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# Company Overview and Strategy

**Mission:**
**Affordable Innovation**
**Reliable Quality**

| | |
|---|---|
| Products Commercially Launched | 3 |
| Products under NDA Review | 2 |
| Products/Combo Therapies under Clinical Development | 10/8 |
| Current Commercial Capacity | 20,000L |
| Expected Total Capacity in 3 years | 80,000L |

| | |
|---|---|
| 2020.12 | HLX01 (rituximab) for Rheumatoid Arthritis NDA Accepted by NMPA |
| 2020.12 | HLX03 (adalimumab, 汉达远®) Launched |
| 2020.09 | HLX04 (bevacizumab, 汉贝泰®) NDA Accepted by NMPA |
| 2020.08 | HLX02 (trastuzumab, 汉曲优®) Approved in China |
| 2020.07 | HLX02 (trastuzumab, Zercepac®) Approved in the EU |
| 2019.05 | HLX01 (rituximab, 汉利康® ) Launched |
| 2015.12 | [illegible] |
| 2011.12 | First NMPA IND Filed (HLX01, rituximab) |
| 2010.02 | Shanghai Henlius Biotech Inc. Founded (co-founded by Fosun Pharma and scientist team headed by Dr. Scott Liu and Dr. Weidong Jiang) |

# Management Team: [illegible]

## Wenjie Zhang

Joined Henlius in [illegible]
25 years of commercial operation experience in pharmaceutical industry. [illegible] president and general manager at Bayer China, Roche China and Amgen China
MBA in Yale University and bachelor degree of microbiology in Shandong University

Executive Director
Chief Executive Officer & President

**Xinjun Guo**
Board Secretary,
Head of Government Affairs and Public Relations

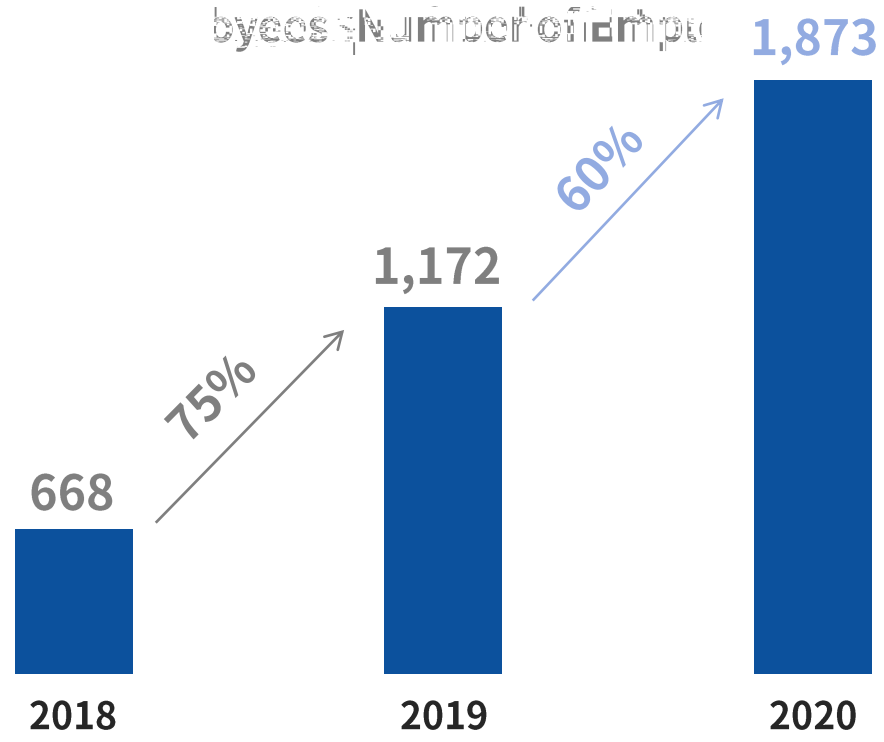
**Wei Huang**
Chief Operation Officer
Head of Manufacturing & Engineering
Joined Henlius in Dec. 2019

**Jason Zhu**
Chief Medical Officer
Joined Henlius in Jan. 2021

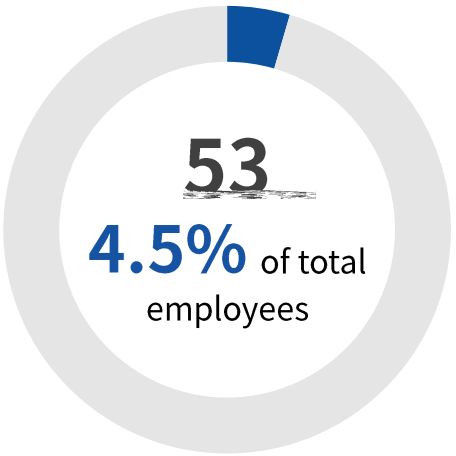
**Simon Hsu**
Chief Technology Officer
Head of Technical Operations & CMC
Joined Henlius in Dec. 2019

**Cecie Jiang**

# Company Size: the Number of Employees Rapidly Grew with Commercial Team Expanding Quickly




## Commercial Team





| R&D | Clinical | Manufacturing | Quality | Commercial | Administrative |
|---|---|---|---|---|---|
| 351 | [redacted] | 437 | 256 | 395 | 203 |



Note: as of Dec 31, 2020

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

## Strategic Goals

| | |
|---|---|
| Overall | While maximizing biosimilar commercial value, rely on self innovative R&D capability complemented with external collaboration and license-in, accelerate innovation with full speed |
| R&D | Synergize China and US R&D centers, strengthen translational medicine capability, advance differentiated innovation |
| Manufacturing | Under the premise of guaranteeing "Henlius Quality", further improve manufacturing capability, optimize manufacturing technology, create competitive economies of scale |
| Commercialization | Build first-class commercial team through innovative marketing, access and commercialization strategies, and highly-efficient sales execution capability |

## Stage 1: Biosimilar

**Build comprehensive commercial capability through forging leading position in biosimilar**

- Accelerate R&D, registration and approval: strive to become first-in-class or tier-1 to launch
- Further expand leading advantages in manufacturing technology, cost and scale
- Rely on our own capability and leverage external cooperation to maximize commercial value of products

## Stage 2: Diversified Innovation

**Accelerate transformation towards diversified innovation including mAb, bispecific, ADC, etc. based on antibody technology**

- Mainly rely on internal R&D: strengthen R&D innovation capability, improve innovation efficiency
- Establish executable and measurable R&D strategy
- License-in new products and new technologies through BD to effectively complement our own pipeline
- Build strong R&D team and capability

## Globalization Strategy

- Commercialize late-stage assets including biosimilars and PD-1 through partnership in the early stage
- Develop mature markets and emerging markets simultaneously
- Actively advance globalization of selected early-stage innovative products

# Accelerate Development of Bio-Innovative Drugs

| Biosimilar Lays Solid Foundation | PD-1 (HLX 10, serplulimab) Entering Harvest Time, Focus on Differentiation and Combo Advantages | Accelerate Innovation through Internal R&D + BD |
|---|---|---|

Three biosimilars have strong competitive edges – 汉利康®（rituximab）、汉曲优®（trastuzumab）、汉达远®（adalimumab）expected to become market leaders through first-mover and sales advantages

Manufacturing advantage generates cost advantage – rapidly increasing capacity and application of advanced technology, continuously decrease manufacturing cost

China & EU-certified global quality standards – endorse "Henlius Quality", lay solid foundation for overseas market expansion

Actively prepare for volume-based procurement – no major impact expected on HLX01 and HLX02, active preparation for HLX03

PD-1 entering harvest time – gradually file NDA for multiple indications such as MSI-H and sq-NSCLC starting from 2021

Combo advantage – HLX10+HLX04 (PD-1+VEGF) for ns-NSCLC, ; HLX10+HLX07 (PD-1+EGFR) for SCCHN

Differentiation advantage –Neo-adjuvant GC, MSI-H, etc.

Overseas sales of innovative drugs – PD-1's multiple global multi-center clinical trials (sq-NSCLC, SCLC, etc.) to prepare for overseas sales

Optimize innovative pipeline, improve innovation quality and efficiency – optimize R&D resource allocation, accelerate development of core high-quality assets (early-stage: EGFR, HER2, etc.; pre-clinical: CD47, TIGIT/PD-L1, etc.)

License-in more high-quality assets through BD – rapidly license-in global high-quality innovative drugs to strongly complement our own innovative pipeline (mAb, bispecific, small molecule, ADC, etc.)

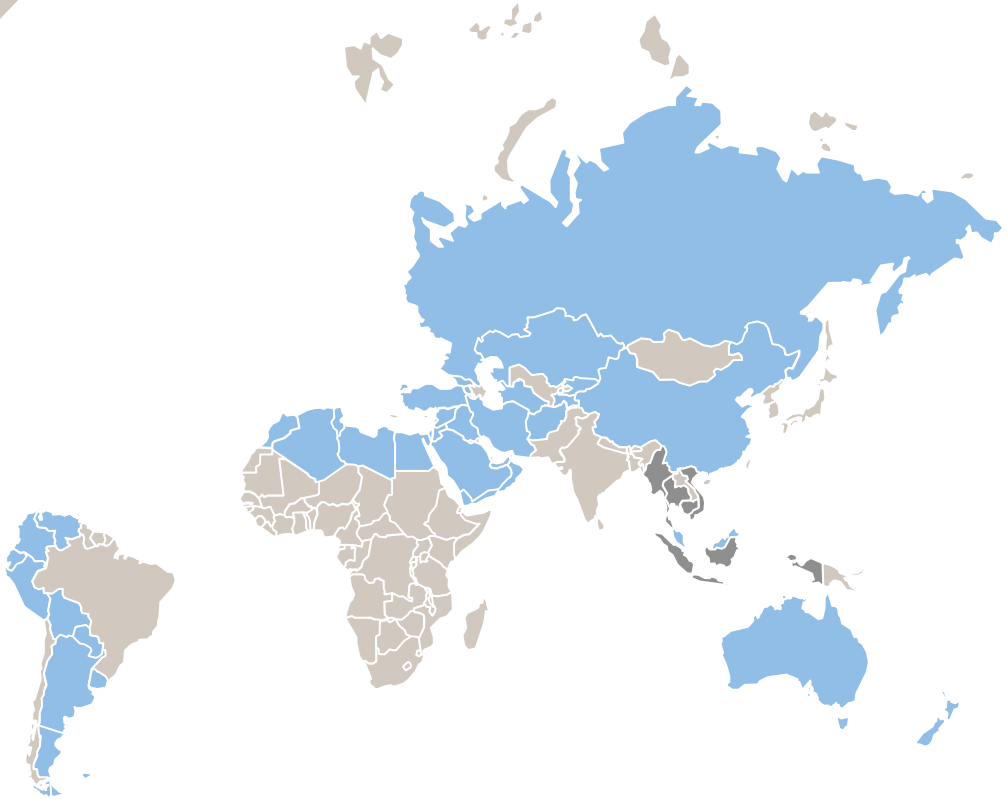
2.1

# 2020 Review: Products and Pipeline

# Biosimilar: Multiple Blockbuster Drugs Have Competitive Advantages in China

| 汉利康 | | | |
| --- | --- | --- | --- |

# Covers EU/UK Markets and More



# Biosimilar: Blockbuster Drugs such as 汉利康®, [redacted], 汉达远®

| Product (Reference Drug) | Target | Indications | Pre-Clinical | IND | Ph I | Ph II | Ph III | NDA | Launched | Global Partners |
|---|---|---|---|---|---|---|---|---|---|---|
| 汉利康® (rituximab) | CD20 | Non-hodgkin's Lymphoma / Chronic Lymphocytic Leukemia | | | | | | | | |
| 汉曲优® (trastuzumab)(1) | HER2 | Breast Cancer / Metastatic Gastric Cancer | | | | | | | | |
| 汉达远® (adalimumab) | TNF-α | Psoriasis / Ankylosing Spondylitis / Rheumatoid Arthritis | | | | | | | | |
| HLX01 (rituximab) | CD20 | Rheumatoid Arthritis | | | | | | | | |
| HLX04 (bevacizumab) | VEGF | Metastatic Colorectal Cancer / Non-squamous Non-Small Cell Lung Cancer | | | | | | | | |
| HLX05 (cetuximab)(2) | EGFR | Metastatic Colorectal Cancer / Squamous Cell Carcinoma of the Head and Neck | | | | | | | | |
| HLX12 (ramucirumab) | VEGFR 2 | Gastric Cancer / Metastatic Non-squamous Non-Small Cell Lung Cancer / Metastatic Carcinoma of the Colon and Rectum | | | | | | | | |
| HLX11 (pertuzumab) | HER2 | Breast Cancer | | | | | | | | |
| HLX14 (denosumab | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |

Core Products



(1) Approved in the EU in July 2020 (EU brand name Zercepac®) approved in China in August 2020 (2) Commercialisation rights in China have been granted to Shanghai Jingze

# Accelerate Innovation, Significantly Improve Innovation Capability

Systematically analyze and target major indications
Explore potential new technology platform and innovative molecules

Fully organize and prioritize [illegible] innovatives, select STAR and NOVA projects to accelerate development

Plan future R&D direction

Optimize pipeline resource allocation

Build systemic decision-making mechanism

Improve [illegible] capability

Build and optimize trans-dept. collaboration mechanism

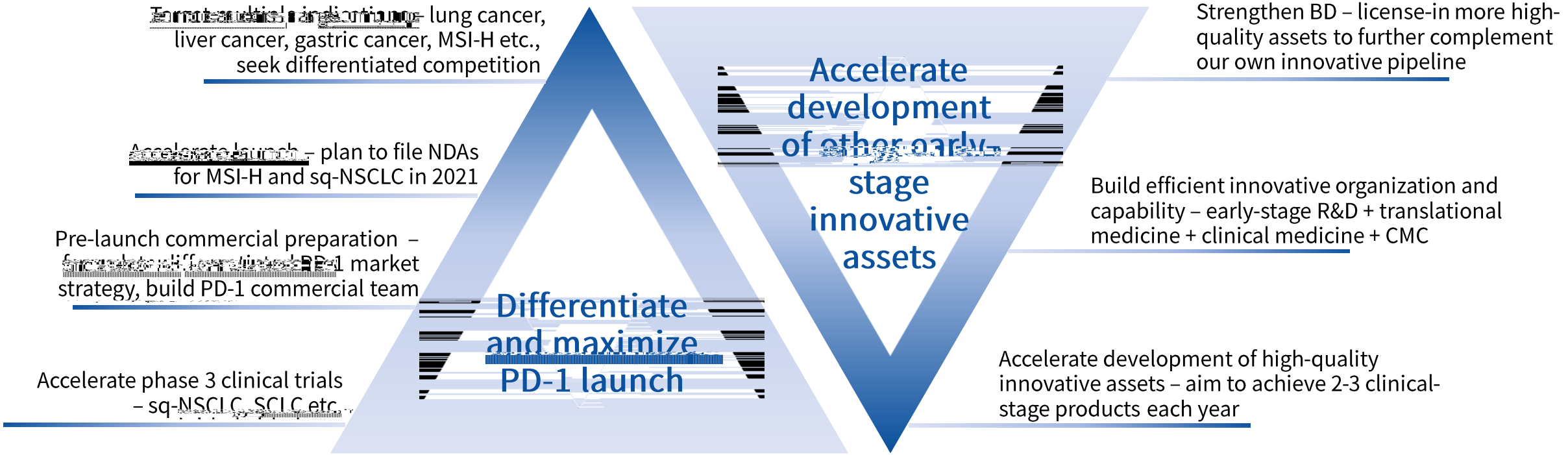
Build effective and systematic R&D decision-making and project initiation mechanisms, fully implement clinical project PGC(1) and establish preliminary early-stage project R-PGC(2)

Clinical medicine
Translational medicine

Create trans-department collaboration mechanism for "product team", improve execution and collaboration, accelerate product development

(1) PGC，Portfolio Governance Committee
(2) R-PGC, Research-Portfolio Governance Committee

# Biosimilar: Differentiate and Maximize PD-1 Launch, Accelerate Development of Other Early-Stage Innovative Assets



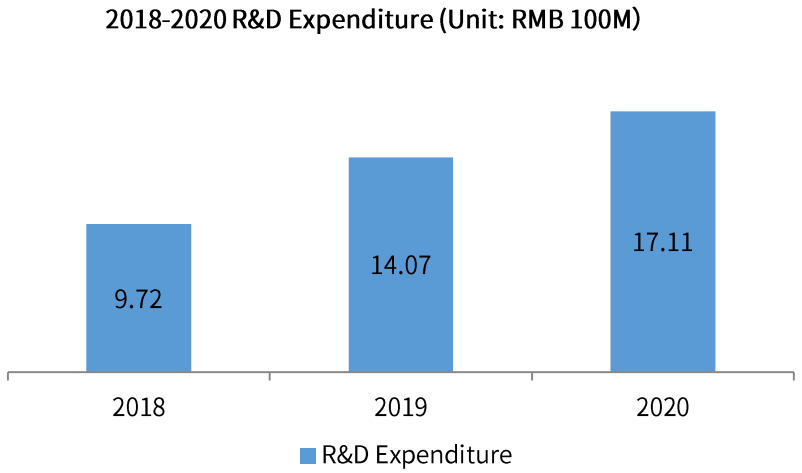
# Bio-Innovative: Led by PD-1, Covering Multiple Innovative Targets

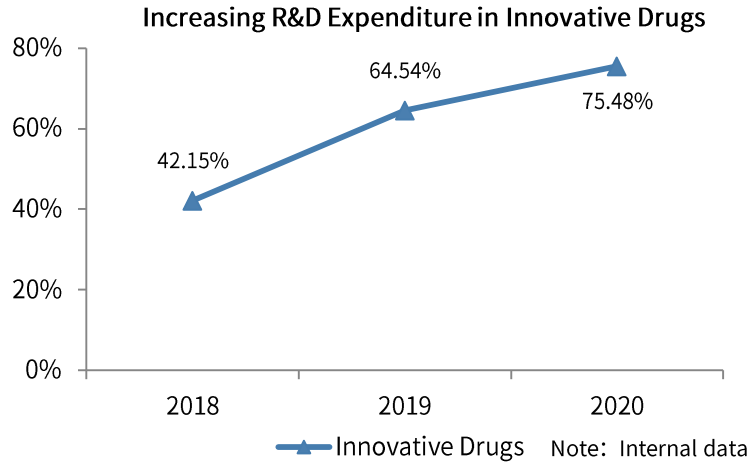
Clinical Stage

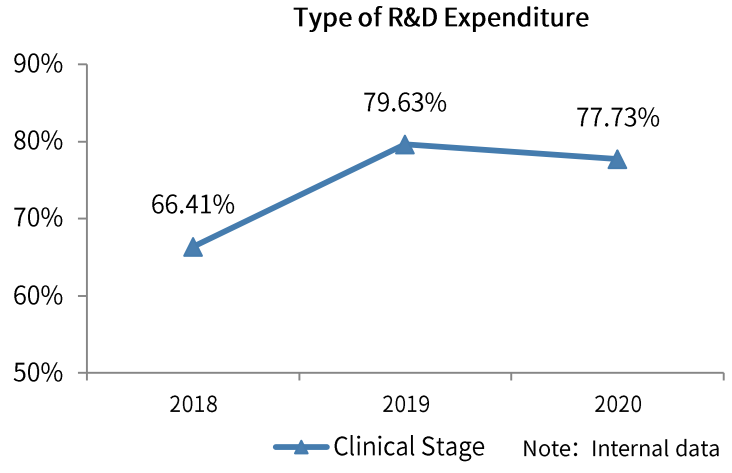
| Product | | Target | Indication | Pre-Clinical | IND | Ph I | Ph II | Ph III | NDA | Launched | Global Partners |
|---|---|---|---|---|---|---|---|---|---|---|---|
| HLX10 | Mono | PD-1 | Microsatellite Instability-High / Deficient Mismatch Repair Solid Tumors | | | | | Expected to file NDA in China around late March / early April | | | KGbio |
| | | | Hepatitis B Virus | | | | | | | | |
| | + Chemo | PD-1 | Locally Advanced / Metastatic Esophageal Squamous Cell Carcinoma | | | | | | | | |
| | | | Squamous Non-Small Cell Lung Cancer | | | | | | | | |
| | | | Extensive-Stage Small Cell Lung Cancer | | | | | | | | |
| | | | Neo-adjuvant Gastric Cancer | | | | | | | | |
| | + HLX04 | PD-1 +VEGF | Non-squamous Non-Small Cell Lung Cancer | | | | | | | | |
| | | | [illegible] Hepatocellular Carcinoma | | | | | | | | |
| | | | Metastatic Carcinoma of the Colon and Rectum | | | | | | | | |
| | + HLX07 | PD-1 +EGFR | Squamous cell carcinoma of the head and neck | | | | | | | | |
| HLX07[1] | | EGFR | Solid Tumors | | | | | | | | |
| HLX20[2] | | PD-L1 | Solid Tumors | | | | | | | | |
| HLX22 | | HER2 | Breast Cancer / Gastric Cancer | | | | | | | | |
| HLX55[3] | | c-MET | Solid Tumors | | | | | | | | |
| HLX04-O[4] | | VEGF | Wet Age-related Macular Degeneration | | | | | | | | ESSEX 亿胜 |
| HLX56[5] | | DR4 | Solid Tumors | | | | | | | | |
| HLX71[6] | | S1 Protein of SARS-CoV-2 | COVID-19 | | | | | | | | |
| HLX70[6] | | | COVID-19 | | | | | | | | |

(1) IND obtained in China / the USA
(2) IND obtained in Australia / China
(3) Obtained commercialisation rights in China / Southeast Asia / Mid Asia / South Asia, etc.
(4) IND obtained in Australia / the USA
(5) Obtained commercialisation rights in China
(6) IND obtained in the USA

# R&D: Total Expenditure Continued to Grow with More on Innovative Drugs




### Two NDAs filed

HLX01 (rituximab) - rheumatoid arthritis

### Initiated three global clinical trials

Completion of enrollment of phase 3 global clinical trial of HLX10+Chemo for squamous non-small cell lung cancer (sq-NSCLC)

FPI in Turkey for phase 3 clinical trials of HLX10+ chemo for extensive-stage small cell lung cancer (ES-SCLC);

Phase 3 clinical trial of HLX04-O (VEGF) for wAMD in AUS has been approved and will start recently, IND has been approved by FDA

### Initiated several clinical trials

[illegible] clinical trials: HLX10+HLX04 (VEGF) for solid tumor (enrolment completed); HLX07 (EGFR) for solid tumor (Clinical report completed), HLX11 (pertuzumab) for BC; HLX14 (Denosumab) for osteoporosis; HLX55 (c-Met) for solid tumor

[illegible] HLX10 (PD-1) +chemo for cervical cancer CC; HLX10 (PD-1) +HLX07 (EGFR) for head and neck squamous cell carcinoma (HNSCC); HLX10(PD-1)+HLX04 (VEGF) for Hepatocellular Carcinoma (HCC) (enrolment completed); HLX10(PD-1)+HLX04 (VEGF) for metastatic colorectal cancer (mCRC)

### Multiple INDs accepted/approved

Bio-innovative drug: HLX26 (LAG-3) for solid tumor/ lymphoma (accepted); HLX56 (DR4) for solid tumor (approved); HLX70 (neutralizing antibody) and HLX71 (ACE2-Fc recombinant protein) for COVID-19 virus

Biosimilar: HLX13 (Ipilimumab) for Melanoma (approved); HLX14 (Denosumab) for osteoporosis (approved); HLX15 (Daratumumab) for MM (approved)

2.2

# 2020 Review: Manufacturing

# Capacity Planning Implemented Steadily, Commercial Capacity Further Increased

## Xuhui Base

Commercial capacity increased from 2,000L in 2019 to current 20,000L

Support commercial manufacturing for 汉利康® (HLX01, Rituximab), 汉曲优® (HLX02, Trastuzumab), and 汉达远® (HLX03, Adalimumab)

Received EU GMP certification


## Songjiang Base (1)

Started pilot production in 2020Q2

Prepare for production needs before commercial operation of Songjiang Base (2)

## Songjiang Base (2)

Total planned land use of about 33 acres

Construction started in June 2019

Manufacturing buildings' structural roof-sealing

Completion and pilot production expected in 2021

# Integrated Platform Advantage: Three Manufacturing Bases Will Further Increase Integrated Platform Advantage


Continue to expand commercial manufacturing bases:
Xuhui Base
Songjiang Base (1)
Songjiang Base (2)

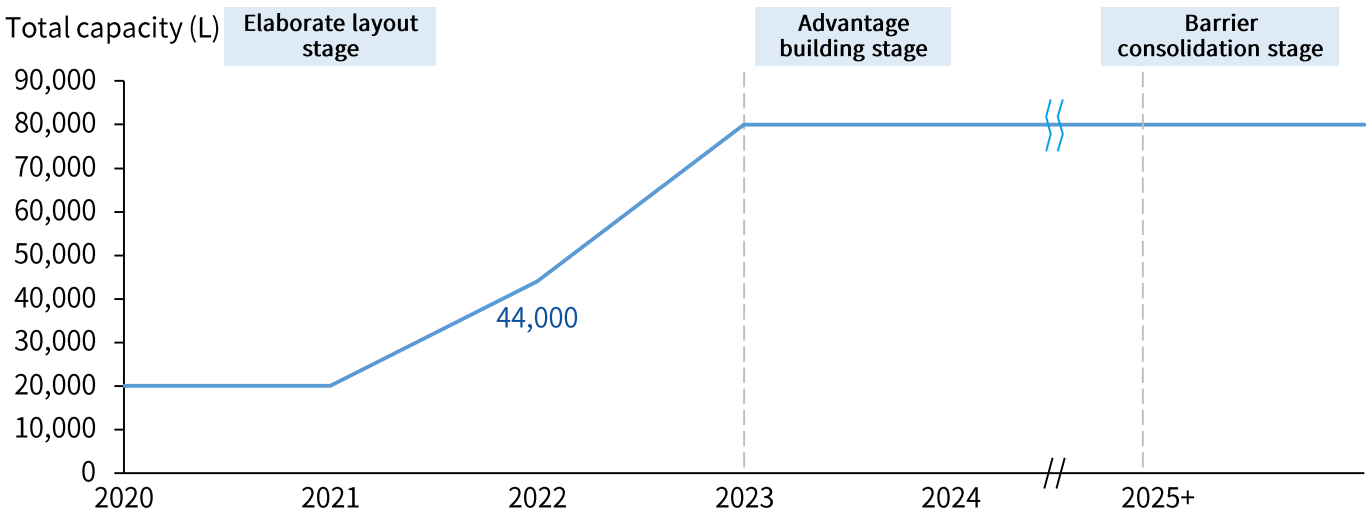
Manufacturing base and matching quality system obtained China and EU GMP certification

First to use innovative manufacturing technology:
Single-use technology
Continuous production technology


Quality management system covers whole product cycle

Benchmarking global highest quality standards with manufacturing base certified by China and EU, lay foundation for global commercialization

## Forecast of Henlius capacity




| Elaborate layout stage (2020-2022) | Advantage building stage (2023-2025) | Barrier consolidation stage (2025+) |
|---|---|---|
| Proper capacity arrangement, pre-match corresponding technology and production line for products, maximize capacity<br><br>Prospective production design and process optimization with the aim to achieve leading total cost<br><br>Explore external CMO possibility | Successfully and commercially apply innovative technology,<br><br>Forecast industry/company's future innovative product type, develop leading technology in advance<br><br>Build domestic leading position with total capacity and technology advantages | Continue to optimize process, build industry-wise quality/cost-leading production line<br><br>Assist government improve biologics manufacturing standards, establish made-in-China quality benchmark |

2.3

# 2020 Review:
# Commercial Operation

# Commercialization Strategy: Achieve Market Share through Differentiation Based on Ecosystem Empowerment

| Build preliminary ecosystem<br>Assist successful product launch | Improve ecosystem<br>Build mature collaboration platform | Build leading position through platform integration strategy |
|---|---|---|
| 2020-2022 | 2023-2024 | 2025 |
| 汉曲优®: efficient market access and coverage, optimize HER2+ patient therapy ecosystem<br><br>汉利康®: fully utilize first-mover advantage to establish and consolidate market-leading position<br><br>汉达远®: utilize partner's rich experience in rheumatology area, develop RA market, build market-leading position<br><br>HLX04 (bevacizumab) : prepare for VBP in advance, grasp opportunity to become major competitor<br><br>HLX10 (PD-1): advance fast launch, indication expansion and market access of PD-1, achieve differentiated competition through I/O combo strategy, rapidly gain market share in multiple tumors | Continue to increase and strengthen our own commercial capability, especially access and market promotion competitiveness<br><br>Promote diversified collaboration for doctor-patient ecosystem, increase and Henlius ecology with mutual empowerment<br><br>Build external collaboration platform for commercial promotion, fully explore mass market potential<br><br>Integrate resources, maximize value combination and commercial value for different products | Form joint force with upcoming rich pipeline, provide wide-ranging solution for doctors and patients<br><br>Promote platform strategy, build industry-leading position<br><br>Diversified business development model |

# 汉利康® (rituximab)and 汉达远® (adalimumab): Become Market Leaders

| 汉利康® (rituximab) | 汉达远® (adalimumab) |
| --- | --- |
| Leader of China Biosimilar | Give every auto-immune disease patient proper and possible treatment |

Become leaders in both core and mass markets

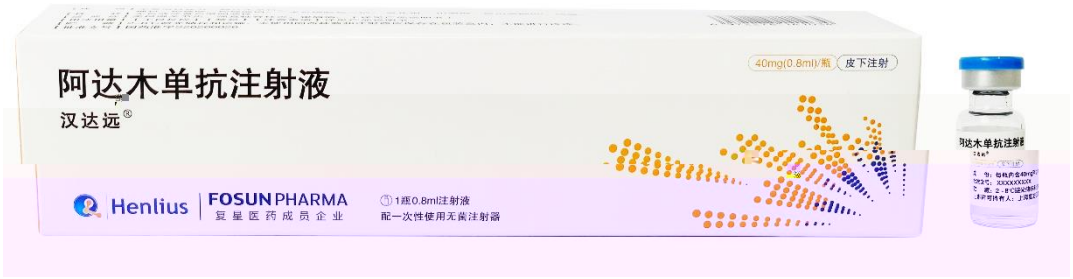
Fully surpass other rituximab competitors

Fully explore market potential of rheumatoid arthritis which is the first-to-launch NDA-filing indication (new drug pathway) in China (accepted by NMPA in Dec. 2020)


Become a leader in China's adalimumab market

Build the best commercial team in China's adalimumab market, cover core and mass markets, drive ramp-up of whole rheumatology market

Fully prepare for biologics volume-based procurement



# 汉曲优®(trastuzumab) – Leaving Any HER2+ Breast Cancer Patient Behind”

Collaboration on Physician Education

Collaborate with medical associations to facilitate community level activities

Empower innovative academic communication platforms and online activities

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

Select high-quality distributors and DTP pharmacies, associations to establish efficient business

Establish an optimized pricing system, stabilize product price

Advocate bio-similar concept to better bidding/economic outcomes

Create strategic partnership-enabled ecosystem

International top-quality standards for competitive differentiation

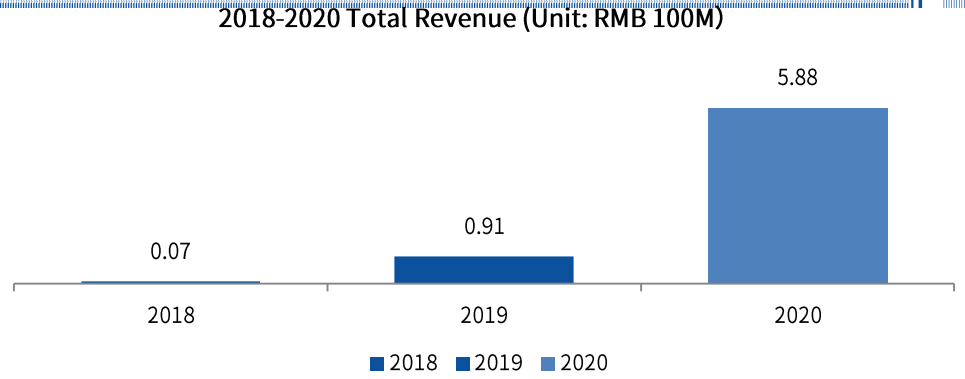
Build a PhIRDA2 Biosimilar Platform, establish industry leadership

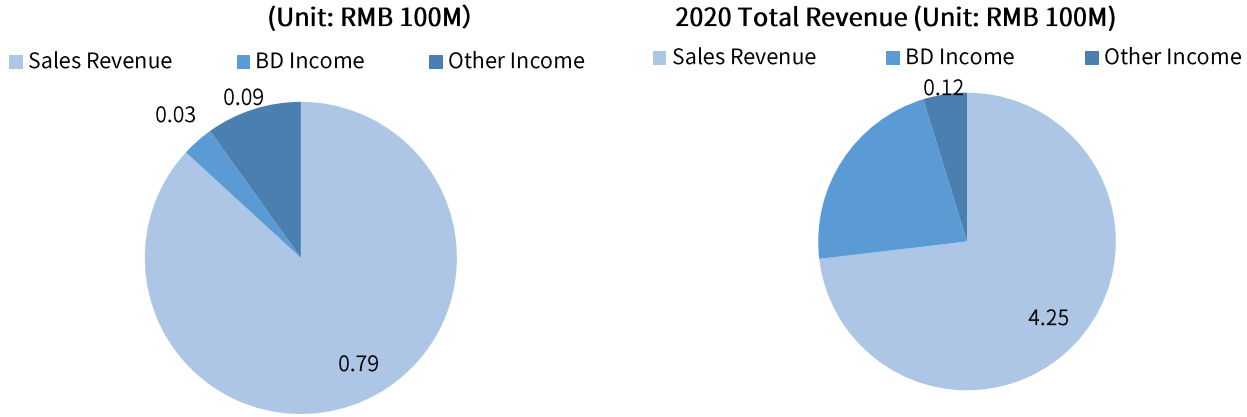
# HLX10 (PD-1, serplulimab) and HLX04 (bevacizumab): Commercial Strategy

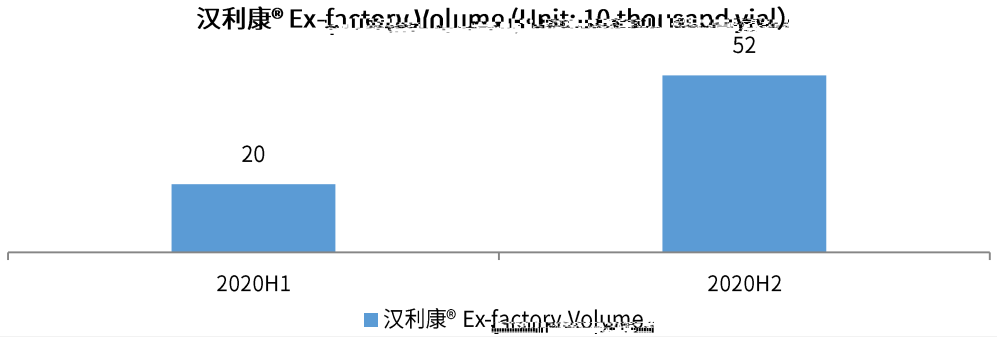
| HLX10 – Cornerstone of I/O Combo: all tumor targeting, differentiated competition, ecosystem empowerment, globalization | | |
|---|---|---|
| Differentiated development, Advance Combo therapy, expand therapeutic area | Launch with excellence<br>Rapidly release market potential | Globalization<br>Further develop overseas markets |
| Accelerate expansion of PD-1 indication<br><br>Actively advance PD-1 combo therapy<br><br>PD-1 + innovative therapy Combo | Differentiated competition, rapidly increase market share<br><br>Rapid access<br><br>Strategic partnership, empower pan-tumor ecosystem | [illegible]wise preparation for entering major markets through global multi-center clinical study<br><br>Achieve overseas market development through global partnership including registration, access, commercialization |

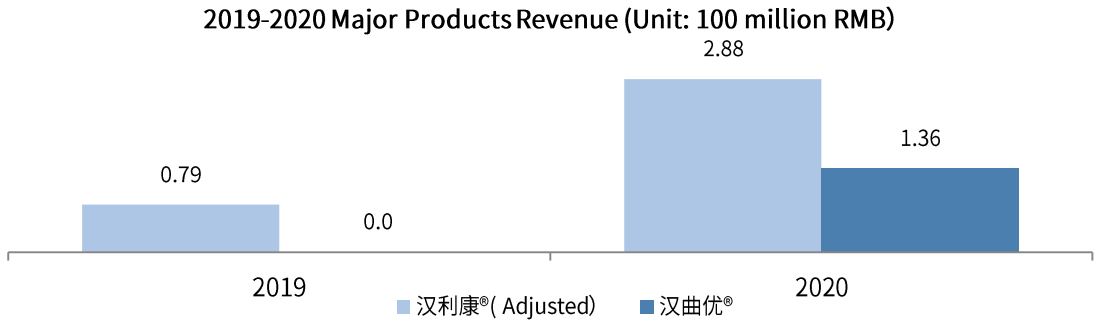
| HLX04 – Backbone of anti-VEGF Combo therapy: [illegible] turn VBP threat into opportunity | | |
|---|---|---|
| Access mass market | Advance market access, prepare for volume-based procurement (VBP) | Explore Combo therapy |
| Build mass market team<br><br>Enhance platform collaboration with mass market<br><br>Rapid deployment for more market share | Centralize best resources for rapid market access in mass market<br><br>Meanwhile fully prepare for VBP and turn threat into opportunity | [illegible] own products through real-world data or clinical studies initiated by researchers |

# 2020 Revenue: Ramp-up of 汉利康® and Launch of 汉曲优® Drove Significant Revenue Growth




## Sales of biosimilars continued to increase

汉利康® (rituximab) and CMI indications (2,000L bioreactor approved, 500mg approved, IH approved (汉利康® retail price: 1,398RMB/100mg)

汉曲优® (trastuzumab) approved in the EU and China

汉达远® (adalimumab) approved in China

## BD projects were carried forward in an orderly manner

汉曲优® (trastuzumab) - cense: Reached exclusive development and commercialization li agreements in South America region with Mabxience; cooperation with Accord upgraded and added exclusive commercial rights in Canada and the USA;

HLX04 (bevacizumab) - Co-development and exclusive license agreement with Essex for bevacizumab (HLX04) in oncology indications outside of China

HLX35 (4-1BB/EGFR) - Co-development and exclusive license agreement with Binacea for HLX35 (4-1BB/EGFR)

[redacted]b – Exclusive license agreement with Chiome for antibodies targeting human Trop2

3

# 2021 Outlook

# Outlook for 2021

## Commercialization

### Capitalize on first-mover advantage and increase the global market coverage of products, continue to commercialize more products

HLX02汉曲优®: fully advance completion of medical insurance activation and tendering/access; complete 70% hospital coverage of top 1000; strive to become market leader with >50% new patient market share in covered market

HLX01汉利康®: continue to advance market expansion, fully become market leader

HLX03汉达远®: complete most of [illegible] tendering/access, and key hospital coverage; fully utilize commercial team's experience in rheumatology area to gain significant market share

HLX04 (bevacizumab): approval expected in 2021Q4, initiate strategic layout preparation

HLX01 (rituximab) - [illegible] the end of 2021 or in the first half of 2022; fully prepare for launch

HLX10 (PD-1): file NDA for MSI-H in the short term; file NDA for sq-NSCLC in 2021H2

## R&D

### Rapidly build diversified clinical-stage innovative [illegible] internal R&D and license-in

[illegible] making mechanism and working mode, and significantly improve the efficiency of R&D

HLX10(PD-1) based clinical trial of immuno-oncology combination therapy for indications of squamous non-small cell lung cancer, non-squamous non-small cell lung cancer, extensive stage small cell lung cancer, esophageal squamous cell carcinoma, gastric cancer, hepatocellular carcinoma, and squamous cell carcinoma will be further promoted in 2021

Accelerate expansion of innovative potential targets, antibody-drug conjugates (ADC) products and oncolytic virus products through license-in

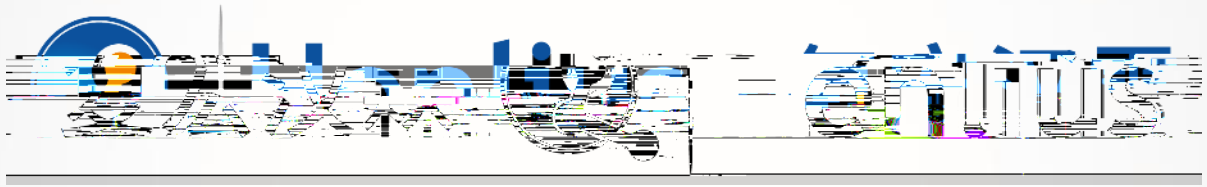
## Manufacturing

### Maintain high quality standards and continue to promote industrialization deployment

Xuhui guaranteeing "Henlius Quality", further promote effective operation, continue to decrease cost; add a pre-filled needle production line

Songjiang Base (1): complete process validation of 24,000L capacity, pilot workshop completes continuous production

Songjiang Base (2): initiate trial production and start relevant validation work



Reliable Quality | Affordable Innovation