
- Exhibits dose-dependent tumour-killing effect in multiple tumour models
- Significant synergistic effect with PD1/PDL1 antibodies
- Significantly outperforms competing molecules, both single and in combination with PD1/PDL1 antibodies

HLXD6018 (mAb)

- Potential **first-in-class monoclonal antibody**
- Clear MOA, unique immune microenvironment modulation effect
- Exhibits good efficacy in a variety of tumour models both single and in combination with immune checkpoint inhibitors
- Can also develop indications of fibrotic diseases

HLXD42 (ADC)

- Potential **first-in-class ADC product**
- TME-dependent activation and release of payload
- Good tumour-killing effect against multiple EGFR inhibitor resistant or mutated solid tumours
- Excellent therapeutic window

HLXD72 (rPro)

- Pioneering **first-in-concept new drug**
- Unique MOA, can simultaneously inhibit inflammatory response and promote damage repair
- Exhibits good efficacy in a variety of inflammatory disease models
- Vast disease population, huge unmet clinical needs

HLXD43 (ADC)

- Potential **first-in-class ADC product**
- TME-dependent activation and release of payload
- Good tumour-killing effect against multiple PD1/PDL1 non-responding or resistant solid tumours
- Excellent therapeutic window

HLXD307 (rPro)

- Pioneering **first-in-concept new drug**
- Unique MOA, can simultaneously lower blood sugar and promote kidney damage repair
- Exhibits good efficacy in DKD models
- Vast disease population, huge unmet clinical needs

2.4

Biosimilar Milestones

Product Pipeline - Biosimilars

	Products	Targets	Indications	Pre-IND	IND	Phase 1	Phase 2	Phase 3	NDA	Launch	Business Partners	
Launched	HANLIKANG (rituximab) ⁽¹⁾	CD20	non-Hodgkin lymphoma, chronic lymphocytic leukemia and rheumatoid arthritis ⁽²⁾	[Progress bar]								FOSUN PHARMA 复星医药, FARMALIA, eurofarma, Abbott
	HANQUYOU (trastuzumab) ⁽³⁾	HER2	breast cancer, metastatic gastric cancer	The first Chinese mAb biosimilar approved both in China and the EU								accord, Cipla, Jacobson, mAbxience, eurofarma, Abbott
	HANDAYUAN (adalimumab) ⁽⁴⁾	TNF-α	rheumatoid arthritis, ankylosing spondylitis, plaque psoriasis, uveitis	[Progress bar]								万邦医药, FOSUN PHARMA 复星医药, Getz pharmz
	HANBEITAI (bevacizumab) ⁽⁵⁾	VEGF	metastatic colorectal cancer, non-squamous non-small cell lung cancer	[Progress bar]								eurofarma
Under Clinical Studies	HANBEITAI (bevacizumab)	VEGF	glioblastoma	[Progress bar]								eurofarma
	HLX11 (pertuzumab) ⁽⁶⁾	HER2	neoadjuvant treatment of breast cancer	[Progress bar]								Organon
	HLX14 (denosumab) ⁽⁷⁾	RANKL	osteoporosis	Global multi-centre clinical study								Organon
	HLX05 (cetuximab) ⁽⁸⁾	EGFR	metastatic colorectal cancer, squamous cell carcinoma of the head and neck	[Progress bar]								3ingze
	HLX12 (ramucirumab)	VEGFR2	gastric cancer, non-small cell lung cancer, metastatic colorectal cancer	[Progress bar]								
	HLX13 (ipilimumab)	CTLA-4	melanoma, renal cell carcinoma, metastatic colorectal cancer	[Progress bar]								
	HLX15 (daratumumab)	CD38	multiple myeloma	[Progress bar]								

(1) Approved by the NMPA in February 2019, being the first Chinese biosimilar.

(2) The only rituximab approved for the treatment of rheumatoid arthritis in China.

(3) Approved in nearly 30 countries, including China, the UK, Germany, France and Australia, trade name registered in Europe: Zerceptac®, trade name registered in Australia: Tuzucip® and Trastucip®.

(4) Approved by the NMPA in December 2020.

(5) Approved by the NMPA in November 2021.

(6) Global commercialisation rights excluding Chinese mainland, Hong Kong, Macao and Taiwan region granted to Organon.

(7) Global commercialisation rights excluding Chinese mainland, Hong Kong, Macao and Taiwan region granted to Organon. Clinical Trial Notification has been acknowledged by the Therapeutic Goods Administration in China and Australia.

(8) Commercialisation rights in China have been granted to Shanghai Jingze.

Globalisation: Out-Licensing in 100+ Countries / Regions

Out-licensed products:

- **7 biosimilars:** HANLIKANG, HANQUYOU, HANDAYUAN, HANBEITAI, HLX05, HLX11, HLX14
- **3 innovative biological drugs:** HANSIZHUANG, HLX04-O, HLX35 (EGFRx4-1BB)

Business Partners


The Evolution of Generics


复星医药





















1H22 Biosimilars license-out overseas:

Organon **US\$541M** (upfront US\$73M)

HLX11 (Pertuzumab), HLX14 (Denosumab)

Including US\$3M for the exclusive license option for HLX13 (Ipilimumab)

Global (ex-China)

Abbott **US\$4.4M** (upfront US\$3M)

HANLIKANG(Rituximab), HANQUYOU (Trastuzumab)

Brazil (semi-exclusive)

Eurofarma **US\$50.5M** (upfront US\$4.5M)

HANLIKANG (Rituximab), HANQUYOU (Trastuzumab), HANBEITAI (Bevacizumab)

16 Latin American countries including Brazil (semi-exclusive)

Getz Pharma **US\$8M** (upfront US\$0.5M)

HANDAYUAN (Adalimumab)

11 emerging markets in Asia, Africa and Europe

Sustainable cash flow from upfront fees, milestone payments and royalties ensure long-term organic growth

Blockbuster Out-licensing Deal

ORGANON

(NYSE: OGN)



MERCK

spinoff in June 2021



International footprint

Global **140+** markets



History **~100 years**

Founded in 1923



2021 Performance

Revenue **US\$6.3B**

Net profit **US\$1.5B**



Market Cap

~ US\$8.3B

HLX11 (Pertuzumab)

Ph 3 neoadjuvant treatment for breast cancer (BC)

HLX14 (Denosumab)

Ph 3 postmenopausal women with osteoporosis (OP)


- Up to a total of **US\$541M** in potential revenue
- Upfront payment of **US\$73M** (70+3)
- Granting of license:
 - ✓ Exclusive commercialisation of HLX11 & HLX14 in ex-China countries, covering mature markets such as the US, the EU and Japan, as well as a number of emerging markets
 - ✓ Option to negotiate an exclusive license for HLX13 (Ipilimumab) (US\$3M)



- **Biosimilar assets cash flow — the largest biosimilar deal in the past 5 years**
- **Industry recognition of Henlius' R&D and manufacturing capabilities**
- **Enhances Henlius' brand awareness in international markets**

A Leading Global Technology Platform for Biologics: Flexible and Efficient to FIH and Commercialisation

- **High throughout developability: selection of robust molecules**
- **Upstream**
 - Stable cell line with high titer
 - Proprietary cell culture media development
 - Intensified process
- **Downstream**
 - Superior bispecific antibody purification platform
 - Highly concentrated UF/DF process
 - Resin/filter sourcing fully localised, cost saving $\geq 50\%$
- **Drug product**
 - Liquid: high concentration & subcutaneous formulation
 - Drug product differentiation: combination product
 - Visible/subvisible particle characterisation and identification
- **Commercial process, product optimisation and characterisation**



State-of-art analytical technologies
Critical quality attribute dataset
Process and product control strategy

2.5

Manufacturing Capacity Breakthroughs

(Strengthen Market Leading Position in Manufacturing Technology & Quality)

Songjiang First Plant: 24,000L Additional Capacity Approved for HANQUYOU

Leading commercial manufacturing capacity

- Total manufacturing capability (SJ1&Xuhui): 48,000L
- Commercial GMP batches: 450+ (2019~)
- Manufacturing success rate: ≥98%
- Manufacturing and quality related employees: 878
- Production intensity: globally leading

Songjiang First Plant approved for commercial operation in May 2022

- Manufacturing capacity: 24,000L
- Commercial Production approval for HANQUYOU (Trastuzumab)
- Products manufactured for clinical trials in Europe: HLX04-O, HLX11, HLX14, etc

Consistent quality management with global GMP standards

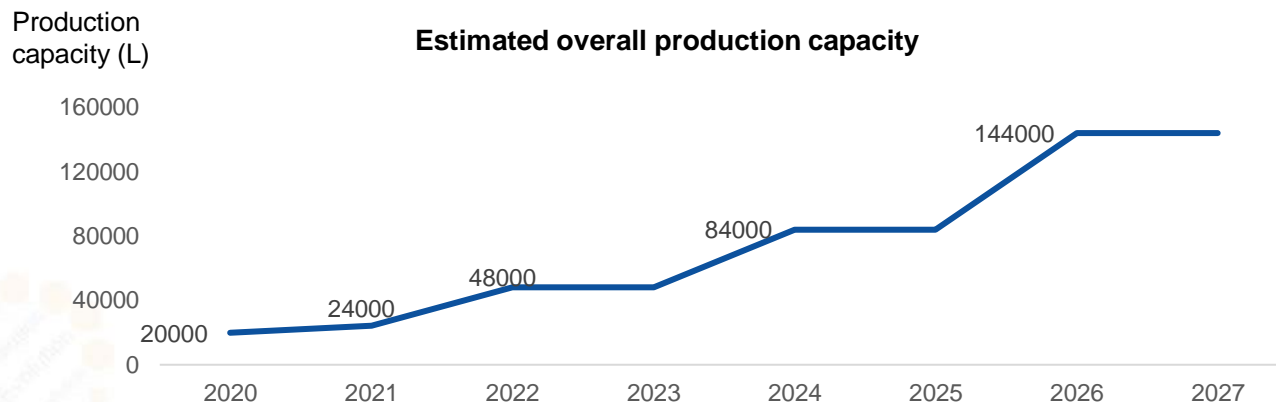
- GMP certified in China and the EU, conducive to be recognised by international audiences in different markets
- Constantly improve the quality management system through audits by clients and regulatory agencies
- Actively prepare for on-site inspections by FDA, EMA

Total Designed Capacity **144,000L**



Ensure high quality and sustainable manufacturing with global GMP standards

Production Capacity to Reach 144,000L by 2026



Xuhui

N: (5+1)*2 KL
S: (5+1)*2 KL



SJ(I)

(6*2KL)*2



SJ(II)

(6*2 KL)*3

4*15 KL



Technology upgrade and innovation

- Established new technology platform
- Expanded the cost advantages of commercial production with **15,000L** stainless steel bioreactor system
- Optimised process to increase efficiency



Production capacity & business improvement

- Accelerate **Songjiang Second Plant** construction to create global leading capacity advantage
- Reasonable layout of production capacity to achieve resource optimisation
- Expand CDMO business segment



Lean operations drive manufacturing efficiency and cost reduction

- Materials and consumables localisation
- Localised multi-source supply chain management
- Lean operation, annual revenue ≥10 million

Estimated Songjiang Second Plant phase 1 production capacity up to **96,000 L**

3

Financial Review & Outlook

Financial Highlights

	1H22 In million RMB	1H21 In million RMB	Growth YOY
Revenue	1,289.4	633.6	103.5%
Gross Profit	983.8	412.2	138.7%
Gross Margin	76.3%	65.1%	11.2%
Operating Expenses*	1,073.7	767.4	39.9%
Net Loss	(252.1)	(393.8)	36.0%
CAPEX	472.7	189.8	149.1%

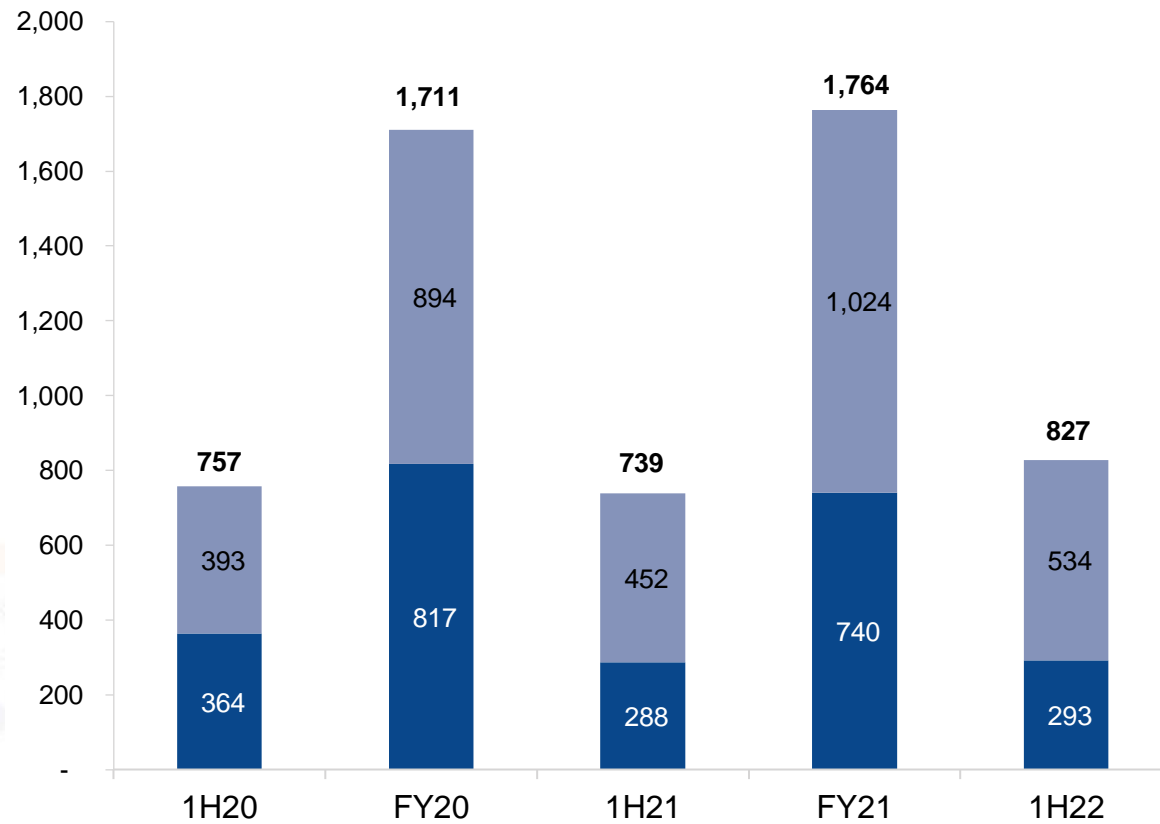
- **Rapid growth of total revenue:** mainly resulted from the increase of sales volumes of our core products HANLIKANG (rituximab) and HANQUYOU (trastuzumab), and the launch of HANSIZHUANG (serplulimab), as well as growing upfront payments from license-out deals
- **Gross profit outgrows revenue, leading to the increase in gross margin:** production efficiency improved as production transferred to our new plant, achieving economies of scale while reducing production costs
- **Net loss narrows down:** efficient management led to income growth and cost reduction

* Note: Operating expenses include selling and distribution expenses, research and development expenses, and administrative expenses.

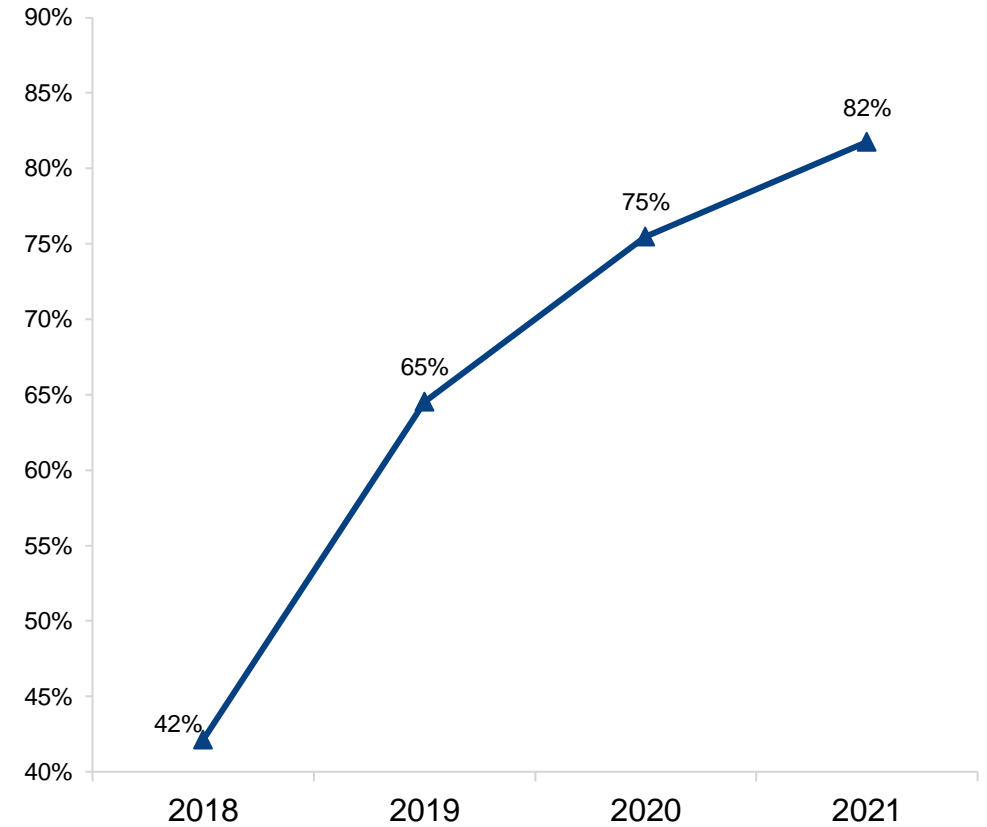
1H22 R&D: Invest in Innovative Drugs and Improve Efficiency

R&D Expenditure (in million RMB)

■ Capitalised ■ Expensed



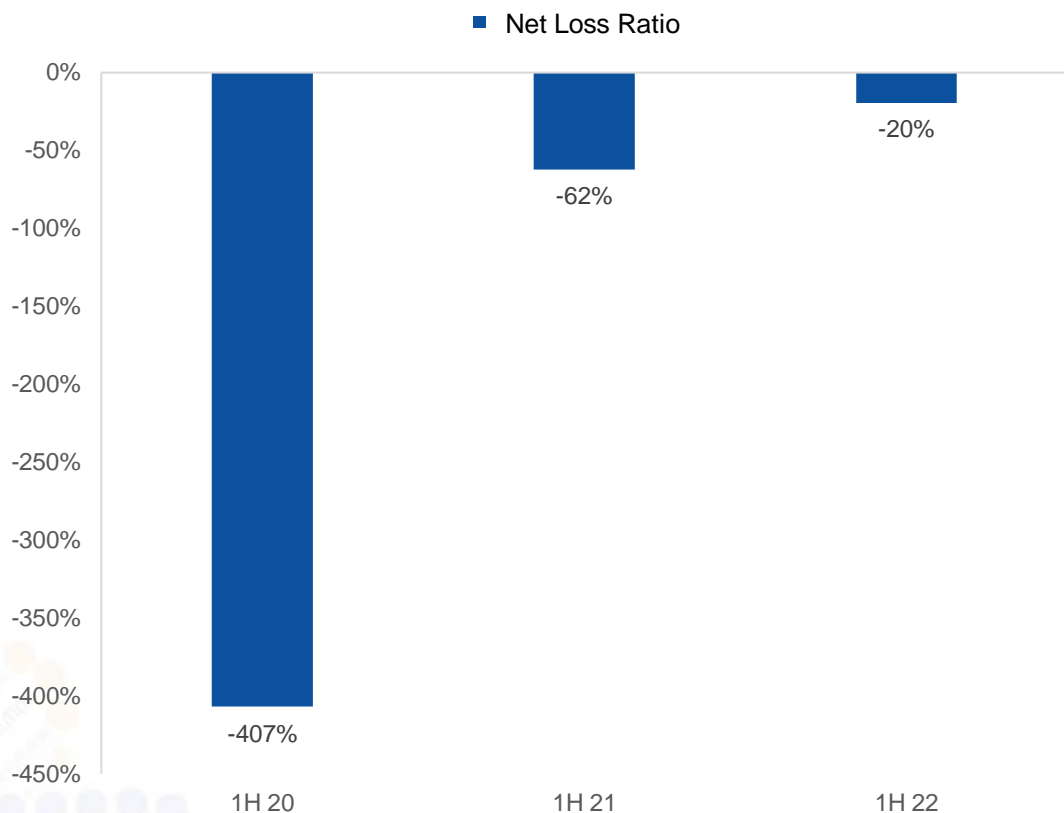
Ratio of Innovative Biological Drugs Expenses



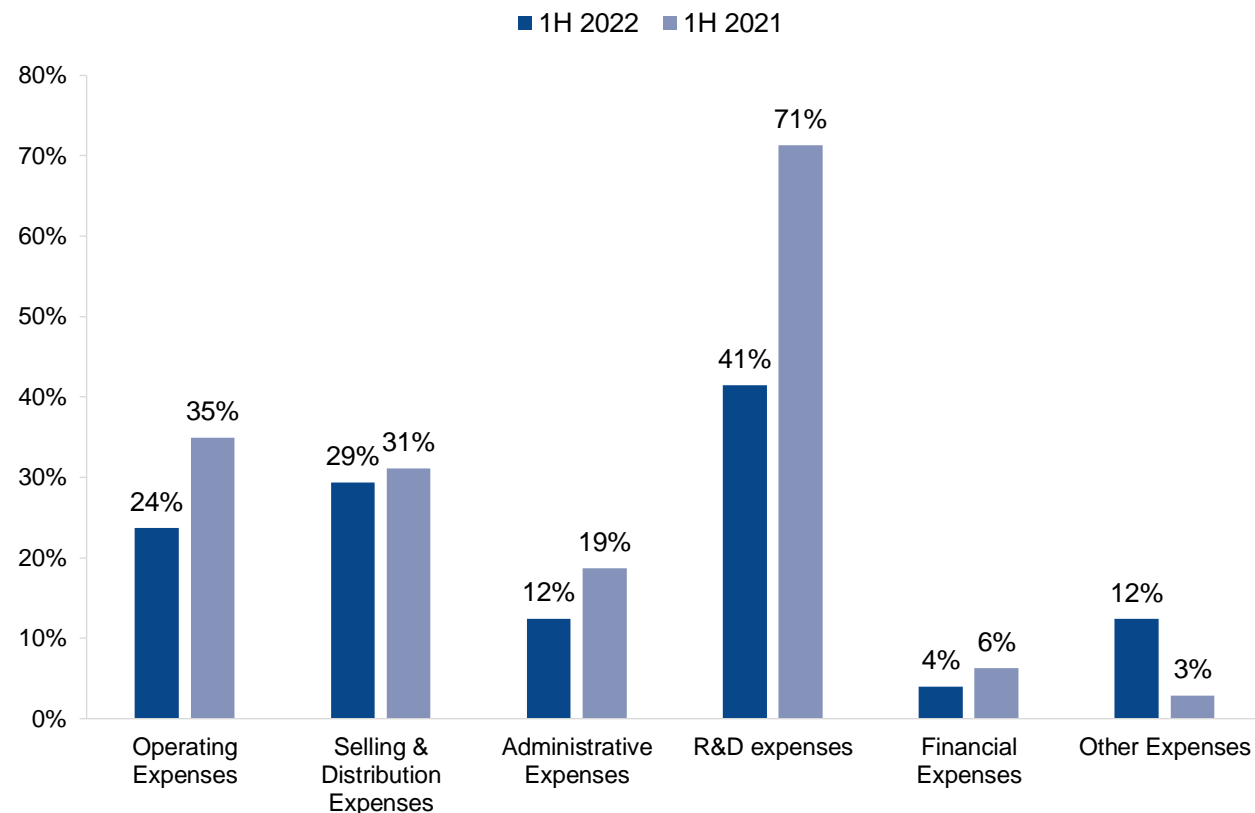
Note: Internal Data

1H22 Profitability: Net Loss Ratio & Expense Ratio Decreased

The Ratio of Loss to Total Revenue Narrowed Down



The Ratios of Expense to Total Revenue Decreased



- **Losses gradually narrowed and the ratio of loss to total revenue decreased significantly:** net loss in 1H22 decreased by RMB 141.7 million to RMB 252.1 million compared with that of 1H21. As revenues rose sharply, the net loss ratio in 1H22 dropped significantly to only 20%.

2H22 Top Priorities for Henlius



Registration, R&D and BD

- Well prepared for FDA BLA submissions of HLX02 and HLX10 in 2023
- Global positioning: accelerate clinical trial progresses of HLX10, HLX208, HLX07, HLX22, HLX11/14, HLX04-O across the globe
- Efficient/differentiated early-stage R&D strategy including ADC, multi-specific antibody, and bispecific antibody
- Further optimise R&D strategy, continuously improve mechanisms and capabilities
- BD: Actively seeking license-in to improve company portfolio, keeping up with license-out for global deployment in the meantime



Manufacturing, Quality and Technical

Speed up SJ2 Construction; Optimise the efficiency of Xuhui&SJ1

- Speed up SJ2 construction progress to ensure entering commercial production phase in 2024
- Further apply lean management method to maximise the capacity of SJ1
- Optimise overall arrangement of production capacity to improve capital return
- Promote the development of next-generation technology to improve efficiency
- Promote local sourcing of key materials



Commercialisation

HANQUYOU becomes a market leader HANSIZHUANG exceeds the targets

- HANQUYOU:
 - Leads the market in HER2 + BC
 - Gains full market access for different specifications (150mg/60mg)
- HANSIZHUANG:
 - Plans ahead for 2023 to become a top-tier player of IO
 - Aims to become China's SCLC market leader in 2023

Rapidly Evolving from *Biotech* to *Biopharma*...

2H22 Performance Guidance

声明

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Henlius

Reliable Quality
Affordable Innovation

