

Henlius (2696.HK)

2020 Annual Results Investor Presentation

March 2021

© 2020 Henlius.

Disclaimer

Henlius, the representor or the provider does not make any warranties, statements or representations, express or implied, on the content of this document (the content of this document may also include forward-looking statements), including but not limited to statements about the timeliness, universality and accuracy of the content for any specific purpose or with regard to the correctness

© 2020 Henlius

1

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

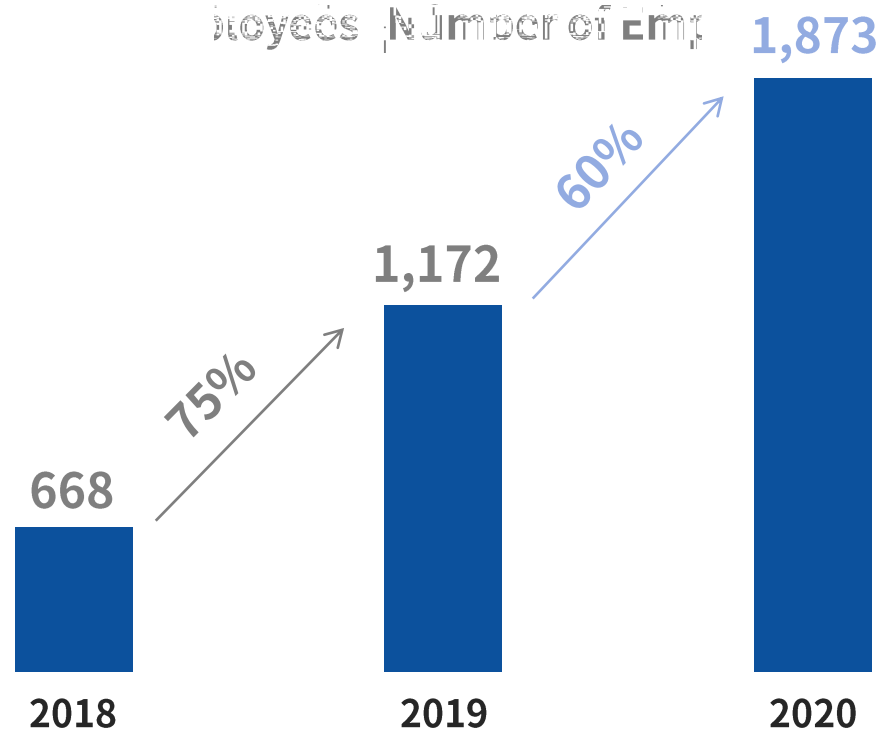


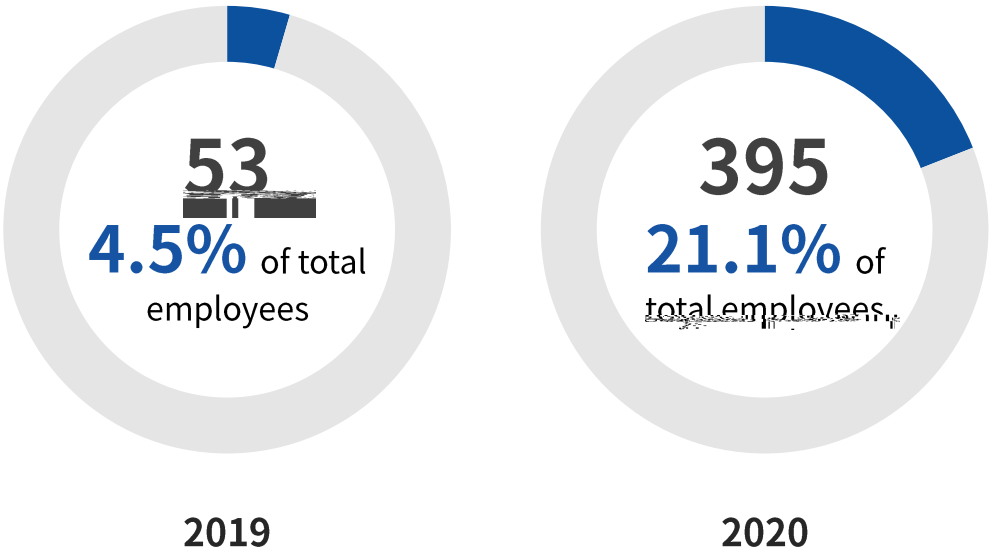
Simon Hsu
Chief Technology Officer
Head of Technical Operations & CMC
Joined Henlius in Dec. 2019



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	

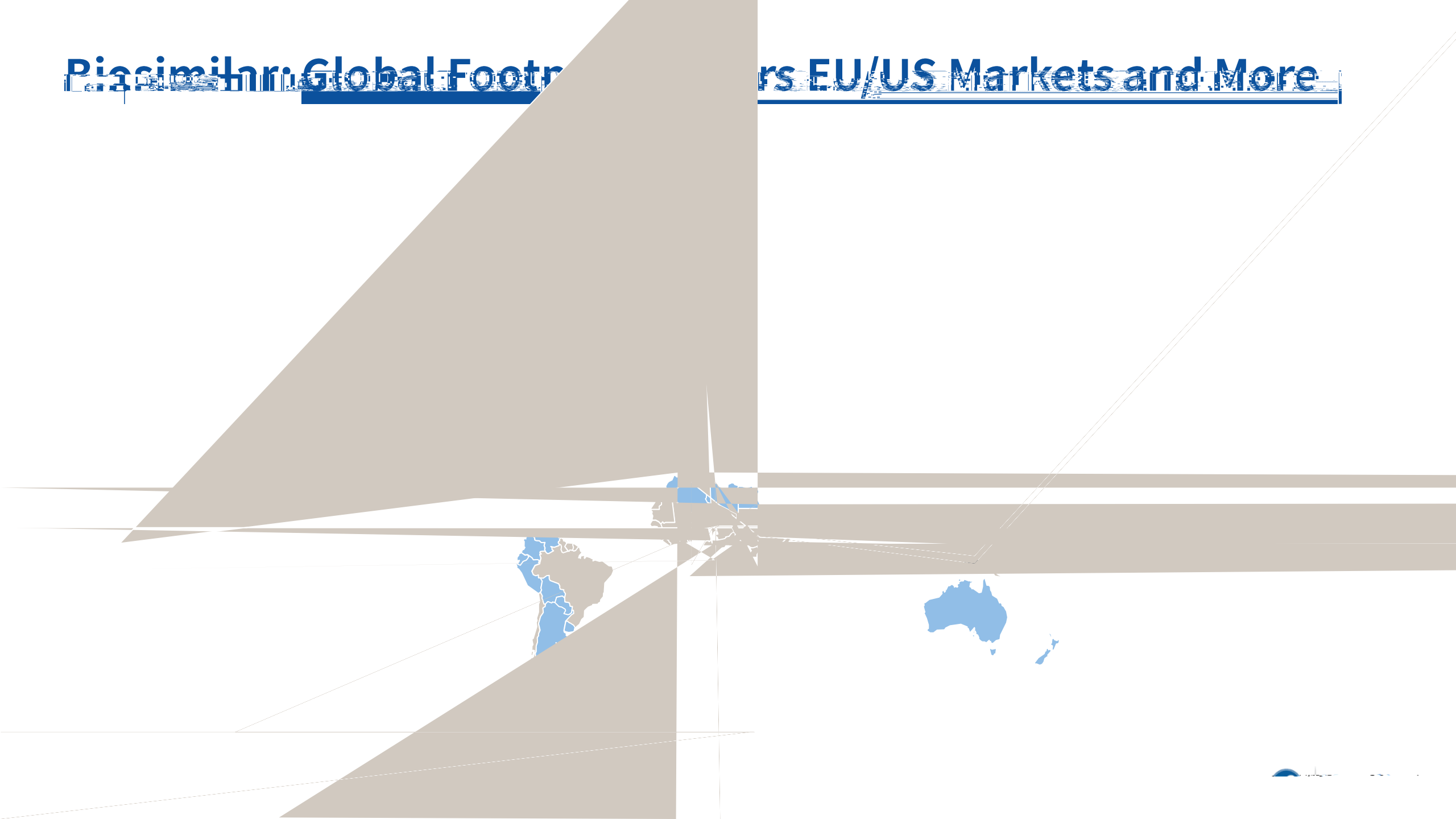
2.1



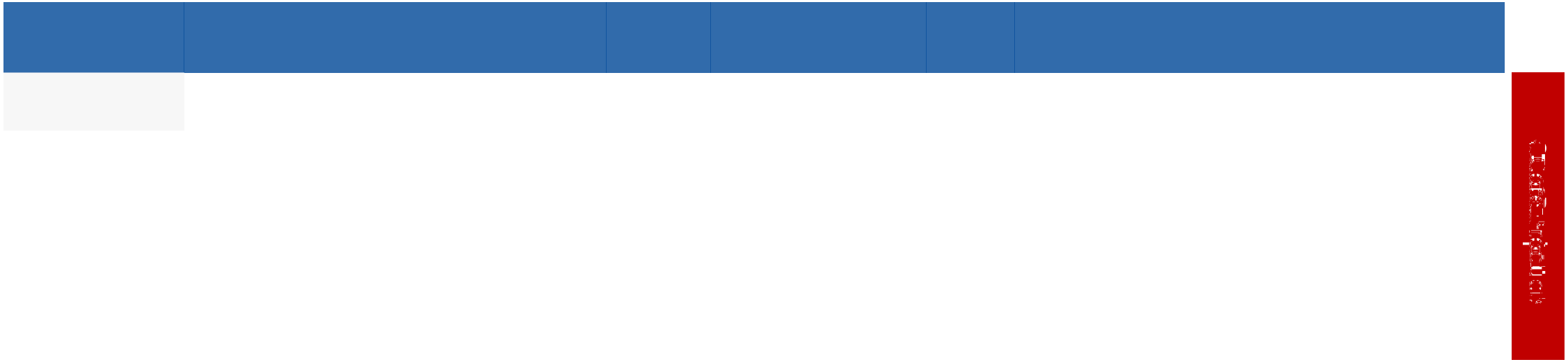
Principles Multiple Blockchain Based Users Competitive Advantages in China

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

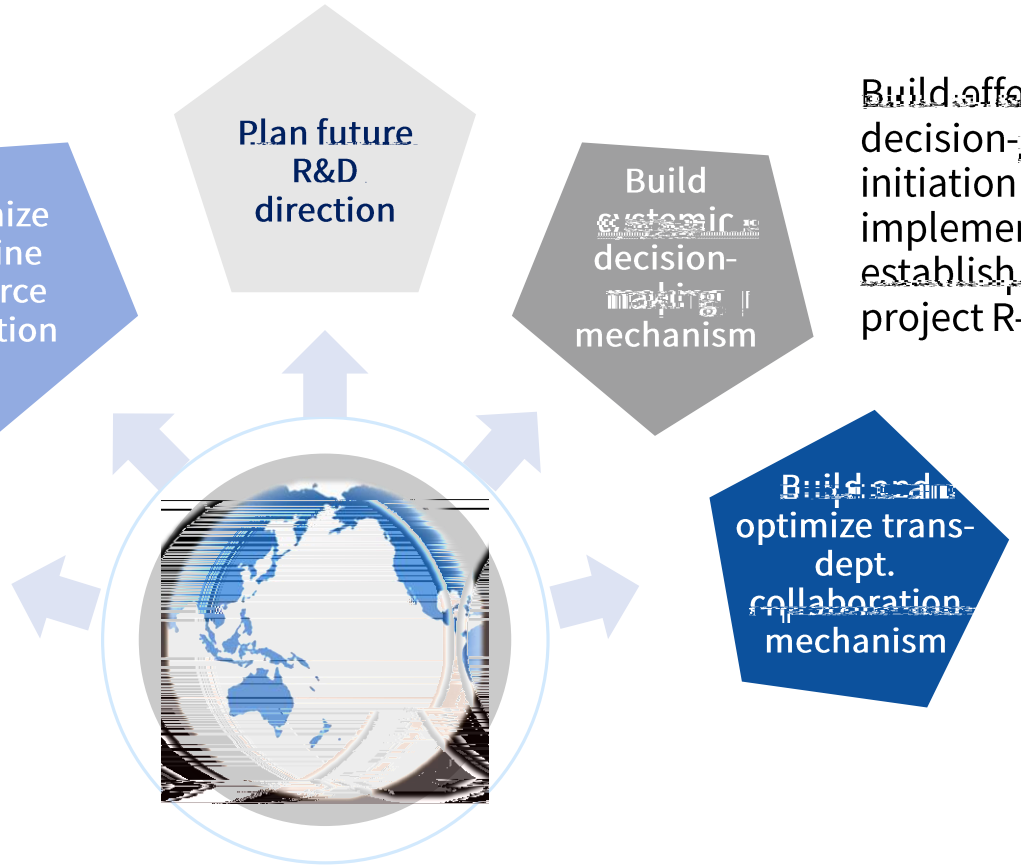
Systematically analyze and target major indications
Explore potential new technology platform and innovative molecules

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

Clinical medicine [illegible]

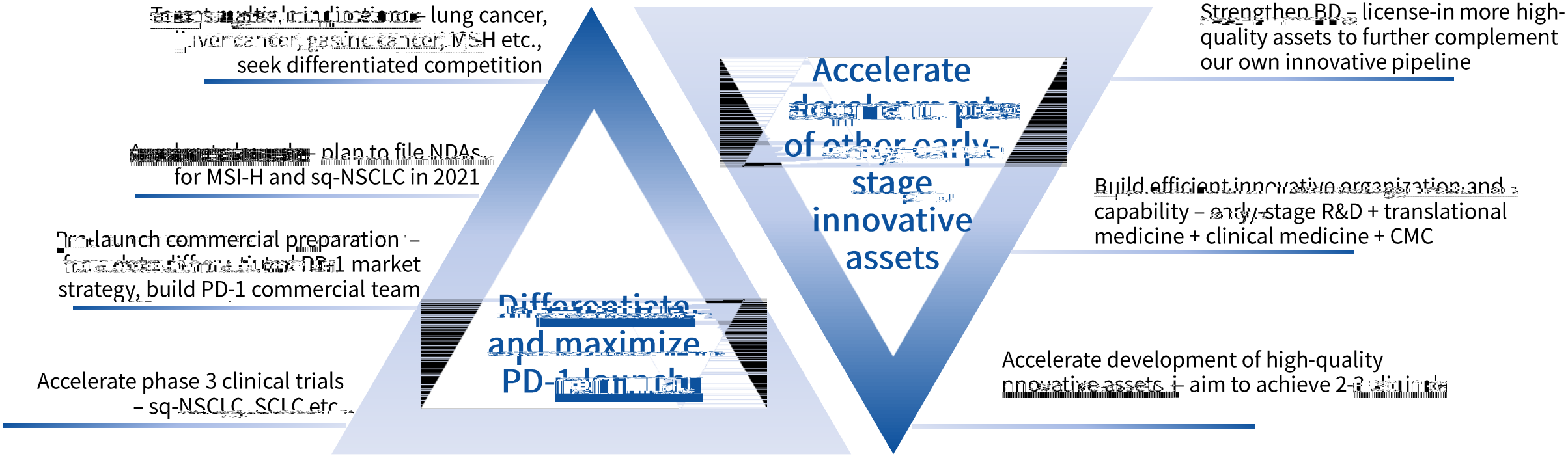
Build effective and systematic R&D decision-making and project initiation mechanisms, fully implement clinical project PGC(1) establish preliminary early-stage project R-PGC(2)

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

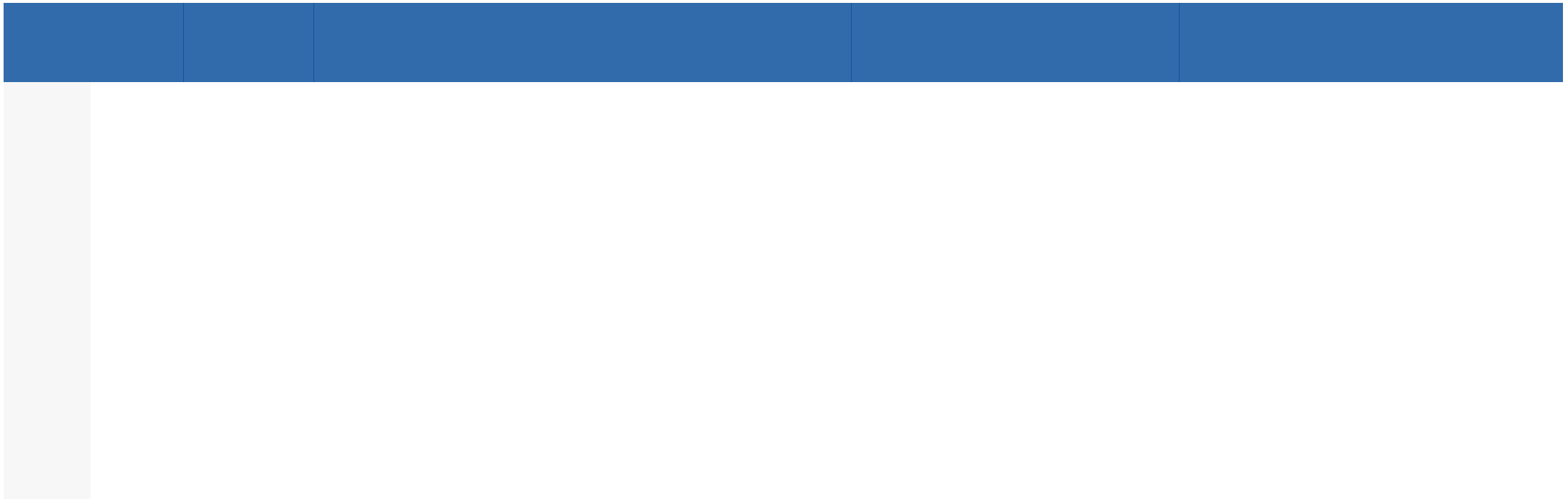


(1) PGC，Portfolio Governance Committee
(2) R-PGC, Research-

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



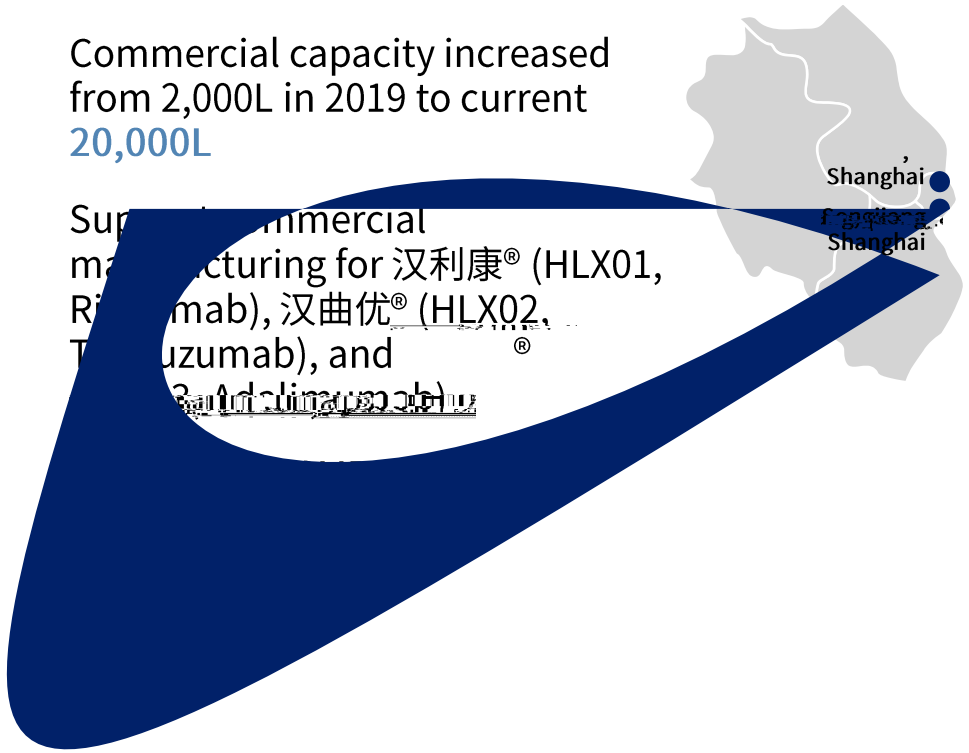
Manufacturing

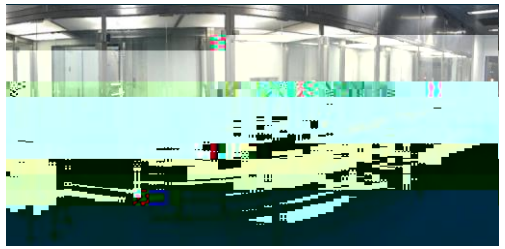
Capacity Planning Implemented Steadily, Commercial Capacity Further Increased

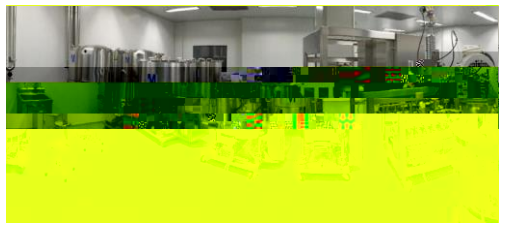
Xuhui Base

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:

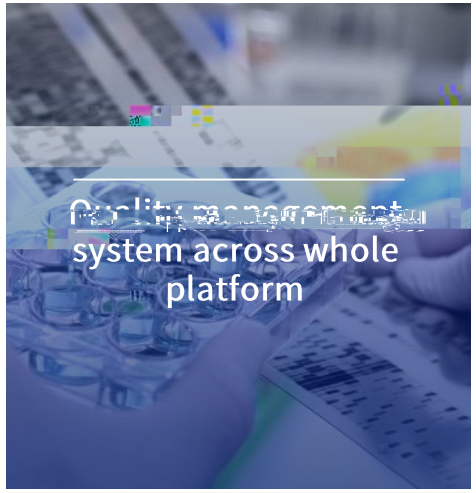
Base

Songjiang Base (1)
Songjiang Base (2)

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

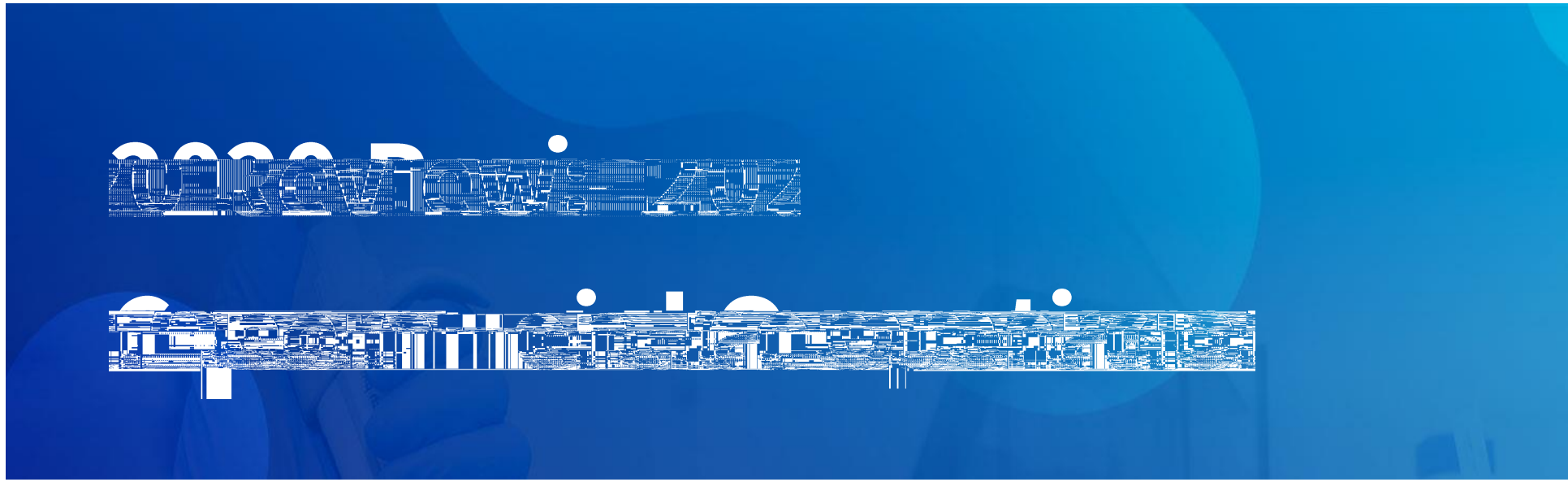
First to use innovative manufacturing technology

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

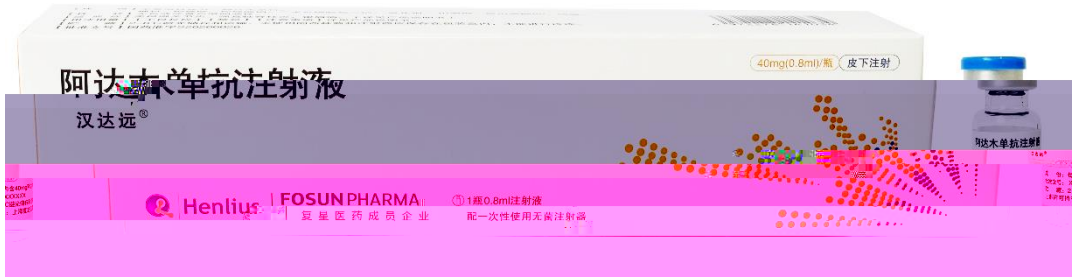
Fully explore market potential of rheumatoid arthritis which is the first and the only NDA-filing indication (new drug pathway) in China (accepted by NMPA in Dec. 2020)

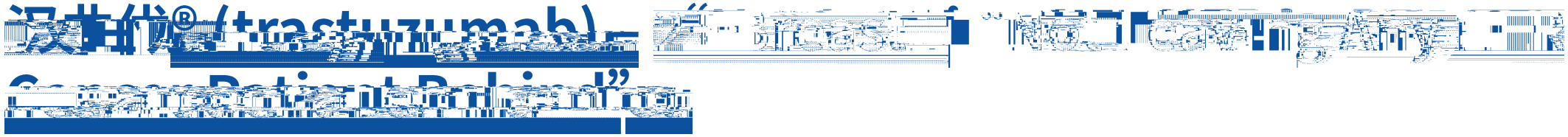
Become a leader in China's adalimumab market

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

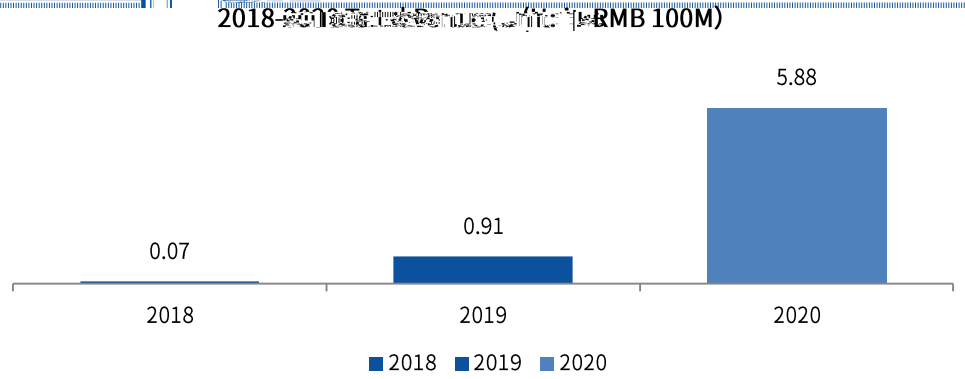
HLX10 – [illegible] all tumor targeting, differentiated competition, ecosystem empowerment, globalization

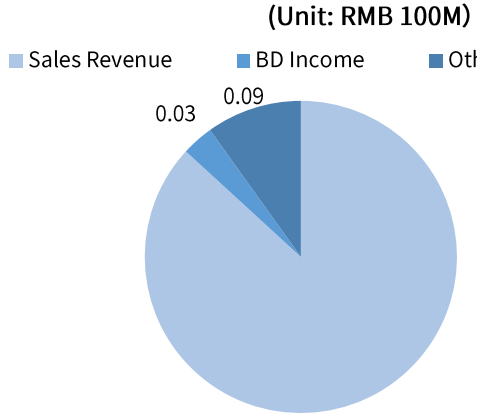
Differentiated development, Advance Combo therapy, expand therapeutic area	Launch with excellence Rapidly release market potential	Globalization Further develop overseas markets
Accelerate expansion of PD-1 indication PD-1 Actively advance 1 combo therapy PD-1 [illegible]	Differentiated competition,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

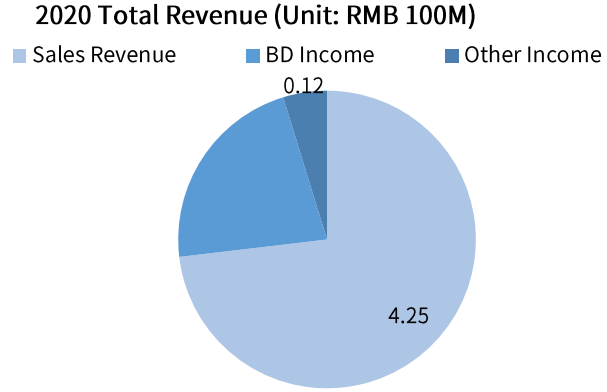
HLX04 – Backbone of anti-VEGF Combo therapy: [illegible] turn VBP threat into opportunity

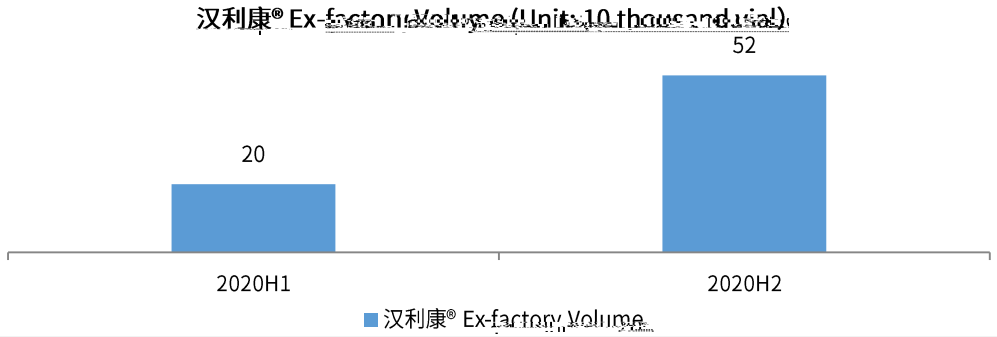
Access mass market	Advance market access, prepare for volume	
Build mass market team Enhance platform collaboration with mass market Enrich indication pipeline, rapid realize market share	Centralize best resources for rapid market access in mass market Meanwhile fully prepare for VBP and turn threat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

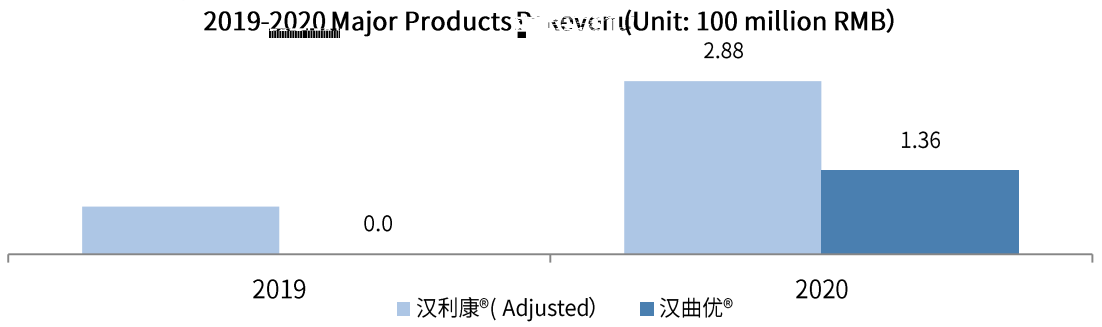
2020 Revenue: Ramp-up of 汉利康® [illegible] of 汉曲优® Drove Significant Revenue Growth











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]

3

2021 Outlook

Outlook for 2021

Commercialization







© 2020 Henlius