



Henlius (2696.HK) 2020 Annual Results Investor Presentation

March 2021

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## **Company Overview**and Strategy



### **Company Mission & Key Milestones**

## Mission: Affordable Innovation Reliable Quality

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Products Commercially Launched	3
Products under NDA Review	2
Products/Combo Therapies under Clinical Development	10/8
<b>Current Commercial Capacity</b>	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	GMP Manufacturing Facility in Operation
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: More Executives Joined Henlius with **Global Background in Recent Years**



**Wenjie Zhang** 

- Joined Henlius in Mar 2019
- 25 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







**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





**Ping Cao** Development









**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





**Wallis Zeng Head of Sales** Joined Henlius in







Sep. 2019







**Cecie Jiang** Head of Quality Management









Wenfeng Xu Senior Vice President of Research and Development







Ningshu Liu Head of Translational Medicine Joined Henlius in Aug. 2020



Xinlei Li Chief Financial Officer Joined Henlius in Dec. 2020

**FOSUN PHARMA** 复星医药



Head of Business







**Kurt Yu** 

Head of Marketing

and Commercial

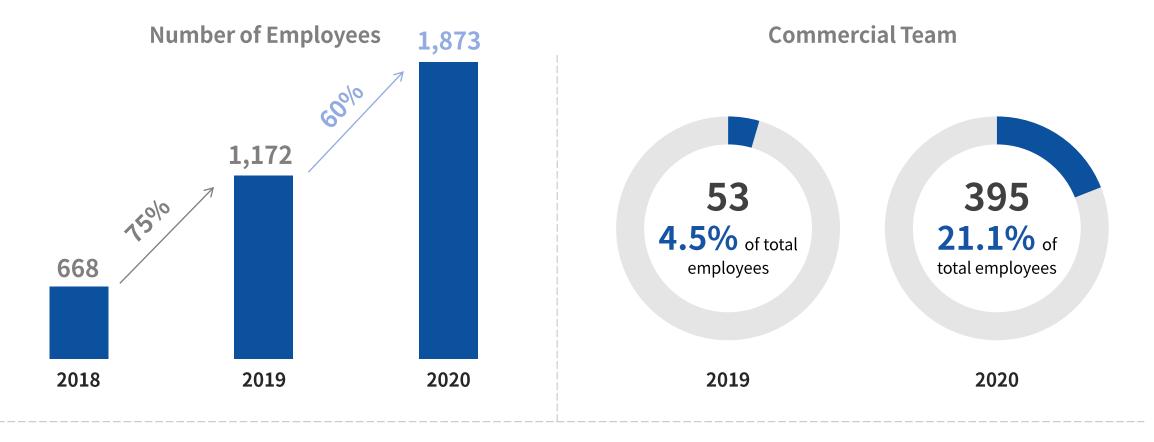
Operation

Joined Henlius in

Aug. 2019

Roche

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



R&D	Clinical	Manufacturing	Quality	Commercial	Administrative
351	231	437	256	395	203



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

### **Strategic Goals**

While maximizing biosimilar commercial value, rely on self innovative R&D capability complemented with external collaboration and license-in, accelerate innovation with full speed

Synergize China and US R&D centers, strengthen translational medicine capability, advance differentiated innovation

Under the premise of

technology, create

guaranteeing "Henlius Quality", further improve

manufacturing capability, optimize manufacturing

competitive economies of

scale **Build first-class commercial** team in the industry through innovative marketing, access and commercialization strategies, and highlyefficient sales execution capability

Stage 1: Biosimilar Build comprehensive commercial capability

Stage 2: Diversified Innovation Accelerate transformation towards diversified

innovation including mAb, bispecific, ADC, etc. based on antibody technology

Accelerate R&D, registration and approval: strive to become first-in-class or tier-1 to launch

through forging leading position in biosimilar

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

- 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



Commercialization

## Company Highlights: Biosimilar Lays Solid Foundation, 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 blockbuster 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 and HLX04 through cost advantage

- 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, HCC; 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 some 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 <sup>®</sup> (rituximab)		汉曲优 <sup>®</sup> (trastuzumab)		汉达远® (adalimumab)		汉贝泰® (bevacizumab)
•	Product positioning: become a leader in China's rituximab market First-mover advantage – First	•	Product positioning: become a leader in China's trastuzumab market First-mover advantage – first	•	Product positioning: become a leader in China's adalimumab market Pricing advantage – current	•	Product positioning: become a strong competitor in China's bevacizumab market  Differentiated clinical data –
	biosimilar in China, first domestic rituximab, 20 months earlier than No.2		domestic trastuzumab, launched nearly 2 years earlier than peers	•	lowest price, greatly improve patient affordability  First domestic adalimumab to		the only domestic bevacizumab with colorectal cancer clinical data
•	The first & the only rituximab that filed NDA for new indication of rheumatoid arthritis in China (2020.12)	•	First self-developed domestic China and EU approved antibody drug Strong sales team – self-built	•	have phase 3 clinical data on psoriasis; sNDA for uveitis accepted (2021.01) Strong sales team – Fosun	•	Huge Combo potential – combo with HLX10 (PD-1) for ns-NSCLC, HCC, etc.  Fully utilize differentiated
•	Strong sales team – Fosun Pharma built dedicated sales team with nearly 400 people		team with nearly 400 people		Pharma had a team with nearly 1,000 people in rheumatology department		advantage of wAMD indication, compete effectively in China and global markets, maximize product value



### Biosimilar: Global Footprint Covers EU/US Markets and More

### Farma de Colombia

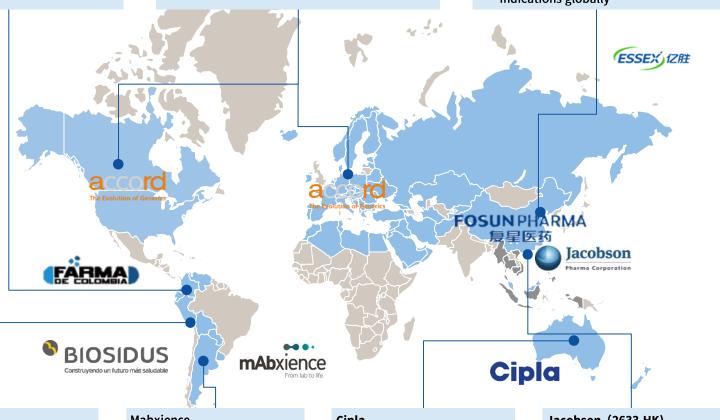
**Exclusive licensing and commercial** rights of rituximab (HLX01) in Colombia, Peru, Ecuador and Venezuela

### Accord

Exclusive commercial rights of trastuzumab (HLX02) in over 70 countries and regions in Europe, MENA, CIS, USA & Canada

### Essex (1061.HK)

Co-development and exclusive license agreement with Essex for bevacizumab (HLX04) in eye disease indications globally



### **Biosidus**

Exclusive commercial rights of rituximab (HLX01) in Argentina, Paraguay, Uruguay and Bolivia

### Mabxience

**Exclusive commercial** rights of HLX02 in Argentina, Uruguay, and **Paraguay** 

### <u>Cipla</u>

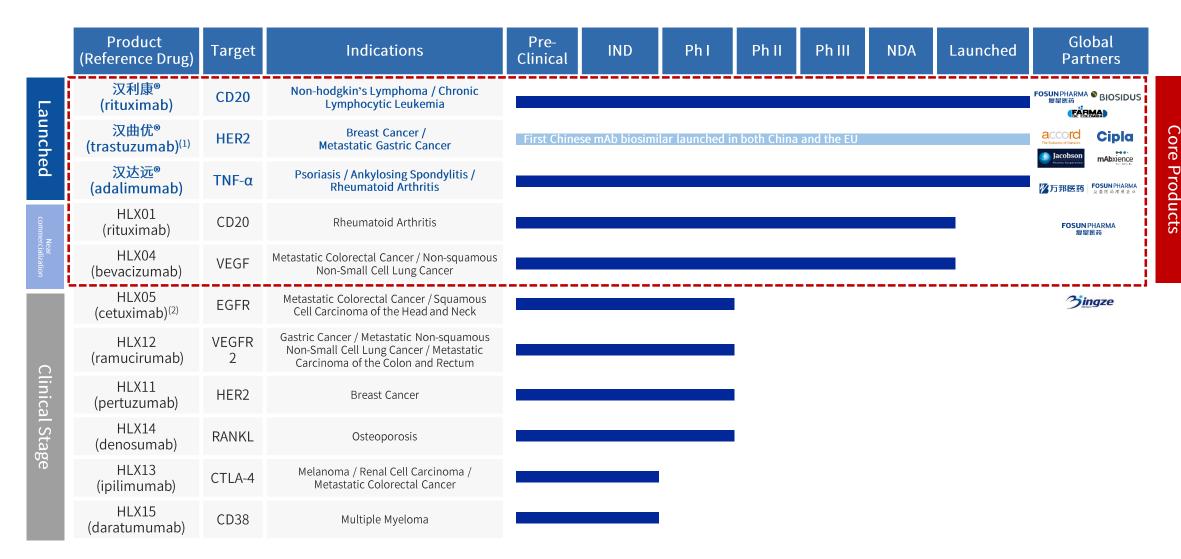
**Exclusive commercial** rights of HLX02 in Australia, New Zealand, Colombia and Malaysia

### Jacobson (2633.HK)

**Exclusive commercial** rights of trastuzumab (HLX02) in Hong Kong and Macau



### Biosimilar: Blockbuster Drugs such as 汉利康®, 汉曲优®, 汉达远®





## Accelerate Innovation: Significantly Improve Innovation Capability

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

 Fully organize and prioritize current biosimilars and bioinnovatives, select STAR and NOVA projects to accelerate development

Optimize pipeline resource allocation

Plan future R&D direction

Build systemic decisionmaking mechanism  Build effective and systematic R&D decision-making and project initiation mechanisms, fully implement clinical project PGC<sup>(1)</sup> and establish preliminary early-stage project R-PGC<sup>(2)</sup>

- Clinical medicine
- Translational medicine

Improve innovation capability



Build and optimize transdept. collaboration mechanism

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



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

Differentiate

and maximize

PD-1 launch

- Target multiple indications lung cancer, liver cancer, gastric cancer, MSI-H etc., seek differentiated competition
- Accelerate launch plan to file NDAs for MSI-H and sq-NSCLC in 2021
- Pre-launch commercial preparation formulate differentiated PD-1 market strategy, build PD-1 commercial team
- Accelerate phase 3 clinical trials
   sq-NSCLC, SCLC etc.

Accelerate development of other early-stage innovative assets

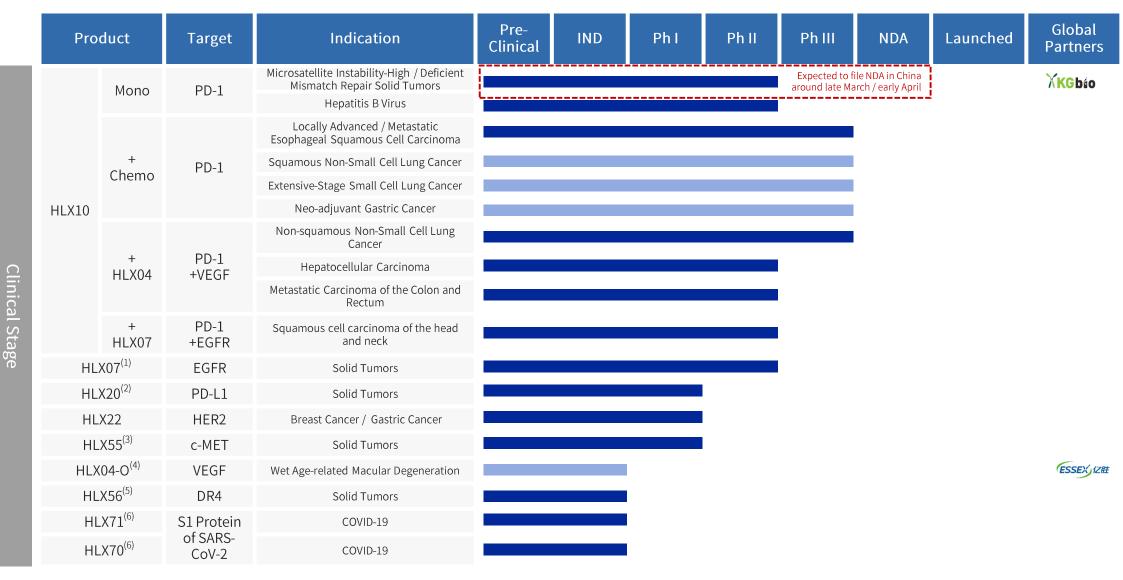
 Strengthen BD – license-in more highquality assets to further complement our own innovative pipeline

 Build efficient innovative organization and capability – early-stage R&D + translational medicine + clinical medicine + CMC

 Accelerate development of high-quality innovative assets – aim to achieve 2-3 clinicalstage products each year



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



<sup>(1)</sup> IND obtained in China / the USA



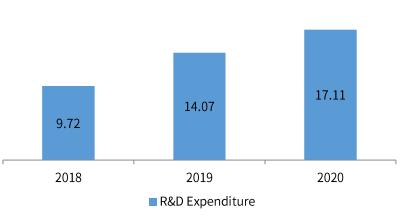
<sup>2)</sup> IND obtained in Australia / China

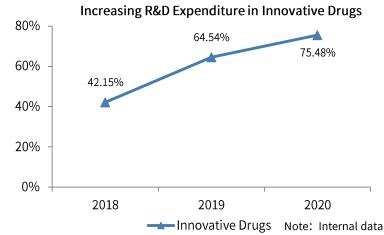
<sup>(3)</sup> Obtained commercialisation rights in China / Southeast Asia / Mid Asia / South Asia, etc.

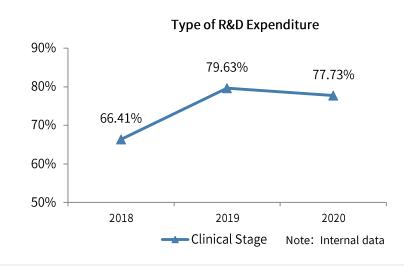
<sup>(5)</sup> Obtained commercialisation rights in China(6) IND obtained in the USA

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

2018-2020 R&D Expenditure (Unit: RMB 100M)







### 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)
- 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

- Initiated five 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
- Initiated four phase 2 clinal trials: HLX10 (PD-1) +chemo for cervical cancer CC; HLX10 (PD-1) +HLX07 (EGFR) for head & 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)

- Planned capacity of 24,000L
- 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 completed in August 2020
- Completion, and pilot production expected in 2021



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

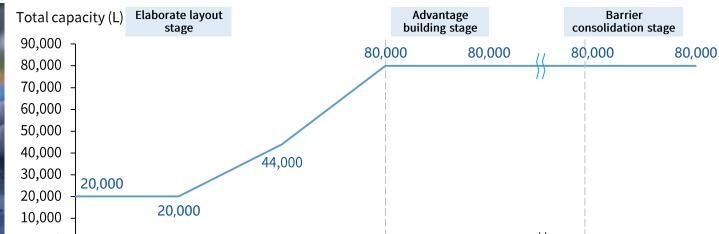
2020

# Manufacturing platform for commercial production with cost 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)

2021

- Proper capacity arrangement, pre-match corresponding technology and production line for products, maximize capacity
- Prospective production design and process optimization with the aim to achieve leading total cost
- Explore external CMO possibility

### Advantage building stage (2023-2025)

2023

2024

2022

- Successfully and commercially apply innovative technology
- Forecast industry/company's future innovative product type, develop leading technology in advance
- Build domestic leading position with total capacity and technology advantages

### Barrier consolidation stage (2025+)

2025+

- Continue to optimize process, build industry-wise quality/costleading production line
- 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 Assist successful product launch

### 2020-2022

- 汉曲优®: efficient market access and coverage, optimize HER2+ patient therapy ecosystem
- 汉利康<sup>®</sup>: fully utilize first-mover advantage to establish and consolidate market-leading position
- 汉达远<sup>®</sup>: utilize partner's rich experience in rheumatology area, develop RA market, build marketleading position
- HLX04 (bevacizumab): prepare for VBP in advance, grasp opportunity to become a major competitor
- 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

### Improve ecosystem Build mature collaboration platform

### 2023-2024

- Continue to increase and strengthen our own commercial capability, especially access and market promotion competitiveness
- Promote diversified collaboration for doctor-patient ecosystem, strongly expand Henlius ecology with mutual empowerment
- Build external collaboration platform for commercial promotion, fully explore mass market potential
- Integrate resources, maximize value combination and commercial value for different products

### Build leading position through platform integration strategy

### 2025

- Form joint force with upcoming rich pipeline, provide whole disease solution for doctors and patients
- Promote platform strategy, build industry leading position
- Diversified business development model



## 汉利康<sup>®</sup> (rituximab)and 汉达远<sup>®</sup> (adalimumab): Become Market Leaders

汉利康® (rituximab)	汉达远 <sup>®</sup> (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 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







## **Cancer Patient Behind**"

### 汉曲优® (trastuzumab) – "Not Leaving Any HER2+ Breast

### **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** Marketing Channel

- 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, establish efficient business channels
- Establish an optimized pricing system, stabilize product price
- Advocate biosimilars, obtain better bidding/access 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

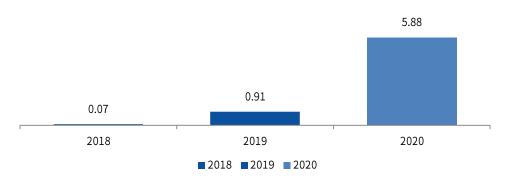
HLX10 – Cornerstone of I/O Combo: all tumor targeting, differentiated competition, ecosystem empowerment, globalization							
Differentiated development, Advance Combo therapy, expand therapeutic area	Launch with excellence Rapidly release market potential	Globalization Further develop overseas markets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

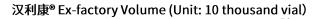
HLX04 – Backbone of anti-VEGF Combo therapy: target mass market, turn VBP threat into opportunity						
	Access mass market	Advance market access, prepare for volume- based procurement (VBP)	Explore Combo therapy			
•	Build mass market team  Enhance platform collaboration with mass market	<ul> <li>Centralize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

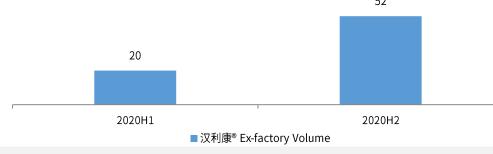


## 2020 Revenue: Ramp-up of 汉利康® and Launch of 汉曲优® Drove Significant Revenue Growth

2018-2020 Total Revenue (Unit: RMB 100M)

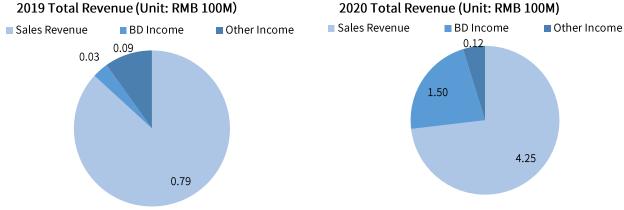


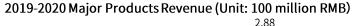


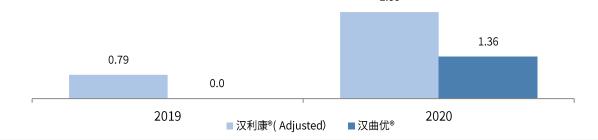


### Sales of biosimilars continued to increase

- 汉利康® (rituximab) 2,000L bioreactor approved, 500mg approved, FL and CLL indications 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) Reached exclusive development and commercialization license agreements in 3 South American countries 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 eye disease indications globally
- HLX35 (4-1BB/EGFR) Co-development and exclusive license agreement with Binacea for HLX35 (4-1BB/EGFR)
- TROP2 Ab Exclusive license agreement with Chiome for antibodies targeting human Trop2



3

### 2021 Outlook



### **Outlook for 2021**

### Capitalize on first-entrant advantages 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<sup>®</sup>: complete most of medical insurance activation and 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) rheumatoid arthritis indication: approval expected by 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

### Rapidly build diversified clinical-stage innovative pipeline through internal R&D and license-in

- Continue to optimize and accelerate the R&D pipeline, improve the decision-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

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

- Xuhui Base: maximize production capacity while 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): initiatetrial production and start relevant validation work





**Reliable** Quality | **Affordable** Innovation

