

Henlius (2696.HK)

2021 Annual Results Investor Presentation

March 2022

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R&D



Manufacturing



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01

Company Overview & Strategy

Company Mission & Key Milestones

Mission:
Affordable Innovation, Reliable Quality

	Products Domestically Launched Currently* / This Year	4/5
	Products Internationally Launched Currently*	1
	NDA's Under Review*	2
	Phase III Trials*	5
	Commercial Capacity Currently* / This Year	24,000L /48,000L

2022H1

2022Q2

2022.02

2021.11

2021.09

2021.04

2020.12

2020.08

2020.07

2019.02

Songjiang First Plant Capacity of 24,000L Expected to be in Commercial Operation

HLX10 (PD-1 mAb, serplulimab) MSI-H Solid Tumor Indication Expected to be Approved

HLX01 (rituximab, HANLIKANG) Innovative Indication for the Treatment of Rheumatoid Arthritis (RA) Approved

HLX04 (bevacizumab, HANBEITAI) Launched

HLX10 (PD-1 mAb, serplulimab) sq-NSCLC Indication NDA Accepted by NMPA

HLX10 (PD-1 mAb, serplulimab) MSI-H Solid Tumor Indication NDA Accepted by NMPA and Proposed to be Granted Priority Review

HLX03 (adalimumab, HANDAYUAN) Launched

HLX02 (trastuzumab, HANQUYOU) Approved in China

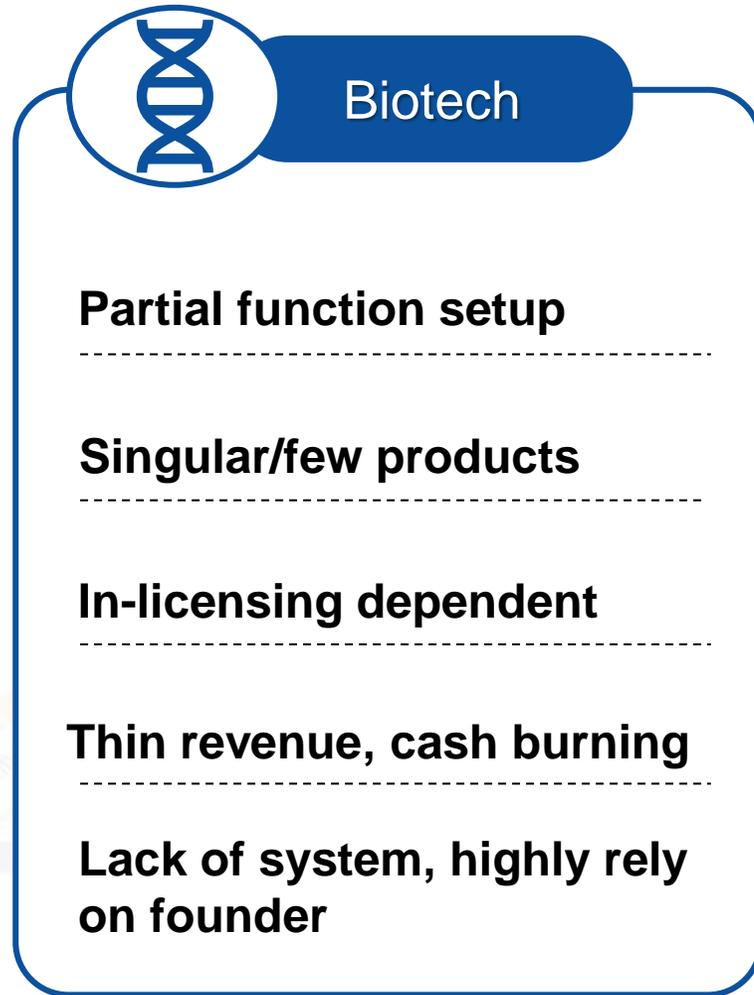
HLX02 (trastuzumab, Zercepac®) Approved in the EU

HLX01 (rituximab, HANLIKANG) Launched

* Note: as of the Latest Practicable Date

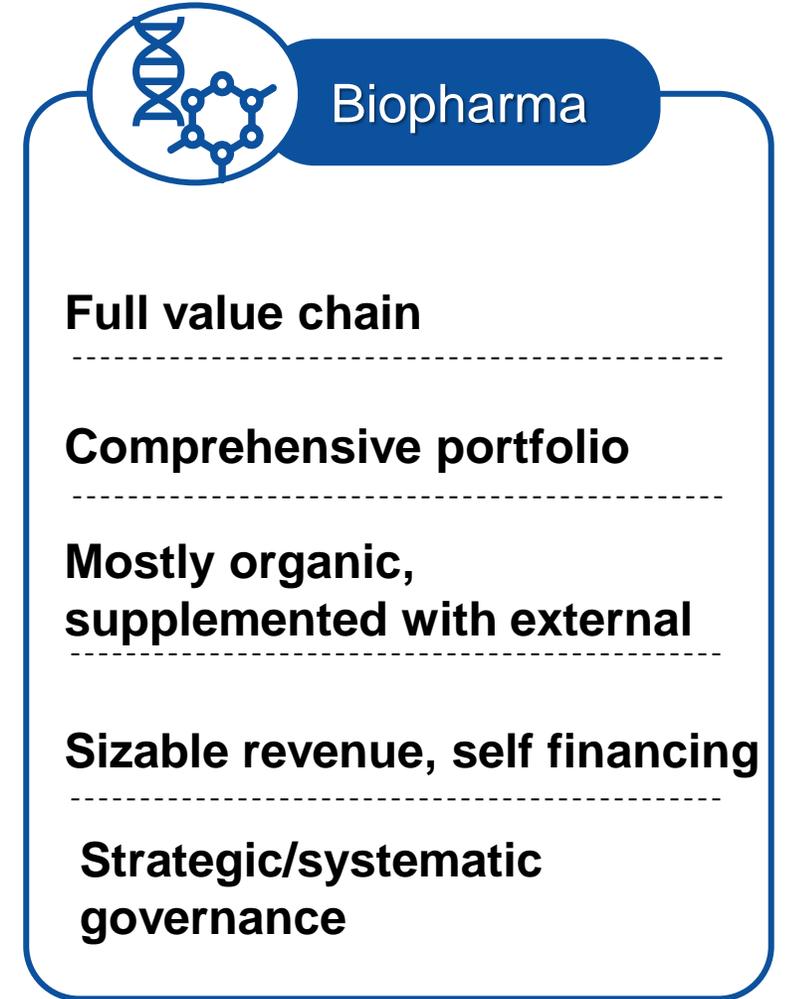
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H-evolution: From Biotech to Biopharma, Operational Enhancement

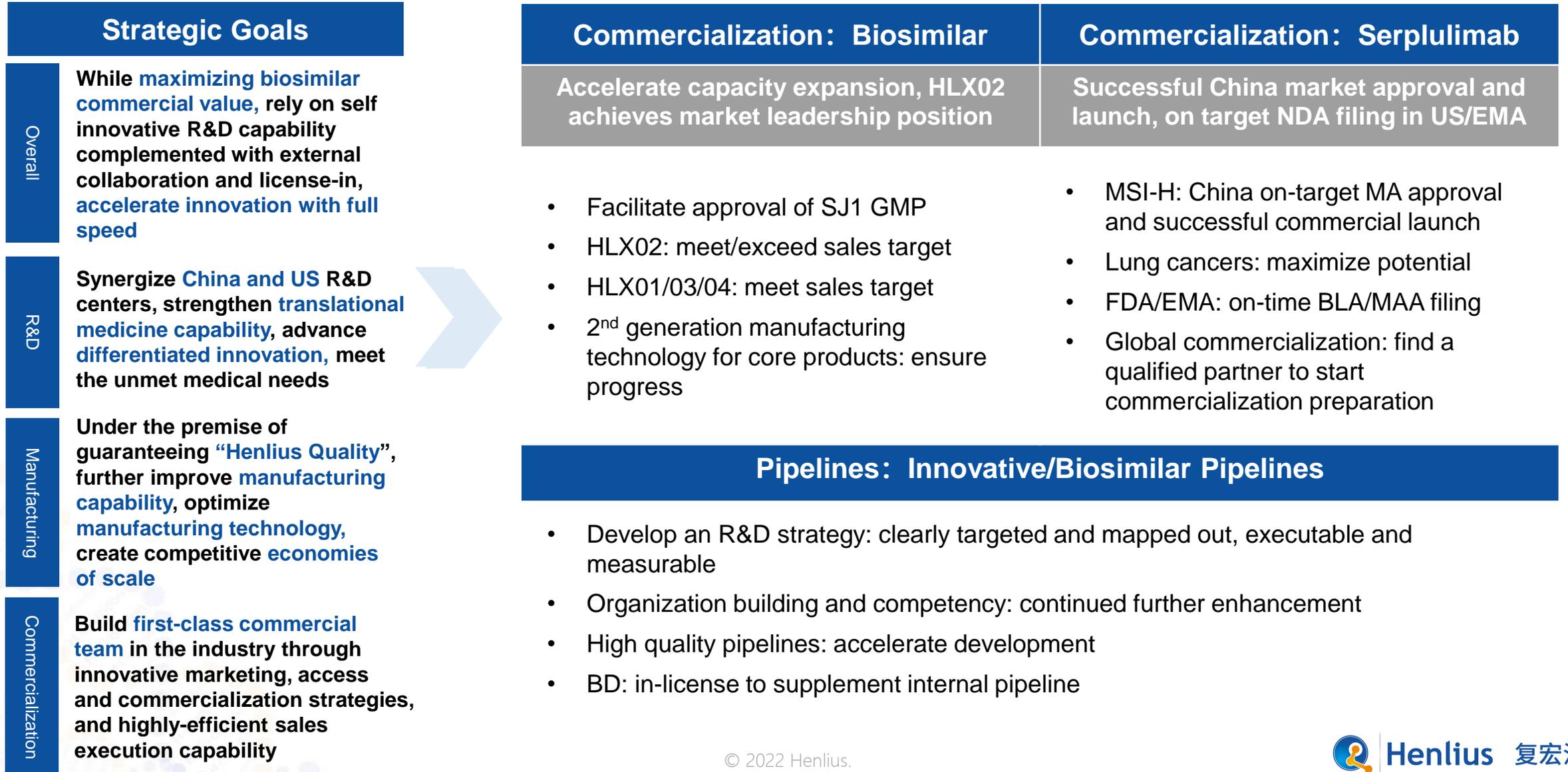


H-evolution 

The central text 'H-evolution' is in white on a dark blue rectangular background. To its right is a blue icon consisting of three parallel chevrons pointing to the right.



Strategy: Maximize Biosimilar Commercial Value, Accelerate Diversified Innovation with Full Speed



02

Organization Capability

A Fully-Integrated Platform



Global R&D, RA, Clinical Development & Operation Platform



- Continuing its momentum for a diversified innovation by enhancing internal innovation capacities and reaching out to more strategic partners;
- Global regulatory filing capabilities with 4 products launched successfully and over 70 clinical approvals obtained worldwide;
- Comprehensive Good Clinical Practice quality management system passing GCP on-site inspections conducted by the NMPA and EMA



Commercial-scale Manufacturing Facilities



- Manufacturing facility scaling up:
 - Xuhui Manufacturing Facility*
 - Songjiang Manufacturing Facility (First Plant)*
 - Songjiang Manufacturing Facility (Second Plant);*
- Site and quality management system certificated by China and the EU GMP and covering the entire product life cycle;
- Pioneering in advanced technologies:
 - Single-use/Stainless steel technology*
 - Continuous manufacturing technology*

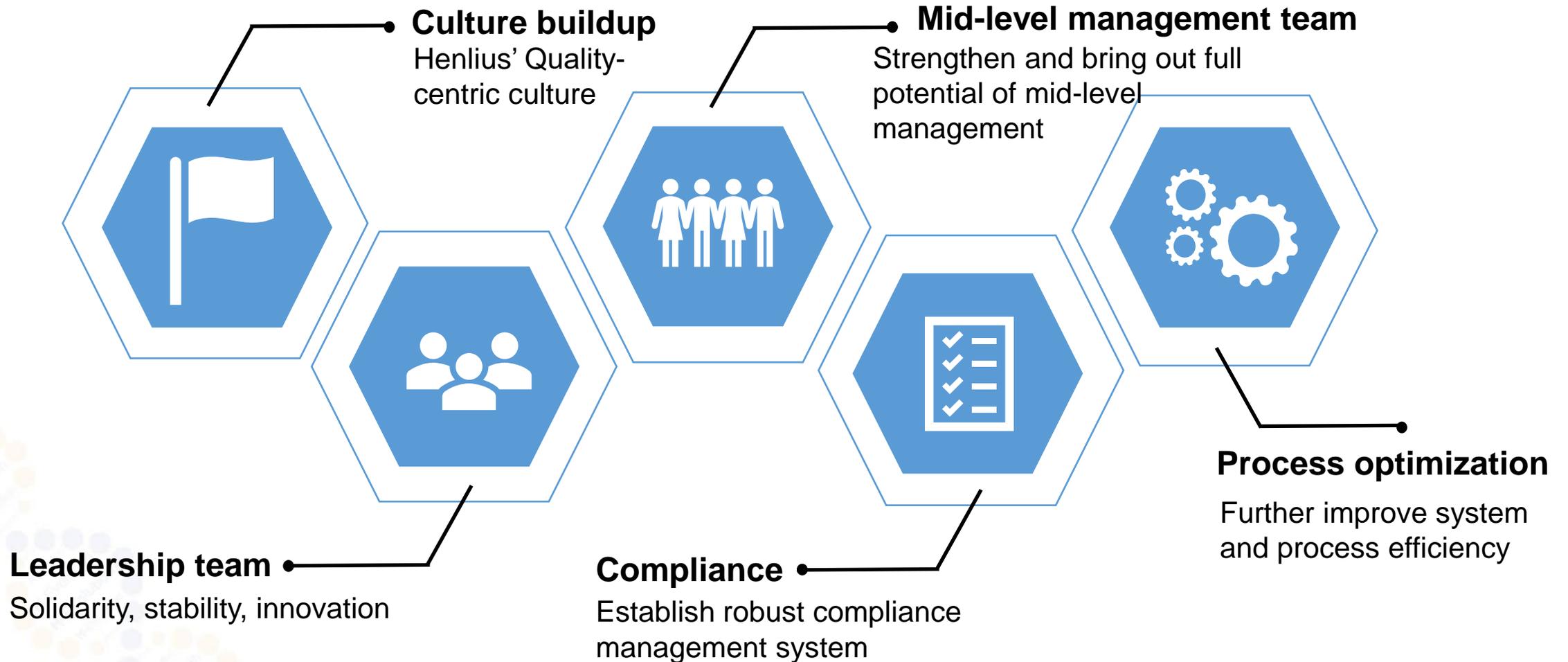


Global Commercial Platform



- Building top in-house commercial team in the industry through the implementation of innovative marketing, access and commercialisation strategies and the execution of highly-efficient sales
- Concluding partnerships with reputable global pharmaceutical companies and expanding presence in major and emerging markets

All-Round Improvement, Casting Henlius-Quality



Management Team: Solidarity, Stability, Innovation



Wenjie Zhang

Chairman

Executive Director and CEO

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



Jason Zhu
President



Wei Huang
Chief Operation Officer
SVP



James Guo
SVP



Jean-Michel Gries
President of Hengenix
Biotech



Gino Li
Chief Financial Officer
VP



Kurt Yu
Chief Commercial Officer
VP



Ping Cao
VP of Business
Development



Timothy Maguire
VP of Business
Development



Wallis Zeng
VP of Oncology
Business Unit



Ming Yang
GM of Immune-Oncology
Business Unit



James Liu
VP of Legal and
Compliance



Yongqiang Shan
GM of Shanghai
Innovation Center



Arthur Sheng
GM of Global Strategy &
PMO



Jim Hua
GM of Finance &
Procurement

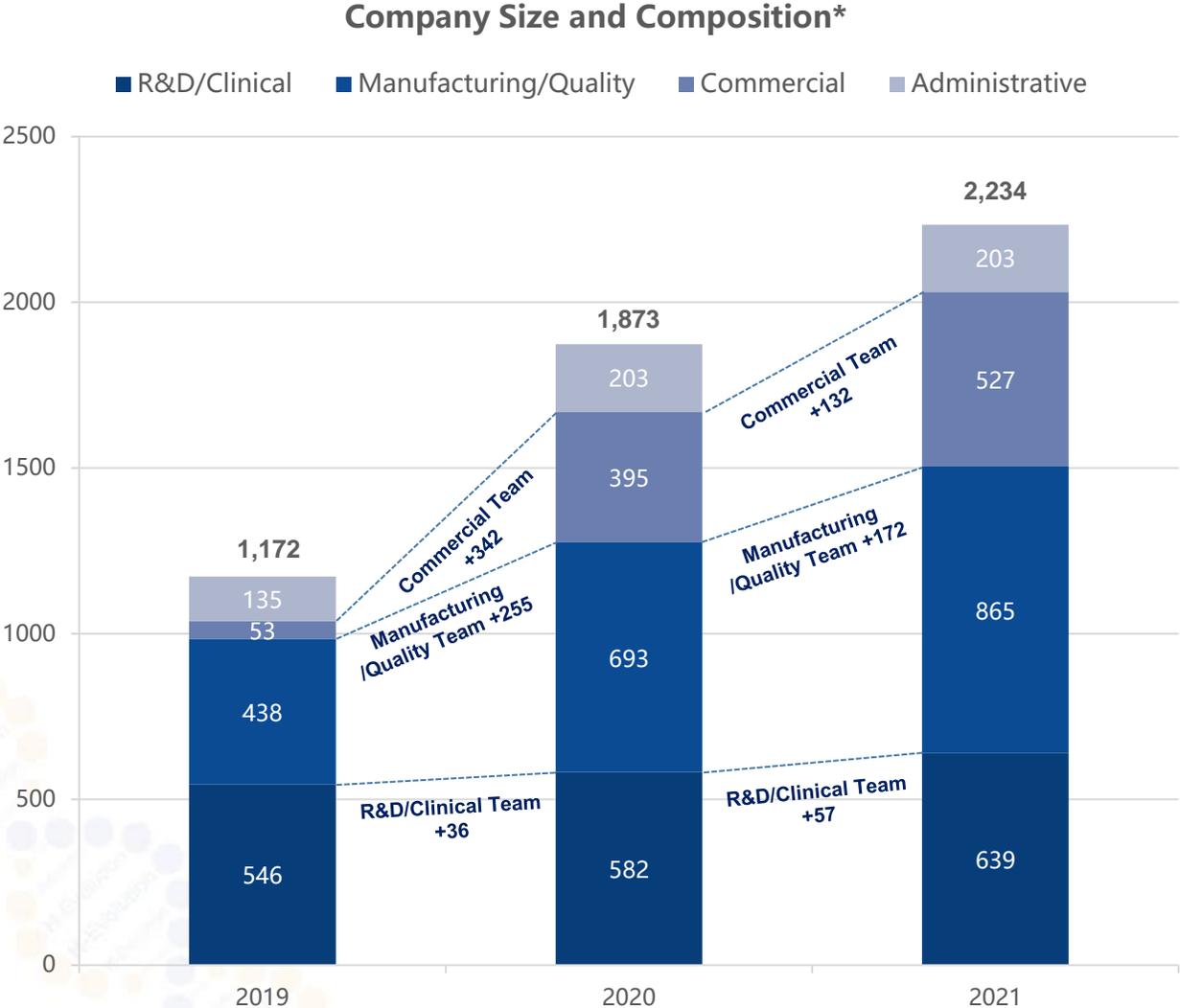


Jasmin Wang
Deputy GM of Quality



Nancy Wang
Board Secretary

Company Size: the Number of Employees Rapidly Grew



R&D	335
Clinical	304
Manufacturing	610
Quality	255
Commercial	527
Administrative	203



Commercial Team



R&D/Clinical Team

* Note: as of December 31, 2021

3.1

R&D



Leader in China Biopharmaceutical Industry

4

Products launched in China



First Chinese biosimilar
HANLIKANG® (rituximab)



First Chinese mAb biosimilar approved in China and the EU
HANQUYOU® (trastuzumab, Zercepac® in the EU)



First China-developed adalimumab biosimilar manufactured in a China and EU GMP-certified manufacturing site
HANDAYUAN® (adalimumab)



The only bevacizumab with metastatic colorectal cancer Phase 3 clinical data in China
HANBEITAI® (bevacizumab)

1

Product launched in the EU



First Chinese mAb biosimilar approved in China and the EU
Zercepac® (trastuzumab)



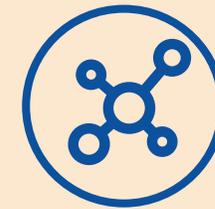
12+9

Candidates / Combo Therapies under Clinical Studies



20+

Clinical studies



70+

Clinical approvals

Diversified Product Pipelines Based on Fully-Integrated R&D Platform- Innovative Biologics

		Products	Targets	Indications	Pre-clinical	IND	Phase 1	Phase 2	Phase 3	NDA	Launch	Business Partners
Expected Soon		mono	PD-1	MSI-H solid tumours 2L+	[Progress bar]						Priority Review Designation	XKGBio
		+chemo	PD-1	squamous non-small cell lung cancer 1L	Global multi-centre clinical study							
Under Clinical Studies	HLX10 (serplulimab injection ⁽¹⁾)	+chemo	PD-1	extensive-stage small cell lung cancer 1L	Global multi-centre clinical study							
				metastatic esophageal squamous-cell carcinoma 1L	[Progress bar]							
				neo-/adjuvant treatment of gastric cancer	[Progress bar]							
		+HANBEI TAI	PD-1+VEGF	non-squamous non-small cell lung cancer 1L	[Progress bar]							
				hepatocellular carcinoma 1L	[Progress bar]							
				metastatic colorectal cancer 1L	[Progress bar]							
		+HLX07	PD-1+EGFR	squamous cell carcinoma of head&neck 2L	[Progress bar]							
				squamous non-small cell lung cancer 1L	[Progress bar]							
		HLX04-O ⁽²⁾	VEGF	wet age-related macular degeneration	[Progress bar]						ESSEX 亿视	
		HLX22 + HANQUYOU	HER2	gastric cancer	[Progress bar]							
HLX07 ⁽³⁾	EGFR	solid tumours	[Progress bar]									
HLX208 ⁽⁴⁾	BRAF V600E	Metastatic colorectal cancer, non-small cell lung cancer, Langerhans cell histiocytosis and Erdheim-Chester disease	[Progress bar]									
HLX20 ⁽⁵⁾	PD-L1	solid tumours	[Progress bar]									
HLX26	LAG-3	solid tumours, lymphomas	[Progress bar]									
HLX35 ⁽⁶⁾	EGFR x 4-1BB	solid tumours	[Progress bar]									
HLX301 ⁽⁷⁾	PD-L1 x TIGIT	solid tumours	[Progress bar]									
HLX23 ⁽⁸⁾	CD73	solid tumours	[Progress bar]						BINACEA PHARMA			

(1) Clinical approvals obtained in China/the US/the EU countries, etc.

(2) Clinical approvals obtained in China/Australia/the US/Singapore/the EU countries, etc.

(3) Clinical approvals obtained in China/the US

(4) Commercialisation rights obtained in China including Hong Kong, Macao and Taiwan region

(5) Clinical approvals obtained in Australia/China

(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 Australia

(8) Clinical approvals obtained in the US

Serplulimab (anti-PD1 mAb): All Tumor Targeting, Differentiate Competition, Empowering a Ecosystem and Global Layout

 **Pave the Way for Globalization**

 **All Tumor Targeting**

 **Global**



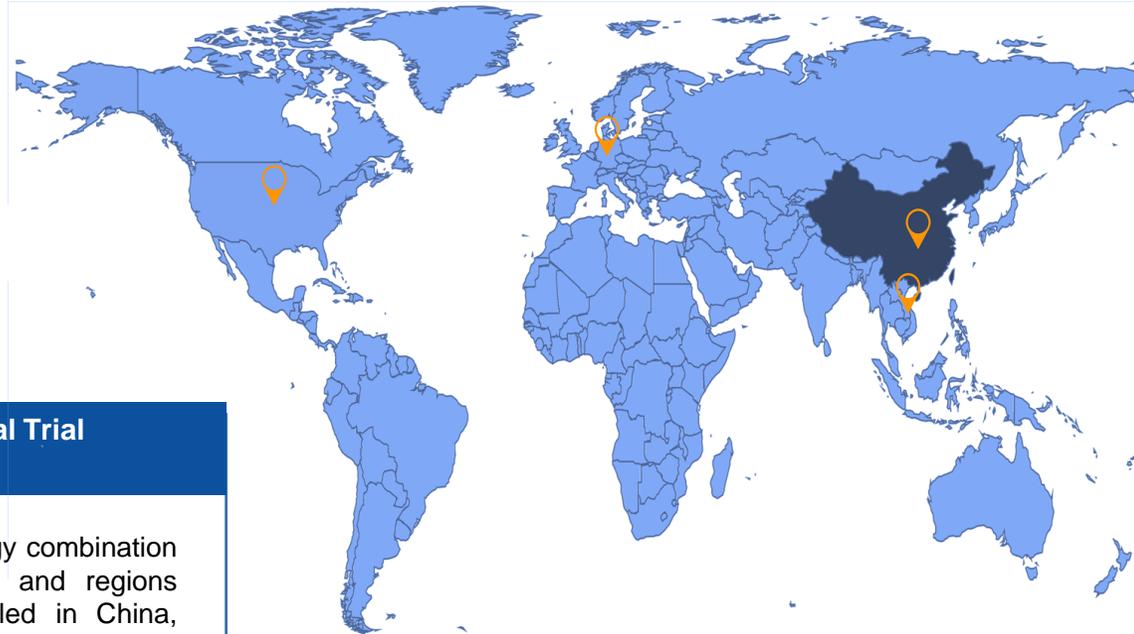
Lung cancer

SC-NSCLC

SCLC

**International Multicenter Clinical Trial
Reach Primary Endpoint**

- Multiple clinical trials of immuno-oncology combination therapy initiated in different countries and regions worldwide; about 2300 subjects enrolled in China, Turkey, Poland, Ukraine, Russia, etc., making Serplulimab a PD-1 product with one of the largest international clinical data pools
- A collaboration agreement reached with KG Bio in 2019, upon which KG Bio is granted exclusive rights to develop and commercialise Serplulimab in 10 Southeast Asian countries



 **China**



MSI-H
solid tumors



Head&Neck



Esophageal



Lung



Gastric



Hepato-
cellular

Actively Propel Clinical Trials of HLX208 (BRAF V600E Inhibitor) and Accelerate to Get on the Market

Strategy	Core Clinical Trials	Stage
<ul style="list-style-type: none"> • “Fast to Market” Project • HLX208 is expected to be the second approved domestic BRAF inhibitor in lung cancer 	<ul style="list-style-type: none"> • Non-Small Cell Lung Cancer (NSCLC) 	Ph 2
<ul style="list-style-type: none"> • “Fast to Market” Project • HLX208 is expected to be the only approved BRAF product (LCH&ECD) in medium and long term 	<ul style="list-style-type: none"> • Langerhans cell histiocytosis (LCH) and Erdheim-Chester Disease (ECD) 	Ph 2
<ul style="list-style-type: none"> • Indication Exploration—quickly start the first-line Phase III clinical trial after getting the efficacy data of HLX208 • HLX208 is at the front of the development progress in mCRC indication 	<ul style="list-style-type: none"> • Metastatic colorectal cancer (mCRC, Mono and Combo) 	Ph 2
<ul style="list-style-type: none"> • HLX208 is expected to be the only approved BRAF product in medium and long term (ATC) 	<ul style="list-style-type: none"> • Anaplastic Thyroid Cancer (ATC) 	Ph 1b/2
<ul style="list-style-type: none"> • To explore the other potential indications 	<ul style="list-style-type: none"> • Melanoma (Mel) • Brain Tumor (BT) • Other Solid Tumor 	Ph 2

Diversified Product Pipelines Based on Fully-Integrated R&D Platform-Biosimilar

	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, rheumatoid arthritis ⁽⁵⁾	[Progress bar]						FOSUNPHARMA 复宏汉霖, FARMA	
	HANQUYOU (trastuzumab) ⁽²⁾	HER2	breast cancer, metastatic gastric cancer	The first Chinese mAb biosimilar approved both in China and the EU						accord, Cipla, Jacobson, mAbxience	
	HANDAYUAN (adalimumab) ⁽³⁾	TNF-α	rheumatoid arthritis, ankylosing spondylitis, plaque psoriasis, uveitis	[Progress bar]						万邦医药, FOSUNPHARMA 复宏汉霖, Getz	
	HANBEITAI (bevacizumab) ⁽⁴⁾	VEGF	metastatic colorectal cancer, non-squamous non-small cell lung cancer	[Progress bar]							
Under Clinical Studies	HLX11 (pertuzumab)	HER2	breast cancer	[Progress bar]							
	HLX05 (cetuximab) ⁽⁶⁾	EGFR	metastatic colorectal cancer, squamous cell carcinoma of the head and neck	[Progress bar]						Jingze	
	HLX12 (ramucirumab)	VEGFR2	gastric cancer, non-small cell lung cancer, metastatic colorectal cancer	[Progress bar]							
	HLX14 (denosumab)	RANKL	osteoporosis	[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) Approved in the EU in July 2020 (EU brand name: Zercepac®); approved in China in August 2020
 (3) Approved by the NMPA in December 2020
 (4) Approved by the NMPA in December 2021

(5) Considered as innovative biologic medicine as the reference drug has not been approved for the indication/Approved by the NMPA in March 2022
 (6) Commercialisation rights in China have been granted to Shanghai Jingze

Preclinical: Effectively Propel the IND Application for Preclinical Projects

- » Emphasize on the preclinical projects, complete the IND application submissions domestically and internationally for preclinical products covering CD35, LAG-3 and CD73 targets.
- » Submit the investigational new drug (IND) application for two preclinical bispecific antibodies in the second half of 2021.

Product (Reference)	Target	Indication	1Q21	2Q21	3Q21	4Q21
HLX15 (Daratumumab)	CD38	Multiple Myeloma	2021/1 NMPA IND Approval			
HLX26	LAG-3	Solid Tumor, Lymphoma	2021/4 NMPA IND Approval			
HLX23	CD73	Advanced solid tumor	2021/5 FDA IND Approval			
HLX301	TIGIT x PD-L1	Solid Tumor	2021/11 TGA IND Approval			
HLX35	4-1BB x EGFR	Solid Tumor	2021/12 NMPA IND Approval			

Pre-Clinical: Dual Innovation Center, One-Team Culture



Emphasize one-team culture and foster close working relationship, open communication and effective collaboration



Leverage global talent pool, innovative therapeutic expertise, key opinion leaders at both sites



Synergize with Henlius strategic development plan, diversified product portfolio and global value chain.

USIC: immune target bsAb

- Core human antibody library (sdAb, naïve)
- scFv and bispecific platforms
- In-house vivarium for immunology research
- Protein expression and cell line technology
- Early developability assessment
- Industrial talents and network



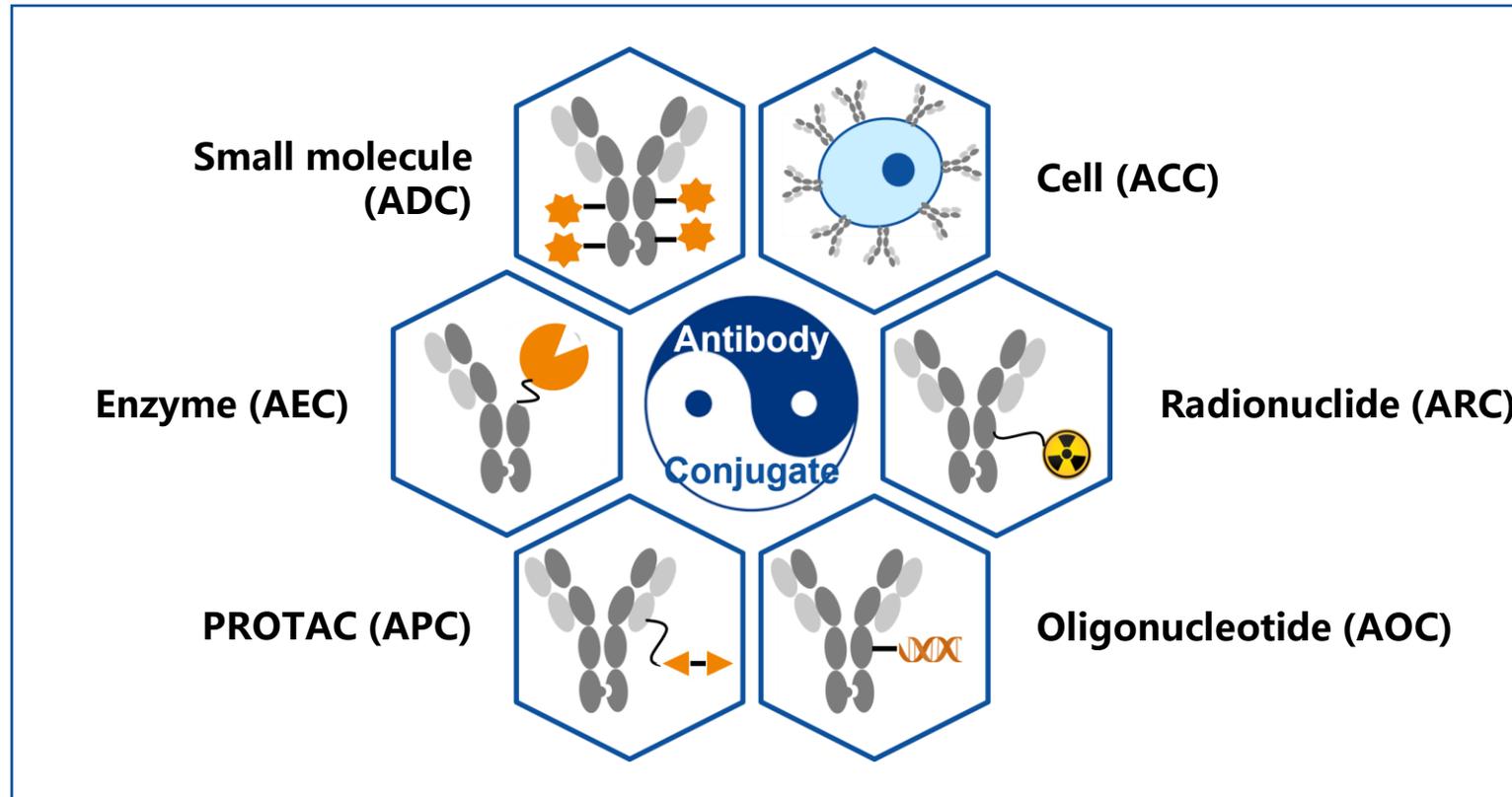
SHIC: Ab/AXC/Novel Therapy

- Antibody-centric, evolved ADC/AXC and new modalities to address unmet clinical needs
- Full-set innovative drug research and development system from target validation, drug discovery, preclinical development, to translational medicine
- High efficient innovative ideation mechanism driven by disease biology, bioinformatics and biomarker
- Protein design and engineer platform based on structural biology and bio-computation
- Closely collaborate with high-level hospitals, universities and institutes and carry out translational research
- Develop differentiated products mainly based on internal innovation and supplemented by externally licensing competitive product/technology

Pre-Clinical: Build Proprietary AXC Technology Platform

»» Antibody-Centric, Evolved Modality (AXC: Antibody X-molecule Conjugate)

Based on antibody and novel conjugating technologies, expand different forms of antibody conjugates to address unmet clinical needs.



3.2

Manufacturing

Integrated Platform Advantage: Manufacturing Bases Construction Will Further Increase Integrated Platform Advantage

Continuous Improvement of Quality Management System In Compliance with Global GMP Standard

- NMPA & EMA certified, FDA to be certified next
- Continue to improve the quality management system through audits from clients and regulatory agencies

Leading Commercial Manufacturing Capacity

- Successful commercial manufacturing batches: 350+
- Production successful rate: $\geq 98\%$
- Overall manufacturing related employees: 900+
- Production intensity: Industry Leading

Creating a Commercial Manufacturing Platform with Cost Advantages

- **Lead the innovation in manufacturing technology:**
 - Single-use technology combined with Stainless steel technology
 - Large-scale stainless steel technology is introduced to reduce GOGS
- **Advance the localization process**
 - Facilitate the localization process of manufacturing materials, consumables and equipment
- **Insist on lean production, lean management and lean operation**

Total Designed Capacity >140,000L



Songjiang Site I: Completed the Construction of Commercial Scale Manufacturing Plant and Pilot Scale Continuous Manufacturing Plant, and Commenced Manufacturing Successfully

- **2021.03**
Completed the construction and qualification of DP filling line
- **2021.04**
Completed the validation of 2nd generation process of DS for HLX02
- **2021.05**
Completed the validation of 2nd generation process of DP for HLX02
- **2021.08**
Songjiang Site I was licensed for production
- **2021.09**
Submitted sNDA for HLX02 2nd generation process



*Commence Commercial Manufacturing
by Mid-2022*

Total capacity increase **+24,000L**

The capacity will no longer be a bottleneck for commercial product supply

*Process Generation Upgrade for
HLX02 Zercepac®*

Productivity Improve

x2



*Completed End to End Continuous
Manufacturing Successfully*

Productivity Improve

x12

First case in China

- **2021.01**
Completed pilot scale-up manufacturing of downstream continuous production process
- **2021.08**
Completed pilot scale end to end continuous manufacturing successfully



Songjiang Site II: Accelerate the Construction of the Intelligent Factory

Total Capacity 36,000L for Phase I 1st & 2nd Stage

- Completed the main structure and secondary structure of the two main production buildings as well as the supporting public utilities and warehouses, and completed the structural roofing and main structure acceptance of the production auxiliary buildings.
- Most of the main production equipment for DS and DP line have been delivered to the site.
- Ready for Engineering Sample Run in Q3 2022.

Phase I 3rd Stage construction program landed with a designed capacity of 60,000L

- Designed 15KL mass stainless steel system to further extend the cost advantage of commercial manufacturing.
- Completed conceptual and foundation design and completed pile foundation construction for the building
- Will be in the full construction phase in 2022.

Intelligent Manufacturing

The total designed capacity up to:

96,000 L

Single-use technology &
Stainless steel technology

*The construction has been fully
accelerated in 2021*

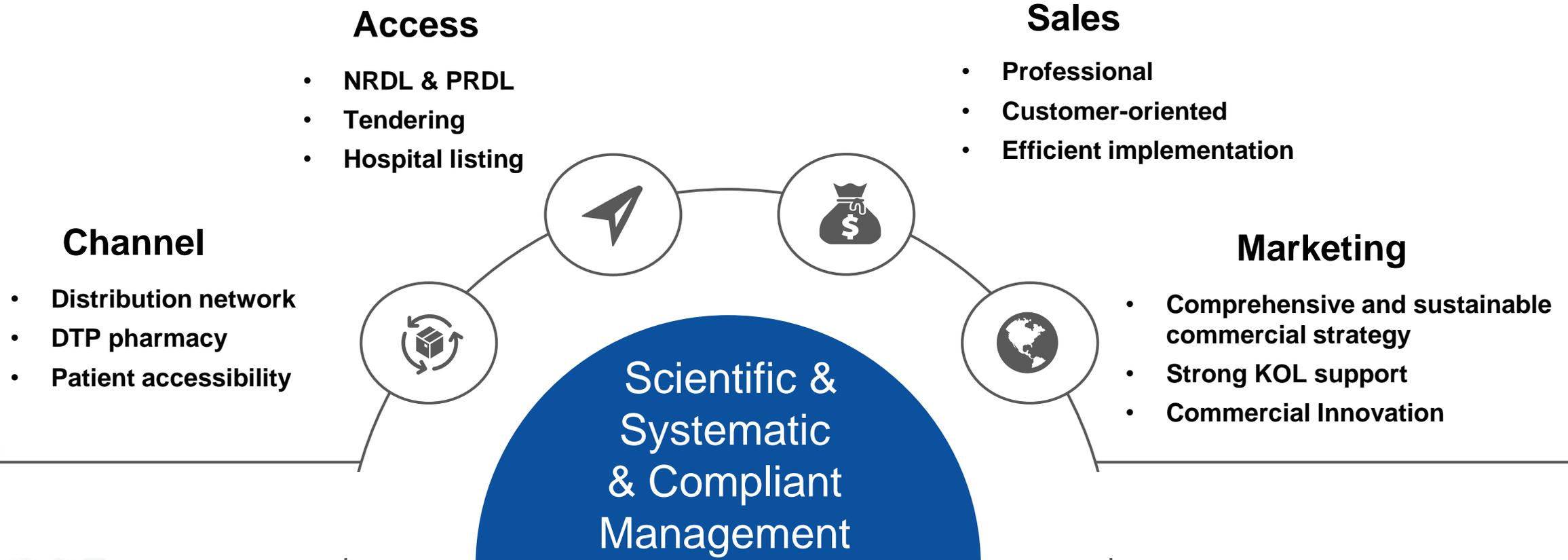


3.3

Commercial Operation

Upgrade Commercialization by Enhancing Core Capabilities

Maximize commercial value of late-stage assets



To achieve healthy and sustainable development through patient-centric partnership strategy & cost-effectiveness management

For Global: Pursuing Strategic Collaborations to Establish Global Presence

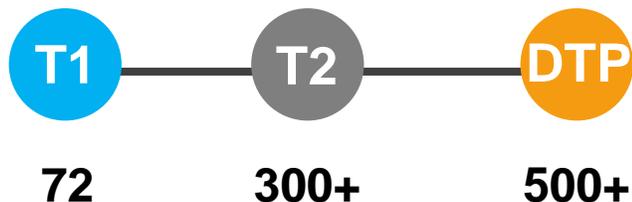


Expanding into emerging markets while entering the European and American mainstream biopharmaceutical market

HANQUYOU[®] (trastuzumab) : Established Commercialization System to Lead Rapid Business Growth

Continue to Optimize Distribution Network

- Optimize distributors & DTP pharmacy, reduce multi-tier distribution to establish an efficient channel and ensure sales continue to increase



Continue to Strengthen Commercial Team

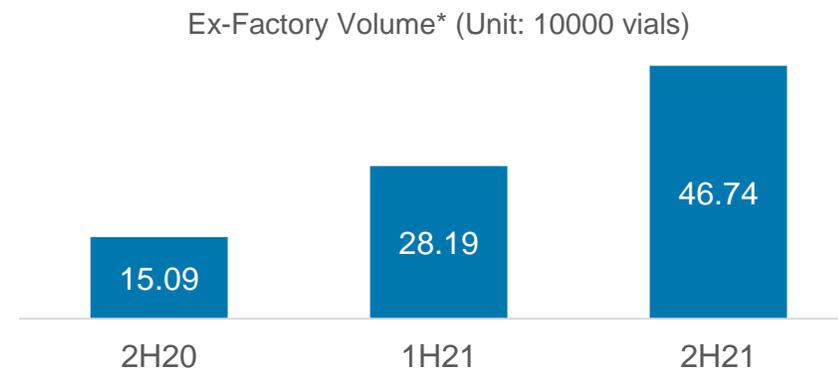
- A commercialization team with about 500 people at the end of the reporting period. Comprehensive coverage of nearly 3,000 hospitals in the six major sales areas across the country, involving approximately 20,000 professional doctors
- Since its launch, above 40,000 HER2+ patients have been treated. Compared with the following trastuzumab, the target doctor group has more experience

* Note: Ex-factory sales volume includes domestic and overseas, based on 150mg for calculation

Market Access Continues to Advance

- Domestic market:** 150mg: completed bidding and medical insurance procurement platform of all provinces and municipalities. Over 70% of the Top 1000 hospitals had admitted the drug. 60mg: launched in Aug 2021, complete 24 provinces and municipalities of medical insurance procurement platform and 16 provinces and municipalities of bidding
- Global Market:** marketed in nearly 20 EU countries and regions. Zercepac[®] (150mg) had successfully entered a number of top hospitals in the UK. 60mg and 420mg launched in Apr and Jun in the EU

Volume Continues to Increase



HANQUYOU® (trastuzumab): “Not Leaving Any HER2+ Breast Cancer Patient Behind”

Collaboration on Physician Education

- Collaborate with medical societies, facilitate at community level
- Empower innovative academic communication platforms and online activities

Collaboration on Testing & Diagnosis

- Collaborate with biomarker testing companies and pathological centres to improve HER2 testing rate and HER+ rate

Collaboration on Patient Affordability

- Collaborate with insurance companies to improve patients' affordability



Collaboration on Market Access

- Collaborate with the government to promote the research of biosimilar medical insurance policy and payment standards
- Collaborate with commercial companies to maximize market and hospital access

Collaboration on Big Data

- Collaborate with big data companies to strengthen PMS* capabilities and to complement clinical evidence from Chinese patients

Collaboration on Patient Education

- Collaborate with academic societies and patient groups to reduce HCP/ patients communication cost and increase adherence

Market Access

- Collaborate with academic institutions on biosimilar pricing management research
- Prepare in advance, quickly complete entering provincial and integrated-planning area medical insurance system
- Establish pricing strategy and payment plan that fit mid-/long-term growth

Channel

- Select high-quality distributors and DTP pharmacies, establish efficient business channels
- Establish an optimized pricing system, stabilize product price
- Advocate biosimilars, obtain better bidding/ access outcomes

Marketing

- Create strategic partnership-enabled ecosystem
- International top-quality standards for competitive differentiation
- Build a PhIRDA2 Biosimilar Platform, establish industry leadership

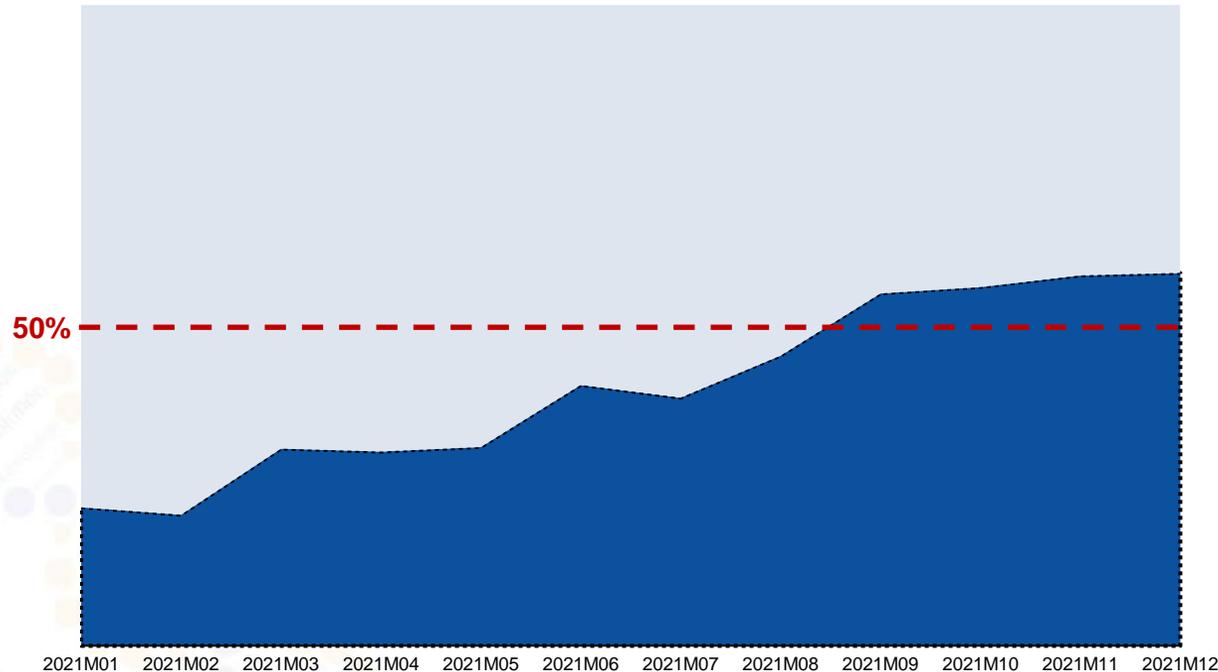
HANQUYOU[®] (trastuzumab) : Excellent Sales Performance to Lead a Healthy and Sustainable Development



Sales Performance

Total accessed market reaches 60% * by Dec. 2021, market share in accessed market surpassed originator starting from Sept 2021

Market Share



Investment-Effectiveness

Enhance sales capability and investment efficiency to achieve healthy and sustainable development

>3M RMB

Productivity

Benchmarking against domestic innovative biopharma (~1.5-2M) *

<55%

Proportion of Sales & Marketing Expenses

Benchmarking against domestic biopharma counterparts (~57%-62%) *

* 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[®] (trastuzumab) Outlook : Become Market Leader by Seizing Opportunities to Increase Sales Volume Quickly

Redefine clinical practice standard of trastuzumab infusion and become the market leader **by launching 60mg specifications**

Expand Production Capacity, which will no longer be a bottleneck **in mid of 2022** once SJ1 steps into commercial production period

- Accelerate bidding and medical insurance procurement platform of 60mg specifications, expected to complete all provinces and municipalities **before Jun. 2022**
- Following 60mg launch strategy, take advantage of 150/60mg as a flexible combo to standardize hospital infusion process to **accelerate hospital listing**
- Establish dual specifications as a standard clinical practice to enhance competitive advantage
- **FTE Expanding**, build an industry-leading standardized, information-based and systematic sales management system, **enhance F.F professionalism and execution, result-oriented**
- Rapidly increase new patient share through key hospital developing, **customer cover expanding, intention patients reserve project**

Achieve market share overtaking at the end of 2022, become the market leader

HANLIKANG[®] (rituximab) :Continue to Increase Volume and Become the Market Leader



Market Access

100mg:

- **28** provinces and municipalities had completed official platform/filed procurement, **30** provinces and municipalities had approved the inclusion of 100mg into the medical insurance procurement platform

500mg:

- **19** provinces and municipalities had completed official platform/filed procurement, **14** provinces and municipalities had approved the inclusion of 100mg into the medical insurance procurement platform

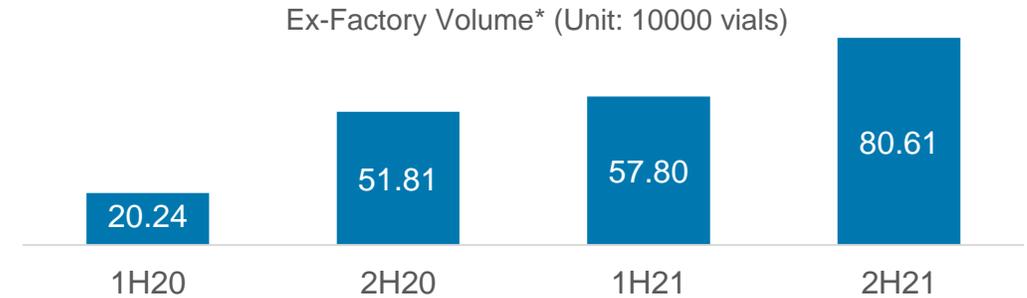
Hospital listing:

- **74%** of the core hospitals had admitted the drug

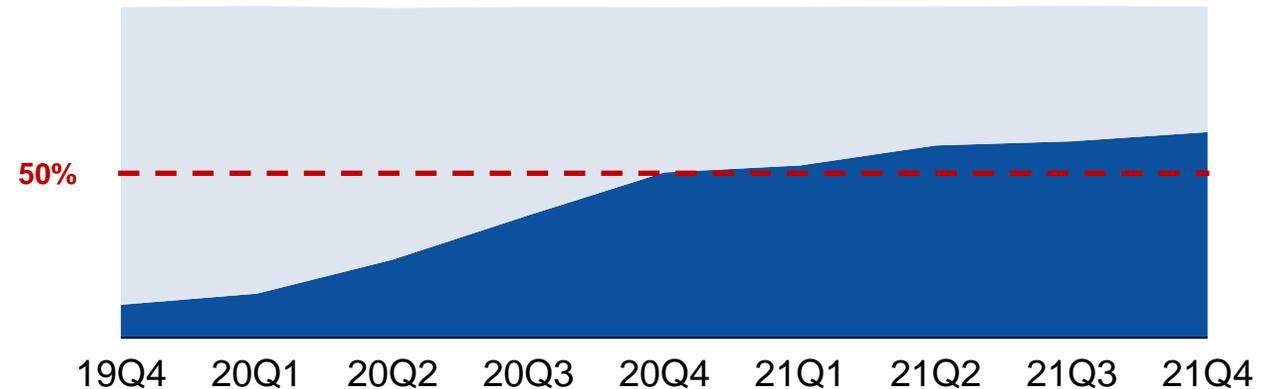


Sales Performance

Ex-factory Sales

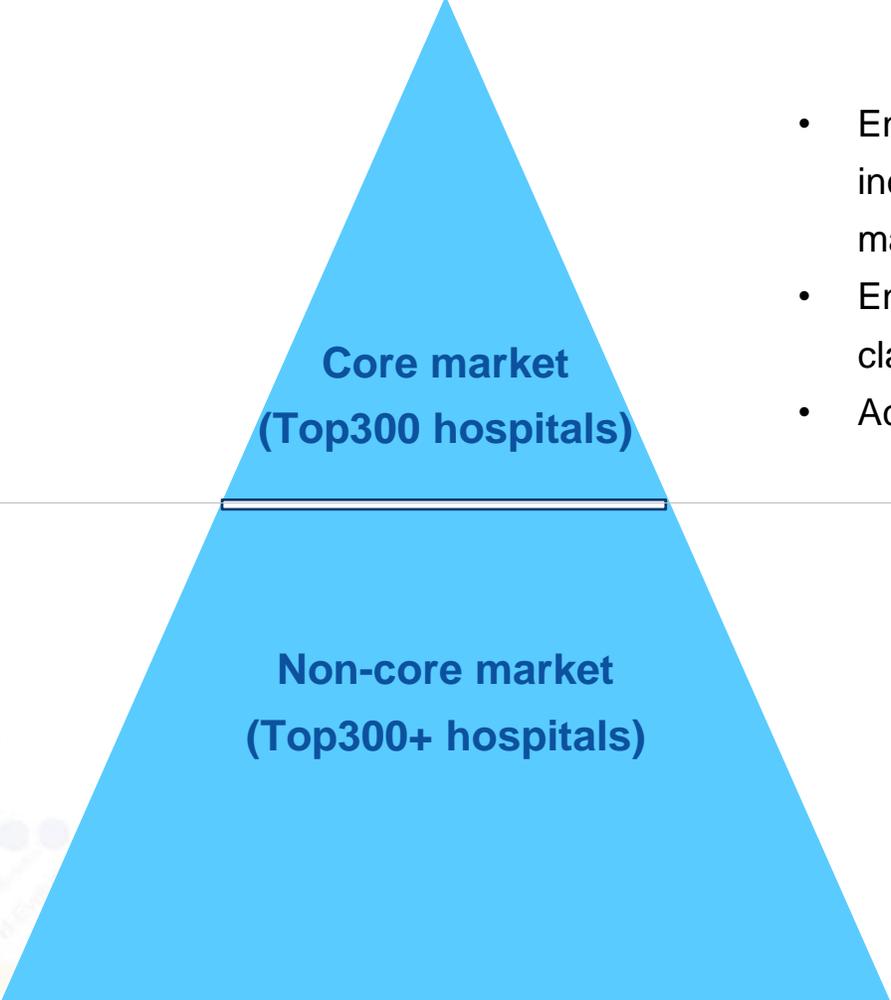


Market Share*



* Data source: 1、internal sales data, ex-factory sales volume based on 100mg for calculation
2、IQVIA CHPA;

HANLIKANG[®] (rituximab) : Take Advantage of First Entrant and Market Segmentation Differentiation



**Core market
(Top300 hospitals)**

- Enhance the brand awareness of HANLIKANG[®] among doctors and the public, and increase the patient share and the DOT by initiating the patient journey management project for lymphoma patients
- Enhance the influence of hospitals by conducting academic exchanges with world-class lymphoma centers through the "zero-lymphoma" project
- Accumulate medical evidence for clinical practice by deepening the real world study

**Non-core market
(Top300+ hospitals)**

- Increase market penetration rate by integrating various resources to accelerate hospital listing
- Expand the coverage of hospitals and customers to realize brand switch.
- Standardize the diagnosis and treatment of lymphoma in subordinate hospitals through collaboration with medical treatment alliance

HANLIKANG® (rituximab) Outlook: Strengthen Brand Penetration and Consolidate Leading Market Position

Improvement on hospital listing in Top 300+ hospitals with low market penetration rate

Improvement on diagnosis and treatment rate of lymphoma in primary hospitals by public-benefit activities, physician education etc.

Launch HANLIKANG®RA indication with huge market potential, bring unique competitive advantage in China marketplace

- Accelerate hospital listing by resources integration and formulation of hospital listing plan that is unique strategy to unique hospital
- Standardize diagnosis and treatment of lymphoma, improve corporate image, market penetration and coverage further by **FTE expanding, enhancing delicacy operation**
- With a low frequency of administration, HANLIKANG® have an obvious advantage of patient compliance, which provides a new clinical option for posterior line treatment when TNFi fails. Accelerate the expansion to the field of rheumatism from top hospitals as starting point

Consolidate rituximab's patient share as well as leading market position

HANSIZHUANG[®] (serplulimab) : Adequate Preparation for Successful Launch

HANSIZHUANG[®] (Serplulimab) Launch Readiness



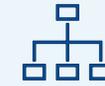
Channel

- Pursue synergistic effect with HLX02, establish efficient distribution network
- Maximize patient accessibility by leveraging DTP pharmacy and infusion center



Access

- Collaborate with academic institutions on bio-innovative drugs pricing management research
- Evaluate and prepare for the National innovative drug negotiation



Team

- Establish 200+ dedicated commercial team, which has a high level of professional communication skills and experienced in oncology market
- Build up team culture of professionalism, execution and compliance

HANSIZHUANG[®] (serplulimab) : Expected to be Approved for MSI-H Solid Tumor Indication Soon



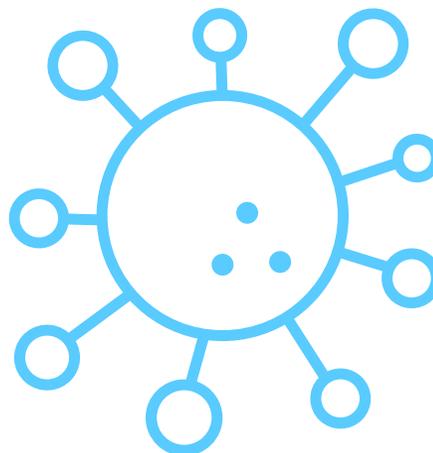
Market Prospects

- 310k+ patients newly diagnosed per year
- Existed in multiple tumor types



Clinical Efficacy Profile

- Highest 12-month OS rate among PD-(L)1 inhibitors
- No significant difference in ORR and DOR compared to Opdivo and Keytruda



MSI-H Solid Tumor
Expected to be approved soon

HANSIZHUANG[®] (serplulimab) : Tap Market Potential through Ecosystem Establishment

Ecosystem Empowerment

Physician Education

Empower innovative academic communication platforms through collaboration with medical societies

Collaboration on Testing & Diagnosis

Improve MSI screening standard and explore innovative patient service modes through collaboration with genetic testing companies



Market Access

Improve patient affordability through PAP initiated by charity foundations and collaboration with the government and commercial insurance to benefit more patients

Patient Education

Increase patient compliance by establishing digital patient education platforms in flagship hospitals based on the collaboration of medical societies.

Market Selection

Focus on core market, classify target hospitals and target customers precisely, differentiate promotion activities, and improve ROI

HANSIZHUANG[®] (serplulimab) : Expected to be Approved for sqNSCLC Indication in the Second Half of 2022



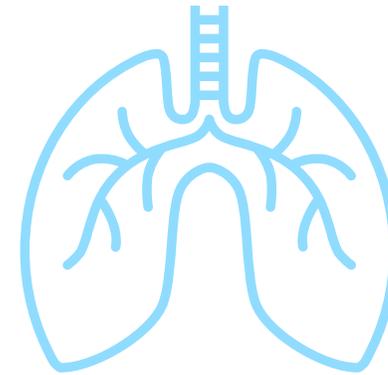
Market Prospects

- 800k+ patients of Lung Cancer newly diagnosed per year (170k+ in sqNSCLC, 120k + in SCLC)
- First anti-PD-1 mAb for first-line treatment of SCLC



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 treatment of SCLC, with better efficacy in Asian group



Lung Cancer

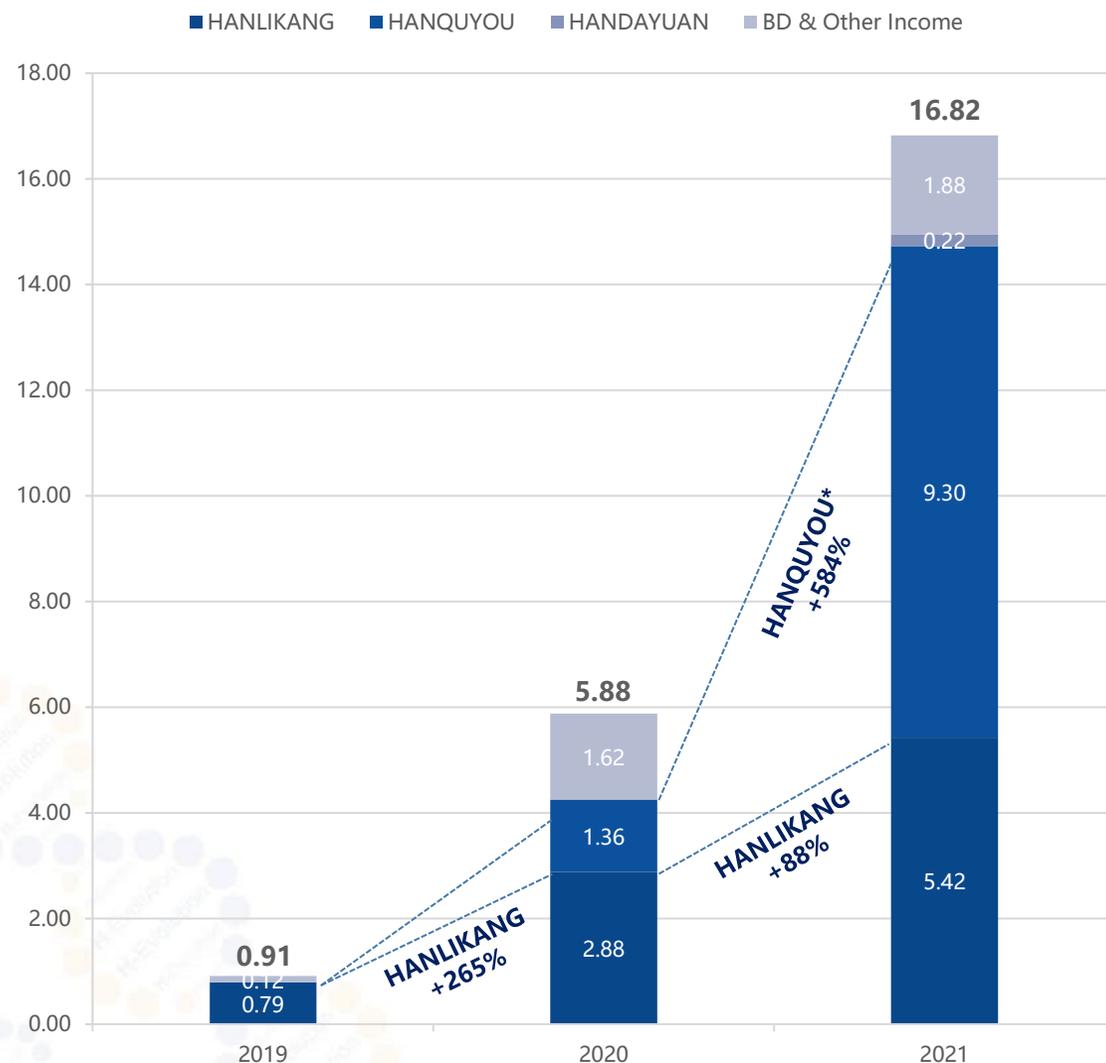
sqNSCLC indication expected to be approved in the second half of 2022

04

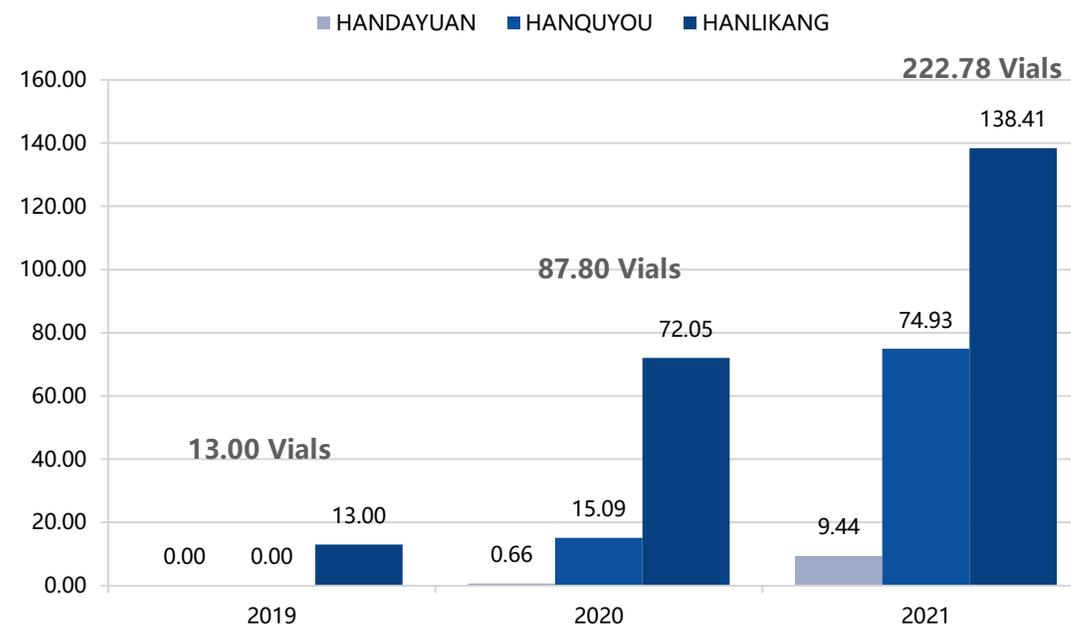
2021 Financial Review & 2022 Outlook

2021 Sales: Increased Rapidly Lead by the Core Products

Composition of Income (in RMB 100M)



Ex-Factory Volume * (in 1000 Vials)

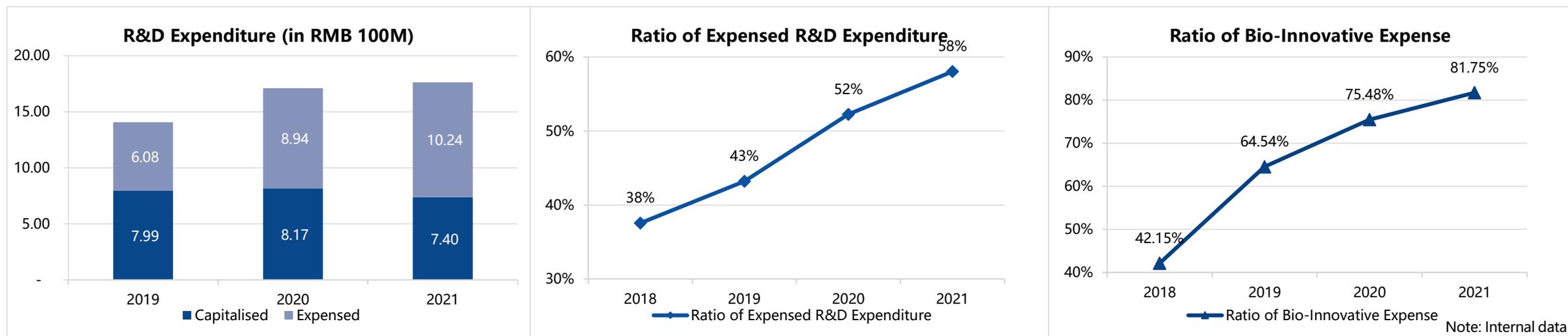


* Note: Internal data. Volumes of HANQUYOU are converted into 150 mg/vial

- Rapid growth of total revenue:** total revenue was approximately RMB 1,682.5 million for the year ended 31 December 2021, representing an increase of approximately RMB 1,094.9 million, or approximately 186.3% compared to approximately RMB 587.6 million for the year ended 31 December 2020, mainly due to the increase of sales volume of our core product HANLIKANG and HANQUYOU*.
- Core product sales continue to increase:** the ex-factory volume of our core products was 2.2 million vials, which is 2.5 times of that in 2020. During the Reporting Period, HANQUYOU* recorded a sales revenue of approximately RMB 930 million, an increase of about RMB 794 million or 584% over 2020. The sales revenue of HANLIKANG was approximately RMB 542.5 million.

* Note: Sales of HANQUYOU included the sales of HANQUYOU, Zercepac and drug substance of trastuzumab

2021 R&D: Expenditure Grow with More on Innovative Drugs



• Maintain overall R&D investment and improve R&D efficiency

- Strengthen clinical operation team, build our own clinical advantage reserve, gradually reduce external CRO suppliers, and turn to rely on internal resources to save costs
- Proactively carry out new R&D projects to accelerate innovation, while partially offsetting expenses through cost reduction and efficiency increase
- During the reporting Period, accelerated the submission of investigational new drug application of pre-clinical research projects covering targets such as CD38, CD73, LAG-3, EGFR×4-1BB and PD-L1×TIGIT

• Progress of international multi-center clinical research projects

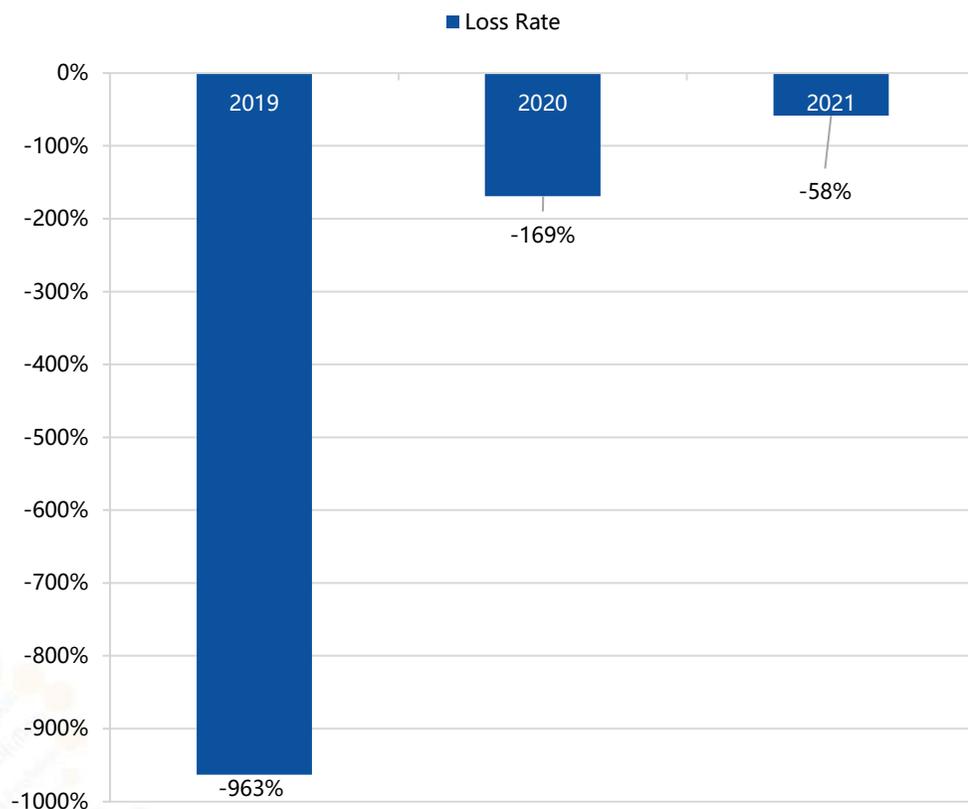
- Application for HLX04-O (VEGF) for the treatment of wet age-related macular degeneration (wAMD) was approved to commence the phase 3 clinical trial in Australia, the United States, Latvia, Singapore and some EU countries such as Spain, Czech Republic and Poland

• Progress of domestic clinical research projects

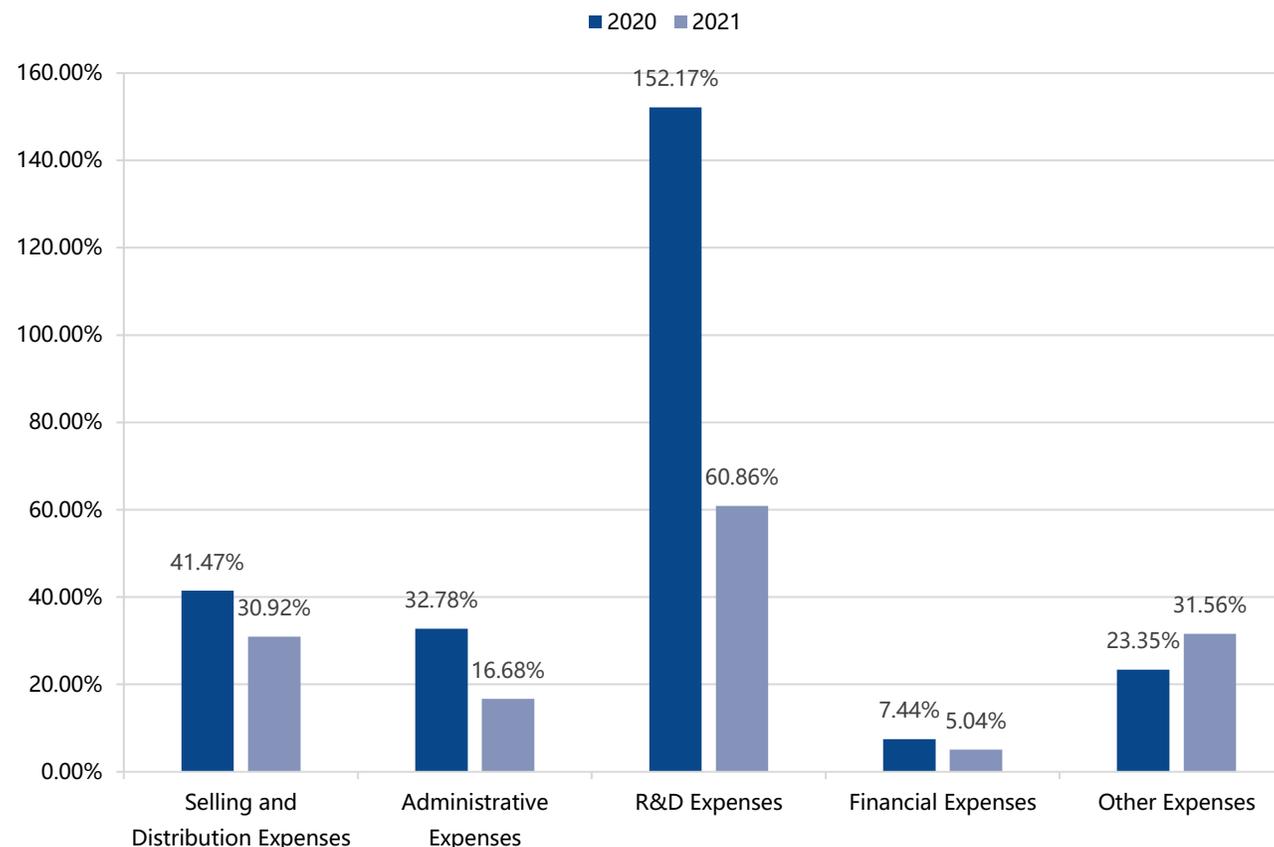
- Enrollment of subject was completed for combo of serplulimab (PD-1) + HANBEITAI (VEGF) for the treatment of advanced hepatocellular carcinoma (HCC)
- First subject dosed in a phase II/III clinical trial for combo of serplulimab (PD-1) + HANBEITAI (VEGF) + chemotherapy for the treatment of metastatic colorectal cancer (mCRC)
- Phase 2 IND of serplulimab (PD-1) + HLX07 (EGFR mAb) was granted by the NMPA
- Enrollment of subject was completed for combo of serplulimab (PD-1) + chemotherapy for the treatment of advanced/metastatic esophageal squamous cell carcinoma (ESCC)
- Phase 3 clinical study of serplulimab (PD-1) for the treatment of ES-SCLC meets primary study endpoint
- First subject dosed in a phase 3 clinical study for HLX04-O (VEGF) for the treatment of wAMD
- First subject dosed in a phase 2 clinical trial of HLX22 (HER2) + HANQUYOU (HER2) + chemotherapy
- First subject dosed in a phase 1 clinical trial of HLX26 (LAG-3)

2021 Loss Ratio & Expense Ratio: Largely Decreased

The Ratio of Loss to Total Revenue Narrowed Down



The Ratio of Expense to Total Revenue



- Losses gradually narrowed and the ratio of loss to total revenue decreased significantly:** loss of Henlius decreased by approximately RMB 9.4 million from approximately RMB 993.5 million for the year ended 31 December 2020 to approximately RMB 984.1 million for the year ended 31 December 2021. As revenues rose sharply, the loss rate in 2021 dropped significantly, which was just one-third of the loss rate in 2020
- Expense category has a large contribution to profit:** compared with 2020, the ratio of all expenses to total revenue in 2021 has decreased. Sales expense ratio decreased a lot mainly because of the accurate control of sales and efficiency impressment

Successful Evolution from *Biotech* to *Biopharma* !



声明

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Reliable Quality
Affordable Innovation

