

# Henlius (2696.HK)

# 2020 Annual Results Investor Presentation

March 2021

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# and

# Management Team: More Executives Joined Henlius with



## Wenjie Zhang

Joined Henlius in [illegible]
25 years of commercial operation experience in pharmaceutical industry
[illegible]
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

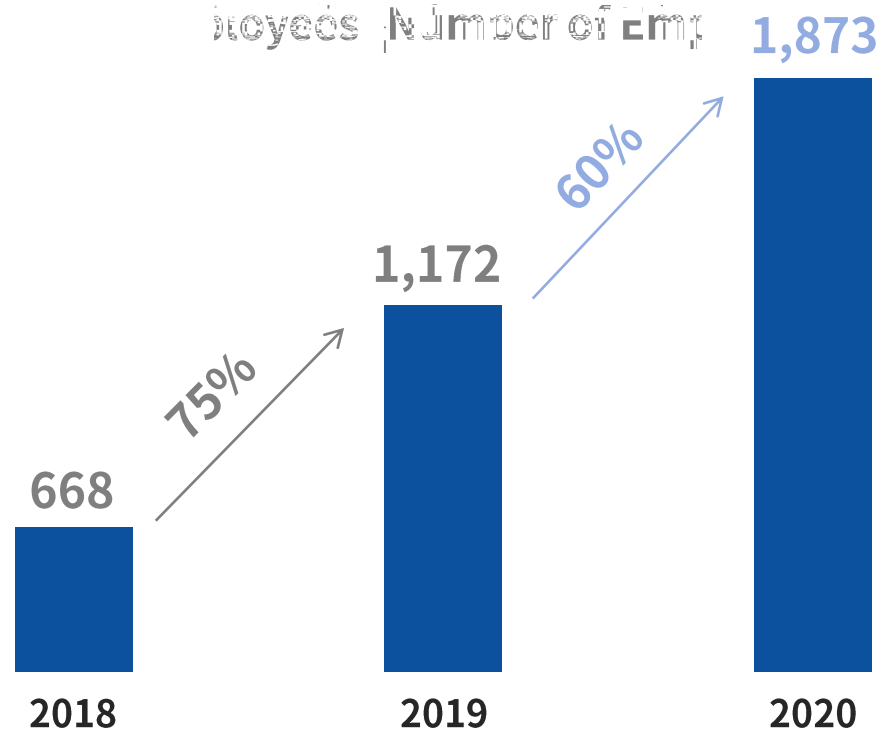


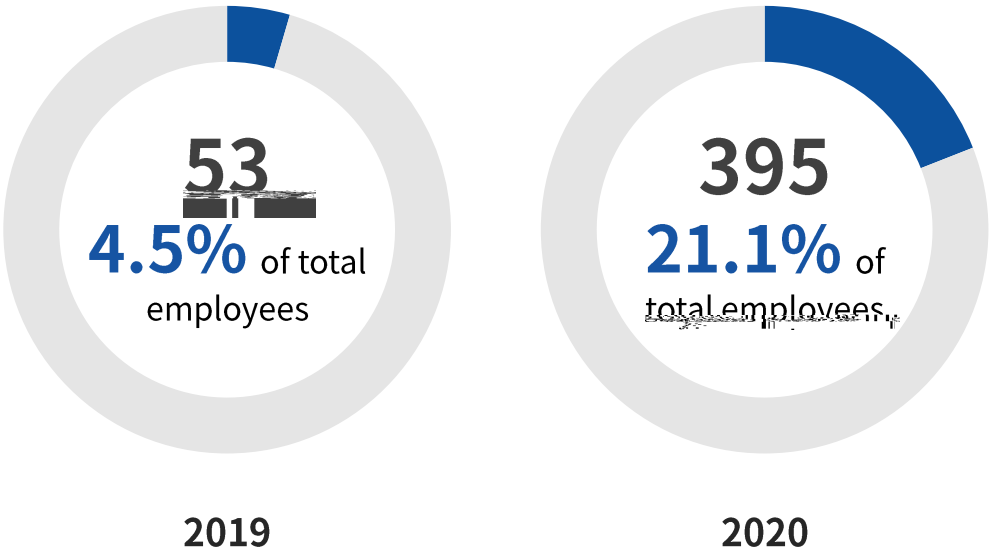
**Simon Hsu**
Chief Technology Officer
Head of Technical Operations & CMC
Joined Henlius in Dec. 2019



**Cecie Jiang**

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




| R&D | Clinical | Manufacturing | Quality | Commercial | Administrative |
|---|---|---|---|---|---|
| 184 | 231 | 437 | 256 | 395 | 203 |

Note: as of Dec 31, 2020

# Company Strategy: Accelerate Diversified Innovation with Full Speed

| Stage 1: Biosimilar | Stage 2: Diversified Innovation |
| --- | --- |
| Build comprehensive commercial capability | Accelerate transformation towards diversified innovation including mAb, bispecific, ADC, etc. |
| strive to become first-in-class or tier-1 to launch | R&D innovation capability improve |
| Further expand leading advantages in manufacturing technology, cost and scale | Establish executable and measurable R&D strategy |
| commercial value of products | 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 RR-1 through partnership in the early stage

# Accelerate Development of Bio-Innovative Drugs

| Biosimilar Lays Solid Foundation | PD-[redacted]serplulimab) Entering Harvest Time, Focus [redacted] and Combo Advantages | Accelerate Innovation [redacted] Internal R&D + BD |
|---|---|---|
| Three biosimilars have strong competitive edges – 汉利康®（chuiximab）、汉曲优®（trastuzumab）、汉达远®（adalimumab）expected to become market leaders through first-mover and sales advantages | PD-1 entering harvest time – gradually file NDA for [redacted] and sq-[redacted] in 2021 | Optimize innovative pipeline, improve [redacted] innovation quality and efficiency – optimize R&D resource allocation, accelerate development of [redacted] quality assets (early-stage: EGFR-HER2, etc.; pre-clinical: CD47, TIGIT/PD-L1, etc.) |
| Manufacturing advantage generates cost advantage – rapidly increasing capacity and application of advanced technology continuously decrease manufacturing cost | Combo advantage – [redacted] (PD-[redacted]) for ns-NSCLC, [redacted]; HLX10+HLX07 (PD-1+EGFR) for SCCHN | 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.) |
| China & EU-certified global quality standards – endorse "Henlius Quality", [redacted] solid foundation for overseas market expansion | Differentiation advantage – Neo-adjuvant GC, MSI-H, etc. | |
| Actively prepare for volume-based procurement – no major impact expected on HLX01 and HLX02, active preparation for HLX03 [redacted] | Overseas sales of innovative drugs – PD-1's [redacted] multi-center clinical trials (sq-NSCLC, SCLC, etc.) to prepare for overseas sales | |

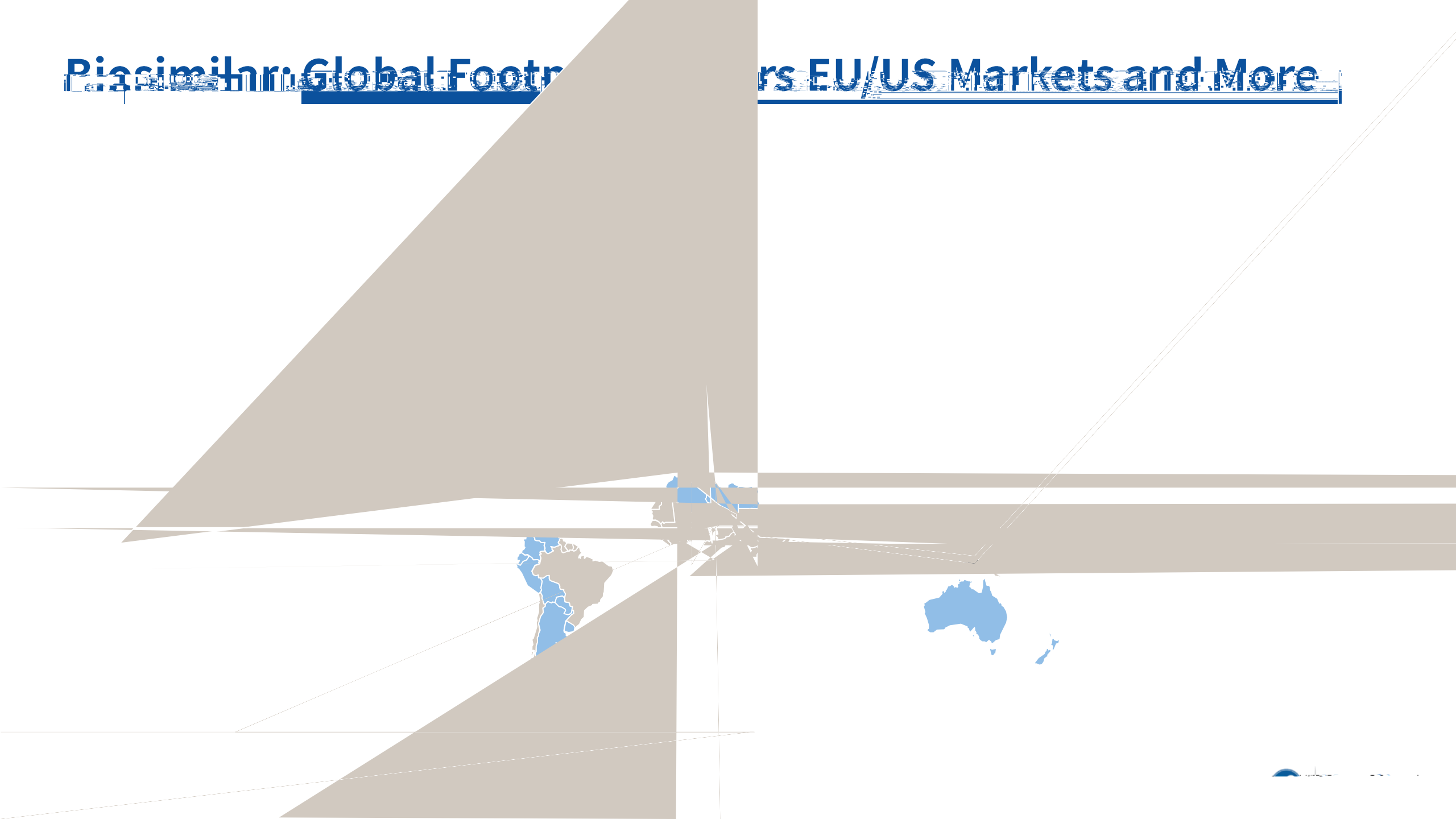
# 2.1



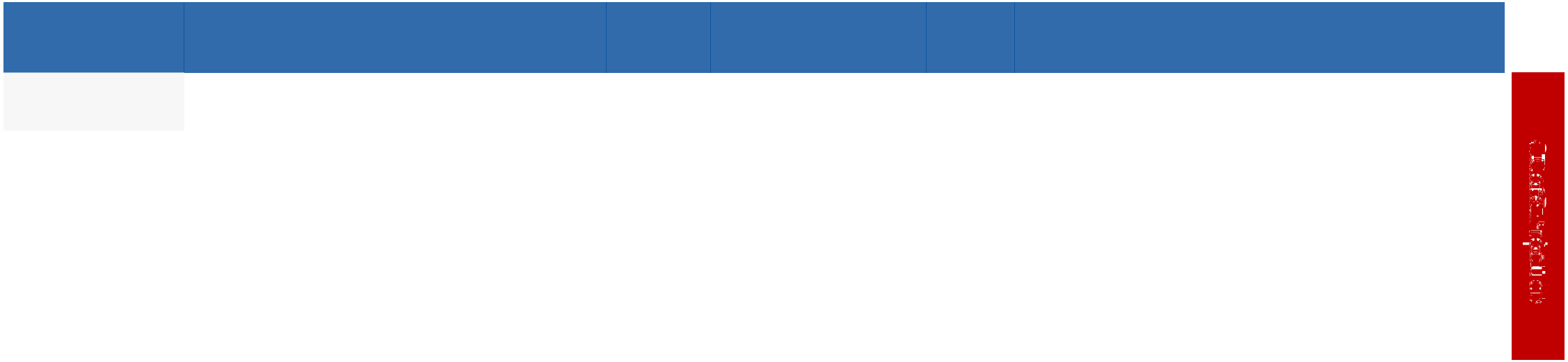
# Principles Multiple Blockchain Based Users Competitive Advantages in China

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

# Plasmiha: Global Footr rs EU/US Markets and More



# Biosimilar: Blockbuster Drugs such as 汉利康®, [illegible]





(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

# Capability

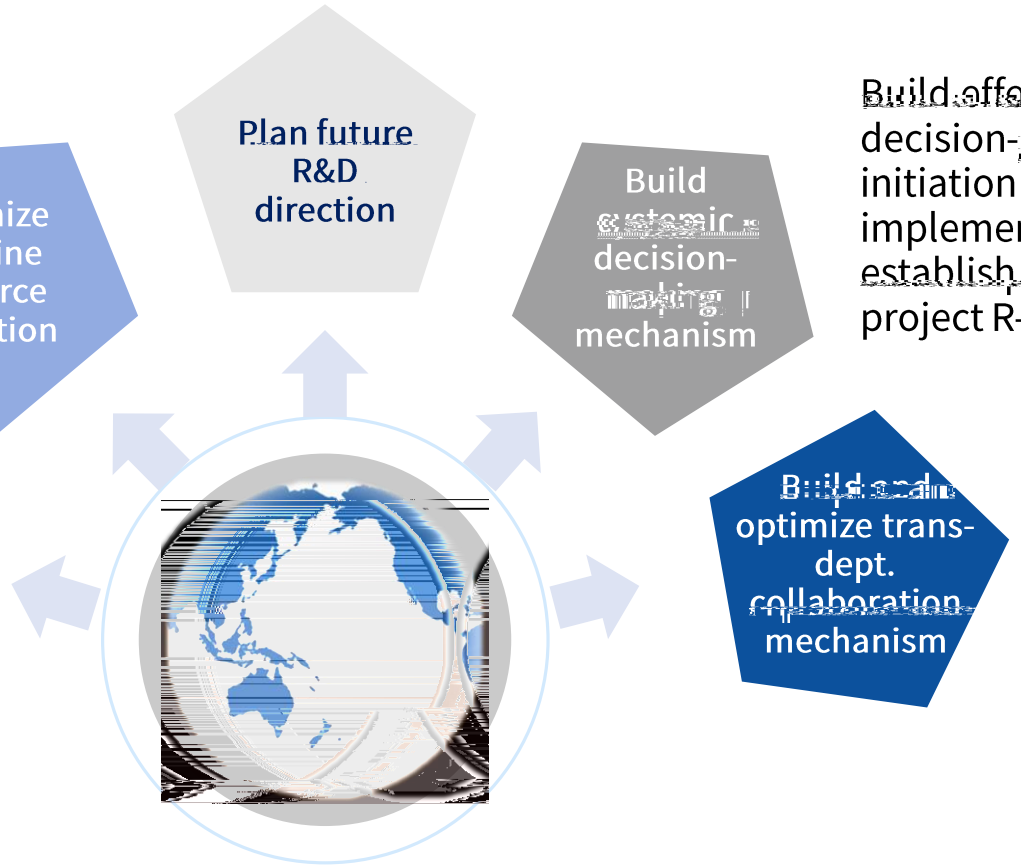
Systematically analyze and target major indications
Explore potential new technology platform and innovative molecules

Fully organize and prioritize [illegible] innovatives [illegible] development

Clinical medicine [illegible]

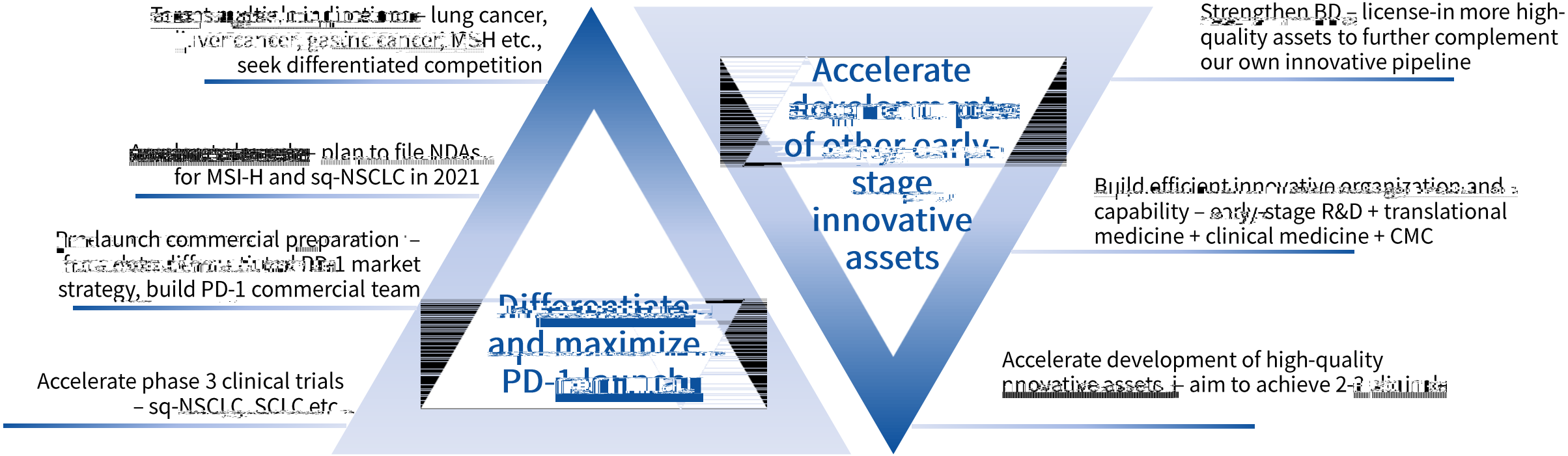
Build effective and systematic R&D decision-making and project initiation mechanisms, fully implement clinical project PGC(1) establish preliminary early-stage project R-PGC(2)

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

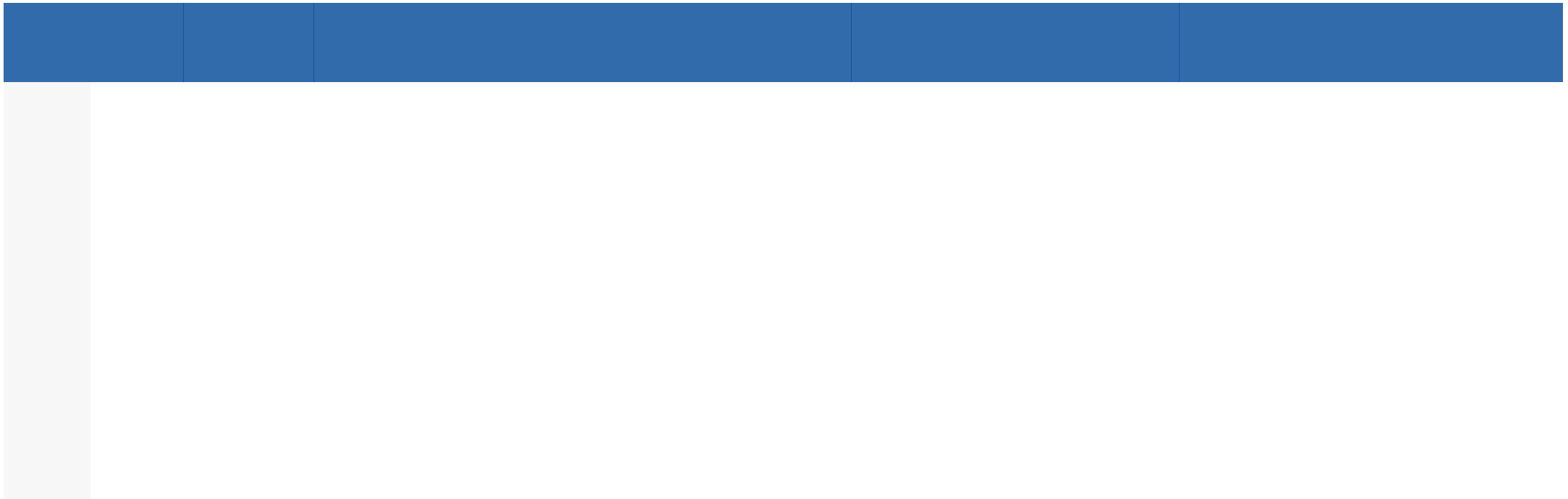



(1) PGC，Portfolio Governance Committee
(2) R-PGC, Research-

# Development of Other Early-Stage Innovative Assets



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



## Two NDAs filed

HLX04 (bevacizumab)

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)

EPI 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)

2.2



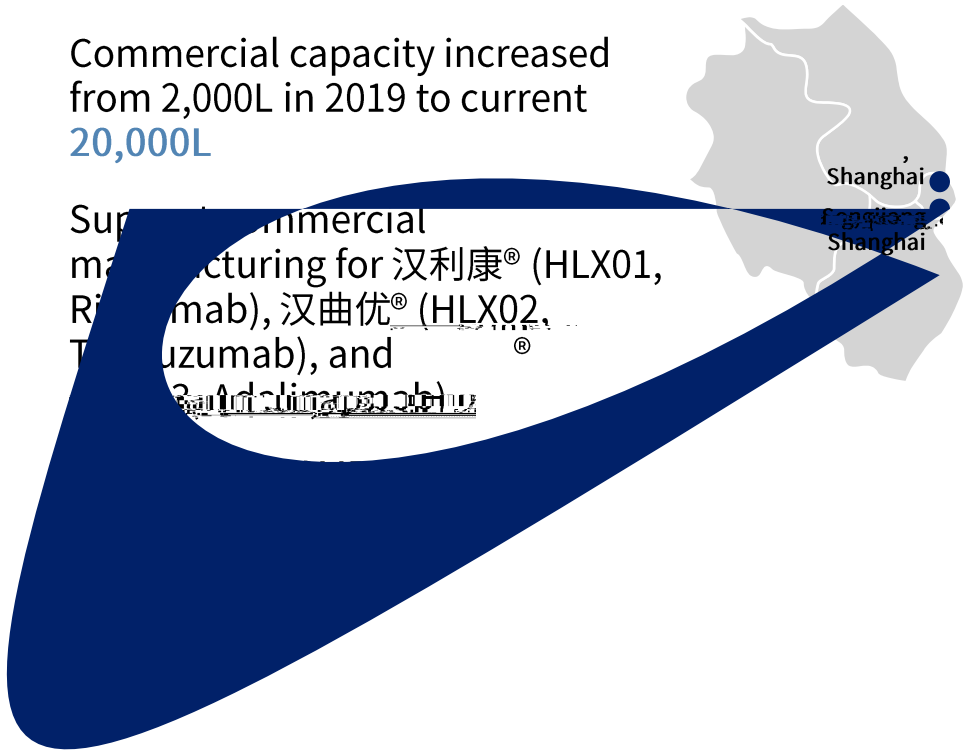
# Manufacturing

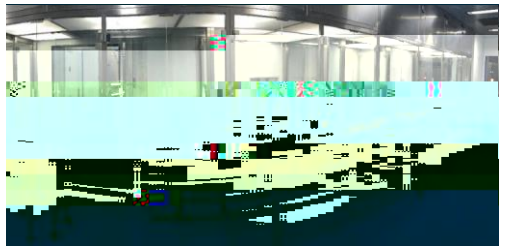
# Capacity Planning Implemented Steadily, Commercial Capacity Further Increased

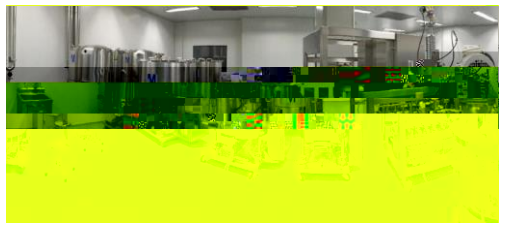
## Xuhui Base

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

Supporting commercial manufacturing for 汉利康® (HLX01, Rituximab), 汉曲优® (HLX02, Trastuzumab), and 汉斯状® (HLX03, Adalimumab)





## Songjiang Base (1)

Started pilot production in 2020Q2

Renovation needs completed 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 completed in April 2020

Completion and pilot production expected in 2021

# Will Further Increase Integrated Platform Advantage




Continue to expand commercial manufacturing bases:

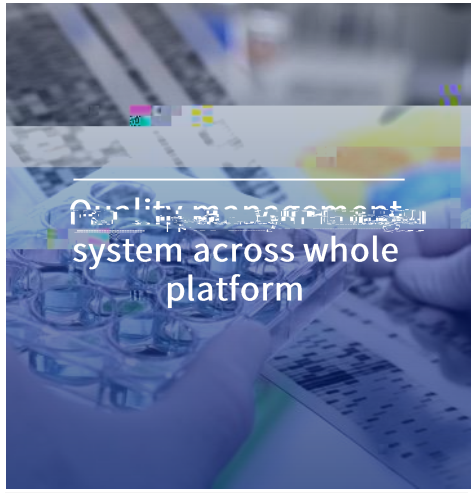
Base

Songjiang Base (1)
Songjiang Base (2)

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

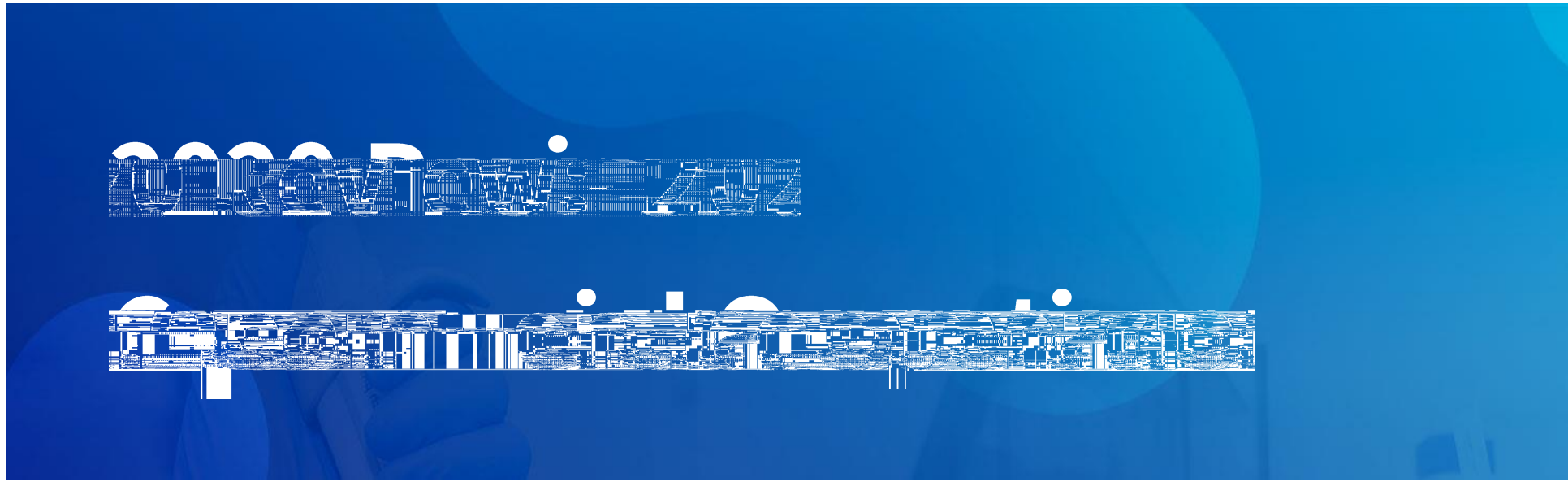
First to use innovative manufacturing technology

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



# 汉利康® [illegible] ®(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 |

[illegible]

Fully surpass other rituximab competitors

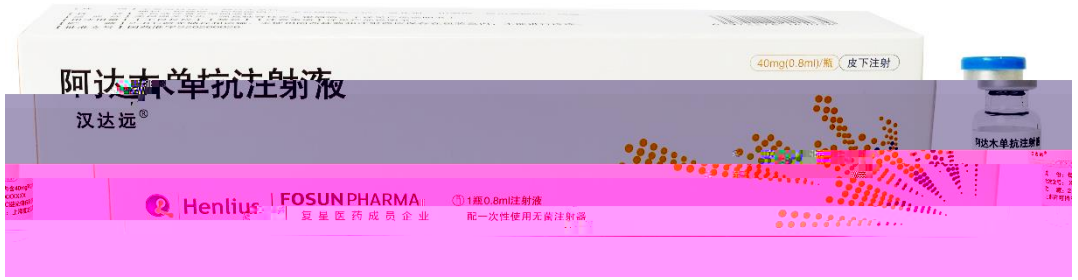
Fully explore market potential of rheumatoid arthritis which is the first and the only NDA-filing indication (new drug pathway) in China (accepted by NMPA in Dec. 2020)

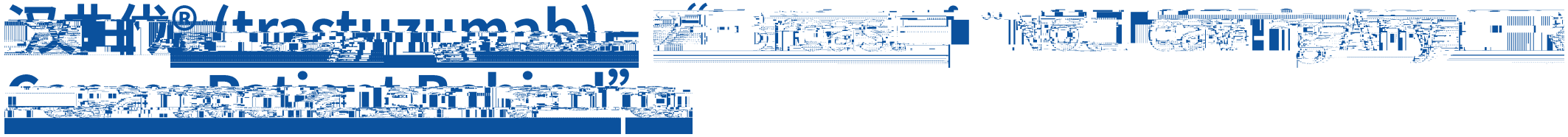
Become a leader in China's adalimumab market

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







communication platforms and online activities

Collaborate with academic institutions on biosimilar pricing management research

Prepare in advance, quickly complete entering provincial and integrated

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

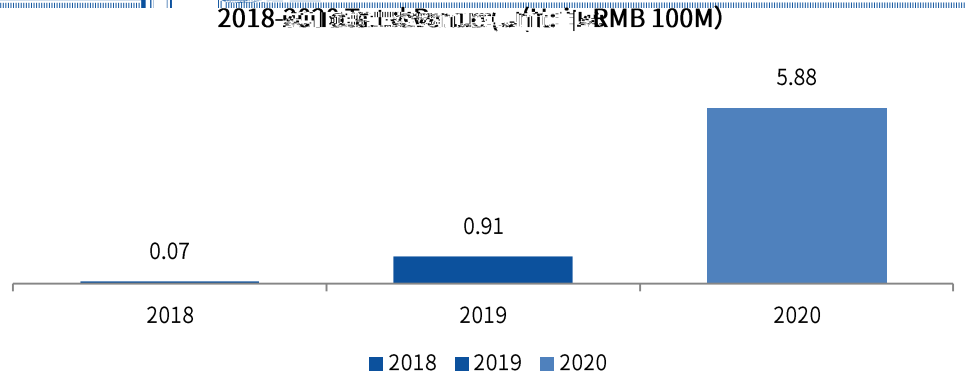
## HLX10 – [illegible] all tumor targeting, differentiated competition, ecosystem empowerment, globalization

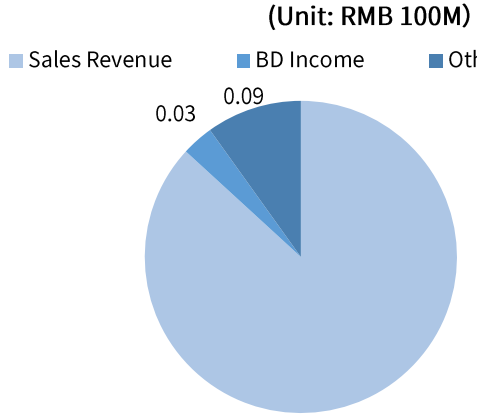
| Differentiated development, Advance Combo therapy, expand therapeutic area | Launch with excellence<br>Rapidly release market potential | Globalization<br>Further develop overseas markets |
|---|---|---|
| Accelerate expansion of PD-1 indication<br><br>PD-1 Actively advance 1 combo therapy<br><br>PD-1 [illegible] | Differentiated competition, rapidly increase market share<br><br>Rapid access<br><br>Strategic partnership, empower pan-tumor ecosystem | Make overseas preparation for entering major markets through global multi-center clinical study<br><br>Achieve maximum market benefit through global partnership including registration, access, commercialization |

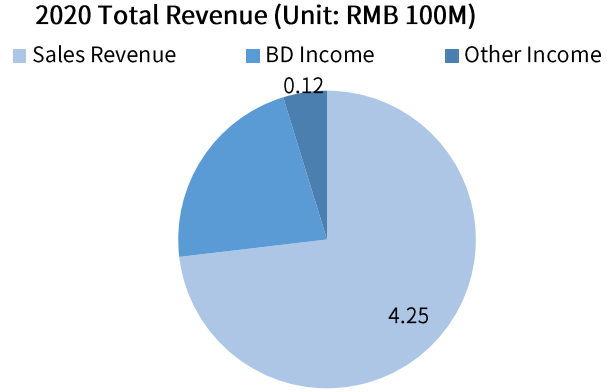
## HLX04 – Backbone of anti-VEGF Combo therapy: [illegible] turn VBP threat into opportunity

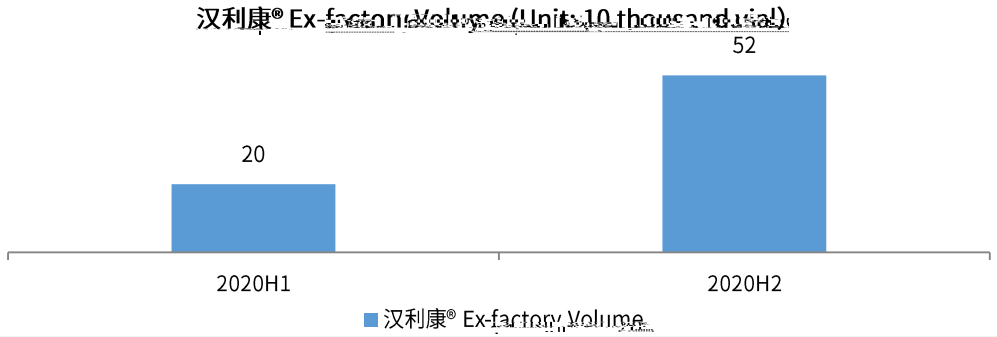
| Access mass market | Advance market access, prepare for volume | |
|---|---|---|
| Build mass market team<br><br>Enhance platform collaboration with mass market<br><br>Enrich indication pipeline, rapid realize market share | Centralize best resources for rapid market access in mass market<br><br>Meanwhile fully prepare for VBP and turn threat into opportunity | Actively explore combo therapy with our own products through real-world data or clinical studies initiated by researchers |

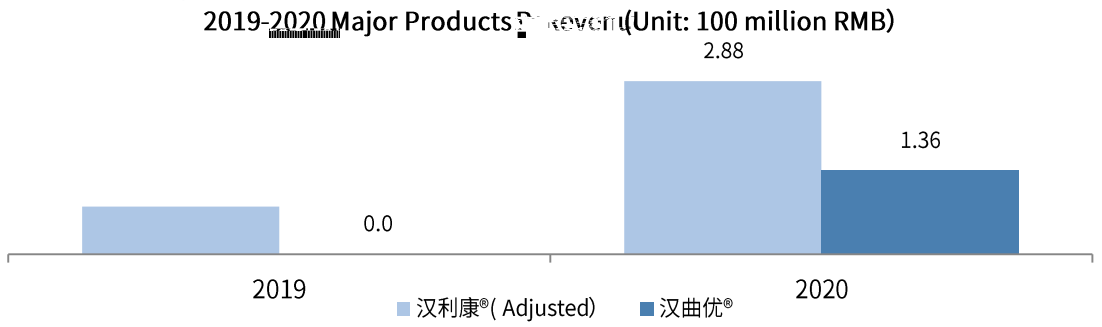
# 2020 Revenue: Ramp-up of 汉利康® [illegible] of 汉曲优® Drove Significant Revenue Growth




## Sales of biosimilars continued to increase

® (rituximab) 2,000L bioreactor approved, 500mg approved, FL and CLL indications approved ( ® retail price: 1,398RMB/100mg)

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

汉达远® approved for [illegible] in China.

## [illegible] projects [illegible] forward in an orderly manner

汉曲优® (trastuzumab) - eached exclusive development and commercialization license [illegible] agreement 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 accordance with [illegible] globally.

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

[illegible] – Exclusive license agreement with Chiome for [illegible]

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# 2021 Outlook

# Outlook for 2021

Commercialization







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